

University of Nebraska-Lincoln Human Research Protections Policies and Procedures

September 8, 2016

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ABBREVIATION LIST

| ABBREVIATIONS | FULL PHRASE |
|---------------|--|
| AE | Adverse Event |
| AAHRPP | Association of Accreditation of Human Research Protection Programs |
| CFR | Code of Federal Regulation |
| CITI | Collaborative IRB Training Initiative |
| COI | Conflict Of Interest |
| COIR | Conflict Of Interest in Research |
| COIRC | Conflict Of Interest in Research Committee |
| DHHS | Department of Health and Human Services |
| FTE | Full Time Equivalent |
| FWA | Federal Wide Assurance |
| HIPAA | Health Insurance Portability and Accountability Act |
| HRPP | Human Research Protection Program |
| IBC | Institutional Biosafety Committee |
| IO | Institutional Official |
| IRB | Institutional Review Board |
| OHRP | Office for Human Research Protections |
| ORR | Office of Research Responsibility |
| PI | Principal Investigator |
| PRIM&R | Public Responsibility in Medicine and Research |
| RSC | Radiation Safety Committee |
| SOP | Standard Operating Procedure |
| UNL | University of Nebraska – Lincoln |

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|  <p>HRPP POLICIES AND PROCEDURES</p> <p>Research Compliance Services Human Research Protections Institutional Review Board</p> | <p>Policy # 1.001</p> <p>Title: <u>The Institution and Its Commitment to the HRPP</u></p> <p>Section: <i>Organizational Commitment to the HRPP</i></p> <p>Date: January 28, 2016</p> |
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1.0 Purpose

The purpose of this policy is to describe the Institution and the commitment to the Human Research Protection Program (HRPP). The UNL HRPP policies and procedures apply to all UNL faculty, students, staff, or affiliates, as appropriate.

2.0 Policy

The Institution is committed to the human participant research protection program through establishment and funding of an Institutional Review Board (IRB) operating in full compliance with Health and Human Services regulations at 45 CFR §46.

2.1 The Institution is comprised of:

A. The University of Nebraska–Lincoln (UNL)

2.2 The Institution is committed to ensuring the existence and evolution of premier educational programs, high quality research, which is conducted with integrity, consistent with ethical standards, and with respect for all individuals and groups (HRPP Policies [#1.004](#) and [#2.001](#))

2.3 The IRB has been authorized by the Institutional Official to review and approve all human participant research conducted by the faculty, students, staff, or other Institutional representatives regardless of where the research is conducted, unless the IRB accepts the review and approval of another duly constituted IRB.

2.4 UNL may conduct FDA regulated research involving human subjects.

A. If UNL does engage in the conduct of FDA-regulated research involving human subjects, the UNL IRB will not complete review of the research but rather, the University of Nebraska Medical Center has been identified as the reviewing entity. An Authorization Agreement is in place between UNL and UNMC to confirm this review responsibility.

B. All UNL FDA-regulated research projects involving human subjects reviewed by the UNMC IRBs must follow all UNMC Human Research Protection Program polices and procedures.

1. UNMC HRPP policies and procedures are available to all UNL investigators during the time of application submission.
2. All UNL investigators subject to FDA regulations and ICH-GCP (E6), as applicable, must submit a UNMC application for UNMC IRB review.

- a. The UNMC Biomedical application requires the PI to certify that they understand the protocol and actions of the research team must comply with:
 - 1) the Common Rule,
 - 2) applicable subparts at 45 CFR 46,
 - 3) applicable FDA regulations,
 - 4) the HIPAA rule,
 - 5) applicable state law,
 - 6) HRPP policies and procedures (including ICH-GCP (E6), and
 - 7) provisions of the IRB-approved protocol.
- 3. UNMC policy #1.12 specifically discusses responsibilities of investigators and the IRB to ensure the approved application includes International Conference on Harmonization - Good Clinical Practice (E6) requirements only when the contract requires.
 - a. At the time UNL HRPP staff notifies the UNL PI that their project is subject to FDA regulations and ICH-GCP (E6) requirements, as applicable, the UNL HRPP staff will also include notification of FDA PI requirements and where to find information on the UNMC website/application.
 - b. The UNMC IRB will also be provided the study contract to ensure full compliance with contractual obligations, specific to ICH-GCP (E6).


2.5 All research involving human embryonic stem cells (hESCs) and human fetal tissue (hFT) will be reviewed by the IRB upon approval from the Scientific Research Oversight Committee (SROC) regardless of whether or not it meets the definition of human subjects research

A. The University of Nebraska-Lincoln's Scientific Research Oversight Committee (SROC) is responsible for the oversight of research involving hESCs and hFT. The SROC was formed at the direction of the Nebraska University (NU) Board of Regents and the NU President. The below referenced National Academies Guidelines for Embryonic Stem Cell Research Committees (ESCRO) was utilized in the creation of the UNL SROC. For the purposes of the research portfolio at UNL, human fetal tissue research is also included under the purview of the SROC and why it is aptly named.

In 2008, the Human Embryonic Stem Cell Research Advisory Committee of the National Research Council and Institute of Medicine published Amendments to the National Academies' Guidelines for Human Embryonic Stem Cell Research.

B. hESC and hFT research will first be reviewed by the SROC. Once

SROC approval is obtained, the SROC Administrator will provide the information to the UNL IRB. The IRB will review all new project forms, continuing review forms, and amendments for hESC/hFT research proposals using the Full Board review method and/or Expedited review process, as applicable. (See the UNL Human Embryonic Stem Cell and Human Fetal Tissue Research Policies and Procedures).

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|  <p>HRPP POLICIES AND PROCEDURES</p> <p>Research Compliance Services Human Research Protections Institutional Review Board</p> | <p>Policy # 1.002</p> <p>Title: <u>Federal Wide Assurance</u></p> <p>Section: <i>Organizational Commitment to the HRPP</i></p> <p>Date: April 1, 2008</p> |
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1.0 Purpose


The purpose of this policy is to describe the agreement with the Department of Health and Human Services Office of Human Research Protection (OHRP) through the FWA.

2.0 Policy

It is the policy of the IRB that this Institution will file and maintain an agreement with OHRP through a FWA. This Institution has declared that all institutional components listed under the UNL FWA (#00002258) must comply with this assurance.

- 2.1 The Institution has determined that **all** human participant research will be governed by the Health and Human Services regulations at 45 CFR §46 and ethical standards regardless of funding source.
- 2.2 The Institution has determined that all of its activities related to human participant research, regardless of funding source, will be guided by the ethical principles found in the Belmont Report.
- 2.3 The Institution has designated establishment and registration of one IRB with provisions for sufficient meeting space and staff to support the IRB’s review and recordkeeping duties (HRPP Policies [# 1.005](#) and [2.003](#)).
 - A. IRB-01 (IRB00000672 – University of Nebraska – Lincoln IRB #1)
- 2.4 The Institution will maintain a list of IRB members identified by name, earned degree, representative capacity, as well as maintenance of current curriculum vitae for each IRB member. Changes in IRB memberships will be reported to OHRP through filing an IRB Registration Update.
- 2.5 The Institution has established HRPP written policies and procedures as required under Health and Human Services regulations at 45 CFR §46.103.
 - A. The IRB will conduct initial and continuing review of research (at intervals appropriate to the degree of risk, but not less than once per year). The investigator and the Institution will be provided written notification of the findings and actions taken by the IRB (HRPP policies [# 3.002](#), [3.003](#), [3.004](#), [3.005](#) and [11.001](#)).
 - B. The IRB will determine, which projects require review more often than annually (HRPP policy [# 3.010](#)) and, which projects require verification from sources other than the investigators that no material changes have occurred since the previous IRB review.

- C.** The IRB shall ensure that proposed changes in approved research protocols are reported promptly and are not initiated without IRB review and approval, except when necessary to eliminate immediate risk to the participant (HRPP policies # [12.001](#), [13.001](#) and [14.001](#)).
- D.** The IRB shall have the authority to observe, or have a third party observe, the consent process and the research.
- E.** RCS shall ensure prompt reporting to the IRB, appropriate institutional officials, and as required any applicable federal regulatory officials (OHRP, National Science Foundation, and other department or agency heads) (HRPP policy # [14.002](#)).
- F.** The IRB shall require confirmation by a qualified person, other than study personnel that a research proposal qualifies for exempt status (HRPP policy # [4.001](#)).

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|  | HRPP POLICIES AND PROCEDURES | Policy # 1.003 |
| Research Compliance Services Human Research Protections Institutional Review Board | Title: <u>Vision, Mission, and Values Statement of UNL</u> | Section: <i>Organizational Commitment to the HRPP</i> |
| | Date: April 1, 2008 | |

1.0 Purpose

The purpose of this policy is to describe the vision, mission, and values statements for UNL.

2.0 Policy

UNL has developed a comprehensive vision, mission, and values statement.

2.1 Vision

The University of Nebraska-Lincoln, chartered by the Legislature in 1869, is that part of the University of Nebraska system, which serves as both the land-grant and the comprehensive public University for the State of Nebraska. Those responsible for its origins recognized the value of combining the breadth of a comprehensive University with the professional and outreach orientation of the land-grant University, thus establishing a campus, which has evolved to become the flagship campus of the University of Nebraska. UNL works cooperatively with the other three campuses and Central Administration to provide for its student body and all Nebraskans the widest array of disciplines, areas of expertise, and specialized facilities of any institution within the state.

2.2 Mission

The role of the University of Nebraska-Lincoln as the primary intellectual and cultural resource for the State is fulfilled through the three missions of the University: teaching, research and service.

Teaching

The people of Nebraska created UNL to provide its citizens with the highest quality of postsecondary education. Therefore, a fundamental mission of the University of Nebraska-Lincoln is teaching. The distinctiveness of the teaching mission at the University of Nebraska-Lincoln lies in its range of undergraduate majors, the character and quality of the faculty, and the extracurricular environment. The University provides students with a wide choice of courses and career options, which often expands the scope of their dreams and ambitions. The size and diversity of the University permits students to mature and to develop their own sense of self-confidence and individual responsibility. The course work is enriched by a faculty that is engaged in active research and creative activity and whose frame of reference is the national and international community of scholars. Having created the first graduate college west of the Mississippi River, the University of Nebraska-Lincoln has historically recognized graduate education to be a central and unique component of its mission. Thus, UNL has primary responsibility in the State for graduate education, especially at the doctoral and professional levels. UNL is unique in possessing the scope of

programs necessary for multidisciplinary instruction at the graduate level, a faculty involved in research necessary to support graduate education, and the libraries, laboratories, computer facilities, museums, galleries, and other ancillary resources required for graduate instruction.

Research

Basic and applied research and creative activity represent a major component of UNL's mission, a component that is recognized in Nebraska legislative statutes, and in its status as both a land-grant and an AAU research university. The quest for new knowledge is an essential part of a research university; it helps define and attract the type of faculty necessary to provide a university education; it distinguishes the quality of the undergraduate students' classroom experience; and it is the necessary component of graduate instruction. As part of its research mission, UNL is dedicated to the pursuit of an active research agenda producing both direct and indirect benefits to the State. The special importance of agriculture, environment, and natural resources is addressed in its research priorities. In addition, UNL conducts a high level of research and creative activities that address in specific ways the issues and problems that confront Nebraska. Through their research and creative activities, faculty at UNL interact with colleagues around the world and are part of the network of knowledge and information that so influences our society. As a consequence, the University serves as the gateway through which Nebraska participates in and shares the gains from technological and cultural developments.


Service

The land-grant tradition creates for the University of Nebraska-Lincoln a special statewide responsibility to serve the needs of Nebraska and its citizens. In addition, many of its service aspects extend to regional, national, and international clientele. Special units such as Extended Education and Outreach, and the Cooperative Extension Division have specific responsibilities to bring the teaching and research resources of the University to a wider clientele. Through Cooperative Extension's partnership with federal, state, and county agencies, UNL has an outreach program in each county in the state. Moreover, all units of the University have a service and outreach mission. To help accomplish this mission, UNL delivers educational services through diverse ways including telecommunications methods and as a participant in the development of regional educational centers especially in those areas where it has statewide responsibilities. The University recognizes its obligation to extend the resources of the University beyond the campus and throughout the State. Serving the needs of Nebraska requires more than responding to the felt needs of the time. UNL must be visionary in its planning and must help the citizens of the state prepare for the future as well as deal with the present.

2.3 Core Values

- Learning that prepares students for lifetime success and leadership.
- Excellence pursued without compromise.
- Achievement supported by a climate that celebrates each person's success.
- Diversity of ideas and people.

- **Engagement** with academic, business, and civic communities throughout Nebraska and the world.
- **Research** and creative activity that inform teaching, foster discovery, and contribute to economic prosperity and our quality of life.
- **Stewardship** of the human, financial, and physical resources committed to our care.

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|  <p>HRPP POLICIES AND PROCEDURES</p> <p>Research Compliance Services Human Research Protections Institutional Review Board</p> | <p>Policy # 1.004</p> <p>Title: <u>Vision, Mission, and Values Statement for the HRPP</u></p> <p>Section: <i>Organizational Commitment to the HRPP</i></p> <p>Date: April 1, 2008</p> |
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1.0 Purpose

The purpose of this policy is to describe the vision, mission, and values statement for the HRPP.

2.0 Policy

The IRB has developed a comprehensive vision, mission, and values statement.

2.1 Vision

The HRPP for UNL, hereafter referred to as the “Institution” and affiliates, will be a nationally known HRPP where:


- A.** Investigators will conduct research with the highest thought, technical skill, and care.
- B.** Investigators will adhere to high standards of research ethics, comply with all applicable federal, state, and local laws and regulations, and always consider the rights and welfare of research participants.
- C.** IRB members and staff will keep abreast of the latest developments in the ethics and regulation of human participant research, and will perform thorough and consistent review of research proposals.

2.2 Mission

The mission of the HRPP is to ensure the protection of human participants who choose to participate in research conducted by investigators at the Institution and affiliates that is part of a broader framework of the responsible conduct of research.

2.3 Values

- A.** Faculty, staff, students, and others who serve as investigators will emphasize the conduct of quality research, which is carried out with scientific integrity and in an ethical manner.
- B.** Investigators will respect all individuals and groups served by this institution.

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|  <p>HRPP POLICIES AND PROCEDURES</p> <p>Research Compliance Services Human Research Protections Institutional Review Board</p> | <p>Policy # 1.005</p> <p>Title: <u>IRB Charter, Appointments, and Administrative Structure</u></p> <p>Section: <i>Organizational Commitment to the HRPP</i></p> <p>Date: August 25, 2015</p> |
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1.0 Purpose

The purpose of this policy is to describe the IRB charter, appointments, and administrative structure.

2.0 Policy

It is the policy of the IRB that the structure and composition of the IRB be in full accordance with Health and Human Services policies at 45 CFR §46.

2.1 IRB Charter

The UNL IRB is a duly constituted IRB , which has established membership in full accordance with the requirements of Health and Human Services regulations at 45 CFR §46.107.

2.2 Institutional Official

The Chancellor has appointed the Associate Vice Chancellor for Research to serve as the Institutional Official (IO) in accordance with the provisions of the Federal Wide Assurance (FWA #00002258). The IO appoints the officers of the IRB and all IRB members and is responsible for the conduct of all human subjects research at UNL.

The IO is ultimately responsible for the following:

- A.** Foster, support and maintain an institutional culture supporting the ethical conduct of all research involving human subjects.
- B.** Ensure the HRPP has the resources and support necessary to comply with all institutional policies and with federal regulations and guidelines that govern human subject research, including:
 1. Ensure HRPP and IRB staffing is commensurate with the size and complexity of the research enterprise.
 2. Ensure adequate HRPP and IRB space, equipment, materials, and technology
 3. Ensure sufficient resources for the production, maintenance, and secure storage of HRPP and IRB records.
 4. Ensure sufficient resources for compliance activities and investigation of noncompliance.
 5. Ensure access to legal counsel.
 6. Support Educational opportunities related to human research protections for IRB members, ORA staff, and all members of the research community.

- C. Oversight of the IRB within the Organization and ensuring the IRB functions independently.
- D. Appointment and oversight of the IRB Chair.
- E. Oversight over the conduct of research conducted by all researchers within the Organization.
- F. Ensure investigators fulfill their responsibilities.
- G. The IO has the authority to further review and disapprove research, but cannot approve research that has been disapproved by the IRB. The IO is kept informed of research activities and decisions of the IRB through on-going and proactive discussions during up-date meetings with the Research Compliance Services Director.
- H. Advise Organizational officials on key matters regarding research conducted within the Organization.

2.3 Research Compliance Services (RCS) Director

The RCS Director (Director) reports to the IO, including on matters concerning compliance with 45 CFR §46 and HRPP policies and procedures. The IO has delegated responsibility for the daily operation of the HRPP to the Director who has a continuous appointment. The Director is primarily involved in the development of HRPP policies and procedures, revision of IRB forms, compliance issues, conflict resolution, and continuing education of both IRB members and investigators.

During the budget review period the RCS Director meets with the IO and Research Finance Director to discuss allocation of resources in comparison to the volume of research and other administrative functions, for example maintenance of HRPP Policies and Procedures.

RCS Director meets with the HRPP staff individually to complete annual personnel performance reviews and in a group setting on an ongoing basis to assess operations and resources.

The CIRC and RCR activities are housed in the same office as the HRPP. The RCS Director also oversees these activities. They are evaluated in a similar manner to ensure their key functions support the HRPP process.

When external services are utilized (i.e. UNMC) HRPP staff will review all project documentation to ensure their review meets relevant accreditation standards. This information is made available to the Director as needed.

2.4 IRB Chair

The IRB Chair works closely with the Director and the IRB vice Chair. The IRB Chair is primarily involved in conducting IRB meetings, reviewing protocols, as needed, reviewing adverse events and serious problems, continuing education of IRB members and investigators, development of policies, procedures and IRB

forms, and serves as a resource for investigators and IRB members regarding issues related to University and federal policies. The Chair can review expedited continuing reviews and changes in protocol as well as some full board continuing reviews and changes by the expedited method. The IRB Chair's term of service is at the discretion of the IO. The IRB Chair has a direct line to the IO and the Chancellor as necessary.

2.5 IRB Vice Chair

The IRB vice Chair works closely with the Director and IRB Chair. The IRB vice Chair is primarily involved in reviewing protocols, as needed, adverse events and serious problems, and chairs the IRB meeting when necessary. The Vice Chair also reviews expedited reviews and changes in protocol and some full board continuing reviews and changes. This individual is appointed by the IO. The length of appointment is at the discretion of the IO. The IRB vice Chair has a direct line to the IO as necessary.


2.6 Research Compliance Services

Research Compliance Services (RCS) serves as the administrative office for the IRB and the HRPP. HRPP staff are hired and operate under the direction of the Director.

HRPP staff may serve as IRB Coordinators. IRB Coordinators, in general, manage the review process of all forms (new protocols, change requests, and continuing reviews) from date of first submission through final approval. The IRB Coordinator, identified via the form page, will sign the form's official approval letter via NUgrant. IRB members are informed of the approvals via Full Board meetings. (See [Policy #2.012](#)).

2.7 Administrative Structure

The IRB has direct access to the RCS Director, IO, Vice Chancellor for Research, and Chancellor.

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|  <p>HRPP POLICIES AND PROCEDURES</p> <p>Research Compliance Services Human Research Protections Institutional Review Board</p> | <p>Policy # 1.006</p> <p>Title: <u>Authority Granted by UNL to the IRB Operating in the HRPP</u></p> <p>Section: <i>Organizational Commitment to the HRPP</i></p> <p>Date: January 28, 2016</p> |
|---|---|

1.0 Purpose

The purpose of this policy is to describe the authority granted by UNL to the IRB operating in the HRPP.


2.0 Policy

It is the policy of the IRB that the Institution provide sufficient resources and decisional autonomy for the IRB to carry out its duties independently of the Institution in full accordance with Health and Human Services policies at 45 CFR §46.

- 2.1 UNL through its Chief Executive Officer, the Chancellor, authorizes the IRB to independently review and approve all human participant research conducted or supported by the faculty, students, staff, or other representatives of UNL, when such research is part of their institutional responsibilities regardless of where the research is conducted unless the IRB accepts the review and approval of another duly constituted IRB with a FWA for research conducted at other study sites.
- 2.2 The IRB shall review and approve all human participant research, in which UNL is engaged (Refer to Policy 3.001, Section 2.6), before it can be conducted on by anyone on the premises of UNL property or facilities.
- 2.3 The Associate Vice Chancellor for Research will serve as the IO.
- 2.4 The IRB, which is housed administratively within Research Compliance Services, shall exercise its authority in full accordance with Health and Human Services regulations at 45 CFR §46 and HRPP policies and procedures. This authority includes review and approval of exempt research under 45 CFR §46.101 (b); research, which qualifies for expedited review under 45 CFR §46.110; and research, which requires review by the full IRB. The IRB has the empowerment, flexibility and discretion to raise the standards of protection above those afforded to research participants in 45 CFR §46 as it deems appropriate and necessary in particular cases although it may not lower the protections below those afforded by 45 CFR §46.
- 2.5 The IRB reviews all research involving human embryonic stem cells (hESCs) and human fetal tissue (hFT), by the direction of the Nebraska University (NU) Board of Regents and the NU President. (See UNL HRPP Policy #1.001, Section 2.5).
- 2.6 IRB members are to report any attempts to unduly influence their decisions to the IRB chair, the Director of Research Compliance Services, or the Associate

Vice Chancellor for Research. The IRB chair, in consultation with the Director of Research Compliance Services and the Associate Vice Chancellor for Research, will investigate the allegations, and if true, will take any needed corrective action.

- 2.7** The Institution will apply 45 CFR §46, including Subpart A, B, C, and D, to all human participant research regardless of funding, with the exceptions noted in [HRPP policy # 5.003, section 2.3](#) for subpart C. Subpart B is intended to apply to all human participant research including that performed in the social and behavioral sciences as noted in [HRPP policy # 5.002, section 2.2](#).
 - A.** If UNL does conduct research involving investigational test articles, human subject's research that would fall under the purview of FDA will be referred to the University of Nebraska Medical Center IRB as per prearranged agreement.
- 2.8** Per Health and Human Services regulations at 45 CFR §46.112 the institution acknowledges that research, which has been approved by the IRB may be subject to further appropriate review by the IO, or his/her designee. However, no official may approve research if it has not been approved by the IRB.
- 2.9** Approval of research by the IRB can be overturned by the IO or his/her designee. The reason(s) for administrative disapproval of research by the IO or his/her designee shall be provided in writing to the IRB. The IRB, which will act in this case as a communication conduit, will notify the Principal Investigator (PI) of any disapproval in writing and provide the reason(s) for the disapproval. The PI may appeal the disapproval through the IRB by submitting a written appeal, which will be communicated to the IO.

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|  <p>HRPP POLICIES AND PROCEDURES</p> <p>Research Compliance Services Human Research Protections Institutional Review Board</p> | <p>Policy # 2.001</p> <p>Title: <u>IRB Membership Requirements and Responsibilities</u></p> <p>Section: <i>IRB Membership & Standard Operating Procedures</i></p> <p>Date: April 27, 2016</p> |
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1.0 Purpose

The purpose of this policy is to describe IRB membership requirements and responsibilities.

2.0 Policy

It is the policy of UNL that the IRB will include an appropriately diverse mixture of backgrounds and experiences in accordance with the Health and Human Services regulations under 45 CFR §46.107. The IRB will adhere to the following policy:

- 2.1 The IRB will have at least five (5) members. Members serve three year terms, which are staggered to provide continuity.
- 2.2 Members will represent varying academic disciplines and have the necessary credentials to provide appropriate review of protocols submitted for review. The IRB will represent the diversity of the community in order to provide guidance on varying perspectives and sensitivities. The IRB will be sufficiently qualified through experience, expertise, and diversity to provide appropriate review of research with a primary focus on protection of human participants.
- 2.3 The IRB will include at least one member that is not affiliated with the Institution. The unaffiliated member must not: 1) have any professional relationship with the Institution as an employee, consultant, volunteer faculty, or student, and 2) be an immediate family member (first degree relative), which has a professional relationship with the Institution.
- 2.4 The IRB will include at least one member whose primary concerns are in scientific areas and at least one member whose primary concerns are in nonscientific areas. IRB staff can be designated as an ex-officio member with voting privileges or as a non-voting ex-officio member.
- 2.5 The IRB will have a non-voting representative from the University’s General Counsel Office serving in an ex officio capacity to offer legal counsel to the Board.
 - A. When legal conflicts arise the counsel to the IRB will provide a legal opinion and resolution to the IRB.
- 2.6 The IRB will include one or more members who are knowledgeable about, and experienced in, working with the vulnerable participants, including: children, prisoners, or handicapped or mentally disabled persons.

- 2.7** Individuals who are part of industry relations or NUtech Ventures are prohibited from:
- A.** Serving as members or ex-officio members of the IRB; and
 - B.** Carrying out day-to-day operations of the review process.
- 2.8** In situations where a prisoner is involved in research under IRB review and the Board does not already have a member with appropriate background and experience to serve in the capacity of prisoner representative, the Board will include an ad-hoc prisoner representative to serve. This individual must have a close working knowledge, understanding, and appreciation of the prison conditions in the facility where the research will be conducted from the perspective of the prisoner.
- 2.9** Where IRB members have conflicts of interest pertaining to the research to be reviewed, members must recuse themselves from the meeting room before the final review discussion and vote, except where requested by the IRB to be present to provide information. IRB members with conflicts of interest must not participate in all types of reviews, including initial review, continuing review, review of modifications, review of unanticipated problems involving risks to participants or others, and review of non-compliance. IRB members also may not serve as reviewers for research in which they have a conflicting interest when asked to review using the expedited continuing procedure.
- 2.10** When review of a proposal requires expertise that is not available on the Board, at its discretion, the IRB will request assistance from an expert consultant. These individuals have access to all documents submitted to the IRB relevant to the specific project under review and may participate at the deliberations and make recommendations on the project but will not vote (see HRPP policy # [2.003](#)).
- 2.11** Alternates are appointed and function in the same manner as the primary IRB members. The alternate's expertise is comparable to those of the primary member. The role of the alternate member is to serve as a voting member of the IRB when the regular member is unable to attend a convened meeting. When an alternate member substitutes for a primary member, the alternate member will receive and review the same materials prior to the IRB meeting that the primary member received or would have received.
- The IRB roster identifies the primary member(s) for whom each alternate member may substitute. The alternate member will not be counted as a voting member unless the primary member is absent. The IRB minutes will document when an alternate member replaces a primary member.
- 2.12** The HRPP Director can attend IRB meetings as a consultant, but cannot vote.
- 2.13** IRB members are expected to be fully engaged in the HRPP and will be involved in carrying out the following responsibilities (when requested by the IRB Chair or designate):
- A.** Serving as a primary or secondary reviewer for new protocols.

- B.** Serving as a primary or secondary reviewer for applications for continuing review.
- C.** Serving as a primary or secondary reviewer for internal unanticipated problems involving risk to the participant or others.
- D.** Serving as a primary reviewer for external adverse events or serious problems.
- E.** Serving as a primary or secondary reviewer for changes in protocol and/or consent documents.
- F.** Serving as a primary reviewer for incidents of noncompliance.
- G.** Serving as an expedited reviewer.
 - 1.** In order to be appointed as an expedited reviewer, the member must have 1 year or more of experience serving on the UNL IRB. Approval of protocol deviations
- H.** Continuing education.

2.14 When the IRB membership changes, the HRPP staff will prepare the notice that will be submitted by the IO to OHRP within thirty (30) business days.

2.15 A membership list of IRB members must be maintained; it must identify members sufficiently to describe each member's chief anticipated contributions to IRB deliberations. The list must contain the following information about members:

- A.** Name
- B.** Earned degrees
- C.** Affiliated or non-affiliated status (neither the non-affiliated member nor an immediate family member of the non-affiliated member may be affiliated with the university).
- D.** Status as scientist (physician-scientist, other scientist, non-scientist or social behavioral scientist). For purposes of this roster, scientific and non-scientific members will be defined according to the guidance from the OHRP:


Members whose training, background, and occupation would incline them to view scientific activities from the standpoint of someone within a behavioral or biomedical research discipline should be considered a scientist, while members whose training, background, and occupation would incline them to view research activities from a standpoint outside of any biomedical or behavioral scientific discipline should be considered a nonscientist.

Additionally, SACHRP Recommendation (Comment and Recommendation Regarding IRB Membership and Definition of Scientist and Non-scientist under 45 CFR 46 and 21 CFR 56) will provide us examples of how we would document clarification of how we are categorizing member's status:

Examples of scientific members (practicing physician or nurse, Ph.D. level bench scientist, medical laboratory technician, etc.) and clearly-defined non-scientific members (attorney, clergy member, ethicist, etc.) should be given, as well as examples of less well-defined but potentially justifiable assignments. The SACHRP guidance should reference the expectation that institutions that choose to categorize an individual as a non-scientist, when the rationale for the categorization is not apparent based on occupation or

training, should maintain written documentation of the reason for the categorization.

- E.** Indications of experience, such as board certifications or licenses sufficient to describe each member's chief anticipated contributions to IRB deliberations.
 - F.** Representative capacities of each IRB member, which IRB member is a prisoner representative (as required by Subpart C), and which IRB members are knowledgeable about or experienced with working with children, pregnant women, decisionally impaired individuals, and other vulnerable populations locally involved in research.
 - G.** Role on the IRB (Chair, Co-Chair, etc.)
 - H.** Voting status (any ex officio members are non-voting members)
 - I.** Alternate status, including the member they alternate with
 - J.** Relationship (e.g., employment) between the individual IRB member and the organization.
- 2.16** The IRB roster is public information and will be made available upon written request. However, the names of any IRB members who reviewed specific protocols will not be released for reasons of confidentiality.

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|  <p>HRPP POLICIES AND PROCEDURES</p> <p>Research Compliance Services Human Research Protections Institutional Review Board</p> | <p>Policy # 2.002</p> <p>Title: <u>IRB Meetings and IRB Member Responsibilities</u></p> <p>Section: <i>IRB Membership & Standard Operating Procedures</i></p> <p>Date: April 1, 2008</p> |
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1.0 Purpose

The purpose of this policy is to describe the structure of IRB meetings and IRB member responsibilities.

2.0 Policy

It is the policy of the IRB that the structure of the IRB meetings and responsibilities of IRB members are clearly defined.

2.1 IRB meeting dates are determined at the beginning of each semester.

2.2 Two (2) weeks before the scheduled IRB meeting, the IRB staff will send an email notification to each member. The IRB members are officially notified of the date, time, and location of the IRB meeting. The email asks the member to respond concerning his/her availability to attend the upcoming IRB meeting.

2.3 Two (2) weeks before the IRB meeting, IRB applications and supporting materials for review will be posted at a secure online site for IRB members.

A. For initial reviews by a convened IRB, all IRB members are provided with:

1. The full protocol or a protocol summary containing the relevant information needed to determine whether the proposed research fulfilled the criteria for approval.
2. Proposed consent document.
3. Recruitment materials.


B. For initial research review by a convened IRB, the primary and secondary reviewers are additionally provided with:

1. The full protocol.
2. Any relevant grant applications.
3. The DHHS-approved sample consent document (when one exists).
4. The complete DHHS-approved protocol (when one exists).

C. Primary and secondary reviewers perform an in-depth review of all pertinent documentation. All other IRB members review all provided materials in enough depth to discuss the information at the convened meeting. When conducting reviews using the expedited continuing procedure, the reviewer receives and reviews all submitted information including, at a minimum, all information that the convened IRB would have received.

2.4 The IRB has a minimum of five (5) regular voting members, plus one (1) non-voting ex-officio member serving as a legal representative and one (1) ad-hoc member serving as the prisoner representative.

- 2.5** A quorum will be established in accordance with federal requirements. If quorum is not met or is lost, the meeting will be postponed and re-convened as soon as possible (see HRPP policy [# 2.011](#)).
- 2.6** IRB Members will serve as primary or secondary reviewers. A primary and secondary reviewer will be assigned to all initial reviews, tabled protocols, changes in protocol, and continuing reviews.
- 2.7** Members will review and vote on IRB policies as required (see HRPP policy [# 2.013](#)).
- 2.8** Persons may be invited to attend IRB meetings as guests under the following conditions:
- A.** Guest attendance is at the discretion of the IRB Chair;
 - B.** Guests may be asked to leave at any time;
 - C.** Guests will be asked to state the purpose of their visit; and
 - D.** Guests attending a meeting where a proposed project has been submitted will be asked to provide information about a proposed study and answer any question the IRB may have regarding the study under review.
 - E.** All requests for visitors to attend an IRB meeting must be directed to the Chair of the IRB. The request must include the name(s) of the visitors, the rationale for the visit, and the proposed visit date. The request will be discussed at the next IRB meeting. If the IRB approves the request, the visitor will be scheduled to attend a meeting of the IRB in the future.
 - F.** If the request is granted, the visitor will be required to sign a confidentiality statement (<http://research/orr/forms.shtml>) and may be requested to leave the room during any discussion as necessary. Visitors will not be allowed to vote.

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|  <p>HRPP POLICIES AND PROCEDURES</p> <p>Research Compliance Services Human Research Protections Institutional Review Board</p> | <p>Policy # 2.003</p> <p>Title: <u>IRB Consultants</u></p> <p>Section: <i>IRB Membership & Standard Operating Procedures</i></p> <p>Date: November 1, 2010</p> |
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1.0 Purpose

The purpose of this policy is to describe the identification, appointment, and role of IRB consultants.

2.0 Policy

It is the policy of the IRB that services of expert consultants will be obtained as needed.

- 2.1 Either before or during review of a protocol, the IRB Chair, assigned IRB reviewer, or the IRB itself will determine if there is a need for appointment of an expert consultant, either a scientist or a non-scientist, in accordance with the provisions of 45 CFR §46.107(f). Depending upon the nature and magnitude of the problem or concern, the IRB may seek more than one (1) consultant.
- 2.2 Consultants will be selected from within the Institution, as well as from outside the Institution based upon the required expertise.
 - A. The IRB chair will defer a protocol to another meeting, or obtain consultation if there is not appropriate scientific, scholarly, or representational expertise.
- 2.3 Consultants will sign a Confidentiality Agreement prior to reviewing any protocol or receiving detailed information regarding the protocol in question.
- 2.4 Consultants generally will produce written reviews and they may participate in the IRB's discussion of the protocol.
- 2.5 Written reviews will be provided to the primary and secondary IRB reviewers. When warranted, copies of written reviews will be provided to all IRB members.
- 2.6 Consultants who attend an IRB meeting may not vote and are excused upon conclusion of discussion of the protocol in question.
- 2.7 Potential consultants will be queried and asked to sign an attestation by the IRB Chair before the meeting as to whether they have any potential conflicts of interest¹ with the relevant investigators or funding agencies. If they do, they will be excused and another consultant found.


¹ The Board of Regents has adopted Regents Policy 3.2.8 and has authorized the implementation of related policies and directive to properly avoid, disclose and manage potential conflicts of interest.

Conflict of interests shall mean situations where a consultant's direct or indirect financial interests may compromise, or have the appearance of compromising, the consultant's professional judgment or behavior in carrying out his or her obligations to the University of Nebraska-Lincoln IRB. This includes indirect personal financial interests that may be obtained through third parties such as a consultant's immediate family, business relationship, or investments. personal financial interests that may be obtained through third parties such as a consultant's immediate family, business relationship, or investments.

2.8

- A.** Potential consultants will be asked to complete a paper based Collaborator Interest Reporting Form.
 - 1.** If the consultant indicates a potential conflict, the COI Coordinator, who works directly with the Conflict of Interest in Research Committee, will review the response to determine if it is a conflict.
 - 2.** If a conflict exists, the person will not be allowed to serve as a consultant for that project.

- 2.9** When the IRB reviews research that involves categories of participants vulnerable to coercion or undue influence, the IRB Chair or Director will ensure that one or more individuals who are knowledgeable about, or experienced in, working with such participants will be present at the meeting.

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|  <p>HRPP POLICIES AND PROCEDURES</p> <p>Research Compliance Services Human Research Protections Institutional Review Board</p> | <p>Policy # 2.004</p> <p>Title: <u>Orientation and Initial Training for New IRB Members and HRPP Staff</u></p> <p>Section: <i>IRB Membership & Standard Operating Procedures</i></p> <p>Date: March 30, 2015</p> |
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1.0 Purpose

The purpose of this policy is to describe the orientation and initial training for new IRB members and Human Research Protections Program (HRPP) staff.

2.0 Policy

It is the policy of the IRB to provide new IRB members and HRPP staff with an orientation and initial training that includes the information necessary to facilitate the performance of assigned responsibilities.


2.1 All new IRB members and HRPP staff must complete anew member orientation. The orientation is conducted by RCS staff.

2.2 The Orientation Packet includes the following materials:

- A.** IRB Membership Roster
- B.** Code of Federal Regulations: 45 §CFR 46
- C.** The Belmont Report
- D.** Federal Wide Assurance (FWA 00002258)
- E.** HRPP Policies and Procedures
- F.** All Current UNL IRB forms and checklists
- G.** Copy of the IRB Member Handbook by Robert Amdur

2.3 All IRB members and staff are required to complete the web-based program, Collaborative IRB Training Initiative (CITI), accessible through the HRPP website (<http://research.unl.edu/orr/humansubjectsresearch.shtml>). IRB members and the RCS staff are required to complete the social science/behavioral research training tract. A minimum passing score of 75% is required to receive CITI certification.

- A.** CITI certification is valid for three years. IRB members' training will remain valid for the time they are serving on the IRB and for three years after the term has ended.

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|  <p>HRPP POLICIES AND PROCEDURES</p> <p>Research Compliance Services Human Research Protections Institutional Review Board</p> | <p>Policy # 2.005</p> <p>Title: <u>IRB Member Conflict of Interest Management</u></p> <p>Section: <i>IRB Membership & Standard Operating Procedures</i></p> <p>Date: April 1, 2008</p> |
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1.0 Purpose


The purpose of this policy is to describe the identification and management of IRB member conflict of interest.

2.0 Policy

It is the policy of the IRB to identify and appropriately manage all IRB member potential conflicts of interest.

- 2.1 Preferably upon receipt of IRB meeting materials, all IRB members must notify the IRB Chair or Vice Chair of a conflict of interest in advance of the upcoming meeting or upon assignment as an expedited, continuing, primary, or secondary reviewer. If the IRB member is uncertain if a potential conflict of interest exists, they are encouraged to consult with the IRB Chair or Vice Chair.
- 2.2 Prior to the beginning of each meeting, IRB members will be asked to declare, but are not required to describe, any conflict of interest related to the protocols under review, which already have not been declared.
- 2.3 The individual can be a member of the IRB; however, he/she cannot participate in the review and approval process for any project in which he/she has a conflict of interest. In cases where the assigned initial reviewer has a conflict of interest, the IRB protocol is re-assigned to another reviewer. When the member has a conflicting interest, he/she will not be present during final discussion and vote, and may be present only at the beginning of the meeting to provide information if requested by the IRB. He/she must be absent from the meeting room during the subsequent discussion and voting phases of the review and may not participate in the vote. The absent member is not counted towards a quorum when the vote on the protocol in question is taken. Minutes must reflect whether or not these requirements have been met.
- 2.4 The following constitute IRB member conflict of interest :
 - A. The IRB member (or an immediate family member, as defined below) serves as a Principal Investigator (PI) or Supervising Investigator and is, accordingly, listed on the IRB application, or has served as a scientific advisor to the PI.
 1. **Immediate family member:** parent(s), or spouse of a parent, spouse, biological or adopted child, or anyone that may be claimed as a dependent under the Internal Revenue Code.

- B.** The IRB member (or an immediate family member) is an advisor (e.g., thesis/dissertation committee member) or a direct supervisor of a trainee's (e.g., graduate or undergraduate student) research.
 - C.** The IRB member (or an immediate family member) has received payments in excess of \$2,000 (when aggregated for the investigator and the investigator's immediate family member) including salary, consulting fees, royalty, or licensing payments from intellectual property, honoraria and/or gifts from the commercial company sponsoring the research, or their representative(s) or with a company with a financial interest in the product or service being tested over the past 12 months or anticipates receiving such payment during the next 12 months.
 - D.** The IRB member (or an immediate family member) has equity interest in the commercial company sponsoring the research or in the product or service being tested, which is worth more than \$2,000 (when aggregated for the investigator and the investigator's immediate family member) or more than 5% of the business entity (when aggregated for the investigator and the investigator's immediate family member) determined by reference to publicly listed prices (excluding mutual funds).
 - E.** The IRB member (or an immediate family member) has any equity interest in the commercial company sponsoring the research and the value cannot be determined by reference to publicly listed prices (e.g., start-up companies).
 - F.** The IRB member (or an immediate family member) holds a paid or unpaid position as director, officer, partner, trustee, or any other significant position (e.g., scientific advisory board/consultant) in the company sponsoring the research or with a company with a financial interest in the product or service being tested.
 - G.** The IRB member (or an immediate family member) holds patent rights or royalties from such rights whose value may be affected by the outcome of the research, including royalties under any royalty-sharing agreements involving UNL.
 - H.** The IRB member (or an immediate family member) has a financial interest (as defined above in items C, D, E, F, or G) in a company, which has a marketed product, or is in the process of developing a new product, which is, or will be, in direct market competition with the product in the protocol under IRB review.
 - I.** The IRB member (or an immediate family member) has a personal relationship, or a conflict, with any investigator(s) listed on the IRB application, which would potentially cause the IRB member to be perceived as less than objective in his/her review.
 - J.** The IRB member (or immediate family member of the IRB member) has an ownership interest or compensation related to the research whose value may be affected by the outcome of the research.
- 2.5** The IRB meeting minutes will record the name of the IRB member with the conflict of interest and indicate that he/she was recused and did not vote.

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|  <p>HRPP POLICIES AND PROCEDURES</p> <p>Research Compliance Services Human Research Protections Institutional Review Board</p> | <p>Policy # 2.006</p> <p>Title: <u>Continuing Education Requirements for IRB Members and HRPP staff</u></p> <p>Section: <i>IRB Membership & Standard Operating Procedures</i></p> <p>Date: April 1, 2008</p> |
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1.0 Purpose

The purpose of this policy is to describe the IRB's program of continuing education for IRB members and HRPP staff.

2.0 Policy

It is the policy of the IRB to provide IRB members and HRPP staff with ongoing continuing education concerning new regulations, new OHRP guidance documents, Association for the Accreditation of Human Research Protection Programs (AAHRPP) accreditation standards, issues in the field of research ethics, OHRP compliance citations, and other subjects of interests, which are related to human participant protection.

- 2.1 CITI certification is valid for three (3) years. When re-certification is required, IRB members and HRPP staff must complete the continuing education modules available through the CITI-based training program.
- 2.2 The IRB website is regularly updated and maintains links to OHRP and other sites of interest to IRB members and HRPP staff. IRB members and HRPP staff are encouraged to access these sites for current issues relating to human participant research protection.
- 2.3 IRB members and staff are provided educational items at each Board meeting. These items may be current journal articles addressing issues of human participant research; new or updated guidance issued by OHRP; or other items of interest.
- 2.4 Publication of new books on research ethics and protection of human participants are available in the HRPP office to IRB members and staff.
- 2.5 On a rotational basis, the IRB Chair and Vice Chair attend the national conferences on human research participant protections for the purposes of continued education.
- 2.6 Members of the HRPP staff are offered the opportunity, on a rotational basis, to attend regional and national conferences on human subject protections.
- 2.7 HRPP staff are encouraged to obtain national Certification for IRB Professionals (CIP) obtained through passing a national examination.

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|  <p>HRPP POLICIES AND PROCEDURES</p> <p>Research Compliance Services Human Research Protections Institutional Review Board</p> | <p>Policy # 2.007</p> <p>Title: <u>Evaluation of IRB Members</u></p> <p>Section: <i>IRB Membership & Standard Operating Procedures</i></p> <p>Date: April 1, 2008</p> |
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1.0 Purpose


The purpose of this policy is to describe evaluation of the performance of IRB members.

2.0 Policy

It is the policy of the IRB to carry out evaluations of IRB members and provide feedback as necessary to individual IRB members.

- 2.1 IRB members are evaluated on an annual basis by the IRB Chair and Vice Chair.
- 2.2 Performance assessment is based upon meeting attendance records, thoroughness of reviews, participation in IRB discussions, and service on subcommittees.
- 2.3 IRB members are chosen by, and serve at, the discretion of the IO, in consultation with the Chair and Director. Members who do not adequately fulfill their responsibilities as judged by the IRB Chair may be asked to step down from IRB membership by the IO. Members missing three (3) meetings in a one-year period will be removed from the IRB. A warning notice will go out after the second (2nd) absence. IRB members may be granted an extended leave due to medical, personal, or professional reasons, then return to complete their term.
- 2.4 If an IRB member's performance is judged to be deficient, the IRB Chair will discuss his/her concerns with the member and seek a satisfactory resolution.
- 2.5 Any IRB member whose contribution to the IRB is judged to be deficient can have his/her appointment terminated by the IO upon recommendation of the IRB Chair.
- 2.6 If an IRB member's appointment is terminated, the IO will notify the member in writing. The IO, at his/her discretion, may notify the IRB member's supervisor or other administrative officials.
- 2.7 Upon request of individual IRB members, the Director and/or IRB Chair will write letters of recommendation, which attest to the quality and value of the member's service on the IRB.
- 2.8 The IRB Chair is chosen from existing members of the IRB by the IO. The chair should be a tenured faculty member of UNL. The Chair is evaluated on an annual basis by the IO and Director.

- 2.9** The appointment of the RCS staff is conducted by the IO. The selection process is overseen by the Director. The IRB staff members are annually evaluated by the Director, who in turn, is evaluated by the IO.
- 2.10** Alternate members are chosen on the basis of availability and specialty need. They are listed on the membership roster. If serving as a substitute for a specific meeting, alternates will receive the same material the primary members received or would have received.
- 2.11** The Director, Chair, and IO meet on an as needed basis to decide who has various responsibilities for the Human Research Protection process to be effective.

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|  <p>HRPP POLICIES AND PROCEDURES</p> <p>Research Compliance Services Human Research Protections Institutional Review Board</p> | <p>Policy # 2.008</p> <p>Title: <u>IRB Member Confidentiality</u></p> <p>Section: <i>IRB Membership & Standard Operating Procedures</i></p> <p>Date: April 1, 2008</p> |
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1.0 Purpose

The purpose of this policy is to describe the requirements for IRB members to maintain the confidentiality of protocol reviews.

2.0 Policy

It is the policy of the IRB to maintain strict confidentiality of all reviews and other actions.

- 2.1 All IRB members will keep confidential all protocols and other information pertaining to research reviewed by the IRB, which is unavailable to non-IRB members.
- 2.2 All IRB review material is saved on the NUgrant system which is username and password protected. Additional files are also saved on the secured folders and access is maintained by UNL Information Systems (IS). IRB material should not be left unsecured in the IRB meeting room. Materials are left in the room at the end of the meeting for proper filing/shredding by RCS staff.
- 2.3 Protocols without a proprietary information/confidentiality restriction may be discussed with expert internal or external consultants. In such cases, the RCS office should be notified. Confidentiality should be safeguarded by assigned consultants.
- 2.4 In the case of protocols with a proprietary information/confidentiality restriction, which require consultation with an internal or external consultant, the RCS office should be notified in advance and approval obtained from the IRB Chair. Confidentiality should be safeguarded by assigned consultants.
- 2.5 All IRB members and internal or external consultants where appropriate, and RCS staff will have a signed RCS Confidentiality Agreement on file in the HRPP office. <http://research.orr/forms.shtml>

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|  <p>HRPP POLICIES AND PROCEDURES</p> <p>Research Compliance Services Human Research Protections Institutional Review Board</p> | <p>Policy # 2.009</p> <p>Title: <u>Full Board IRB Reviewer Assignment</u></p> <p>Section: <i>IRB Membership & Standard Operating Procedures</i></p> <p>Date: June 5, 2014</p> |
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1.0 Purpose

The purpose of this policy is to describe IRB reviewer assignment for *full board* meetings and *expedited review*.

2.0 Policy

It is the policy of the IRB to assign reviewers who have the necessary scientific/scholarly expertise in the area of research under review for projects initially reviewed under the Expedited method refer to Policy 4.002.

- 2.1 The HRPP Staff, in consultation as necessary with the IRB Chair and Vice Chair, will assign reviewers (primary and secondary) for *full board* meetings.
- 2.2 At least one (1) of the assigned reviewers for the *full board* meeting must have the necessary scientific/scholarly expertise in the area of research under review, or the services of an expert consultant can be used.
- 2.3 The IRB Chair, Vice Chair, one voting member from the committee, and a trained RCS staff person (also voting member) together comprise a standing subcommittee for the review of expedited continuing protocols. The reviewer will complete the Expedited Continuing Review checklist to document review under the expedited procedure.
- 2.4 The IRB Chair or Vice Chair are designated to complete the review of expedited change in protocol requests. For minor and major changes, the reviewer will complete the Expedited Change in Protocol checklist to determine whether the modifications meet the criteria allowing review using the expedited procedure, and if so, whether the research with the proposed modifications meets the regulatory criteria for approval.
- 2.5 Each IRB member receives the following documentation, as applicable:
 - A. Complete Protocol Application form
 - B. Proposed Consent / Parental Permission / Assent Form(s)
 - C. Recruitment materials / subject information
 - D. Data collection instruments (including all surveys and questionnaires)
 - E. Relevant grant applications
 - F. Sponsor's protocol (when one exists)
 - G. Investigator's brochure (when one exists)
 - H. DHHS-approved sample informed consent document (when one exists)
 - I. Complete DHHS-approved protocol (when one exists)

If an IRB member requires additional information to complete the review they may contact the investigator directly or may contact the IRB Office to make the request of the investigator.


Protocol reviewers will use the Institution's Full Board New Protocol Form Checklist as a guide to completing their review.

- 2.6** For continuing review of research by a convened IRB, each IRB member receives the following documentation, as applicable:
- A.** Complete Approved Protocol including approved consent/assent forms, recruitment materials, data collection instruments, grant applications
 - B.** The continuing review application
 - C.** The updated (newly proposed) informed consent/assent form(s)
 - D.** Any modifications made to the protocol (previously approved or proposed)
 - E.** Any publications that have been made as a result of the research

In conducting continuing review of research not eligible for expedited review, all IRB members are provided and review all of the above material. At the meeting, the Primary and Secondary Reviewers lead the IRB through the completion of the regulatory criteria for approval in the FB Reviewer Checklist: Continuing Review.

If an IRB member requires additional information to complete the review they may contact the investigator directly or may contact the IRB Office to make the request of the investigator.

- 2.7** In conducting continuing review under expedited review, the reviewers receive all of the material reviewed by the primary reviewer in full review. The reviewer(s) complete the FB Reviewer Checklist: Continuing Review to determine whether the research meets the criteria allowing continuing review using the expedited procedure, and if so, whether the research continues to meet the regulatory criteria for approval.
- 2.8** For expedited review of protocol modifications, the reviewer(s) complete the FB Reviewer Checklist: Change in Protocol checklist to determine whether the modifications meet the criteria allowing review using the expedited procedure, and if so, whether the research with the proposed modifications meets the regulatory criteria for approval. The reviewer(s) is given the complete protocol which includes the complete history of the project along with the requested modification materials.
- 2.9** For full review of protocol modifications, at the meeting, the primary reviewer presents an overview of the modifications and leads the IRB through the completion of the regulatory criteria for approval. All of the board members receive the complete protocol which includes the complete history of the project along with the requested modification materials.

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|  <p>HRPP POLICIES AND PROCEDURES</p> <p>Research Compliance Services Human Research Protections Institutional Review Board</p> | <p>Policy # 2.010</p> <p>Title: <u>Written Reviews by IRB Members and Development of the IRB Review Letter</u></p> <p>Section: <i>IRB Membership & Standard Operating Procedures</i></p> <p>Date: April 1, 2008</p> |
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1.0 Purpose


The purpose of this policy is to describe the procedures for submission of review by IRB members.

2.0 Policy

It is the policy of the IRB to encourage IRB reviewers to submit comments regarding the IRB application, the detailed protocol, the consent/assent documents, and other pertinent issues. Comments will be submitted via NUgrant at the meeting. Members who will not be present at the meeting may also submit their comments via the review checklist on NUgrant.

- 2.1 Reviews are summarized and submitted at the IRB meeting.
- 2.2 An individual reviewer checklist may be submitted for each project being reviewed.
- 2.3 Significant deficiencies and/or major points of clarification, which require revision of the IRB Application, should be described fully, sequentially, and referenced to sections of the IRB application using the IRB Review Form. The detailed protocol should be referenced as necessary.
- 2.4 Significant deficiencies (i.e., errors, inadequate explanations, non-disclosure of pertinent information such as risks(s), and excessively high readability level) should be described sequentially according to the section of the consent form (i.e., the elements of consent).
- 2.5 It is not necessary to comment on format or standardized statements. The IRB staff will add any necessary changes to the review letter.
- 2.6 IRB reviewers should refrain from *editorializing* relative to either the application or the consent/assent documents unless necessary.
- 2.7 If any IRB member wishes to assist an investigator in carrying out revisions for minor improvement of language, this assistance should be accomplished via a post-IRB review personal consultation. The IRB review letter should refer to this consultation as the mechanism by which further details will be provided.
- 2.8 IRB review letters, which reflect the decisions of the board, are developed by the RCS staff in consultation with the IRB Chair and/or Vice Chair. Once approved by the IRB Chair and/or Vice Chair, the letter is sent to the PI via NUgrant.

IRB review letters must be written in a clear, explanatory, and facilitative fashion in order to assist investigators in understanding the rationale for any IRB concerns and mandated changes to the protocol and consent/assent documents.

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|  <p>HRPP POLICIES AND PROCEDURES</p> <p>Research Compliance Services Human Research Protections Institutional Review Board</p> | <p>Policy # 2.011</p> <p>Title: <u>IRB Quorum and Voting Requirements</u></p> <p>Section: <i>IRB Membership & Standard Operating Procedures</i></p> <p>Date: November 1, 2010</p> |
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1.0 Purpose

The purpose of this policy is to describe IRB quorum and voting requirements.

2.0 Policy

It is the policy of the IRB to conduct full board meetings in compliance with Health and Human Services regulations at 45 CFR §46.108(b).

2.1 A full board meeting cannot be convened without the presence of a quorum. A duly constituted quorum must include: a simple majority of the voting membership. The minutes reflect what capacity each member is serving for that meeting. The IRB administrator has the responsibility to monitor the members present at convened meetings and determine that meetings are convened appropriately and remain so.

2.2 When the IRB reviews any protocols, amendments, unanticipated problems involving risk to the participants or others, adverse events, or compliance problems related to research involving prisoners a prisoner representative must be present in accordance with 45 CFR §46.304(b) (see HRPP policy [#5.003](#)).

2.3 IRB members who abstain from voting (recorded as an abstention) are included in the quorum.

2.4 Any IRB member who has a conflict of interest will be recused in accordance with Health and Human Services regulations at 45 CFR §46.107(e). IRB members with a conflict of interest are prohibited from participating in the discussion or from voting and will only provide information upon request of the IRB (see HRPP policy [#3.007](#)).

2.5 If attendance at a convened *full board* meeting falls below a quorum, the meeting will be adjourned and reconvened at the earliest possible time, but in no case, later than ten (10) business days after the adjourned meeting.


2.6 No motion shall pass unless a **simple majority** of the IRB members, which constitute a quorum are present (in person, audio or video conference, or web with video exchange) during the discussion and vote in favor of the motion. If a member must leave the meeting *temporarily* (e.g., answer a call) before the vote is taken, the vote can be delayed. Voting by absentee is not permitted. If a motion fails to pass by a simple majority vote, other motions will be entertained. If no further motions are made, the protocol or issue under discussion shall automatically be deemed to have been tabled and shall be referred, as needed, to an IRB subcommittee for further study.

2.7 The attendance at convened meetings typically includes at least one member who represents the general perspective of participants, one member who is unaffiliated with the Institution, and one member who is a non-scientist and will be documented in the minutes.

A. The member representing the general perspective of the participants, the unaffiliated member, and non-scientific member may be represented by one person or they may be represented by two or three different person.

2.8 At the discretion of the IRB Chair, voting may be by written ballot, a show of hands, or voice vote. The official meeting minutes will record, without individual identification, the number of votes to approve, disapprove, table, or abstain.

2.9 Whenever an issue arises during an IRB meeting, the minority opinion will be included in the minutes of the meeting.

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|  <p>HRPP POLICIES AND PROCEDURES</p> <p>Research Compliance Services Human Research Protections Institutional Review Board</p> | <p>Policy # 2.012</p> <p>Title: <u>IRB Minutes</u></p> <p>Section: <i>IRB Membership & Standard Operating Procedures</i></p> <p>Date: April 1, 2008</p> |
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1.0 Purpose

The purpose of this policy is to describe the requirements for minutes of IRB meetings.


2.0 Policy

It is the policy of the IRB to maintain minutes of IRB meetings in accordance with Health and Human Services regulations at 45 CFR §46.115(a) (2).

- 2.1 The IRB minutes will include a) core minutes and b) detailed review letters to investigators, which are cited as addenda in the core minutes and thus are an official component of the minutes.
- 2.2 The core IRB minutes will identify the IRB members who are present, IRB alternates who are serving to replace an IRB primary member, IRB alternates who are non-voting and are present, consultants, and administrative staff who are present, and any guests in attendance at the meeting.
 - A. Core minutes will include a record of alternate members who are serving in the place of a primary member.
 - B. Minutes may also include justification of any deletion or substantive modification of information concerning risks or alternative procedures contained in the DHHS-approved sample consent document.
- 2.3 The core IRB minutes will include 1) the names of IRB members who have a conflict of interest and are recused (absent) from the discussion and the vote, and 2) a notation indicating that a conflict of interest was the reason for the absence.
- 2.4 The core IRB minutes will include the names of IRB members who do not have a conflict of interest, but are absent from the room at the time of the vote.
- 2.5 The core IRB minutes will include the vote counts for all board actions (e.g., for, against, and abstentions).
- 2.6 The core IRB minutes will include a written summary of the discussion and resolution of controverted issues. A controverted issue is clarified for the purposes of this policy as one, which generated a contentious discussion among members of the IRB over a human participant protection issue. Examples include, but are not limited to:
 - A. Concerns over the acceptability of the risk-benefit relationship of the research.

- B. Concerns over additional protections for a vulnerable participant population and whether the protocol meets the requirements of Subpart C or D.
 - C. Concerns over investigator's qualifications.
 - D. Justification of deletion or substantive modification of information concerning risks or alternative procedures contained in the DHHS-approved sample consent document.
 - E. Concerns related to noncompliance.
- 2.7** The core IRB minutes will include a determination of when continuing review is required more often than annually, as required by Health and Human Services regulations at 45 CFR §46.109(e). This determination will be based upon factors such as: the risk level of the research, inclusion of a vulnerable participant population, and a history of noncompliance.
- 2.8** The core IRB minutes will include the length of time of an approval for both full board and expedited protocols.
- 2.9** The core IRB minutes will include specific comments relevant to the inclusion of certain (e.g., vulnerable) populations.
- 2.10** The core IRB minutes will include an IRB determination of which projects need verification from sources other than the investigator that no material changes have occurred since the previous IRB review. This determination will be based on a history of noncompliance as well as other factors as the IRB deems appropriate.
- 2.11** In addition to the review of pending applications, meeting minutes may include information regarding expedited continuing approvals, modifications, continuing reviews approved, exempt approvals, and any other business appropriate for IRB meetings.
- 2.12** The IRB minutes addenda (detailed review letters to investigators) will include the following as applicable:
- A. The basis for requiring changes in or disapproving research.
 - B. IRB required modifications of the initial IRB application, detailed protocol, consent/assent documents, requested clarifications, and additional information.
 - C. IRB required modifications of amendments to the IRB application and consent/assent documents.
 - D. IRB required actions in response to reports of unanticipated problems involving risk to the participant or others.
 - E. Documentation of compliance with the requirements of Health and Human Services regulations at 45 CFR §46 Subparts B, C and D as applicable, including documentation of determinations required by the regulations and the protocol-specific findings justifying those determinations.
 - F. Documentation of compliance with Health and Human Services regulations at 45 CFR §46.111(b), which require additional protections for vulnerable participants, such as decisionally impaired persons, economically or socially disadvantaged persons, and terminally ill patients.

- G.** Documentation of IRB determinations involving waiver or alteration of informed Consent, in accordance with Health and Human Services regulations at 45 CFR §46.116(d) including protocol-specific findings justifying those determinations (see HRPP policy [# 9.006](#)).
 - H.** Documentation of IRB determinations involving a waiver of the requirement for obtaining a signed consent form in accordance with Health and Human Services regulations at 45 CFR §46.117(c)(1)(2) (<http://research.unl.edu/orr/Waiver.doc>)
- 2.13** Copies of the core minutes are available on NUgrant to all appropriate individuals.
- 2.14** The IO and all IRB members have access to complete copies of IRB minutes, which include the appended IRB review letters, via NUgrant.
- 2.15** The complete IRB minutes will be provided to OHRP, auditing groups, and the courts in accordance with all applicable federal, state, and institutional requirements.

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|  <p>HRPP POLICIES AND PROCEDURES</p> <p>Research Compliance Services Human Research Protections Institutional Review Board</p> | <p>Policy # 2.013</p> <p>Title: <u>HRPP Policy Review and Approval</u></p> <p>Section: <i>IRB Membership & Standard Operating Procedures</i></p> <p>Date: July 28, 2015</p> |
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1.0 Purpose

The purpose of this policy is to describe the review and approval process for HRPP policies.

2.0 Policy

It is the policy of the IRB to continually, and at least annually, assess the adequacy of existent policies and the need for new policies as the field of research ethics and human participant protection evolves. At least annually the IRB administrator will send an email communication to IRB members asking them to review existing HRPP policies and procedures and assess the adequacy of policies and the need for new policies.

- 2.1 Proposed HRPP policies, which impact significantly the IRB review system, investigators, and the Institution will be reviewed and approved by the IRB with the Chair acting as designated signatory, the Director, the IRB Administrator, the IO, and in some cases, the Chancellor. HRPP internal administrative policies will be given to the IRB for their information but do not require formal approval.
- 2.2 When a draft policy is scheduled for review at the IRB meeting, all members of the IRB will be given a copy of the draft policy approximately one week in advance of the meeting.
- 2.3 All IRB members will be invited to attend the meeting at which the policy will be reviewed.
- 2.4 All IRB members have the right to cast their vote (for, against, abstain) either in person at the IRB meeting or via email. IRB members may provide written statements in support of their vote or ask other IRB members to express their opinions at the meeting.
- 2.5 In instances where approval of a policy is necessary before the next regularly scheduled meeting, voting procedure by email alone will be allowed for consideration of a policy.
- 2.6 In order for a policy to be approved or disapproved, two-thirds of the entire IRB membership must vote in favor, either in person or by email, for the motion to carry.


2.7 If the motion to approve a policy fails to pass, the draft policy may be referred to the IRB Chair or an IRB subcommittee for further discussion and revision before re-consideration.

3.0 Distribution of HRPP Policies and Procedures to the Campus

3.1 Notices are posted on the NUgrant website and HRPP website.

3.2 Notices will be included in the ORED Research Newsletter.

3.3 Changes to policies are reviewed at individual and group trainings.

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|  <p>HRPP POLICIES AND PROCEDURES</p> <p>Research Compliance Services Human Research Protections Institutional Review Board</p> | <p>Policy # 2.014</p> <p>Title: <u>IRB Records</u></p> <p>Section: <i>IRB Membership & Standard Operating Procedures</i></p> <p>Date: April 1, 2008</p> |
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1.0 Purpose

The purpose of this policy is to describe the maintenance and composition of IRB records.


2.0 Policy

It is the policy of the IRB that records will be maintained in full accordance with Health and Human Services regulations at 45 CFR §46.

- 2.1 Under Health and Human Services regulations at 45 CFR §46.115, the IRB will maintain documentation of all IRB activities.
- 2.2 Where appropriate, the IRB office will maintain all records, reports, and other required documents as specified by federal regulations and UNL policies on record retention. The following documentation will be maintained for a minimum of three years following the closure of the study for the purpose of IRB approval.
 - A. Copies of all research protocols reviewed.
 - B. Scientific evaluations, if any, which accompany the protocols.
 - C. Progress reports submitted by research investigators.
 - D. Reports of injuries to participants.
 - E. Reports of unanticipated problems involving risk to participants (including adverse event reports) and documentation of IRB review of these reports.
 - F. Minutes of IRB meetings.
 - G. Records of continuing review activities.
 - H. Copies of all correspondence between the IRB, the IRB office, and the research investigator.
 - I. List of IRB members and alternates.
 - J. DHHS-approved sample consent documents.
 - K. Statements of significant new findings provided to participants.
 - L. Records pertaining to research which is conducted must be stored securely in the IRB Office and must be retained for at least 3 years after completion of the research. IRB records not associated with research or for protocols cancelled without participant enrollment will be retained at the facility for at least 3 years after closure.
- 2.3 The IRB protocol files will include:
 - A. IRB application.
 - B. Detailed protocol.
 - C. Federal grant applications (as appropriate).
 - D. Approved informed consent/assent documents. (as appropriate)
 - E. Correspondence of evidence of scientific and scholarly merit review of proposals (as appropriate).
 - F. Initial IRB review letter to the PI, including citations of appropriate federal regulations utilized during IRB review of research involving prisoners (45 CFR §46 Subpart C) and/or children (45 CFR §46 Subpart D).

- G.** PI response to the IRB review letter.
- H.** Further correspondence regarding IRB review of the application.
- I.** Final IRB approval letter. The letter must include documentation of approvals under Health and Human Services regulations for exempt status [45 CFR §46.101(b)] and expedited continuing status [45 CFR §46.110].
- J.** For protocols granted exempt status, the file will include documentation of the exemption. Documentation of verified exemptions consists of the reviewer's citation of a specific exemption category and written concurrence that the activity described in the investigator's request satisfies the conditions of the cited exemption category. The exempt determination is reported at the next convened IRB meeting and documented in the minutes. ([HRPP Policy 4.001](#))
- K.** IRB approval of recruitment materials and copies of the IRB approval materials.
- L.** All requests for changes and the correspondence pertaining to the request. Copies of the modified IRB approved and stamped consents and/or protocols associated with the request.
- M.** All Continuing Reviews and the correspondence pertaining to the request. Copies of the consent documents approved in conjunction with continuing review.
 - 1.** IRB records for initial and continuing review by the expedited procedure must include: the specific permissible category, a description of action taken by the reviewer, the approval period and any determinations required by the regulations including protocol-specific findings supporting those determinations.
- N.** IRB records also must document any determinations required by the regulations and protocol-specific findings supporting those determinations, including:
 - 1.** Waiver or alteration of the consent process.
 - 2.** Research involving pregnant women, fetuses, and neonates.
 - 3.** Research involving prisoners.
 - 4.** Research involving children.
- O.** All interim progress reports.
- P.** Reports of unanticipated problems (internal adverse events, internal fatal adverse events, external adverse events, and unanticipated problems involving risk to the participant or others) and the correspondence pertaining to the reports. (Copies of supporting documentation and consent documents will be attached to the report.)
- Q.** Incidents of noncompliance, including documentation of investigation, correspondence, and reports to institutional officials and OHRP, where appropriate.
- R.** Results from correspondence regarding the findings.
- S.** IRB records for initial and continuing review by expedited continuing procedure include:
 - 1.** The specific permissible category.
 - 2.** Description of action taken by the reviewer.
 - 3.** Any determinations required by the regulations, along with protocol specific findings justifying those determinations.

- 2.4** The electronic IRB protocol record is created and maintained; electronically by order of date, with the most current records at the top of the table on NUgrant. Additional rows in the table are added as new forms are submitted.
- 2.5** Electronic IRB protocol records are maintained in the HRPP office until the protocol is completed or terminated. The complete electronic record is maintained until three years after the original closure or termination date.
- 2.6** The IRB maintains a secure database. The database is under constant revision to add information necessary to more efficiently provide service to the IRB and investigators. Currently the database contains:
- A.** IRB protocol number
 - B.** Title of Protocol
 - C.** Review category (exempt, expedited continuing, or full board).
 - IRB records cite the specific category of exemption where applicable.
 - D.** Date protocol was received, dates of full board meeting(s), approval, ending, continuing review, date protocol was entered, date for reminders (if necessary), date of approved protocol change, date additional information is requested by.
 - E.** Status of the study (approved, disapproved, pending review, preliminary approval, tabled, terminated, withdrawn, and preliminary review)
 - F.** Principal investigator's name and contact information (department, address, phone number, and email address)
 - G.** Supervising investigator's name and contact information (department, address, phone number, and email address)
 - H.** Special considerations (videotaping, audio taping, chemical materials, radioactive materials, photography, etc.)
 - I.** Funding status and source
 - J.** Investigator type (faculty, graduate, staff, post-doctoral student, undergraduate)
 - K.** Project type (research, demonstration, class project, independent study, class evaluation, other)
 - L.** Number of participants
 - M.** Types of participants (adults, UNL students, minors, adults with legal representatives, persons with limited civil freedom, person with psychological impairment, persons with mental retardation, persons with neurological impairment, HIV positive persons, pregnant women, fetuses, victims, others)
 - N.** Waivers (check if granted)
 - O.** PI training records
- 2.7** The HRPP also maintains a separate password protected database for the purpose of storing electronic records not stored in NUgrant, for example, IRB membership rosters, noncompliance records, IRB member training, etc.

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|  <p>HRPP POLICIES AND PROCEDURES</p> <p>Research Compliance Services Human Research Protections Institutional Review Board</p> | <p>Policy # 3.001</p> <p>Title: <u>Investigational Activities Requiring IRB Review and Approval</u></p> <p>Section: <i>Initial IRB Review of Protocols</i></p> <p>Date: August 28, 2015</p> |
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1.0 Purpose

The purpose of this policy is to describe investigational activities requiring IRB approval when UNL investigators are engaged in human subjects research activities.

1.1 Systematic Investigation, for the purposes of this policy, *is an activity that involves a prospective plan that incorporates data collection, either quantitative or qualitative, and data analysis in order to answer a question.*

Therefore, you have research when the *prospective plan that incorporates data collection, either quantitative or qualitative, and data analysis in order to answer a question is designed to develop or contribute to generalizable knowledge.*

2.0 Definitions

2.1 Research is defined by DHHS regulations at 45 CFR §46.102(d) as, “*a systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge.*” Activities that meet this definition may be funded or unfunded, or may be conducted as a component of another program not usually considered research. For example, demonstration and service programs may include evaluation components, which constitute research activities under this definition.

The Belmont Report provides further clarification of “research” as follows: “... *the term ‘research’ designates an activity designed to test a hypothesis, permit conclusions to be drawn, and thereby to develop or contribute to generalizable knowledge (expressed, for example, in theories, principles, and statements of relationships).*”

Research is defined by FDA regulations as any experiment that involves a test article and one or more human subjects and that either is subject to requirements for prior submission to the Food and Drug Administration under Section 505(i) or 520(g) of the act, or is not subject to requirements for prior submission to the Food and Drug Administration under these Sections of the act, but the results of which are intended to be submitted later to, or held for inspection by the Food and Drug Administration as part of an application for a research or marketing permit. The term does not include, experiments that are subject to the provisions of part 58 of this chapter, regarding non-clinical laboratory studies. An experiment, as defined in 21 CFR 312, includes any use of a drug other than the use of a marketed (approved) drug in the course of medical practice.

2.2 Human Subject is defined by DHHS regulations at 45 CFR §46.102(f) as, “a living individual about whom an investigator (whether professional or student) conducting research obtains, 1) data through intervention or interaction with the individual, or 2) identifiable private information” [Intervention includes both physical procedures by which data are gathered (for example, venipuncture) and manipulations of the subject or the subject’s environment that are performed for research purposes.]

Interaction includes communication or interpersonal contact between investigator and subject.

Private information includes information about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place, and information that has been provided for specific purposes by an individual and that the individual can reasonably expect will not be made public (for example, a medical record). Private information must be individually identifiable (i.e., the identity of the subject is or may readily be ascertained by the investigator or associated with the information) in order for obtaining the information to constitute research involving human subjects.

In this set of policies, the word “participant” is substituted for the word “subject”.

Human subject as define by FDA regulations is an individual who is or becomes a subject in research, either as a recipient of the test article or as a control. A subject may be either a healthy human or a patient. In the case of a medical device, a human subject/participant also means a human on whose specimen an investigational device is used.

Human Participant Research for the purposes of this policy is defined as an activity that meets the definitions of “research” and involves “human subjects” as defined either by HHS regulations or by FDA regulations.

In order for an activity to constitute “human participant research”, all of the following criteria must be met:

- A. The primary intent is to conduct a systematic investigation, using an appropriate research design involving human subjects, in order to test a hypothesis.
- B. There is an implicit or explicit data analysis plan which will permit scientifically valid conclusions to be drawn.
- C. This activity is designed to develop or contribute to generalizable knowledge, i.e., designed in such a way as to generate data/results that would be applicable broadly, to individuals other than to just those participating in the study.

2.3 Intervention *includes both physical procedures by which data are gathered (e.g., drawing blood) and manipulations of the participant or the participant's environment that are performed for research purposes.*

2.4 Interaction *includes communication or interpersonal contact between investigator and participant.*

2.5 Private Information *includes information about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place, and information which has been provided for specific purposes by an individual, and which the individual can reasonably expect will not be made public (e.g., medical record information).*

2.6 Engagement in Research

In general, the Institution is considered engaged in non-exempt in human subjects research when the involvement of Institution faculty, staff, or students in a project includes any of the following (based on OHRP *Guidance on Engagement of Institutions in Human Subjects Research* found at <http://www.hhs.gov/ohrp/policy/engage08.html>):

- A.** The receipt of an award through a grant, contract, or cooperative agreement for non-exempt human subjects research (i.e. awardee institutions), even where all activities involving human subjects are carried out by employees or agents of another institution.
- B.** Intervention for research purposes with any human subjects of the research by performing invasive or noninvasive procedures.

Examples of invasive or noninvasive procedures include drawing blood; collecting buccal mucosa cells using a cotton swab; administering individual or group counseling or psychotherapy; administering drugs or other treatments; surgically implanting medical devices; utilizing physical sensors; and utilizing other measurement procedures.

- C.** Intervention for research purposes with any human subject of the research by manipulating the environment.

Examples of manipulating the environment include controlling environmental light, sound, or temperature; presenting sensory stimuli; and orchestrating environmental events or social interactions.

- D.** Interaction for research purposes with any human subject of the research.

Examples of interacting include engaging in protocol dictated communication or interpersonal contact; asking someone to provide a specimen by voiding or spitting into a specimen container; and conducting research interviews or administering questionnaires.

- E.** Obtaining the informed consent/assent of human subjects for the research.

- F. Obtaining for research purposes identifiable private information or identifiable biological specimens from any source for the research. It is important to note that, in general, those who obtain identifiable private information or identifiable specimens for non-exempt human subjects research are considered engaged in the research, even if the Institution's faculty, staff, or students do not directly interact or intervene with human subjects. In general, obtaining identifiable private information or identifiable specimens includes, but is not limited to:
1. observing or recording private behavior;
 2. using, studying, or analyzing for research purposes identifiable private information or identifiable specimens provided by another institution; and
 3. using, studying, or analyzing for research purposes identifiable private information or identifiable specimens already in the possession of the investigators.

In general, OHRP considers private information or specimens to be individually identifiable as defined in 45 CFR 46.102(f) when they can be linked to specific individuals by the investigator(s) either directly or indirectly through coding systems.

2.7 Individually Identifiable Information is information where the identity of the subject is or may readily be ascertained by the investigator or associated with the information.

2.8 Systematic Investigation, for the purposes of this policy, *is an activity that involves a prospective research plan that incorporates data collection, either quantitative or qualitative, and data analysis in order to answer a research question.*

2.9 Investigations designed to develop or contribute to **generalizable knowledge** *are those designed to draw general conclusions (i.e., knowledge gained from a study may be applied to populations outside of the specific study population), inform policy, or generalize findings.*

3.0 Policy

IRB approval is required for **all** research involving human participants as defined above, which is conducted by faculty, students, staff, or others under the jurisdiction of the IRB, (i.e. research performed on the premises of UNL, when UNL is engaged in the research, as well as research involving human participants conducted elsewhere by UNL investigators as part of their institutional responsibilities, unless the investigation is conducted under a cooperative research agreement.)

In reviewing research involving human participants, the IRB will apply 45 CFR §46 and all other definitions of human research as defined in applicable policy or regulatory criteria and in accordance with HRPP Policy #1.002. The IRB does not review activities which do not meet the definitions of research involving human participants under 2.1 and 2.2 above.

The IRB classifies research as social science/ behavioral or biomedical.

3.1 Classification of Human Participant Research

A. Social Science and Behavioral Research

Social science and behavioral research includes all research performed with intent to develop generalizable knowledge (i.e., test a hypothesis and draw conclusions) about behaviors, attitudes and interactions among and between individuals, groups, and cultures. Generally this category of research has no intent of producing a diagnostic, preventive, or therapeutic benefit to the participant who is not seeking nor expecting a health benefit from the research. There may, or may not, be any prospect of direct participant benefit associated with this category of research.

Types of research involving human participants that may fall under the social science and behavioral research category include, but not limited to, for example:

1. Qualitative social science research
2. Ethnographic research
3. Oral History research
4. Observational research
5. Survey research

6. Education research
7. Criminal justice research

B. Biomedical Research

Biomedical research at UNL generally, but not exclusively, refers to clinical/patient oriented investigations, biomedical engineering research, and exercise science and nutrition studies research.

3.2 Non-Research Activities

A. Quality Improvement

In general, quality improvement projects are not considered research unless there is a clear intent to use the data derived from the project to contribute to generalizable knowledge.

If a quality improvement project is completed (i.e., all the data is collected, analyzed, and conclusions have been drawn) and the decision is made to publish or present the data, it is research. Depending on whether or not participant identifiers are maintained, it may qualify as exempt research.

B. Student Projects

When there is a clear intent to conduct a systematic investigation designed to develop or to contribute to generalizable knowledge, then student projects are considered research, which might be indicated, for example, by publication in a peer review journal and/or presentation at a national or regional meeting. However, a student project that is presented, for example, as a poster or a seminar *within the academic confines of the Institution only*, and is not intended to contribute to *generalizable* knowledge, generally is not considered research. In this case, the student's supervisor and/or

department are responsible to exert appropriate oversight of the project and to consult with the HRPP office as needed.

3.3 Determination of When an Activity Constitutes Human Participant Research

Any individual who is unsure whether or not a proposed activity constitutes “research involving human subjects” should contact the HRPP office for guidance. HRPP staff and/or the IRB Chair will determine whether a given project is subject to 45 CFR §46 and any other requirements dictated by a federal sponsor. HRPP staff and the IRB Chair will use the OHRP Human Subject Decision Charts (Human Subject Regulations Decision Charts, September 24, 2004) as necessary to determine whether the research meets the DHHS definition of “research” and involves “human subjects” as defined by DHHS regulations. Research activities that involve FDA-regulated drugs, devices, or biologics will be reviewed by the Director. If the Director determines that the research falls under 21 CFR 50 and 56, the research will be referred to the biomedical IRB with which UNL has a reciprocal agreement: the University of Nebraska Medical Center. The investigator will be instructed that all of the requirements of that IRB must be complied with and that the IRB Office must be provided with copies of all communications with that IRB. The research conduct and reporting requirements contained in this document also will have to be met for FDA-regulated research. When there is any question concerning whether or not an investigator will be engaged in research, HRPP staff and/or the IRB Chair will consult with OHRP.


Decisions about whether an activity represents human participant research are made promptly and conveyed to the individual seeking guidance. All decisions will be explained fully in order to ensure the Institution’s faculty, staff, and students understand the criteria used in making the determination.

3.4 Type of Review

The type of IRB review required depends upon the proposal classification (e.g., full board, expedited continuing, or exempt). HRPP staff and the IRB Chair will use the OHRP Human Subject Regulations Decision Charts (September 24, 2004) as necessary in determination of the type of review (<http://www.hhs.gov/ohrp/humansubjects/guidance/decisioncharts.htm>).

3.5 Sponsored Research

- A.** The University agrees to follow the research protocol, applicable state and federal law, and UNL’s ethical standards.
- B.** The sponsor agrees to follow UNL’s policies and procedures regarding the dissemination and publication of findings from sponsored research.

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|  <p>HRPP POLICIES AND PROCEDURES</p> <p>Research Compliance Services Human Research Protections Institutional Review Board</p> | <p>Policy # 3.002</p> <p>Title: <u>Ethical Principles Governing Research Under the Jurisdiction of the IRB</u></p> <p>Section: <i>Initial IRB Review of Protocols</i></p> <p>Date: April 1, 2008</p> |
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1.0 Purpose

The purpose of this policy is to describe the ethical principles, which govern research under the jurisdiction of the IRB.

2.0 Policy

It is the policy of the IRB that all research which is reviewed and approved by the Board and conducted under its jurisdiction will generally conform to the following guidance documents: 1) The Nuremberg Code and 2) The Belmont Report. Health and Human Services regulations (45 CFR §46) reflect the basic ethical principles for the conduct of human participant research found in these documents.

All researchers, participating personnel, and IRB members are charged with upholding the ethical principles contained in the aforementioned guidance documents as they apply to the research project in question. The IRB protocol, reviewer checklist, and the process of IRB review is designed to help IRB members and investigators ensure that research reflects the highest possible ethical standards (HRPP policy [# 3.004](#)).

2.1 The Nuremberg Code

The Nuremberg Code contains 10 basic principles which are presented in abbreviated form below:

- A.** Obtain voluntary consent of the participant.
- B.** Design the study to yield results for the good of society, otherwise unobtainable through other means.
- C.** Base studies involving humans on animal experiments.
- D.** Avoid physical and mental suffering and injury to the participant or others.
- E.** Do not conduct the study if death or disabling injury is an expected result.
- F.** The degree of risk should never exceed the humanitarian importance of the problem to be solved by the research.
- G.** Protect the participant from injury, disability, or death.
- H.** Be scientifically qualified to conduct the study.
- I.** Allow the participant to voluntarily withdraw at any time.
- J.** Be prepared to stop the study when continuation is likely to result in injury, disability, or death to the participant.

2.2 The Belmont Report

In 1979, the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research released the “*Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects of Research*”. The three basic ethical principles described in the Belmont Report are:

- A. Respect for Persons**


The ethical principal of respect for persons has two components: acceptance of individual autonomy and protection of those with diminished autonomy. Autonomous individuals demonstrate the ability to make informed choices and act on those choices. These choices must be acknowledged and accepted by others as a demonstration of respect, as long as those choices are not harmful to others. Conversely, it must also be recognized that some individuals may be incapable of making informed choices and require special protection. The principle of respect for persons in the research context is demonstrated through the process of informed consent, including the process of assent and proxy consent for potential participants requiring special protections.

B. *Beneficence*

The principle of beneficence is defined in two ways: (1) do no harm, and (2) maximize the potential benefits and minimize all potential harms (e.g., risks) related to research participation. While there is an imperative that no harm comes to the participant, it should be recognized that there is potential for harm due to unknown factors associated with the research. To minimize this risk, the potential benefits to the participant and society must be determined and maximized.

C. *Justice*

The principle of justice implies a sense of “fairness”. Justice occurs when the burdens and benefits are equally carried by all. To achieve justice in the research context, recruitment of potential participants must occur without discrimination, bias, or undue influence in order to distribute the burdens and benefits of research equitably for individual and society good. Inequities must be justified.

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|  <p>HRPP POLICIES AND PROCEDURES</p> <p>Research Compliance Services Human Research Protections Institutional Review Board</p> | <p>Policy # 3.003</p> <p>Title: <u>Initial Application Submission</u></p> <p>Section: <i>Initial IRB Review of Protocols</i></p> <p>Date: April 1, 2008</p> |
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1.0 Purpose

The purpose of this policy is to describe IRB deadlines, submission materials, and the IRB pre-review process.

2.0 IRB Deadlines

Application forms and submission deadlines can be obtained through the HRPP website (<http://research.unl.edu/researchresponsibility/human-research-protections-programirb-forms-policy-and-guidance-page>). Full board reviews must be submitted to the IRB office at the beginning of the month to be considered for review at that meeting. Incomplete submissions may result in delay of IRB review. Applications are reviewed in the order in which they are received.

Proposals that qualify for expedited review or exempt status may be submitted to the IRB at any time. In order to qualify for expedited review, the protocol must be no more than minimal risk and classified under one or more of the categories listed in HRPP policy [# 4.002](#).

3.0 Materials to Include in the IRB Submission of Initial Applications

An electronic copy of each of the following (as applicable) must be submitted to the IRB.

3.1 *IRB Application*

The application must include sufficient detail to facilitate IRB review. This application can be found and must be submitted via NUgrant (<http://nugrant.unl.edu>).

3.2 *Informed Consent and Assent Form(s)*

The consent and assent forms must be appropriate for the proposed study population (e.g., adult, proxy, parental, youth, and child). Examples can be obtained from the HRPP website (<http://research.unl.edu/researchresponsibility/human-research-protections-programirb-forms-policy-and-guidance-page>).

3.3 *Participant Recruitment Material(s)*

Copies of all advertisements, letters, transcripts of broadcast materials and other recruitment material must be provided for IRB review (where applicable).

3.4 *Description of performance site for all non-Institutional sites*

Performance sites are defined as (1) sites where Institutional investigators or staff interact with participants, collect data, or solicit consent, or (2) sites over which the IRB has responsibility. Performance sites do not include other sites

participating in a multi-center study which have an IRB. All performance sites must be identified

3.5 Other Relevant Materials

- A.** Originals or copies of all surveys, assessment tools, screen shots of websites and other relevant materials must be submitted for IRB review.
- B.** Where applicable, a copy of the detailed protocol and a copy of the *complete* grant narrative (i.e., excluding form pages, budget, bio sketches, etc.).


4.0 IRB Pre-Review

As new applications are created via NUgrant, the protocol will be assigned a project ID. Once submitted, the PI receives an on screen message verifying the protocol was successfully submitted. The IRB approval number, which includes the project ID, will be provided to the PI when the project is approved. This IRB approval number will be the identifier of the project for the life of the study.

All applications submitted for IRB review are screened by the HRPP staff. Specifically, the application will be screened to determine that:

- 4.1** All required documents have been submitted and are complete.
- 4.2** All personnel listed on the application (PI, Secondary Investigator, and other Participating Personnel) have human subjects training (required training in the protection of human participants - see HRPP policy # [3.009](#)). If a person does not have current CITI training, they will be notified of the requirement during the pre-review process.
- 4.3** The PI and Secondary Investigator will be contacted via an email sent through NUgrant to correct errors, provide missing documents, or provide additional information.

HRPP staff will determine, with advice of the IRB Chair as needed, whether a project should be scheduled for expedited, or full board review. IRB reviewers, for full board review will be assigned by an HRPP staff person in consultation with the IRB Chair, as needed.

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|  <p>HRPP POLICIES AND PROCEDURES</p> <p>Research Compliance Services Human Research Protections Institutional Review Board</p> | <p>Policy # 3.004</p> <p>Title: <u>Criteria for IRB Approval of Research</u></p> <p>Section: <i>Initial IRB Review of Protocols</i></p> <p>Date: March 30, 2015</p> |
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1.0 Purpose

The purpose of this policy is to describe the criteria required for IRB approval of *non-exempt* research.

2.0 Policy

It is the policy of the IRB that all non-exempt research proposals (expedited and full board) will undergo a rigorous review which will allow a determination that the protocol meets: 1) the criteria specified in Health and Human Services regulations at 45 CFR §46.111 and 2) IRB HRPP policies and procedures. 45 CFR §46.111 criteria are listed as follows and are the reference guide for all IRB review.

- (a) In order to approve research covered by this policy the IRB shall determine that all of the following requirements are satisfied:
- (1) Risks to subjects are minimized: (i) by using procedures which are consistent with sound research design and which do not unnecessarily expose subjects to risk, and (ii) whenever appropriate, by using procedures already being performed on the subjects for diagnostic or treatment purposes.
 - (2) Risks to subjects are reasonable in relation to anticipated benefits, if any, to subjects, and the importance of the knowledge that may reasonably be expected to result. In evaluating risks and benefits, the IRB should consider only those risks and benefits that may result from the research (as distinguished from risks and benefits of therapies subjects would receive even if not participating in the research). The IRB should not consider possible long-range effects of applying knowledge gained in the research (for example, the possible effects of the research on public policy) as among those research risks that fall within the purview of its responsibility.
 - (3) Selection of subjects is equitable. In making this assessment the IRB should take into account the purposes of the research and the setting in which the research will be conducted and should be particularly cognizant of the special problems of research involving vulnerable populations, such as children, prisoners, pregnant women, mentally disabled persons, or economically or educationally disadvantaged persons.
 - (4) Informed consent will be sought from each prospective subject or the subject's legally authorized representative, in accordance with, and to the extent required by [§46.116](#).
 - (5) Informed consent will be appropriately documented, in accordance with, and to the extent required by [§46.117](#).
 - (6) When appropriate, the research plan makes adequate provision for monitoring the data collected to ensure the safety of subjects.
 - (7) When appropriate, there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data.

- (b) When some or all of the subjects are likely to be vulnerable to coercion or undue influence, such as children, prisoners, pregnant women, mentally disabled persons, or economically or educationally disadvantaged persons, additional safeguards have been included in the study to protect the rights and welfare of these subjects.

The IRB information requirements, which reflect approval criteria, are described in the IRB application and the IRB Reviewer checklist. Final copies of approval letters from research sites outside of UNL such as Lincoln Public Schools, companies, etc. must be submitted before final approval of the application can be given and research can begin.

The reviewer performing the reviews are to use either the EP (Expedited) or the FB (Full Board) Reviewer Checklist as appropriate. The reviewer checklist assists in determining whether:

- A. Research undergoing initial review can be approved.
- B. Research undergoing continuing review can be approved
- C. Modification to previously approved research can be approved.

2.1 Criteria for IRB Approval

A. Purpose of the study

The IRB will determine if the background and literature citations support the stated purpose of the study (see HRPP policy [#3.006](#)).

B. Characteristics of the participant population

The IRB will examine the characteristics of the proposed participant sample to determine whether the eligibility criteria are appropriate with respect to the nature and goals of the research and that the selection of participants is equitable without any form of discrimination or bias. Factors such as the required number of participants, age range, sex, race/ethnicity, and health status will be considered. Any proposed exclusion of persons on the basis of age, sex, reproductive status, race/ethnicity, or any other stated factor must be justified scientifically by the investigator. In particular, the following will be examined:

1. **Accrual**

The IRB must be assured that the maximum number of participants consented to this study is sufficient for the purpose of this study and sufficient justification is provided.

2. **Gender**

The IRB must be assured that the proposed distribution is suitable for the purpose of the study and appropriate justification for the inclusion or exclusion of males or females is provided. Furthermore, women of childbearing potential and pregnant women should not be excluded from participation in research unless sufficient justification is provided.

3. **Age range of participants**

The IRB must be assured that the proposed age range is suitable for the purpose of the study and appropriate justification for the inclusion or

exclusion of particular age groups or persons, such as children or the elderly, is provided.

4. *Race and ethnicity*

The IRB must be assured that the proposed distribution of participants by race/ethnicity is suitable for the purpose of the study and appropriate justification for the inclusion or exclusion of particular persons or groups is provided.

5. *Vulnerable participants*

The IRB will determine if the research is appropriate for inclusion of vulnerable populations under Health and Human Services regulations at 45 CFR §46, Subpart C (prisoners [HRPP policy [# 5.003](#)]) and Subpart D (children [HRPP policy [# 5.004](#)]). In addition, the IRB will determine if special protections are required for decisionally impaired persons (HRPP policy [# 5.005](#)) as well as other potentially vulnerable populations.

6. *Inclusion/exclusion criteria*

The inclusion and exclusion criteria are appropriate for the purpose of this study. The stated exclusion criteria minimize risk to potential subjects.

C. *Methods and procedures*

The IRB will review the experimental design in order to be assured that the potential risks to the participants are minimized and the potential benefits maximized by utilization of procedures consistent with sound research design and which do not unnecessarily expose participants to risk (see HRPP policy [#3.006](#)). Additionally, the IRB must determine if the interventions and follow-up procedures are appropriate for the stated purpose of the research and, whenever appropriate, procedures are used which already will be performed on the participants for diagnostic or treatment purposes. Interventions and procedures considered standard of care must be clearly identified.

The IRB accepts the need for certain types of behavioral and social science studies to employ strategies that include either deception and/or the withholding of information. Employment of such strategies must, however, be justified. In general, deception is not acceptable if, in the judgment of the IRB, the participant would have declined to participate had they been informed of the true purpose of the research. Studies that use deception and/or the withholding of information as part of their experimental design must meet all the requirements of 45 CFR §46.116(d), described below, and include a post-study debriefing, unless an exception is granted by the IRB.

In the event that a study includes the use of deception, the investigator must:

1. Provide a justification for the deception (i.e., why the study could not be conducted without deception);
2. Describe the manner of deception (e.g., the participants are not informed of the true intent of the study) and/or how the deception will take place (e.g. a confederate will simulate an accident);

3. Note whether the deception results in any increased risk to participants (e.g. confederates engage in a staged altercation which could result in emotional upset); and
4. Describe how any additional risks would be minimized (where appropriate).

D. Data storage and confidentiality

1. The IRB will review the methods to be used to protect confidentiality and will ensure that appropriate protections are in place in consideration of the nature of the research, the vulnerability of the participant population, and the risk associated with a breach of confidentiality.
2. If research data with participant identifiers will be made available to persons other than the listed investigators, sponsor, or federal agency, the IRB will review the justification for sharing this data and determine acceptability in accordance with all applicable regulations, including the HIPAA Privacy Rule (see HRPP policies [# 10.001](#) and [10.002](#)).
3. If the research involves the collection of sensitive information where a breach of confidentiality would constitute a serious risk, the IRB will consider the need for a Certificate of Confidentiality (see HRPP Policy [#3.011](#)). The IRB may also waive documentation of informed consent in accordance with 45 CFR §46.117(c).

E. Risk – Benefit Assessment

1. Potential Risks

Both immediate and latent (delayed) risks of any procedure involving human participants will be reviewed by the IRB to ensure that risks to participants are identified and minimized. The estimated probability, severity, average duration, and reversibility of any potential harm will be considered according to available empirical data. Furthermore, since certain populations of vulnerable participants may be at greater risk than others, the IRB will take into consideration the potential risk characterization of the participant and ensure that appropriate additional protections are in place.

2. Risk Classification

Risk is classified as: 1) minimal, 2) greater than minimal, or 3) significant. The IRB will review carefully the risk classification of the research, as it will determine the type of IRB review and interim review requirements.

Minimal risk is defined as follows: "The probability (of occurrence) and magnitude (seriousness) of harm or discomfort (e.g., physical, psychological, social) associated with the research are not greater than those ordinarily encountered in daily life (of healthy persons in the general population) or during the performance of routine physical or psychological examinations or tests."

A uniform standard of minimal risk based upon the daily life of a normal, average, healthy person living in a safe environment or during the performance of routine physical or psychological examinations or tests he/she would be expected to encounter will normally be used for

research involving adults except in certain projects receiving funding from different federal sources such as the Department of Defense (DOD) (see Policy 15.004 Section 5.0 Risk Evaluation). However, under certain circumstances, application of the minimal risk classification will be based upon a consideration of the risks inherent in each participant's life thereby resulting in a relative standard of minimal risk *which is more stringent*. Factors such as age, repetitive procedures, and vulnerability will be considered in determining if a study qualifies as minimal risk.

When research involves children, a uniform standard of minimal risk also will be used, which is based upon the daily life of a normal, average, healthy child living in a safe environment or the performance of routine psychological and medical examinations he/she would be expected to encounter as part of a standard well-child examinations.

3. Minimization of risk (safety and data monitoring)

The IRB will review data and safety monitoring that must fit the design, nature, and risk profile of the research. In some cases, the research will require a data safety monitoring plan (see HRPP policy [#3.010](#)). The IRB will determine whether or not a research project requires review more often than annually (HRPP policy [# 3.010](#)) and will establish an appropriate reporting and/or monitoring procedures that may include observation of the consent process, observation of on-going research, or review of research records (see HRPP policies [# 7.001](#)).

In order to approve research in which the IRB considers provisions for monitoring data to ensure the safety of participants to be appropriate, the IRB will determine that the research plan makes adequate provisions. The following items will be addressed, where appropriate, during the IRB review.

- a. What safety information will be collected, including serious adverse events?
- b. How the safety information will be collected (e.g., with case report forms, at study visits, by telephone calls with participants).
- c. The frequency of data collection, including when safety data collection starts.
- d. The frequency of periodicity of review of cumulative safety data.
- e. The plan might include establishing a data monitoring committee and a plan for reporting data monitoring committee findings to the IRB and the sponsor, including the frequency of reporting.
- f. For studies that do not have or are not required to have a data monitoring committee and are blinded, have multiple sites, enter vulnerable populations, or employ high-risk interventions, the IRB needs to carefully review the data and safety monitoring plan and determine whether a data monitoring committee is needed.

- g. If not using a data monitoring committee, and if applicable, statistical tests for analyzing the safety data to determine whether harm is occurring.
- h. Provisions for the oversight of safety data (e.g., by a data monitoring committee).
- i. Conditions that trigger an immediate suspension of the research, if applicable.

The IRB also will determine whether a research project requires verification from sources other than the investigators that no material changes have occurred since the previous IRB review (HRPP policy [# 3.010](#)).

4. Potential Benefits

The IRB will review the anticipated benefits to both the participant and to society. In addition, the IRB will consider whether the benefits are maximized to the greatest extent possible through proper protocol design. Financial or other forms of compensation are not considered a benefit to be derived from research participation. Although the participant may consider financial compensation a desirable outcome, this fact will not be used in the risk-benefit analysis.

5. Risk-Benefit Analysis

The IRB will examine the relationship of the risks to the benefits identified in the application. The following is a series of principles, which the IRB will take into consideration:

- a)** In research involving the study of the efficacy and safety of a therapeutic or diagnostic method, where there is the potential for participants to receive a direct health benefit (e.g., clinical research), the risk-benefit relationship of the research must be at least as favorable to the participant as that presented by alternate standard therapies available to the participant in the non-research context.
- b)** In research involving a combination of a standard therapy (used solely for the benefit of the participant and not part of the research protocol) with specified research procedures, the anticipated benefits of the therapy must not be used to justify exposing participant to the risks associated with the research procedures. Conversely, only the risks associated with the research procedures should be used in determining acceptability of the risk-benefit relationship.
- c)** In research that has no likelihood or intent of producing a diagnostic, preventive, or therapeutic benefit to the subject (e.g., behavioral research and non-clinical biomedical research), the potential risk to the participant must be outweighed or balanced by the potential benefit to the participant *and/or* by the potential benefit to society.

6. Alternatives to Participation

The IRB will review the alternatives outside of the research context that are available and may be of reasonable benefit to the participant.

F. Participant Financial Obligations

The IRB will review the financial obligations of the participant relative to participating in the study. The IRB application should clearly identify who will be financially responsible for research related interventions or procedures, as well as other potential costs of participation (e.g., travel, child care, food).

G. Compensation for participation

The IRB will review the amount of compensation for participation (monetary, as well as other forms) in order to ensure that it is not coercive and is fair (see HRPP policy [# 3.015](#)).

H. Conflict of Interest

The IRB will review potential conflicts of interest of the research personnel, which has been reviewed by the Conflict of Interest Review Committee (CIRC) (see HRPP policy [# 3.007](#)). This review will be based upon the Board's charge to ensure protection of the rights and welfare of human participants. This charge includes authority to:

1. Ensure disclosure in the consent document of any financial interests, which are judged by the IRB to be relevant to the participant's decision whether or not to participate in research.
2. Ensure there is an appropriate plan for monitoring of the research, which may involve observation of the consent process, auditing of records, and interim reporting of research results to the IRB.
3. Require informed consent be obtained by a qualified individual other than the person(s) identified as having a conflict. If the IRB finds that the conflict of interest management plan requires additional measures, the Board will alter the management plan in accordance with its charge and forward the revised plan to the Conflict of Interest Coordinator.

I. Participant identification and recruitment

The IRB will review the method of prospective participant identification and recruitment in order to be assured it is ethically and legally acceptable (see HRPP policy [# 3.016](#)). Advertisements (e.g., newspaper ads, fliers, radio ads, etc.) used to recruit participants are considered an extension of the recruitment and informed consent processes, and therefore, must be reviewed by the IRB.

J. Informed consent

The IRB will review both the consent form and the process of informed consent as described in the IRB application to ensure that consent will be sought only under appropriate circumstances, which allow the prospective participant to engage in thoughtful decision making. Specifically, the IRB will determine the following:

1. The process of consent/assent is appropriate in consideration of the nature of the research, risks of the research, and characteristics of the participant population (see HRPP policy [# 9.002](#)).

2. All required consent/assent document(s) utilize the appropriate IRB approved templates (<http://research.orr/forms.shtml>).
3. The informed consent form(s) contain the elements of informed consent required by Health and Human Services regulations (see HRPP policy [# 9.002](#)).
4. The assent form(s) contain the IRB-required elements of assent (see HRPP policies [# 9.002](#) and [9.004](#)).
5. The documentation of informed consent conforms to HRPP policy [# 9.002](#).

K. Investigator qualifications

The IRB (see HRPP policy [#3.008](#)) will review the PI's qualifications and must be assured:

1. The investigator has the appropriate qualifications and licensure (if any) to carry out the procedures involving human participants with an acceptable degree of risk.
2. The investigator has adequate facilities and equipment to conduct the research with an acceptable degree of risk.
3. The principal or secondary investigator must be affiliated with UNL.
4. For student projects, a UNL faculty member must be listed as the secondary investigator/advisor. A staff member should not be listed as the secondary investigator/advisor unless specific circumstances allow. An unaffiliated person may not be listed as the secondary investigator/advisor.

L. Scientific and scholarly merit and resource review

The IRB must ensure that the research has undergone substantive scientific and scholarly merit and resource review (see HRPP policy [#3.006](#)).

- 2.2** Prior to final approval by the IRB, letters of endorsement must be submitted from all research sites, which include acknowledgement of any specifications regarding their own participation and what access, services, facilities, or personnel they are going to provide for the research project.

If the Institution is the lead site for a multi-institutional protocol, and data are collected and analyzed at UNL, or adverse events or serious problems tracked at UNL, then a copy of the approval from the IRB of all reporting sites must be provided. If additional sites are added after approval of this application, then letters of IRB approval must be submitted as they become available.

Letters of agreement must be received from study sites not associated with the Institution (such as schools, nursing homes, and prisons), stating that the site administrator is aware of the study and will allow the Institutional PI and study personnel to utilize their site to conduct the study.

2.3 IRB Review Checklist


All IRB members are provided IRB reviewer checklists. IRB reviewers are encouraged to use the checklists as a guide, but are not required to submit completed forms. Primary and secondary reviewers submit completed forms as part of their reviewer responsibilities.

2.4 Office of Sponsored Programs Review

All applications for funding must be submitted to Office of Sponsored Programs. If human participants are involved, Office of Sponsored Programs will inform PI to contact the IRB. It is the responsibility of the PI to secure IRB approval.

2.5 Additional Administrative Review (expedited continuing and full board protocols)

Research that has been approved by the IRB may be subject to further appropriate review and approval or disapproval by officials of the institution. Those officials cannot, however, approve any research project unless it is first approved by the IRB. When a study is considered controversial, particularly from a community-based standpoint, the IRB Chair will forward a copy of the protocol to the IO (or designee) and the PI will be so notified.

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|  <p>HRPP POLICIES AND PROCEDURES</p> <p>Research Compliance Services Human Research Protections Institutional Review Board</p> | <p>Policy # 3.005</p> <p>Title: <u>IRB Initial Review Categories</u></p> <p>Section: <i>Initial IRB Review of Protocols</i></p> <p>Date: April 1, 2008</p> |
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1.0 Purpose

The purpose of this policy is to describe the IRB initial review categories.

2.0 Policy

It is the policy of the IRB that research must be appropriately classified as exempt, expedited continuing, or full board review in accordance with Health and Human Services regulations at 45 CFR §46.

2.1 Exempt Review

If a proposal is initially submitted as exempt via the NUgrant system, the proposal will be reviewed using the exempt review procedure. If the proposal qualifies for exempt status in accordance with Health and Human Services regulations at 45 CFR §46.101(b) (1-6), the proposal will be assigned into one of the six exempt categories (see HRPP policy [# 4.001](#)).

2.2 Expedited review

If an investigation involves not more than minimal risk activities that qualify for expedited review status in accordance with 45 CFR §46.110, the proposal will be reviewed using an expedited review procedure (see HRPP policy [# 4.002](#)).

After the review takes place, the investigator will be notified of the IRB's decision concerning the proposal via NUgrant. Reviewed proposals will be assigned to one of three categories:

A. **Approval and Full Release**

The proposal is approved and released. The investigator may begin the study.

B. **Approval with modifications, contingent upon IRB Chair/expedited reviewer or, unless otherwise specified, IRB Associate acceptance of specific modifications and/or clarifications**

The investigator will be notified, in writing, as to the nature of the required modifications and/or clarifications. As soon as the investigator complies in writing with all requirements, a release will be issued and the investigator may begin the study.

C. **Referred for full IRB review**

The IRB Chair(s), Vice Chair or IRB Administrator, has a serious concern and has determined the proposal should be reviewed by the full IRB.

2.3 Full Board Review

Proposals that do not qualify for exempt or expedited review will be submitted to the full IRB.

After the IRB meeting, the investigator will be notified in writing of the IRB's decision concerning the proposal. In accordance with the IRB's decision, the IRB letter will specifically detail items requiring clarification, modification or justification. The PI will be requested to respond to IRB concerns. The IRB minutes should reflect the IRB determination.

Reviewed proposals will be assigned to one of six (6) categories:

A. *Approval and full release*

No modifications or clarifications are required and the investigator may begin the study.

B. *Conditional approval, contingent upon IRB Chair HRPP or designee acceptance of specific modifications/clarifications*

This category is restricted to modifications/clarifications that are not directly relevant to the regulatory determinations. The investigator will be notified in writing as to the nature of the required modifications and/or clarifications. When the investigator complies, in writing, with all requirements as determined by the IRB Chair/Vice Chair or HRPP designee, a release will be issued and the investigator may begin the study.

C. *Conditional approval, contingent upon full IRB re-review of specific modifications/clarifications*

This category is restricted to modifications/clarifications, which are considered substantive in nature. The investigator will be notified in writing as to the nature of the required modifications and/or clarifications. When the investigator complies, in writing, with all requirements as determined by the full IRB at a convened meeting, a release will be issued and the investigator may begin the study.

D. *Tabled*

This category is restricted to applications where the IRB requires a significant amount of additional information and/or has a serious concern. The investigator will be notified in writing of the IRB's decision concerning the proposal. The IRB Chair, Vice Chair and/or a member of the Board may be assigned to discuss the proposal with the investigator.


When the investigators submit the required materials for re-review, the tabled protocol will be reviewed at the next IRB meeting in adherence with published submission deadlines for full board meetings. Whenever possible, the two IRB reviewers who performed the initial review will be assigned to re-review the protocol. When that is not possible, IRB reviewers are encouraged to consult, as necessary, with previous reviewers in order to resolve any problems or concerns, which may still exist.

E. *Disapproved*

This category is restricted to applications, which have very serious design flaws and/or participants will be placed at undue risk. The investigator has the right of appeal to the IRB, which must be requested in writing. When necessary, the IRB will seek consultation from nationally recognized experts in the field, other IRBs, OHRP, and the National Science Foundation Office of the Inspector General (OIG). Every attempt will be made to resolve the identified problem(s). The IRB, however, retains final authority over whether or not a proposal can be approved.

F. *Decline to complete the review*

This category is restricted to applications, which are significantly deficient in information or content. Consequently, adequate review of the protocol could not take place. The Application will be returned to the PI with instructions to review and revise the application in consideration of application instructions and guidelines and resubmit the application to the IRB when ready.

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|  <p>HRPP POLICIES AND PROCEDURES</p> <p>Research Compliance Services Human Research Protections Institutional Review Board</p> | <p>Policy # 3.006</p> <p>Title: <u>Scientific and Scholarly Merit Review of Proposals</u></p> <p>Section: <i>Initial IRB Review of Protocols</i></p> <p>Date: April 1, 2008</p> |
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1.0 Purpose

The purpose of this policy is to describe the requirements for scientific and scholarly merit review of all research proposals submitted to the IRB for review.

2.0 Policy

It is the policy of the IRB that all research proposals must undergo a substantive scientific or scholarly merit and resource review per Health and Human Services regulations at 45 CFR §46.111(a)(1)(i) and 45 CFR §46.115(a)(1).

2.1 The IRB, utilizing member expertise and/or consultants, will evaluate the scientific and scholarly validity of a proposed study. The IRB has broad-based disciplinary expertise, which allows a judgment to be made that the proposed research meets the following criteria in consideration of the need to satisfy scientific and scholarly merit requirements:

- A.** The research uses procedures consistent with sound research design.
- B.** The research design will allow the proposed research question to be answered.
- C.** The knowledge to be gained from the research is sufficiently important from the research or training perspective.
- D.** The risk/benefit relationship is acceptable. When the IRB does not have sufficient expertise, the Board will utilize a consultant (HRPP policy [# 2.003](#)).

3.0 Other UNL Committees Providing Proposal Review

A. Institutional Biosafety Committee (IBC)

Federal law requires the establishment of an Institutional Biosafety Committee (IBC) at institutions where the research involves recombinant DNA molecules or human testing of materials containing recombinant DNA (including gene transfer and some vaccine trials.)

At UNL, the IBC is appointed by the Associate Vice Chancellor for Research and consists of the Chairman, faculty, and community representatives. Two community members, with no UNL affiliation other than membership on the IBC, are required and appointed to represent the interest of the surrounding community with respect to health and the protection of the environment.

The IBC, as a whole, represents collective expertise and research experience in recombinant DNA, infectious agents and biological safety in experiments, which may pose potential risks to human health or to the environment.

The IBC is responsible for ensuring that research conducted at UNL is in compliance with the National Institutes of Health Guidelines for Research Involving Recombinant DNA, drafting campus Biosafety policies and procedures as well as reviewing individual research proposals for Biosafety concerns.

The PI is required to inform Office of Sponsored Programs of all recombinant DNA experiments that are not exempted from the National Institutes of Health guidelines. The projects must be reviewed and approved by the IBC prior to the initiation of the research using IBC application form and review process (<http://ehs.unl.edu/committees/>).

PIs who wish to perform research using bio-hazardous materials must submit an application to the IBC. Applications are required for research that involves the use of:

1. Recombinant DNA
2. Vaccine/Gene Therapy
3. Infectious Agents
4. Toxins


If the PI is working with potentially infectious agents and human participants, IBC review is necessary in addition to review by the IRB. Final approval by the IRB is contingent upon final approval by the IBC and the Radiation Safety Committee. Normally, IBC review will precede IRB review and the assigned IRB reviewer is notified by HRPP staff of any concerns expressed by the IBC. If, however, IBC review follows IRB review and the IBC identifies concerns that merit review by the full IRB, the protocol will be referred for re-review at a convened meeting.

The IBC is authorized by the Chancellor to limit or suspend any research that does not comply with UNL Biosafety policies and procedures.

B. Radiation Safety Committee (RSC)

The RSC operates under the auspices of the Department of Environmental Health and Safety at UNL. The RSC is charged with ascertaining that all experimental or research uses of radioactive materials and/or ionizing radiation in or on human beings conform to the currently accepted radiation protection regulations and practices, and the UNL Radioactive Material License on file with the Nebraska Health and Human Services System.

The Director serves on the IBC and the RSC to facilitate communication between committees, including the IRB.

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|  <p>HRPP POLICIES AND PROCEDURES</p> <p>Research Compliance Services Human Research Protections Institutional Review Board</p> | <p>Policy # 3.007</p> <p>Title: <u>Conflict of Interest Review by the IRB and Office of Sponsored Programs</u></p> <p>Section: <i>Initial IRB Review of Protocols</i></p> <p>Date: April 1, 2008</p> |
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1.0 Purpose

The purpose of this policy is to describe the IRB and Office of Sponsored Programs review process for determining conflict of interest involving all covered persons as defined by the UNL Conflict of Interest Policy.

2.0 Definitions

2.1 Financial Interest Related to Research means financial interest in the sponsor, product, or service being tested, or competitor of the sponsor or product or service being tested.

2.2 Significant Financial Interest means anything of monetary value, either from the sponsor or entities other than the sponsor, including but not limited to, salary or other payments for services (e.g. consulting fees or honoraria); equity interests (stocks, stock options or other ownership interests); and intellectual property rights (patents, copyrights and royalties for such rights). This includes:

- A.** Ownership interest, stock options, or other financial interest related to the research either from the sponsor or entities other than the sponsor that:
 - 1. amounts to more than \$5,000 when aggregated OR
 - 2. (stock) is not publicly traded on a stock exchange OR
 - 3. is not governed by an arrangement that would prevent any outcome of the research to possibly affect the value of the ownership interests OR
 - 4. exceeds 5% interest in any one single entity when aggregated
- B.** Compensation related to the research that:
 - 1. amounts to more than \$5,000 over the past year when aggregated OR
 - 2. is not governed by an arrangement that would prevent any outcome of the research to possibly affect the amount of compensation.
- C.** Proprietary interest related to the research including, but not limited to, a patent, trademark, copyright or licensing agreement.
- D.** Board or executive relationship related to the research, regardless of compensation.

2.3 Ownership interest means any ownership interest, stock options, or other financial interest whose value cannot be readily determined through reference to public prices (generally, interests in a nonpublicly traded corporation), or any equity interest in a publicly traded corporation during the time the investigator is carrying out the study.

2.4 Compensation affected by the outcome of the research means compensation that could be higher for a favorable outcome than for an unfavorable outcome, such as compensation that is explicitly greater for a favorable result or compensation to the

investigator in the form of an equity interest in the sponsor of a covered study or in the form of compensation tied to sales of the product, such as a royalty interest.

2.5 Proprietary interest means property or other financial interest in the product including, but not limited to, a patent, trademark, copyright or licensing agreement.

2.6 Payments made by an organization to the investigator or the institution exclusive of the costs of conducting the research during the time the investigator is carrying out the study. This includes, but is not limited to:

- A.** Income from seminars, lectures or teaching engagements
- B.** Income from service on advisory committees or review panels
- C.** Grants to fund ongoing research
- D.** Compensation in the form of equipment
- E.** Retainers for ongoing consultation

2.7 Patent is an official written document securing to an inventor for a term of years the exclusive right to make, use, or sell an invention.

2.8 Royalty is compensation for an invention.

2.9 Key research personnel are those individuals who: 1) obtain consent from human subjects; 2) recruit human subjects; or 3) evaluate the response of human subjects.

3.0 Policy

It is the policy of the IRB that the Principal Investigator, the responsible party for the research, declare all significant financial interests. These policies and procedures apply to financial conflicts of interest and are guided by Code of Federal Regulations (Title 42 of the Code of Federal Regulations (CFR) Part 50 Subpart F) that promotes objectivity in research to ensure conflict of interests do not adversely affect the protection of participants or the credibility of UNL's Human Research Protection Program (HRPP).


Therefore conflicts of interest should be eliminated where feasible, and effectively disclosed and managed when elimination is not feasible.

3.1 The IRB New Protocol Submission Form includes a financial disclosure section for the PI. (*Consideration must be given, when appropriate, to including other key study personnel in financial disclosure requirements.*)

3.2 When the research involves human participants, the Chair of the IRB, or his/her designee, may participate in the initial review, as necessary, to determine if there is a potential financial conflict of interest.

Any investigator, key personnel, and/or their immediate family, who hold(s) a significant financial interest shall be deemed to have a potential conflict of interest, which requires review by the Conflict of Interest Research Committee (CIRC) and the IRB.

- 3.3** When it is determined that the principal investigator or other key personnel have a significant financial interest related to the research, the individual must describe the financial interest and any steps planned to prevent the financial interest from interfering with the design, conduct, or reporting of the research, including interfering with the protection of participants.
- 3.4** The COI Coordinator will review all potential conflicts of interest and recommend an appropriate management plan. The CIRC will review and approve the CIRC management plan.
- 3.5** The CIRC will perform its review prior to IRB review. The IRB, in addition to the IRB application form and supporting documents, will be provided with a copy of the CIRC management plan.
- 3.6** The full IRB will review the potential conflict of interest and the CIRC management plan in terms of the Board's obligation to ensure protection of the rights and welfare of human participants. This charge includes authority to:
- A.** Ensure disclosure in the consent document of any financial interests of the investigator that are judged by the IRB to be relevant to the participant's decision whether or not to participate in research.
 - B.** Ensure there is an appropriate plan for monitoring of the research, which may involve observation of the consent process, auditing of records, and interim reporting of research results to the IRB.
 - C.** Require informed consent be obtained by a qualified individual other than the person(s) identified as having a conflict.
- 3.7** The IRB will forward the results of the IRB review, including any modified management plan back to the COI Coordinator. The CIRC will review and approve the CIRC management plan and the plan will be carried out by the COI Coordinator. However it should be noted that the CIRC may not delete any IRB COI management recommendation within the authority of the Board as previously specified under 2.5 A, B, and C.

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|  <p>HRPP POLICIES AND PROCEDURES</p> <p>Research Compliance Services Human Research Protections Institutional Review Board</p> | <p>Policy # 3.008</p> <p>Title: <u>Qualification and Responsibilities of Research Personnel</u></p> <p>Section: <i>Initial IRB Review of Protocols</i></p> <p>Date: July 28, 2015</p> |
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1.0 Purpose

The purpose of this policy is to describe the qualifications and responsibilities of personnel involved in the conduct of human participant research.

2.0 Policy

It is the policy of the IRB that all personnel involved in the conduct of human participant research must possess the required experience, skill, and appropriate licensure.

2.1 All research personnel listed on the IRB application are required to complete Human Subjects Protection training through the CITI program (see HRPP policy [# 3.009](#)). The IRB will not approve new protocols, changes, or re-approve existing protocols until *all* listed personnel in the IRB application have been trained.

2.2 The following are the classifications of study personnel:

A. *Principal Investigator (PI)*

This individual assumes *overall* responsibility for the study design, and as such, for the development and submission of the protocol to the IRB; the obtaining of informed consent/assent from prospective participants by all authorized personnel listed on the application; the conduct of the research; receipt of all necessary committee approvals; and the publication of the findings that ensue from data collection.

1. Only one (1) individual may be listed as a PI for a study.
2. Students may function as the PI, and therefore may be listed on the protocol as PI. However, a UNL faculty member-advisor must supervise the project and be listed on the protocol as a Supervising Investigator. UNL Staff members should not supervise the student unless specific circumstances allow as reviewed by RCS staff and/or IRB.
3. IRB approval is contingent upon receipt of documentation of committee approvals specific to IBC, Radiation Safety, Conflict of Interest.
4. IRB approval is contingent upon receipt of Export Control clearance for international studies and DoD funded research.

B. *Supervising Investigator(s) & Other Key Personnel*

These individuals assume *shared* responsibility for the project design, and as such, contribute substantively to the development and submission of the protocol to the IRB; the obtainment of informed consent/assent from prospective participants; the conduct of the research; and the publication of the findings that ensue from data collection.

C. *Participating Personnel*

These individuals are faculty or graduate students who have a limited or no role in project design. Therefore, these personnel typically do not participate in the development and submission of the IRB protocol. Regardless of their specific duties on the project, participating personnel must have sufficient knowledge about the protocol and study design to effectively perform their respective project role.

D. *Limited Research Worker*

These individuals are eligible to take the Abbreviated Training through the CITI program but must meet the criteria listed below to qualify for such status.


Eligibility Criteria to be considered a "*Limited Research Worker*":

Must meet all of the following conditions to be eligible for abbreviated training:

1. Have no responsibilities in project design
2. Are not enrolled as a graduate student at UNL.
3. Are not UNL faculty.

And must meet at least one of the following conditions:

4. Have very limited independent decision-making in study implementation and data collection
5. Have no role in data collection, but may have access to participant identity and confidential data.

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|  <p>HRPP POLICIES AND PROCEDURES</p> <p>Research Compliance Services Human Research Protections Institutional Review Board</p> | <p>Policy # 3.009</p> <p>Title: <u>Required Training in the Protection of Human Participants</u></p> <p>Section: <i>Initial IRB Review of Protocols</i></p> <p>Date: July 27, 2016</p> |
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1.0 Purpose

The purpose of this policy is to describe training requirements for all personnel involved in conducting human participant research.

2.0 Policy

It is the policy of the IRB that all personnel involved in the conduct of exempt and non-exempt human participant research must receive training in the protection of human participants.

2.1 Collaborative IRB Training Initiative (CITI)

Training in the protection of human participants is primarily accomplished through completion of this web-based training program.

A. Personnel to be certified

Research personnel listed on the IRB application, NUgrant project summary page and consent document(s) *by name* must complete one of the existing CITI trainings. Research personnel are classified as follows:

1. PIs
2. Supervising Investigators (if any) and Key Personnel
3. Participating Personnel
4. Limited Research Worker

B. Training tracks

1. *Behavioral/Social Science*: Basic Course to be completed by PIs, Supervising investigators, key and participating personnel at UNL who conduct behavioral or social science studies.
2. *Biomedical*: Basic Course to be completed by PIs, Supervising Investigators, and participating personnel at UNL who conduct biomedical studies (e.g., exercise science, nutrition, or any study determined by the IRB).
3. *Limited Research Worker: Abbreviated CITI training.*

At their discretion and in their best judgement, HRPP staff may accept other training or a combination of training depending on content of courses completed and date of training completion. Courses must demonstrate equivalency in curriculum when compared with the CITI training tracks in B.1 and B.2 and/or B.3. HRPP Staff will consult with the RCS Director and/or IRB Chairperson as necessary.

C. Student research

All undergraduate, graduate, and post-doctoral trainees conducting human participant research (exempt and non-exempt) who have responsibility for

project design and integrally involved in data collection must take the basic CITI course.

D. *External investigators or subcontract recipients*

The IRB will accept certificates of training from other institutions when research personnel include external investigators or subcontract recipients who have been trained elsewhere and are under the legal jurisdiction of that institution with respect to compliance with federal regulations. A copy of any certification must be provided to the HRPP office.

- E. *New research personnel added to IRB-approved research*** All new employees serving as investigators, participating personnel, and Limited Research Workers must complete CITI training prior to addition as research personnel to any research study. The IRB will accept certificates of training from prior institutions *only* if the other institution utilized the CITI training system.

F. *IRB approval of research*

All new and current research personnel must be CITI trained/certified prior to IRB approval of initial research applications, continuing review applications and change request applications. Approval for initial research applications, continuing review applications and change request applications will not be granted within 30 days of any listed personnel member's CITI training expiration.

G. *Access to the CITI training program*

A link to the CITI Training Program is available through the HRPP website (<http://research.unl.edu/researchresponsibility/required-and-optional-training/>). Following registration, the individuals will be able to immediately access the system.

H. *Test data confidentiality*

Individual test scores are confidential. The webmaster and staff supporting the distance learning software at the University of Miami where the data are processed and stored have access to individually identifiable quiz scores. Additionally, the IRB staff will have access to the individual test scores to determine if the test taker achieved the minimum passing score. Aggregate, anonymous quiz data will be used by course faculty to help improve course content and quiz questions. There will be no further disclosure of individually identifiable quiz results or aggregate institutionally identifiable results beyond that mentioned above.

I. *Minimum passing score required for certification*

The IRB requires a passing score of 75% overall to receive CITI certification.

J. *CITI certification renewal*

Certification for training using the CITI course is valid for 3 years from the original date of completion. Certification must be renewed at that time in order for the individual to be listed as an authorized study personnel in new IRB applications or continuing review forms. Certification renewal is available through the CITI Continuing Education Course.

To renew certification:

1. UNL faculty, students, and staff must complete the appropriate track Continuing Education Course or the initial course.
2. The IRB requires a passing score of 75% overall to receive a renewal of CITI certification.

K. Training Documentation

1. CITI training certificates are available through the CITI program. HRPP staff update the NUgrant system as needed via the PI Lookup function.
2. Current training documentation of all listed personnel must be available prior to project approval.

2.2 Other training requirements


- A. All research personnel listed on the IRB application are expected to read The Belmont Report, which is posted on the OHRP website (www.hhs.gov/ohrp/).
- B. All research personnel listed on the IRB application are expected to read UNL IRB policies, which are applicable to their research and, which can be accessed on the HRPP website (<http://research/orr/forms.shtml>).
- C. All research personnel listed on the IRB application are expected to be reasonably familiar with the requirement of Health and Human Services regulations at 45 CFR §46, which can be accessed on the HRPP website (www.hhs.gov/ohrp/).

2.3 Investigator Initiated Training

- A. In certain circumstances such as in community based participatory research, training through the CITI program may not be as affective and appropriate to ensure knowledge of human research participant protections. Any investigator proposing the use of training other the CITI program for unaffiliated personnel members must have approval through RCS and the IRB.
- B. Appropriate documentation of training must also accompany the proposed training process and documentation of training must be submitted to the HRPP staff in accordance with the Section 2.1.K.

2.4 Other Available Training

The HRPP website, which is regularly updated and contains links to OHRP and other websites, serves as the primary educational resource and outreach tool for the campus. In addition, the IRB staff conducts workshops on an on-going basis for investigators and project coordinators and IRB Policy updates appear on the HRPP website.

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|  <p>HRPP POLICIES AND PROCEDURES</p> <p>Research Compliance Services Human Research Protections Institutional Review Board</p> | <p>Policy # 3.010</p> <p>Title: <u>Assessing the Need for Interim Continuing Review, Monitoring and Verification for Sources Other than the Investigator</u></p> <p>Section: <i>Initial IRB Review of Protocols</i></p> <p>Date: April 1, 2008</p> |
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1.0 Purpose

The purpose of this policy is to describe the criteria that the IRB will use at both initial and continuing review in determining the need for 1) IRB review more often than annually, 2) increased monitoring, and 3) verification from sources other than the investigator that no material changes have occurred since previous IRB review.

2.0 Policy

It is the policy of the IRB that that all non-exempt research will be assessed at both initial and continuing review in accordance with the requirements set forth by Health and Human Services regulations at 45 CFR §46.103(b)(4).

2.1 Increased Monitoring and/or Interim Continuing Review


- A. Unless specifically waived by the IRB, research that meets any of the following criteria may require review more often than annually:
 - 1. Significant risk to research participants (e.g., death, permanent or long lasting disability or morbidity, severe toxicity) without the possibility of direct benefit to the participants;
 - 2. The involvement of especially vulnerable populations likely to be subject to coercion (e.g., institutionalized psychiatric patients, incarcerated minors); or
 - 3. A history of serious or continuing non-compliance on the part of the PI.
- B. The following factors may determine which studies require review more frequently than on an annual basis and/or additional data monitoring:
 - 1. The probability and magnitude of anticipated risks to participants;
 - 2. The likely medical condition of the proposed participants;
 - 3. The overall qualifications of the PI and other members of the research team;
 - 4. The specific experience of the PI and other members of the research team in conducting similar research;
 - 5. The nature and frequency of adverse events observed in similar research at this and other institutions;
 - 6. The novelty of the research making unanticipated adverse events and/or serious problems more likely; and/or
 - 7. Any other factors that the IRB deems relevant.
- C. When the IRB determines the need for increased monitoring, this oversight may be accomplished by either: 1) submission of interim reports by the PI, or 2) auditing of investigator records by HRPP Staff. The PI will be notified of these requirements in writing.

- D. If the IRB determines the need for more frequent continuing review, the PI will be notified in writing and the IRB approval period will be set accordingly. Based on the criteria factors of 2.1.A and 2.1.B The IRB shall determine whether the research shall be reviewed more often than annually.

2.2 Verification from Sources Other than the Investigator. The following circumstances may require verification from sources other than the investigator that no material changes have occurred since the previous IRB review:

- A. History of noncompliance.
- B. Recurrent delays in submitting amendments.
- C. High number of IRB approval expirations.
- D. Failure to respond to IRB review letters or other correspondence in a timely manner.

When the IRB determines that verification from sources other than the investigator is necessary, the HRPP staff and/or IRB member(s) will perform the necessary verification by conducting an audit.

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|  <p>HRPP POLICIES AND PROCEDURES</p> <p>Research Compliance Services Human Research Protections Institutional Review Board</p> | <p>Policy # 3.011</p> <p>Title: <u>Certificate of Confidentiality</u></p> <p>Section: <i>Initial IRB Review of Protocols</i></p> <p>Date: March 30, 2015</p> |
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1.0 Purpose

The purpose of this policy is to describe the process for applying for a Certificate of Confidentiality.

2.0 Policy

It is the policy of the IRB that a Certificate of Confidentiality may be required for certain research proposals where the potential of disclosure of sensitive, personally identifiable information creates significant risk of harm or damage to the participant.

2.1 Purpose

- A. Certificates are issued for the purpose of protecting identifiable research information from compelled disclosure. The certificate allows the investigator and others who have access to research records to refuse to disclose identifying information on research participants in any civil, criminal, administrative, legislative, or other proceeding, whether at the federal, state, or local level.
- B. Federal funding of the research is not a prerequisite.
- C. A Certificate does not prevent voluntary disclosures such as limited disclosure to protect the participant or others from serious harm, as in cases of child abuse.
- D. A research protocol cannot rely on a Certificate to withhold data if the participant consents in writing to the disclosure.

2.2 Applicable Research

- A. The project must be categorized as research (see HRPP policy [# 3.001](#) for a definition of research).
- B. The research must be IRB-approved.
- C. The information collected must be “sensitive” (e.g., disclosure will involve significant harm or damage to the participant).
- D. Personally identifiable information is collected during the research.
- E. The investigator and/or the IRB determine that a Certificate is necessary to minimize risk to participants.
- F. Certificates are issued for single, well-defined research projects rather than groups or classes of projects. Occasionally a Certificate can be issued for cooperative multi-site projects. A coordinating center or “lead” institution can apply on behalf of all institutions involved in the protocol. The lead institution must ensure that all participating institutions conform to the application assurances and inform participants appropriately about the Certificate, its protections, and circumstances in which voluntary disclosures would be made.

2.3 Sensitive Research Categories


- A.** Information relating to sexual attitudes, preferences, or practices.
- B.** Information relating to the use of alcohol, drugs, or other addictive substances.
- C.** Information pertaining to illegal conduct.
- D.** Information that, if released, could damage a participant's financial standing, employability, or reputation within the community.
- E.** Information that would normally be recorded in a patient's medical record, and the disclosure of which could reasonably lead to social stigmatization or discrimination.
- F.** Information pertaining to an individual's psychological well-being or mental health.
- G.** Genetic information.

2.4 Application Process

- A.** Principal investigators conducting research collecting sensitive human participant information may apply for a Certificate of Confidentiality.
- B.** In addition to the completed application, the PI will be required to provide documentation of IRB approval and a copy of the informed consent form(s) as it would read if a Certificate of Confidentiality is obtained (e.g., explains the Certificate, its protections and the circumstances in which voluntary disclosures might be made).
- C.** Both the PI and the IO are required to sign the Certificate application.
- D.** As an example, detailed instructions and further information may be found on the National Institutes of Health website at:
http://grants.nih.gov/grants/policy/coc/appl_extramural.htm.

2.5 Final IRB Approval

- A.** Investigators must provide final approval of the Certificate of Confidentiality to the IRB.
- B.** If the Certificate applies to UNL only, no additional documentation is required after final submission to the UNL IRB.
- C.** If the Certificate applies to multiple sites and UNL is the lead institution, the HRPP staff will maintain accurate records to include but not limited to:
 - 1.** List of all participating sites agreeing to uphold the Certificate of Confidentiality
 - 2.** All approved consent documents from each participating site
 - 3.** All executed authorization agreements

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|  <p>HRPP POLICIES AND PROCEDURES</p> <p>Research Compliance Services Human Research Protections Institutional Review Board</p> | <p>Policy # 3.012</p> <p>Title: <u>External IRB Approval of Cooperative Research</u></p> <p>Section: <i>Initial IRB Review of Protocols</i></p> <p>Date: April 1, 2008</p> |
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1.0 Purpose

The purpose of this policy is to describe the conditions under which the IRB will accept external IRB review and approval of cooperative research.

2.0 Policy

It is the policy of the IRB that, in recognition of the importance of cooperative, multi-site research and the potential for duplication of effort, the IRB may agree to enter into a joint review arrangement and rely upon the review of another qualified IRB, in accordance with Health and Human Services regulations at 45 CFR §46.114.

2.1 Conditions

- A. UNL faculty, staff, or students will conduct the research solely at an external institution under the authority of that institution’s IRB.
- B. The external institution has accepted full responsibility to protect the rights and welfare of all participants enrolled within its institution, in accordance with Health and Human Services regulations at 45 CFR §46.
- C. The external institution has a Federal Wide Assurance (FWA) approved by OHRP.
- D. The UNL IRB has received a copy of the protocol, consent/assent document(s), and the external IRB approval.

2.2 IRB Review


The UNL HRPP staff will review the submission in consultation with the IRB Chair as needed, and is authorized to accept external IRB approval. The full IRB will be notified accordingly.

2.3 IRB Authorization Agreement

- A. The external IRB will be notified of the decision to accept external IRB approval.
- B. An IRB Authorization Agreement will be created and signed by the RCS Director or authorized individual from each institution.

2.4 Multi-site research

When UNL is the lead in a cooperative multi-site human participant research project, the principal investigator must go through the usual IRB application and review process. External institutions must make an independent decision about whether to accept UNL’s determinations.

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|  <p>HRPP POLICIES AND PROCEDURES</p> <p>Research Compliance Services Human Research Protections Institutional Review Board</p> | <p>Policy # 3.013</p> <p>Title: <u>Research Records Retention and Security</u></p> <p>Section: <i>Initial IRB Review of Protocols</i></p> <p>Date: April 1, 2008</p> |
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1.0 Purpose

The purpose of this policy is to describe the requirements for retention and security of research records.

2.0 Policy

It is the policy of the IRB that the research record maintained by the IRB and PI must: 1) contain an accurate and complete account of the conduct of the study; 2) be maintained and stored securely; and 3) be retained for the required amount of time following completion of the research in accordance with Health and Human Services regulations under 45 CFR §46.115(b), and sponsor requirements as applicable.

2.1 Research Record

The research record must include, but is not limited to:

- A.** Initial proposal: 1) IRB application; 2) detailed protocol; 3) grant (if applicable); 4) consent forms (if applicable); 5) case report forms (if applicable)
 - B.** Applications for continuing review and corresponding documents
 - C.** Requests for change to the protocol and/or consent forms
 - D.** Reports of adverse events and unanticipated problems involving risk to the participant or others
 - E.** Single participant protocol deviation and retrospective protocol by the violation reports.
 - F.** Issues of noncompliance
 - G.** IRB-PI correspondence
 - H.** Any other protocol-related documentation not covered by the above.
- The PI also will maintain copies of sponsor contracts and correspondence (if applicable) and subject files that should contain: 1) signed consent documents; 2) laboratory results and 3) other applicable information.


2.2 Security of Research Records

- A.** All research records must be maintained and stored securely, in a manner that protects participants' privacy and confidentiality by preventing unauthorized access (e.g., locked file cabinets and offices; fax machines placed away from high traffic areas, and use of study participant identifiers known only to research staff).
- B.** All research databases must comply with UNL Information Security policies and procedures relating to the safeguarding of electronic confidential information.

- C. Records are accessible for inspection and copying by authorized representatives of federal agencies or departments at reasonable times and in a reasonable manner.

2.3 Retention of Research Records

- A. Social science, behavioral and biomedical research records must be retained for at least *three (3) years* beyond the closure or termination of the study, or longer as required by sponsors.
- B. If the investigator resigns from UNL before the end of the designated period, the department of record must maintain the research records unless otherwise specified. The investigator, however, may have a copy of the research records in accordance with applicable UNL records policies.
- C. If a protocol is cancelled without participant enrollment, records are retained for at least three years after cancellation.

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|  <p>HRPP POLICIES AND PROCEDURES</p> <p>Research Compliance Services Human Research Protections Institutional Review Board</p> | <p>Policy # 3.014</p> <p>Title: <u>PI Disagreements with IRB Decisions</u></p> <p>Section: <i>Initial IRB Review of Protocols</i></p> <p>Date: April 1, 2008</p> |
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1.0 Purpose

The purpose of this policy is to describe the procedure a PI may take to express disagreement with IRB decisions.

2.0 Policy

It is the policy of the IRB that PIs have the right to disagree with IRB decisions and seek resolution.

- 2.1** The results of the IRB expedited continuing or full board review will be conveyed to the PI by the IRB Chair, Vice Chair, and/or IRB staff through written correspondence. Individual IRB members are not permitted to discuss the results of the IRB review with the PI unless instructed to do so by the IRB Chair or the IRB.
- A.** If a PI disagrees with the IRB's written decision, he/she is encouraged to contact the HRPP office and/or the IRB Chair and provide a written response detailing justification for the disagreement.
 - B.** If the disagreement is related to a substantive human protection issue and the protocol was reviewed by the full IRB, the protocol will be referred back to the full IRB.
 - C.** An appeal of a disapproved research project must be reviewed at a full board meeting.
 - D.** If the disagreement does not represent a substantive human protection issue, the IRB Chair will seek a resolution.
 - E.** If resolution of the disagreement requires direct interaction with the PI, the PI may be invited to attend a portion of the IRB meeting to address Board concerns.
- 2.2** Any PI who believes there is a conflict of interest on the part of any IRB member relative to his/her protocol is encouraged to contact the IRB Chair and/or the IO. All necessary steps will be taken to immediately resolve the problem.
- 2.3** Investigators who have concerns or suggestions regarding the Institution's human research protection program should convey them to the Institutional Official or other responsible parties (e.g. college dean, departmental chair) regarding the issue, where appropriate. The Institutional Official will investigate the issue, and where deemed necessary, convene the parties involved to form a response to the investigator to make necessary RCS Director will be available to address investigators' questions, concerns, and suggestions.

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|  <p>HRPP POLICIES AND PROCEDURES</p> <p>Research Compliance Services Human Research Protections Institutional Review Board</p> | <p>Policy # 3.015</p> <p>Title: <u>Compensation and Incentives for Research Participants</u></p> <p>Section: <i>Initial IRB Review of Protocols</i></p> <p>Date: July 19, 2012</p> |
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1.0 Purpose

The purpose of this policy is to describe compensation for research participants.

2.0 Policy

It is the policy of the IRB that compensation for research participants may be acceptable if: 1) the possibility of coercion or undue influence is minimized, and 2) the compensation is considered a recruitment incentive, not a benefit, in accordance with Health and Human Services regulations at 45 CFR §46.116.

Compensation may include extra credit, cash, gift cards, items (i.e., books, pens, t-shirts, etc.). The type and amount of compensation is considered on a case by case basis in relation to the participant population, amount of time required to participate, and the risks related to the research.

2.1 Requirements

- A.** Compensation for participation is not an obligation of the researcher toward the participant. Compensation may be offered, but is not required.
- B.** Participation in research should not require financial sacrifice, but should be revenue neutral for participants.
- C.** Compensation should not be used as a “benefit” to offset risks (either quantitative or qualitative) associated with the research.
- D.** Generally, compensation should be based upon the premise that participation in research requires time and effort from the participant. Compensation, when offered, should be based on a reasonable consideration of the duration of time spent in preparation for, participation in, and recovery from, research interventions, in addition to the effort expended during the research activities.

Interventions are understood to include such elements as procedures performed, visits to a clinic or research setting, phone interviews, or surveys completed. If appropriate, such compensation should include all parties involved. For example, if a family member is required to be present to drive a research participant home after a procedure, his/her time can be compensated.

- E.** Compensation above these levels must be justified by the investigator and must comply with the enumerated principles.
- F.** In order to minimize the risk that cumulative compensation for prolonged participation could unduly influence participation, the compensation plan should be described clearly in the consent form, including the portion of compensation that will be received at each study milestone, as well as the

total amount to be paid. Justification for the specific compensation plan needs to be provided and comply with the enumerated principles.

Credit for payment is to accrue as the study progresses and not be contingent only upon the participant completing the study. Any amount paid as a bonus for completion should be reasonable and not so large as to unduly induce participants to stay in the study when they would otherwise have withdrawn.


- G.** Payments for involvement of young minors (<16 years) in research should not be made directly to the minor. Depending on the justification, minors can be offered an age appropriate item through their parents for their participation, such as a toy or gift certificate. With appropriate scientific rationale and justification, 16- through 18-year-olds may be compensated directly.
- H.** UNL IRB does not allow payment in exchange for referrals of prospective participants (finder's fees), nor does it allow payments to the organization or research staff designed to accelerate recruitment that were tied to the rate or timing of enrollment (bonus payments).

2.2 Use of Incentives

Incentives, such as lotteries, can be used in research studies. Incentives are often used in studies where the budget is too small to compensate all participants. Incentives are not participant compensation, per se, because not all participants are awarded. Due to the concerns relating to fairness and the potential for coercion and undue influence, the IRB will consider such plans for participant compensation on a case-by-case basis, with appropriate justification provided by the PI.

If a researcher intends to include an incentive in their research, the following items must be addressed in the protocol and informed consent documents:

- A.** Description of the odds of "winning"
The odds of winning as stated to the participant must remain at least as good as what the researcher promised. For example, the researcher plans to recruit 25 participants and tells the participants that the odds of winning are 1 in 25. Thirty participants are recruited. The researcher now must offer two incentives so that the odds remain at least 1 in 25. The odds can improve, but they cannot become worse.
- B.** Description of when the participants will be notified if they will receive the incentive.
- C.** Description of the prize.
- D.** Description of who is conducting the drawing. In some cases, a person who is not a part of the research team should conduct the drawing. This would show that an unbiased person selected the winner.
- E.** If the odds of winning the incentive are not very good (i.e., 1 in 1000), it may be appropriate to provide an explanation to the participant that the population can understand.

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|  <p>HRPP POLICIES AND PROCEDURES</p> <p>Research Compliance Services Human Research Protections Institutional Review Board</p> | <p>Policy # 3.016</p> <p>Title: <u>Recruitment of Participants Through Advertisements</u></p> <p>Section: <i>Initial IRB Review of Protocols</i></p> <p>Date: April 1, 2008</p> |
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1.0 Purpose

The purpose of this policy is to describe the IRB requirements for recruitment of participants through advertisements.

2.0 Policy

It is the policy of the IRB that all participant recruitment strategies including printed newspaper advertisements, bulletins, fliers, multimedia, radio, and television must be reviewed and approved before they can be used to recruit potential participants.

2.1 *Design of the Advertisements.* Advertisements should be limited to information a potential participant may need to determine if they are interested and eligible to participate in a study.

A. Appropriate items to include in an advertisement are:

1. Name and address of the investigator and associated institution.
2. Purpose of the research.
3. Eligibility criteria (in shortened form).
4. Listing of realistic benefits to the participant.
5. Time or other commitments required from the participant.
6. Location of the research, contact person, and phone number for further information.
7. If applicable, incentives, which are intended to motivate the potential participant to consider participating in the research project should be described, e.g., direct payment, lottery.

B. The following are not permitted to be included in advertisements:

1. State or imply a certainty of favorable outcome or other benefits beyond what is outlined in the consent document and the protocol.
2. Make claims, either explicitly or implicitly that the research procedures are safe or effective for the purposes under investigation.
3. Include any exculpatory language.

C. Printed advertisements (e.g., newspaper ads and bulletins) should use appropriate font size and bolding in order to ensure the prospective participant is not misled by having their attention inappropriately drawn to a particular section of the advertisement.

D. In the case of newspaper ads, the investigator should ensure that the layout and font size approved by the IRB is reflected in the final published copy.

2.2 *Submission of Advertisements.* Draft copies of all advertisements including radio and television scripts must be submitted to the IRB for review and


approval. An advertisement may be reviewed by either the full IRB or by the *expedited continuing* method if it qualifies in accordance with Health and Human Services regulations at 45 CFR §46.110(b) (1) and (2).

2.3 IRB Record of Advertisements. The investigator should provide a copy of the published newspaper ad to the IRB. All bulletins posted at the Institution must be kept on file in the IRB study file.

2.4 The IRB review will include:

1. The information contained in the advertisement.
2. The mode of its communication
3. The final test copy of printed advertisements.
4. The final audio/video taped advertisements.

The IRB ensures that advertisements do not emphasize the payment or the amount to be paid by such means as unduly large or bold type. A final copy of the recruiting advertisement must be sent to the IRB upon final printing or publication.

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|  <p>HRPP POLICIES AND PROCEDURES</p> <p>Research Compliance Services Human Research Protections Institutional Review Board</p> | <p>Policy # 3.017</p> <p>Title: <u>Individual Investigator Agreements</u></p> <p>Section: <i>Initial IRB Review</i></p> <p>Date: June 5, 2014</p> |
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1.0 Purpose

The purpose of this policy is to describe the IRB’s requirements for review and approval of an external Individual Investigator.

2.0 Policy

It is the policy of the IRB to allow collaborating independent investigators or collaborating institutional investigators as described in the OHRP Guidance titled, “Guidance on Extension of an FWA to Cover Collaborating Individual Investigators and Introduction of the Individual Investigator Agreement,” to be covered under the UNL Federal wide Assurance through an approval mechanism.

3.0 The IRB Chairperson, the RCS Director or their designee(s) must first review and approve the Individual Investigator’s project involvement before their work with respect to the project begins.

3.1 A collaborating independent investigator is defined as:

- a) Having no affiliation with UNL;
- b) Conducting collaborative research activities outside of UNL;
- c) Not acting in an affiliated capacity with respect to their involvement in the research being conducted.

3.2 A collaborating institutional investigator is defined as:

- a) Having no affiliation with UNL;
- b) Conducting collaborative research activities outside of UNL;
- c) Is an employee, volunteer, agent or acting on behalf of an external site that does not hold an Assurance with respect to their involvement in the research being conducted;
- d) The non-assured institution, if applicable, in which the collaborating individual investigator is affiliated must not regularly conduct human subject’s research.

4.0 The following conditions must be met for the consideration of the review and approval of an independent or collaborating individual investigator:

4.1 The UNL Investigator must be the Primary Investigator (PI), or the Co-Investigator on a multi-institutional study with the UNL IRB acting as the IRB of record through a signed Authorization Agreement;


4.2 The UNL PI must agree to direct and appropriately supervise all collaborative research activities that will be performed by the Individual Investigator;

- 4.3** The Individual Investigator must be willing to sign an Individual Investigator Agreement with the UNL IRB and all records must be maintained by the UNL IRB. The agreement will document willing acceptance to abide by all applicable federal, international, state and local laws, regulations and policies;
 - 4.4** The Individual Investigator must agree to abide by all determinations of the UNL IRB and agrees to accept final authority and decisions of the UNL IRB.
 - 4.5** A collaborating Individual Investigator must have received institutional permission for the research to be conducted at their facility, if applicable.
 - 4.6** The Individual Investigator must have received the following documents via the UNL PI: The Belmont Report, a copy of the HHS regulations at 45 CFR 46, a copy of the FWA and applicable Terms of the FWA for UNL; and relevant institutional policies and procedures applicable to the UNL HRPP.
 - 4.7** The Individual Investigator must meet both the HRPP human subjects training requirements and the project-specific conflict of interest documentation requirements as well.
 - 4.8** The Individual Investigator agrees to report any changes to the project (via the UNL PI) before the changes are implemented.
 - 4.9** The Individual Investigator agrees to immediately report any unanticipated problems or adverse events to the IRB and the UNL PI.
 - 4.10** The Individual Investigator, when responsible for enrolling subjects, agrees to obtain, document and maintain records of participant's informed consent or the legally authorized representative's consent, if applicable.
 - 4.11** The Individual Investigator agrees to cooperate with all UNL IRB requirements including continuing review, when applicable, record keeping, reporting and certification of the research when required and must provide all information requested by the UNL IRB in a timely manner.
- 5.0** The UNL PI must provide all required documents to their IRB Coordinator via NUgrant corresponding with a specific IRB project for review processing. Documents include:
- 5.1** A signed Individual Investigator Agreement;
 - 5.2** A copy of the Investigator's CV or resume;
 - 5.3** A completed Individual Investigator Role Description form;
 - 5.4** A completed and signed Conflict of Interest form;
 - 5.5** A copy of the investigator's human subjects training completion report(s). A Basic course must accompany any copy of a refresher course if the training was completed through the CITI website;

5.6 Documentation of site permission, if applicable;

Please refer to the Individual Investigator Agreement Guidance Document for additional guidance and templates.

Note: The UNL PI assumes overall responsibility for all actions of the Individual Investigator related to the research.

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|  <p>HRPP POLICIES AND PROCEDURES</p> <p>Research Compliance Services Human Research Protections Institutional Review Board</p> | <p>Policy # 4.001</p> <p>Title: <u>Exempt Research</u></p> <p>Section: <i>Exempt & Expedited review</i></p> <p>Date: April 1, 2008</p> |
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1.0 Purpose

The purpose of this policy is to describe the process for determining whether a research proposal is eligible for *exempt* status.

2.0 Policy

It is the policy of the IRB that all proposed *exempt* research is reviewed by the HRPP staff, in consultation with the IRB Chair or RCS Director as needed, to determine that the research meets at least one of the categories of exemption from federal regulations for protection of human research participants in accordance with Health and Human Services regulations at 45 CFR §46.101(b).

2.1 Categories of research eligible for exempt status

- A.** Research conducted in established or commonly accepted educational settings, involving normal educational practices, such as (i) research on regular or special education instructional strategies; or (ii) research on the effectiveness of, or the comparisons, among instructional techniques, curricula, or classroom management methods.

Educational research proposals are *exempt* providing all of the following conditions are met:

1. All of the research is conducted in a commonly accepted educational setting (e.g., public school).
2. The research involves normal educational practices (e.g., comparison of instructional techniques).
3. The study procedures do not represent a significant deviation in time or effort requirements from those educational practices already existent at the study site.
4. The study procedures involve no increase in the level of risk or discomfort attendant in normal, routine educational practices.
5. Provisions are made to ensure the existence of a non-coercive environment for those students who choose not to participate.
6. The school or other institution grants written approval for the research to be conducted.

NOTE: Educational projects that do not meet the above-listed conditions are not exempt and must undergo expedited, continuing, or full board review.

- B.** Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior. If the research involves any of the following, then this exemption does not apply: (1) Information obtained is recorded in such a manner that human participants can be identified, directly or through identifiers linked to the participants; AND b) any disclosure of the human

participants' responses outside the research could reasonably place the participants at risk of criminal or civil liability or be damaging to the participants' financial standing, employability, or reputation. (2) The research involves surveys, interviews or participant observation with children. (3) The research involves observation or sensitive aspects of a participant's behavior.

NOTE: Projects involving oral histories are not considered research unless the projects a) utilize a "systematic investigation" with analysis of data to answer a scientific question and b) are designed to develop or contribute to generalizable knowledge.

- C. Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior that is not *exempt* under B above, if: (1) the human participants are elected or appointed public officials or candidates for public office, or (2) federal statute(s) require(s), without exception that the confidentiality of the personally identifiable information will be maintained throughout the research and thereafter.
- D. Research involving the collection or study of EXISTING data, documents, and records, pathological specimens, or diagnostic specimens, if: (1) these sources are publicly available or (2) the information is recorded by the investigator in such a manner that participants cannot be identified, directly or through identifiers linked to the participants.

Note: ALL of the data must exist prior to the start of the research for this exemption to apply.

- E. Research and demonstration projects which are designed to study, evaluate, or otherwise examine public benefit or service program heads, and which are designed to study, evaluate or otherwise examine: (1) public benefit or service programs; (2) procedures for obtaining benefits or services under those programs; (3) possible changes in or alternatives to those programs or procedures; or (4) possible changes in methods or levels of payment for benefits or services under those programs, if: (i) The projects are conducted by or subject to the approval of Federal Department or Agency heads, and (ii) there is no statutory requirements for IRB review, and (iii) the research does not involve significant physical invasions or intrusions upon the privacy of participants, and (iv) the exemption is invoked with authorization or concurrence by the funding agency.

NOTE: ALL of these criteria must be met for this exemption to apply.

- F. Taste and food quality evaluation and consumer acceptance studies, if (1) wholesome foods without additives are consumed, and (2) a food is consumed that contains a food ingredient at or below the level found to be safe, or agricultural chemical or environmental contaminant at or below the level found to be safe by the Food and Drug Administration, or approved by the Environmental Protection Agency or the Food Safety and Inspection Service of the U.S. Department of Agriculture.

NOTE: Research which involves photographing, audiotaping, or videotaping of participants during the research may be granted an exemption with some discretion as it relates to identifiability or sensitivity of the research. Projects involving photographing, audiotaping, or videotaping will be reviewed on a case by case basis to determine the risk in relation to the identifiability of the photographs, audios, and/or videos along with the sensitivity of the

questions being asked. The use of scrambling technologies, such as voice alteration or blurring/masking, also will be taken into consideration.

2.2 Ineligible Research

- A. Sensitive survey research that is identifiable where the disclosure of the human participants' responses outside the research could reasonably place the participants at risk of criminal or civil liability or be damaging to the participants' financial standing, employability, or reputation.
- B. The research involves survey, interviews, or participant observation with children.
- C. Research involving prisoners, persons who are decisionally or psychologically impaired, persons who are economically or educationally disadvantaged and other participant populations determined to be vulnerable upon review.


2.3 Ethical Considerations

Although *exempt* research is not covered by the federal regulations, this research is not *exempt* from the ethical guidelines of the Belmont Report. The individual making the determination of exemption may require additional protections for participants in keeping with the guidelines of the Belmont Report.

2.4 Process of Review

- A. The PI must complete and submit the IRB application form on-line via NUgrant.
- B. Utilizing the Exempt Determination Checklist, HRPP staff, in consultation with the IRB Chair as needed, will determine whether an exemption should be granted. The complete exempt protocol application will be reviewed ([HRPP Policy 2.014](#))
- C. All *exempt* research involving human participants must maintain an ethically appropriate standard, which serves to protect the rights and welfare of the participants. This involves informed consent as necessary and confidentiality of data.
- D. If the HRPP office determines that the research qualifies for *exempt* status, the investigator will be notified upon certification of exemption via the NUgrant system.
- E. *Exempt* research, once certified, does not require annual review. Projects that are certified as *exempt* are valid for five years.
- F. All modifications of protocols including *exempt* research must be submitted to the IRB. *Exempt* research, which requires modification during the course of the study whereby it is no longer *exempt*, must be resubmitted to the IRB prior to implementation of the modification.
- G. The HRPP office reserves the right to refer applications for *exempt* research to either the *expedited review* procedure or the full IRB for review as necessary.

NOTE: Two checklists are used in the exempt review process. They are the Human Participants Determination Checklist and the Exemption Determination Checklist.

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|  <p>HRPP POLICIES AND PROCEDURES</p> <p>Research Compliance Services Human Research Protections Institutional Review Board</p> | <p>Policy # 4.002</p> <p>Title: <u>Expedited Research</u></p> <p>Section: <i>Exempt & Expedited review</i></p> |
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1.0 Purpose

The purpose of this policy is to describe the *expedited review* process for initial and continuing review.

2.0 Policy

It is the policy of the IRB that *expedited review* will be conducted in accordance with Health and Human Services regulations at 45 CFR §46.110. Protocols reviewed and approved by the *expedited* method must 1) be no more than minimal risk; 2) involve only procedures listed in one or more of the categories specified in the Federal Register (63 FR 60364-603-67, November 9, 1998); and 3) meet all the criteria specified in Health and Human Services regulations 45 CFR §46.111. *Expedited review* may be used to perform continuing review in accordance with HRPP Policy # 11.001.

Three (3) applicable criteria must be met for the initial or continuing review using the expedited continuing procedure, these include:

1. The current and future research procedures present no more than minimal risk to participants (Not required for category (8) (b)).
2. The identification of the participants or their responses will not reasonably place them at risk of criminal or civil liability or be damaging to their financial standing, employability, insurability, reputation, or be stigmatizing, unless reasonable and appropriate protections will be implemented so that risks related to invasion of privacy and breach of confidentiality are no greater than minimal. (Not required for category (8) (b)).
3. The research is not classified.

2.1. Qualifying Categories of Research

A Collection of blood sample by finger stick, heel stick, ear stick, or venipuncture as follows:

1. From healthy, non-pregnant adults who weigh at least 110 pounds. In studies in which more than 400 ml of blood is to be drawn within an 8 week period, the participant must have a baseline hemoglobin level of 12.0 grams. After 250 ml of blood has been drawn, the hemoglobin level must be retested; anyone whose hemoglobin has fallen below 11.0 grams must be withdrawn from the study.
2. From other adults and children, considering the age, weight, and health of the participants, the collection procedure, the amount of blood to be collected and the frequency with which it will be collected. For these participants, the amount drawn may not exceed the lesser of 50 ml or 3 ml per kg in an 8 week period and collection may not occur more frequently than 2 times (or research sessions) per week.

Note: Health and Human Services regulations at 45 CFR 46.402(a) define children as “persons who have not attained the legal age for consent to treatments or procedures involved in the research, under the applicable law of the jurisdiction in which the research will be conducted.”

Although according to Nebraska state statute # 43-303, “Child means an individual under nineteen years of age”, this definition is irrelevant for determining which individuals under Nebraska law meet the DHHS definition of children. To determine under Nebraska law which individuals meet the DHHS definition of children, the relevant Nebraska laws define the legal age to consent to treatment or procedures involved in some research. In some cases, individuals such as emancipated minors or minors requesting treatment for contraceptives, venereal disease, or drug abuse, have reached the legal age under Nebraska law to provide consent. These individuals are “children” under Nebraska law, but are not “children” under DHHS regulations, in that the additional protections of Subpart D are not required because these individuals have reached the legal age to consent to the treatments or procedures involved in the research.

- B.** Prospective collection of biological specimens for research purposes by non-invasive means.

Examples include:

1. Hair and nail clippings in a non-disfiguring manner;
 2. Deciduous teeth (at time of dental exfoliation) or if routine patient care indicates a need for extraction;
 3. Permanent teeth if routine patient care indicates a need for extraction;
 4. Excreta and external secretions (including sweat);
 5. Uncannulated saliva collected either in an unstimulated fashion or stimulated by chewing gumbase or wax, or by applying a dilute citric solution to the tongue;
 6. Placenta removed at delivery;
 7. Amniotic fluid obtained at the time of rupture of the membrane prior to, or during, labor.
 8. Supragingival and subgingival dental plaque and calculus, provided the collection procedure is not more invasive than routine prophylactic scaling of the teeth and the process is accomplished in accordance with accepted prophylactic techniques.
 9. Mucosal and skin cells collected by buccal scraping or swab, skin swab, or mouth washings.
 10. Sputum collected after saline mist nebulization.
- C.** Collection of data through non-invasive procedures (not involving general anesthesia or sedation) routinely employed in clinical practice (excluding procedures involving x-rays or microwaves). Where medical devices are employed, they must be cleared or approved for marketing. (Studies intended to evaluate the safety and effectiveness of the medical device are not generally eligible for *expedited review*, including studies of cleared medical devices for new indications.)

Examples include:

1. Physical sensors that are applied either to the surface of the body or at a distance and do not involve input of significant amounts of energy into the participant or an invasion of the participant's privacy.
 2. Weighing or testing sensory acuity.
 3. Magnetic resonance imaging.
 4. Electrocardiography, electroencephalography, thermography, detection of naturally occurring radioactivity, electroretinography, ultrasound, diagnostic infrared imaging, doppler blood flow, and echocardiography.
 5. Moderate exercise, muscular strength testing, body composition assessment, and flexibility testing where appropriate for the age, weight, and health of the individual.
- D.** Research involving materials (data, documents, records, or specimens) that have been collected, or will be collected solely for non-research purposes (such as medical treatment or diagnosis).
Note: Some research in this category may be exempt from the Health and Human Services regulations for the protection of human participants. This listing refers only to research that is not exempt.
- E.** Collection of data from voice, video, digital, or image recordings made for research purposes.
- F.** Research on individual or group characteristics or behavior (including, but not limited to, research on perception, cognition, motivation, identity, language, communication, cultural beliefs or practices, and social behavior) or research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies.
Note: Some research in this category may be exempt from the Health and Human Services regulations for the protection of human participants. This listing refers only to research that is not exempt.
- G.** Continuing review of research previously approved by the convened IRB meets one of the following conditions:
1. Where (a) the research is permanently closed to the enrollment of new participants; (b) all participants have completed all research interventions; and (c) the research remains active only for long-term follow-up of participants, **OR**
 2. Where no participants have been enrolled and no additional risks have been identified, **OR**
 3. Where the remaining research activities are limited to data analysis.

2.2 Expedited review process

- A.** The HRPP staff will perform a pre-review of all applications, which qualify for *expedited review*, using the OHRP Human Subject Regulations Decision Charts (September 24, 2004) as necessary (<http://www.hhs.gov/ohrp/humansubjects/guidance/decisioncharts.htm>). The IRB staff will obtain clarifications from the PI and ask for revision of submission documents, if necessary.

Once the pre-review is completed, the HRPP staff will assign the *expedited reviewer* based on reviewer expertise. If warranted by the nature of the proposal, more than one IRB voting member will be assigned to serve as *expedited reviewer(s)*. The HRPP staff, in consultation with the Director and

Chair if necessary, determines whether IRB members have the expertise to conduct the expedited review (See Policy 2.001, Section 2.13, Item G).

When appropriate, consultants will be used to provide any needed expertise warranted by the nature of the proposal (See Policy #2.003 and 8.004). If consultants are used, the currently designated expedited reviewer will conduct a regulatory review in conjunction with the consultant review.

- B. If more than one (1) IRB member is designated to conduct a review, the final determination will be made by the Chair if the members do not agree.

The reviewer(s) are provided and review all submitted information, including all information required by the convened IRB.

- C. The IRB Chair, Vice Chair, HRPP Staff or assigned IRB reviewer, retains the right to refer any protocol for review by the full IRB. However, it should be noted that the reviewers may not disapprove the research. A research activity may be disapproved only after full IRB review.

- D. The *expedited reviewer* will utilize the IRB review criteria specified in HRPP Policy # 3.004. An IRB reviewer checklist is available for use by the reviewer. The reviewer using the expedited procedure evaluates and documents whether research undergoing initial or continuing review using the expedited procedure:

1. Meets the three applicable criteria.
2. Represents one or more approvable categories of research.

- E. After a protocol or amendment is approved using the *expedited review* procedure, the full IRB will be notified through listing the approval in the minutes.


- F. Any IRB member can access the complete study file via NUgrant and can make any concerns known at the full IRB meeting. Even if a protocol, or an amendment, has been approved using the *expedited review* procedure, the full IRB can require modification of the protocol and/or consent documents(s). Additionally, the full IRB can suspend the study or halt accrual if warranted.

- G. Expedited review actions – See Policy 3.005

2.3 Documentation of Expedited continuing review

Review conducted under an *expedited continuing review* will be documented in the IRB letter to the PI sent via the NUgrant system. This documentation will include:

- A. Identification of the specific permissible categories justifying the *expedited continuing review*.
- B. Documentation of the review and action taken by the IRB Chair, or designated reviewer, and any findings required under the Health and Human Services regulations.

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|  <p>HRPP POLICIES AND PROCEDURES</p> <p>Research Compliance Services Human Research Protections Institutional Review Board</p> | <p>Policy # 5.001</p> <p>Title: <u>Additional Protections for Vulnerable Populations</u></p> <p>Section: <i>Vulnerable Populations and Special Classes of Participants</i></p> <p>Date: April 1, 2008</p> |
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1.0 Purpose

The purpose of this policy is to describe additional protections for vulnerable populations.

2.0 Policy

It is the policy of the IRB that the vulnerability of a potential participant population will be evaluated to ensure that appropriate protections are in place for any participant who may be vulnerable in accordance with Health and Human Services regulations at 45 CFR §46.111(a)(3).

Health and Human Services regulations at 45 CFR §46 provide special protections for prisoners (Subpart C) and children (Subpart D). 45 CFR §46 does not, however, include **specific** requirements for the protection of other vulnerable participant populations, such as decisionally impaired persons, terminally ill, economically or educationally disadvantaged persons, or other vulnerable populations. In these situations, the IRB, in consultation with the investigator, will determine the appropriate means to protect the rights and welfare of the individuals.

2.1 Definition

- A. Vulnerable population** is defined as an individual or group of individuals with limited autonomy (e.g., lacks independence in decision making for a variety of reasons) or is otherwise at increased risk compared to non-vulnerable individuals. Within any population of vulnerable participants, individuals will have different levels of vulnerability based on the level of capacity, circumstance, or condition affecting independent decision-making.

2.2 Categories of Vulnerable Populations

Vulnerable populations may be categorized according to the following groups:

- A.** Prisoners (Subpart C) (see *HRPP policy # 5.003*)
- B.** Children (Subpart D) (see *HRPP policy # 5.004*)
- C.** Pregnant women (Subpart B) (see *HRPP policy # 5.002*)
- D.** Fetuses and neonates (Subpart B) (see *HRPP policy # 5.002*)
- E.** Decisionally impaired (see *HRPP policy # 5.005*)
- F.** Comatose
- G.** Terminally ill
- H.** Economically disadvantaged
- I.** Educationally disadvantaged
- J.** Socially disadvantaged
- K.** Employees and students (see *HRPP policy # 5.006*)
- L.** Others as determined by the IRB and investigator

2.3 Factors Determining Vulnerability


- A.** The nature of the research.
- B.** The risks of the research.
- C.** An increased probability of risk occurrence in the proposed population.
- D.** Degree of autonomy, or limited autonomy, present in the proposed population.
- E.** The clinical status of the proposed population.
- F.** The educational status of the proposed population.
- G.** The economic status of the proposed population.
- H.** The presence of a support system (e.g., family and friends) for the proposed population.
- I.** Cultural or social factors associated with the proposed population.

2.4 Additional Protections for Vulnerable Populations

Upon determining the vulnerability of an individual or population, the IRB and investigator will provide special protections against risk. These additional protections will include those specified by HRPP policies for research involving pregnant women, prisoners, children, or decisionally impaired participants.

Other additional protections, as deemed necessary by the IRB, may also be included:

- A.** The use of an extended consent process.
- B.** The use of a consent monitor.
- C.** Appointment of a participant advocate.
- D.** Involvement of the participant's family and/or friends.
- E.** Limits placed on risk.
- F.** Exclusion from participating in the research.
- G.** Increased safeguards to protect privacy and confidentiality.
- H.** Increased monitoring of the research by the IRB or other mechanisms.
- I.** More stringent withdrawal criteria.
- J.** Longer study follow-up.

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|  <p>HRPP POLICIES AND PROCEDURES</p> <p>Research Compliance Services Human Research Protections Institutional Review Board</p> | <p>Policy # 5.002</p> <p>Title: <u>Research Involving Pregnant Women, Human Fetuses, and Neonates</u></p> <p>Section: <i>Vulnerable Populations and Special Classes of Participants</i></p> <p>Date: April 1, 2008</p> |
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1.0 Purpose

The purpose of this policy is to describe the IRB requirements for research involving pregnant women, fetuses, and neonates.

2.0 Policy

UNL HRPP policies provide for additional protections for pregnant women, fetuses, and neonates involved in research. These policies are described below.

Research, which is funded by DHHS must satisfy the additional protections described in 45 CFR §46 subpart B. For all other research, additional protections are identical to those found in 45 CFR §46 subpart B except as indicated in 2.2 (A) (2) (b)

2.1 Definitions

- A. *Pregnancy:*** Period from confirmation of implantation of a fertilized egg within the uterus until the fetus has been delivered. Implantation is confirmed through a presumptive sign of pregnancy (e.g., missed periods or a positive pregnancy test). While confirmation may be in error, investigators must presume that a living fetus was present until evidence is presented to the contrary.
- B. *Fetus:*** The product of conception from implantation until delivery.
- C. *Viable neonate:*** A neonate, after delivery that can survive to the point of independently maintaining heartbeat and respiration. (A viable neonate is covered by Health and Human Services regulations at 45 CFR §46, Subparts A and D.)
- D. *Nonviable neonate:*** A neonate after delivery that, although living, is not viable.

2.2 IRB Review

In addition to review of research under Health and Human Services regulations at 45 CFR §46 (Subpart A), the IRB must provide special review of all behavioral/social science research where pregnant women, fetuses and/or neonates are involved.

A. Research involving pregnant women or fetuses

1. Pregnant women may be involved in research funded by DHHS if all of the following conditions are met:
 - a) Appropriate preclinical studies, including studies on pregnant animals and clinical studies involving non-pregnant women, have been conducted and provide data for assessing potential risks of pregnant women and fetuses.

- b) Any risk to the fetus is caused solely by interventions that offer *direct benefit* for the woman or fetus, *or* if there is *no* prospect of direct benefit: 1) the risk to the fetus must not be greater than minimal and 2) the purpose of the research is the development of important biomedical knowledge that cannot be obtained by any other means.
 - c) Any risk to the pregnant woman or the fetus is the *least* possible to achieve the research objectives.
 - d) Consent of the pregnant woman *alone* is required for research which:
 - 1) Offers direct benefit to the pregnant woman only, **OR**
 - 2) Will not directly benefit the woman or fetus but: a) there is no more than minimal risk to the fetus, and b) the purpose of the research is to develop important knowledge and the data cannot be obtained by any other means.
 - e) Consent of the pregnant woman *and* father is required if the research offers direct benefit to *only* the fetus. However, the father's consent is not required if he is unavailable, decisionally impaired, temporarily incapacitated, or if the pregnancy resulted from rape or incest.
 - f) The consent must fully disclose the reasonable foreseeable impact of the research on the fetus (e.g., risk).
 - g) Assent and parental permission for pregnant children participation in research must be obtained in accordance with Health and Human Services regulations 45 CFR §46, Subpart D (see HRPP policy [# 5.004](#)).
 - h) No inducements, monetary or otherwise, will be offered to terminate a pregnancy.
 - i) Individuals engaged in research will have no part in any decisions as to the timing, method, or procedures used to terminate a pregnancy.
 - j) Individuals engaged in research will have no part in determining the viability of a neonate.
2. Pregnant women may be involved in research if all of the following conditions are met:
- a) Appropriate preclinical studies, including studies on pregnant animals and clinical studies involving non-pregnant women, have been conducted and provide data for assessing potential risks of pregnant women and fetuses.
 - b) If any risk to the fetus is caused solely by interventions that offer *direct benefit* for the woman or fetus, *or* if there is *no* prospect of direct benefit, the risk to the fetus must not be greater than minimal.
 - c) Any risk to the pregnant woman or the fetus is the *least* possible to achieve the research objectives.
 - d) Consent of the pregnant woman *alone* is required for research which:
 - 1) Offers direct benefit to the pregnant woman only, **OR**
 - 2) Offers direct benefit to the woman *and* fetus, **OR**

- 3) Will not directly benefit the woman or fetus but there is no more than minimal risk to the fetus.
- e) Consent of the pregnant woman *and* father is required if the research offers direct benefit to *only* the fetus. However, the father's consent is not required if he is unavailable, decisionally impaired, temporarily incapacitated, or if the pregnancy resulted from rape or incest.
- f) The consent must fully disclose the reasonable foreseeable impact of the research on the fetus (e.g., risk).
- g) Assent and parental permission for pregnant children participation in research must be obtained in accordance with Health and Human Services regulations 45 CFR §46, Subpart D (see HRPP policy # [5.004](#)).
- h) No inducements, monetary or otherwise, will be offered to terminate a pregnancy.
- i) Individuals engaged in research will have no part in any decisions as to the timing, method, or procedures used to terminate a pregnancy.
- j) Individuals engaged in research will have no part in determining the viability of a neonate.

B. Research involving placenta, dead fetus(s) or fetal material

Research involving the placenta, dead fetus, or fetal material after delivery may occur if all federal, state, or local laws and regulations are met. If any information associated with the material used in the research can be linked in any way to a living person, Health and Human Services regulations view the living person as a research participant and the research is subject to the regulations discussed in this policy. *Note: The State of Nebraska has no applicable local or state laws or regulations.*

C. Research not otherwise approvable

The Health and Human Services Secretary may conduct or fund research that the IRB does not feel meets the above policy if the following conditions are met:

1. The IRB finds that the research, which will be funded by Health and Human Services, presents a reasonable opportunity to further the understanding, prevention, or alleviation of a serious problem affecting the health or welfare of pregnant women, fetuses or neonates, *and* the Secretary has determined through consultation with a panel of experts that the research does, in fact, meet the requirements of 45 CFR 46.204;
- OR**
2. The Secretary determined that the research presents a reasonable opportunity to further the understanding, prevention, or alleviation of a serious problem affecting the health and welfare of pregnant women, fetuses or neonates; is conducted in accord with sound ethical principles; and informed consent will be obtained. *Note: For non-Health and Human Services funded research, involving pregnant women, fetuses, or neonates, the UNL IRB will convene an equivalent panel of experts to advise the IRB.*


2.3 Non-pregnant participants who become pregnant during research

If a participant becomes pregnant while actively participating in a research protocol, the investigator must:

- A.** Determine if it is in the best interest of the pregnant participant to continue participating in the study or terminate participation in the study by completing the report on unanticipated problems or adverse event(s) involving risks to research participants or others, as described in HRPP Policy [# 13.001](#).
- B.** If it is in the best interest of the pregnant participant to remain in the study, adequate justification must be provided to receive IRB Chair approval for the participant to continue participation. If it is not in the best interest of the participant to continue, the participant's participation must be terminated.
- C.** The study must be re-reviewed by the full IRB, as soon as possible, in consideration of this policy.

2.4 Documentation of IRB findings under Subpart B

The IRB will fully document compliance with Subpart B in the minutes of the IRB meeting by documenting the required determinations and protocol-specific findings justifying those determinations.

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|  <p>HRPP POLICIES AND PROCEDURES</p> <p>Research Compliance Services Human Research Protections Institutional Review Board</p> | <p>Policy # 5.003</p> <p>Title: <u>Research Involving Prisoners</u> <i>Vulnerable Populations and Special Classes of Participants</i></p> <p>Section:</p> <p>Date: November 1, 2010</p> |
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1.0 Purpose

The purpose of this policy is to describe the procedure for research involving prisoners.

2.0 Policy

It is the policy of the IRB that the IRB will adhere to Health and Human Services regulations at 45 CFR §46, Subpart C provides for additional protections for prisoners involved in social/behavioral and biomedical research. These special protections include individuals who are prisoners at the time of enrollment in the study, as well as participants that become incarcerated after enrollment in a study. The IRB will apply Subpart C to all research involving prisoners regardless of funding, with one exception described under “Special Circumstances” (See section 2.3 below.)

2.1 Definitions

- A. **Prisoner** is defined by Health and Human Services regulations as any individual involuntarily confined or detained in a penal institution. The term is intended to encompass individuals sentenced to such an institution under a criminal or civil statute, individuals detained in other facilities by virtue of statutes or commitment procedures, which provide alternatives to criminal prosecution or incarceration in a penal institution, and individuals detained pending arraignment, trial, or sentencing.
- B. **Minimal risk in prisoner research** is defined by Health and Human Services regulations as “the probability and magnitude of *physical or psychological* harm that is normally encountered in the daily lives, or in the routine medical, dental, or psychological examination of *healthy persons*.”

2.2 Permitted Research Involving Prisoners.

Social/behavioral and biomedical research may involve prisoners as participants only if:

- A. The IRB has reviewed, approved, and determined that the research falls under one of the categories listed below in Section 2.7. In the case of DHHS-funded research, the IRB also must certify the approval to OHRP as described in 2.9.
- B. The proposed research must fall within one of the following categories of permissible forms of research:
 1. Study of the possible causes, effects, and processes of incarceration and of criminal behavior, provided that the study presents *no more than minimal risk, and no more than inconvenience* to the participants.

2. Study of prisons as institutional structures, or of prisoners as incarcerated persons, provided that the study presents *no more than minimal risk, and no more than inconvenience* to the participants.

For the remaining two categories, it should be noted that final approval, as indicated below, rests with the Secretary of Health and Human Services with OHRP acting on behalf of the Secretary. Following IRB approval, the entire research proposal (including the IRB- approved protocol, any relevant Health and Human Services grant application or proposal, consent documents, any IRB application forms, and any other information requested or required by the IRB for initial review) will be submitted to OHRP. OHRP will consult with appropriate experts, including experts in penology medicine and ethics, and publish notice, in the Federal Register, of intent to approve such research. Health and Human Services, through OHRP, will issue its approval in writing to the IRB.

3. Research on conditions particularly affecting prisoners as a class (for example, research on social and psychological problems, such as alcoholism, drug addiction and sexual assault).
4. Research on practices, both innovative and accepted, which have the intent and reasonable probability of improving the health or well-being of the participant. In cases in which those studies require the assignment of prisoners in a manner consistent with protocols approved by the IRB to control groups which may not benefit from the research, the study may proceed only after the proposal is reviewed by OHRP (as discussed above).

For research which is not funded by Health and Human Services, neither certification to OHRP nor expert review for Categories 3 and 4 is required. The IRB will only approve research, which fits one or more of the designated categories. In addition, the IRB will, at its discretion, convene an equivalent expert review body to review studies classified as 3 or 4.

2.3 Special Circumstances

A. **When a previously enrolled participant becomes a prisoner**

When a previously enrolled research participant becomes a prisoner and the relevant research was *not* reviewed and approved by the IRB in accordance with the requirements of Health and Human Services regulations at 46 CFR §46, Subpart C, the principal investigator must report the situation to the IRB immediately. Upon notification that a previously enrolled research participant has become a prisoner and the principal investigator wishes to have the prisoner continue to participate in the research, the IRB will promptly re-review the protocol in accordance with the requirements of Subpart C (as applicable).

All research activities and interventions for the now incarcerated prisoner-participant must stop until the protocol is reviewed under the requirements of Subpart C, except where the PI can justify that it is in the best interest of the participant to remain in the Health and Human Services -funded research study while incarcerated. The IRB Chair may determine that the participant may continue to participate until all the requirements of Subpart C are satisfied.

B. When a potential participant is an adolescent detained in a juvenile detention facility

If a potential participant is an adolescent detained in a juvenile detention facility, the individual is both a child and a prisoner. In such a case, Health and Human Services regulations at 45 CFR §46 Subpart C (prisoners involved in research) and 45 CFR §46 Subpart D (children involved in research) apply and will be satisfied.

C. When the PI indicates that the proposed participant population may have high risk of incarceration during the course of the study (but currently does not include prisoners)

The IRB may choose to review the proposal under Health and Human Services regulations at 45 CFR §46 Subpart C. However, it should be noted that predetermination of a participant population's potential for incarceration carries additional risks of violating the rights of justice and respect for persons. The definitions of minimal risk and the risk/benefit analysis may not truly be applicable to the participant population.

2.4 Expedited review of research involving prisoners

Health and Human Services regulations allow *expedited review*, however OHRP recommends that the convened IRB review all research involving prisoners. Therefore, the IRB will normally not use *expedited review* for protocols, changes, or continuing review of research involving prisoners.

- A.** If the expedited review process is used for minor modifications to research, one of the two procedures described in 2.4.C.2 below may be used based on the type of modification.
- B.** Modifications involving more than a minor change reviewed by the convened IRB
 - 1.** The same procedure used for initial review must be used including the responsibility of the prisoner representative to review the modification and participate in the meeting (as described in Section 2.6).
- C.** Continuing review
 - 1.** The same procedure used for initial review must be used for continuing review including the responsibility of the prisoner representative to review the continuing review materials and participate in the meeting (as described in Section 2.6).
 - a)** If no participants have enrolled, the research may receive continuing review using the expedited procedure under expedited category #8 (See [Policy #4.002](#) Expedited Research).
 - 2.** Research involving interaction with prisoners may be reviewed by the expedited procedure, if a determination is made that the research involves no greater than minimal risk for the prison population being studied.
 - a)** The prisoner representative must concur with the determination that the research involves no greater than minimal risk.
 - b)** The prisoner representative must review the research as a reviewer, designated by the chair or consultant. This may be as the sole reviewer or in addition to another reviewer, as appropriate.
 - c)** Review of modifications and continuing review must use the same

procedures for initial review using this expedited procedure including the responsibility of the prisoner representative.

3. Research that does not involve interaction with prisoners (e.g. existing data, record review) may be reviewed by the expedited procedure, if a determination is made that the research involves no greater than minimal risk for the prison population being studied.
 - a) Review by a prisoner representative is not required.
 - b) The prisoner representative may review the research as a reviewer or consultant if designated by the IRB chair.
 - c) Review of modifications and continuing review must use the same procedures as initial review.
- D. When a participant is incarcerated temporarily while enrolled in a study
 1. If the temporary incarceration has no effect on the study, keep the participant enrolled.
 2. If the temporary incarceration has an effect on the study, handle according to the guidance in 2.4.A-2.4.C.

2.5 Research involving prisoners and exemption under 45 CFR §46.301(a). Health and Human Services regulations do not allow exemption of research involving prisoners (see 45 CFR §46.101(i), footnote 1).

2.6 IRB Membership Requirements

In addition to federal requirements regarding any research involving human participants, the IRB will satisfy the following additional requirements when the research involves prisoners, regardless of funding source:

- A. The majority of the members of the IRB will not have an association with the prison(s) involved in the study (excluding the prisoner members).
- B. At least one member of the IRB present at the IRB meeting and involved in the review will be a prisoner or a prisoner representative. The prisoner representative will have a close working knowledge, understanding, and appreciation of prison conditions from the perspective of the prisoner.
 1. The prisoner representative must be a voting member of the IRB. The prisoner representative may be listed as an alternative member who becomes a voting member when needed.
 2. The prisoner representative must review research involving prisoners, focusing on the requirements in Subpart C or equivalent protections. The prisoner representative will receive all review materials pertaining to the research (as will the rest of the committee).
 3. The prisoner representative must be present at a convened meeting when the research involving prisoners is reviewed. If the prisoner representative is not present, research involving prisoners cannot be reviewed or approved.
 - a) The prisoner representative may attend the meeting by phone, video-conference, or webinar, as long as the representative is able to participate in the meeting as if they were present in person at the meeting.
 4. The prisoner representative must present his/her review either orally or in writing at the convened meeting of the IRB when the research involving prisoners is reviewed.

- C. The IRB will notify OHRP of any change in the IRB roster by the addition or change of a prisoner representative, as required by Health and Human Services regulations at 45 CFR §46.103(b) (3). The IRB will be aware of the impact of roster changes on quorum requirements under Health and Human Services regulations at 45 CFR §46.108(b).
- D. The IRB is aware that the special composition requirement for research involving prisoners involves not only the initial review of the protocol, but also continuing review, protocol/consent amendments, review of reports of unanticipated problems involving risks to participants, and all other IRB matters pertaining to the protocol.

2.7 IRB Findings

The IRB will follow all pertinent federal regulations pertaining to human participant research, as well as make seven additional findings for research involving prisoners regardless of funding source:

- A. The research represents one of the categories permissible under Health and Human Services regulations pertaining to research involving prisoners.
- B. Any possible benefits to the prisoner through his/her participation in the research, when compared to the general living conditions, medical care, quality of food, amenities and opportunity for earnings in the prison, are not of such a magnitude that his/her ability to weigh the risks of the research against the value of such advantages in the limited-choice environment of the prison is impaired.
- C. The risks involved in the research are commensurate with risks that would be accepted by non-prisoner volunteers.
- D. Procedures for the selection of participants within the prison are fair to all prisoners and immune from arbitrary intervention by prison authorities or prisoners. Unless the principal investigator provides to the IRB justification in writing for following some other procedures, control participants will be selected randomly from the group of available prisoners who meet the characteristics needed for that particular research project.
- E. The information is presented in language which is understandable to the participant population.
- F. Adequate assurance exists that parole boards will not take into account a prisoner's participation in research in making decisions regarding parole, and each prisoner is clearly informed in advance that participation in the research will have no effect on his or her parole.
- G. If the IRB finds there may be a need for follow-up examination or care of participants after the end of their participation, adequate provision has been made for such examination or care, taking into account the varying lengths of individual prisoner's sentences and for informing participants of this fact.

2.8 Documentation of IRB Findings

Per federal regulations, the IRB will prepare and maintain adequate documentation of IRB activities. For the purposes of Subpart C, the IRB activities include making the specific findings required under Health and Human Services regulations along with protocol-specific findings justifying those determinations. OHRP accepts documentation of protocol-specific information justifying each IRB finding required under 45 CFR §46.305(a) to be one way of


adequately documenting the IRB activities required under Subpart C. The IRB will follow the aforementioned OHRP guidance.

2.9 Health and Human Services Funded Research - Notification To OHRP

- A.** The IRB is responsible for providing certification to OHRP that the IRB has made the seven findings applicable to Health and Human Services funded research involving prisoners. The IRB will send OHRP a certification letter to this effect, which includes:
 - 1.** The name and address of the Institution
 - 2.** Identification of the research protocol and relevant Health and Human Services grant application or protocol.
 - 3.** A copy of all paperwork necessary for IRB initial review (IRB-approved protocol, relevant Health and Human Services grant application or proposal, IRB application, consent(s), etc.).
 - 4.** Verification of the presence of a prisoner representative during consideration of the study.
 - 5.** Verification of the seven required findings (listed above).
 - 6.** Determination that the research meets one of the above categories of research permissible by federal regulations.
- B.** Prisoner research certification letters should be mailed to the OHRP Prisoner Research Contact person in the Office for Human Research Protections at the Department of Health and Human Services.

2.10 Department of Defense regulated research involving prisoners

- A.** Research involving prisoners of war is prohibited.
- B.** The IRB must be aware of the definition of “prisoner of war” for the Department of Defense component granting the addendum.

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|  <p>HRPP POLICIES AND PROCEDURES</p> <p>Research Compliance Services Human Research Protections Institutional Review Board</p> | <p>Policy # 5.004</p> <p>Title: <u>Research Involving Children</u> <i>Vulnerable Populations and Special Classes of Participants</i></p> <p>Section:</p> <p>Date: August 28, 2015</p> |
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1.0 Purpose

The purpose of this policy is to describe the procedures for research involving children.

2.0 Policy

It is the policy of the IRB that the board will review all *exempt* and *non-exempt* research proposals involving participation of children in accordance with Health and Human Services regulations at 45 CFR §46 Subpart D and applicable state law. The IRB will classify the research in accordance with Subpart D and document how and why the proposal meets the requirements.

2.1 Definitions

A. Age of majority is defined, according to Nebraska State Statute 43-2101. It states that all persons under nineteen years of age are declared to be minors, but in case any person marries under age of nineteen years, his or her minority ends. If the potential participant is Native American living on federal tribal lands, regardless of the state, federal law has set the age of majority at age 18.

HRPP staff, in consultation with the IRB chair, will determine which individuals meet the DHHS definition of “children” in the cases that the research is conducted outside Nebraska or under Native American jurisdiction.

1. Nebraska law, with some exceptions, sets forth a higher age of majority (19 years) than most other states. When other legal conflicts arise the counsel to the IRB will provide a legal opinion and resolution to the IRB.

B. Assent is defined as a child’s affirmative agreement to participate in research. Mere failure to object should not, absent affirmative agreement, be construed as assent.

C. Children are defined as persons who have not attained the legal age for consent to treatments or procedures involved in the research, under the applicable law of the jurisdiction in which the research will be conducted. In Nebraska a child is an individual who is under 19 years of age and is not emancipated as set forth in Neb. Rev. Stat. §43-2102, which states:

All persons under nineteen years of age are declared to be minors, but in case any person marries under the age of nineteen years, his or her minority ends.

It should be noted that under Nebraska law minority status also ends when a minor enlists in the armed forces before his or her nineteenth birthday.

NOTE: The definition of informed consent under Nebraska law is found in Neb. Rev. Stat. §44-2816 which states:

Informed consent shall mean consent to a procedure based on information which would ordinarily be provided to the patient under like circumstances by health care providers engaged in a similar practice in the locality or in similar localities. Failure to obtain informed consent shall include failure to obtain any express or implied consent for any operation, treatment, or procedure in a case in which a reasonably prudent health care provider in the community or similar communities would have obtained an express or implied consent for such operation, treatment, or procedure under similar circumstances.

When the research is conducted in Nebraska: In DHHS regulations “children” are persons who have not attained the legal age to consent to treatments or procedures involved in some research, under the applicable law of the jurisdiction in which the research will be conducted. In Nebraska, individuals under the age of 19 years with the exceptions noted below are considered to be “children” as defined by DHHS regulations because they have not attained the legal age to consent to treatments or procedures involved in some research and the additional protections of Subpart D are required. The exceptions to this rule are the following individuals who are able to consent to treatments or procedures involved in the research, so that they do not meet the DHHS definition of “children” and the additional protections if Subpart D are not required:

- Emancipated minors.
- Individuals of any age where the research procedures are limited to:
 - Use of contraceptives.
 - Treatment for venereal disease.
 - Treatment for drug abuse.

NOTE: For research conducted in jurisdictions other than Nebraska, the research must comply with the laws regarding the legal age of consent in all relevant jurisdictions. The General Counsel for the University’s Office will provide assistance with regard to the laws in other jurisdictions.

- D. *Commensurate*** is defined as the requirement that children and/or their guardians are familiar with procedures that are reasonably similar in nature and risk proportionally to those the child has experienced, or is expected to experience, and not restricted to specific situations the child has experienced or will likely experience in the future.
- E. *Disorder or condition*** is defined as a specific (or set of specific) physical, psychological, neuro developmental, or social characteristic(s) that an established body of scientific evidence or clinical knowledge has shown to negatively affect children’s health and wellbeing or to increase their risk of developing a health problem in the future.

F. *Dissent* is defined as a child's decision to decline participation in research.

G. *Emancipated minor* is defined as a legal status conferred upon persons who have not yet attained the age of legal competency as defined by Nebraska state law, but who are entitled to treatment as if they had. Some minors do not meet the DHHS definition of "children," such as in Nebraska individuals under 19 years of age who are legally emancipated or who are otherwise able to consent to the procedures involved in research. Federal regulations require that to take part in research the legally effective consent must be obtained from such individuals or their legally authorized representative.

Emancipated minor shall mean a person under nineteen years of age who is married or in the military, and it shall also mean a person under nineteen years of age who resides apart from his or her parents; is not under the care, custody, control, or supervision of his or her parents; and who receives no financial support or services from his or her parents and is responsible for securing his or her own support. The emancipation of a child is a question of fact, to be determined by the peculiar facts and circumstances of each case, and may be proved by circumstantial evidence, by an express agreement, or implied from the conduct of the parties. Emancipation may be terminated by a change of circumstances. For a general discussion of emancipation of minors, see *Accent Service Company v. Ebsen*, 209 Neb. 616(1993).

H. *Guardian*. A guardian is defined as an individual who is authorized under applicable State or local law to consent on behalf of a child to general medical care (45 CFR 46.402 (e)). Under Nebraska law, a person becomes a guardian by acceptance of a testamentary appointment (in other words, via a will) or upon appointment by the court (Neb. Rev. Stat §30-2605). Under Nebraska law, individuals appointed as guardians can consent to medical care on behalf of the ward, therefore such individuals would be guardians according to the DHHS definition.

NOTE: For research conducted in jurisdictions other than Nebraska, the research must comply with the laws regarding legally authorized representative in all relevant jurisdictions. The General Counsel of the University's Office will provide assistance to the investigator with regard to the laws in other jurisdictions.

Note: For additional information on Guardianship, refer to the Guardian Guidance Document.

I. *Legally authorized representative*. Legally authorized representative is defined as an individual or judicial body authorized under applicable law to give informed consent on behalf of a prospective subject to the subject's participation in the procedure(s) involved in the research (21 CFR 50.3 (m)). IRBs and clinical investigators should familiarize themselves with applicable local statutes and regulations pertaining to the definition of a legally authorized representative.

Parents and guardians meet the DHHS and Nebraska definitions of a legally authorized representative. For persons with a “Power of Attorney”, whether the power of attorney in a given case will convey the authority to consent to participation on behalf of the principal in research depends on the specific language used in the durable power of attorney document.

The term “legally authorized representative” is not defined in the Nebraska revised statutes. Under Nebraska law there are essentially two different circumstances under which a person can act as a guardian or “legally authorized representative” for another adult. The investigator makes the decision about whether a person is a legally authorized representative, i.e., falls under the above. In general, researchers at UNL conducting research in Nebraska and enrolling adults unable to consent can get permission for those individuals to participate in research from:

- an individual’s court appointed guardian which includes *de facto* health care Power of Attorney; or
- a person having “Power of Attorney” for another person.

NOTE: For research conducted in jurisdictions other than Nebraska, the research must comply with the laws regarding legally authorized representative in all relevant jurisdictions. The General Counsel of the University’s Office will provide assistance to the investigator with regard to the laws in other jurisdictions.

Note: For additional information on Legally Authorized Representatives, refer to the Guardian Guidance Document.

- J. *Minimal risk*** is defined as the risks that normal, average, healthy children encounter while living in safe environments or the risks associated with routine physical or psychological examinations or tests. The determination of minimal risk should take into account that 1) children face differing risks at different ages, 2) risks associated with repetitive tests may increase, and 3) special/unique characteristics may make a certain population more vulnerable than average children (e.g., hemophilia). The risks associated with routine examinations or tests are equivalent to a routine well-child examination.
- K. *Minor increase over minimal risk*** is defined as the determination whether the research procedures or interventions present a minor increase over minimal risk. The IRB will consider the following five criteria: magnitude, probability, duration, cumulative characteristics, and irreversibility of risk to the child.
- L. *Parent*** is defined as a child’s biological or adoptive parent. Under Nebraska law, parents are the natural guardians of their minor children. Neb. Rev. Stat. §30-2608(a) states:

The father and mother are the natural guardians of their minor children and are duly entitled to their custody and to direct their education, being themselves competent to transact their own business and not otherwise

unsuitable. If either dies or is disqualified for action, or has abandoned his or her family, the guardianship devolves upon the other...

Therefore, in Nebraska a father or mother of a child under the age of nineteen can act as a “legally authorized representative” of that child so long as their rights have not been terminated by law and so long as their minor child is not married or in the armed forces. For research conducted in jurisdictions other than Nebraska, the research must comply with the laws regarding the legal age of consent in all relevant jurisdictions. The Office of General Counsel will provide assistance with regard to the laws in other jurisdictions.

- M. *Permission*** is defined as the agreement of parent(s) or guardian(s) to the participation of his/her (their) child or ward in research.
- N. *Vital importance*** is defined as the research is essential for the scientific understanding or evaluation of procedures to alleviate the disorder or condition and perceived as essential to the understanding or amelioration of the child’s disorder by practitioners and family stakeholders.

2.2 Categories of Research

Health and Human Services regulations specify that research involving children must be approvable under one or more of the following four (4) categories:

- A. Research not involving greater than minimal risk** (e.g. most educational studies, studies in which behavior is not manipulated) **(45 CFR §46.404)**
 - 1. The potential risks must be outweighed, or balanced, by the potential benefits to the participants and/or society.
 - 2. Adequate provisions must be made for soliciting assent of the children and permission of the parent(s) or guardian(s).
- B. Research involving greater than minimal risk, but presenting the prospect of direct benefit to the individual participants** **(45 CFR §46.405)**
 - 1. The risk is justified by the anticipated benefit to the participants.
 - 2. The relation of the anticipated benefit to the risk is at least as favorable to the participants as that presented by available alternative approaches.
 - 3. Adequate provisions are made for soliciting the assent of the children and permission of their parent(s) or guardian(s).
- C. Research involving greater than minimal risk and no prospect of direct benefit to individual participants, but likely to yield generalizable knowledge about the participant’s disorder or condition** **(45 CFR §46.406).**
 - 1. The risk represents a minor increase over minimal risk.
 - 2. The intervention or procedure presents experiences to participants that are reasonably commensurate with those inherent in their actual or expected medical, dental, psychological, social, or educational situations.
 - 3. The intervention or procedure is likely to yield generalizable knowledge about the participant’s disorder or condition, which is of vital importance for the understanding or amelioration of disorder, or condition.

4. Adequate provisions are made for soliciting assent of the children and permission of their parent(s) or guardian(s).

D. Research, not otherwise approvable, which presents an opportunity to understand, prevent, or alleviate a serious problem affecting the health or welfare of children (45 CFR §46.407).

The IRB will submit this category of research to Health and Human Services for approval, *if* the research is funded by Health and Human Services. If the research is not Health and Human Services-funded, the IRB will, at the board's discretion, convene an equivalent expert review panel.

2.3 Process of Consent/Assent

- A. In accordance with 45 CFR 46.408(b) the IRB must determine that adequate provisions have been made for soliciting the permission of each child's parent or guardian.

In general, if an individual is not a parent, they can permit a child to take part in research only if that individual is legally authorized to make health care decisions for the child. Under federal law this is the case even for social and behavioral research. Before obtaining permission from an individual who is not a parent, make sure that the person is legally authorized to make health care decisions for the child. If needed, ask for written documentation of the individual's authority to make health care decisions on behalf of the child. If the person has such authorization, the individual can permit the child to take part in the research. If the person does not have such authorization, the individual cannot permit the child to take part in the research.

Parents or guardians must be provided with the basic elements of consent as stated in 45 CFR 46.116(a) (1-8) and any additional elements the IRB deems necessary.

The IRB may find that the permission of one parent is sufficient for research to be conducted under 45 CFR 46.404 or 45 CFR 46.405. The IRB's determination of whether consent must be obtained from one or both parents will be documented in the consent checklist when a protocol receives expedited review, and in meeting minutes when reviewed by the convened committee.

Consent from both parents is required for research to be conducted under 45 CFR 46.406 and 45 CFR 46.407 unless:

- 1) One parent is deceased, unknown, incompetent, or not reasonably available; or
- 2) When only one parent has legal responsibility for the care and custody of the child.

B. Consent of a Mature Minor

A minor may, with IRB approval, legally consent on his/her own behalf when he/she does not meet the DHHS definition of "child". In Nebraska, if a participant under the age of 19 is legally declared emancipated, he/she may

consent to participate in research because the individual no longer meets the DHHS definition of a child and therefore, Subpart D does not apply.

C. Assent of Children

In addition to the obtainment of parental/legal guardian consent (permission), the investigator must also solicit assent of minor participants age 7 years or older, unless the participants displays intellectual or emotional development below that of the average 7-year-old child. Obtainment of assent shows respect for a child's developing autonomy. In most circumstances (non-therapeutic research), a child's deliberate objection should be regarded as a veto to his/her involvement in the research.

D. Purpose of Assent

Assent serves to provide information to the child and to allow the child to dissent. With these purposes in mind, the following points should be considered when writing the *Youth or Child Assent Form*.

1. In deciding whether to seek assent, the minor's age is an important criterion, but intellectual and emotional development also need be considered. The child must be able to identify the benefits and risks of the research, and to be able to reason about the consequences of participation as well as a typical 7 year old;
2. When there is uncertainty as to whether assent should be sought from the child or adolescent, an independent psychological examiner should be employed to help evaluate the minor's decision-making capacities;
3. A valuable function of seeking assent from the minor is to provide information that the minor and his/her parents may use in their decisions concerning the research; and
4. In seeking assent, undue advantage should not be taken of the child's developmental limitations related to his/her voluntariness (acquiescence to authority figures and any lack of ability to express his/her rights).

E. Dissent of Children

Dissent from participation or withdrawal from research is always to be honored unless the protocol affords access to a therapeutic intervention that is not otherwise available. In that case, parental consent for therapeutic intervention may override a child's dissent. However that information must be provided to the child prior to the intervention procedure.

F. Waiver of Assent

Parents or guardians may, with IRB approval, override a young child's objections to interventions that hold the prospect of direct benefit to the child in accordance with 45 CFR §46.408(a). Assent may also be waived by the IRB under 45 CFR §46.116(d).

G. Situations Where Minors Are Not Children

Under the following circumstances, minors are not considered "children" and can consent for themselves:

1. If the research only involves a treatment for, which a minor's consent is permissible under applicable law (e.g., use of contraceptives, treatment for venereal disease or substance use).
2. If a participant under the age of 19 is legally declared emancipated, he/she may consent to participate in research.

H. Waiver of Parental Permission

1. The IRB may determine that a research protocol is designed with conditions of a subject population for which parental or guardian permission is not a reasonable requirement to protect the subjects (for example, neglected or abused children) provided an appropriate mechanism for protecting minor research subjects is substituted, and that the waiver is not inconsistent with Federal, State, or local law. The choice of an appropriate mechanism would depend upon the nature and purpose of the activities described in the protocol, the risk and anticipated benefit to the research subjects, and their age, maturity, status, and condition.

In these situations, with appropriate scientific rationale and justification, the IRB may approve a waiver of the requirements for parental permission as described in Subpart D of the HHS Regulations at 45 CFR 46.

2. In cases where criteria for waiver of parental permission under Subpart D could not be met, waiver of parental permission could also be obtained when the research meets the criteria for waiver of informed consent in 46.116(d):
 - a) The research involves no more than minimal risk to the subjects;
 - b) The waiver or alteration will not adversely affect the rights and welfare of the subjects;
 - c) The research could not practicably be carried out without the waiver or alternation; and
 - d) Whenever appropriate, the subjects will be provided with additional pertinent information after participation.

I. Wards

Health and Human Services regulations at 45 CFR §46.408 set specific requirements for children who have been declared wards of the state or any other agency, institution, or entity.

Wards can participate in research approved under §46.406 or § 46.407 if:

1. The research is related to their status as a ward.
2. The research is conducted in schools, camps, hospitals, institutions, or similar settings where the majority of children involved in research are not wards.
3. The IRB will require appointment of an advocate for each child who is a ward:
 - a) The advocate serves in addition to any other individual acting on behalf of the child as a guardian or in the absence of the parent(s).
 - b) The advocate may represent more than one child.

- c) The advocate must have the background and experience to act in the best interest of the child for the duration of the child's participation in research.
- d) The advocate must not be associated in any way with the research, the investigator(s), or the guardian organization. The federal regulations do not specifically exclude IRB members from serving as a child advocate if the other conditions are met.

J. Re-consent of participants reaching the age of majority

1. All minor participants actively participating in an IRB-approved study must be consented using the adult IRB-approved informed consent document *at the first visit after reaching the legal age of majority*. If the minor participated in a study that is completed, except for data analysis, re-consent is not required.
2. If, upon reaching the age of majority, the now adult participant is found decisionally impaired or is of diminished capacity, the participant remains vulnerable and the proxy/parental consent remains in effect. This must be documented in the study records and the IRB must be notified.
3. The now adult participant has the right to refuse to continue participation in the study. This is to be respected and undue pressure or coercion to continue may not be applied. While new data may not be collected on participants refusing participation, existing prior data collected under the assent/proxy consent process can be used.

2.4 Consent and Assent Documents

A. Parental/Guardian Consent Form

If the participant is under the age of 7 years, only a *Parental/Guardian Consent Form* is required. The *Parental/Guardian Consent Form* should include all relevant elements of informed consent as outlined previously and be written in a *proxy* consent style that indicates it is the parent, or legal representative, who is consenting to allow the minor to participate in the study. The standard statements must be modified for the Parent Consent form (*e.g., all references to "you" must be changed to "your child"*).

B. Youth Assent Form


If the participant is 13-18 years of age, a *Youth Assent Form* is required. The *Youth Assent Form* is based on the adult consent form, but should be revised to meet the cognitive and educational level of an average youth. The assent form must contain *simple* language written at the appropriate educational level of the youngest prospective participant in the youth age range. In some research projects, it may be necessary to utilize two assent forms written to accommodate participants at either end of the age range. The *Youth Assent Form* must contain all of the required elements of consent previously outlined in the IRB Guidelines except instructions about emergency care and rights of research participants, and should follow the general format of the adult consent form.

C. Child Assent Form

1. If the participant is under the age of 7 years, only a *Parental/Guardian Consent Form* is required. However, verbal assent should be obtained as appropriate.
2. If the participant is 7 through 12 years of age, a *Child Assent Form* is required. The *Child Assent Form* must be *brief*, without subheadings, and contain *extremely simple* language arranged in brief paragraphs. The assent form must contain the following elements: title of the research study; opportunity to ask questions; basis for participant selection; purpose of the study; explanation of procedures; potential risks/discomforts; potential benefits; statement concerning consultation with parents; freedom to withdraw; and confidentiality statement.
(<http://research/orr/forms.shtml>).

2.5 Documentation of IRB Findings

Per federal regulations, the IRB will prepare and maintain adequate documentation of IRB activities. For the purposes of Subpart D, the IRB activities including making the specific findings required under Health and Human Services regulations along with protocol-specific findings justifying those determinations. OHRP accepts documentation of protocol-specific information justifying the IRB finding under Health and Human Services regulations at 45 CFR §46.404, §405, or §406. IRB actions will be documented in the approval letter.

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|  <p>HRPP POLICIES AND PROCEDURES</p> <p>Research Compliance Services Human Research Protections Institutional Review Board</p> | <p>Policy # 5.005</p> <p>Title: <u>Research Involving Decisionally Impaired Participants</u></p> <p>Section: <i>Vulnerable Populations and Special Classes of Participants</i></p> <p>Date: April 1, 2008</p> |
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1.0 Purpose

The purpose of this policy is to describe additional protections for decisionally impaired participants.

2.0 Policy

It is the policy of the IRB that research involving decisionally impaired participants who cannot provide voluntary informed consent must include appropriate additional protections in accordance with the requirements of Health and Human Services regulations at 45 CFR §46.111(b).

2.1 Definitions

A. Decisionally impaired participants

A person that lacks the ability to reason, exhibit sound judgment and provide voluntary consent to participate in research. The impairment may fluctuate (e.g., mental disorders), decline with time (e.g., Alzheimer's), or result from health conditions (e.g., coma or other infirmity).

B. Legally Authorized Representative

The term "legally authorized representative" is not defined in the Nebraska revised statutes. Under Nebraska law there are essentially two different circumstances under which a person can act as a guardian or "legally authorized representative" for another adult. The investigator makes the decision about whether a person is a legally authorized representative, i.e., falls under the above. In general, researchers at UNL conducting research in Nebraska and enrolling adults unable to consent can get permission for those individuals to participate in research from:

- an individual's court appointed guardian which includes *de facto* health care Power of Attorney; or
- a person having "Power of Attorney" for another person.

C. Institutionally Authorized Surrogate

In the absence of a legally authorized representative as described in 2.1(B), no one can provide legally effective consent on behalf of a participant to the participant's participation in research. Under federal regulations Institutionally Authorized Surrogates who do not meet the DHHS definition of Legally Authorized Representatives may not provide consent on behalf of another individual unless the IRB has waived the requirement for informed consent.

2.2 Acceptable Research

- ##### A.
- A decisionally impaired participant may participate in research involving *greater than minimal risk* only if the research potentially offers an acceptable level of *direct therapeutic benefit* to that participant.

- B. A decisionally impaired participant may participate in research involving *minimal or slightly above minimal risk* without direct participant benefit if a Legally Authorized Representative is available and provides proxy consent.

2.3 Use of Proxy Consent

- A. If the prospective participant is decisionally impaired, the participant's Legally Authorized Representative must provide written proxy consent.
- B. If the prospective participant is decisionally impaired, but is capable of executing a Durable Power of Attorney, the prospective participant may grant authority to the holder of the Durable Power of Attorney to give written informed consent to participate in research on their behalf. The Durable Power of Attorney in this case is a Legally Authorized Representative.
 1. The Durable Power of Attorney may already be in effect or one may be appointed to grant proxy consent for research participation.
 2. The Durable Power of Attorney is to be used only with prior approval of the IRB.
 3. The Durable Power of Attorney cannot be used if the prospective participant has a Legally Authorized Representative.
 4. The prospective participant must understand the meaning of a Durable Power of Attorney and appoint someone of their choice.
 5. The person appointed as a Durable Power of Attorney must be willing to do so and understand the responsibilities involved.
 6. Employees of UNL are **not** eligible for appointment as holder of a Durable Power of Attorney for a prospective participant unless they are the spouse, adult child, parent, or relative of the prospective participant.
 7. A nursing home (e.g., owner, part-owner, manager, administrator, or employee, as well as spouses of these individuals) providing residential care to a participant or a community based program is **not** eligible for appointment as holder of a Durable Power of Attorney for prospective participants.
 8. Signed copies of the Durable Power of Attorney form should be maintained by the investigator.
 9. The HRPP office must be contacted prior to appointing a Durable Power of Attorney (Ph# 402-472-6965).
- C. If the potential participant does **not** have a Legally Authorized Representative and is judged by the investigator to both lack the capacity to give consent **and** execute a Durable Power of Attorney, the research may only be conducted if the IRB waives the requirement for consent.

2.4 Proxy Consent Form


The *Proxy Consent Form* must include all required elements of the informed consent and be written in the proxy consent style that indicates that the Legally Authorized Representative is providing permission to allow the decisionally impaired participant to participate in the study.

2.5 Adult Assent Form

The *Adult Assent Form* is based on the adult consent form, but should be written in *simple* language aimed at the appropriate cognitive level of the decisionally impaired participants to be enrolled in the study. The *Adult Assent Form* must contain all required elements of consent.

2.6 Application of Laws

IRB and/or investigators must apply State and local laws that reach beyond Federal laws relevant to research involving humans as participants. Examples of such laws are reporting of child abuse and educational privacy laws. University counsel is available for advice in all cases as needed and requested. UNL's HRPP staff and or members of the IRB have access at all times to university legal counsel for assistance in applying laws to other than federal law regarding research involving human participants.

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|  <p>HRPP POLICIES AND PROCEDURES</p> <p>Research Compliance Services Human Research Protections Institutional Review Board</p> | <p>Policy # 5.006</p> <p>Title: <u>Research Involving Extra Credit Compensation</u></p> <p>Section: <i>Vulnerable Populations and Special Classes of Participants</i></p> <p>Date: December 1, 2011</p> |
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1.0 Purpose

Students are in a subordinate position to faculty members and instructors; therefore potential for coercion or undue pressure exists when course credit is awarded for research participation. For this reason, recruitment of students in the laboratory or classroom requires additional safety considerations.

2.0 IRB Protocol Requirements for Extra Credit Compensation

The following must be included in the IRB protocol submitted through NUgrant:

1. Class syllabus

- a. Description of the proposed research activity along with the points allowed for extra credit must be submitted with the IRB protocol. It is recommended that the extra credit for research be worth no more than 2% of the class grade.
- b. Personal identifiers, that is, names, initials, social security numbers, or institutional id numbers (i.e. NUID) should not be included in the research records in order to earn credit.
- c. Description of alternative non-research activities for credit
 - i. The alternative activity should be equivalent in time, energy, and effort to participating in the research activity. For example, if the research requires a half hour to participate, the alternative activity should take the same amount of time to complete.
 - ii. Alternative activities should not be graded. If the research participant receives the credit for participating regardless of the quality of their participation, the alternative should be assessed on a similar participated/did not participate differentiation.
 - iii. Alternate activities may include but are not limited to the following.
 - a. Attend a specific presentation on campus.
 - b. Watch a specific video
 - c. Participation in alternative research studies.


2. Recruitment procedures clearly addressing:

- a. The nature of the supervisory relationship between the investigator and the prospective participants (e.g., includes students in a class being taught by the investigator).
 - i. If participants are being recruited from the investigator's laboratory or class, describe procedures used to avoid potential coercion (e.g., use of a general bulletin board posting and not engage in one-on-one solicitation; use of an individual to obtain consent that does not have any supervisory or instructional role relative to the prospective participant).

3. Reference to approved department subject pool protocols, if applicable.

3.0 Exclusions and Considerations

1. Students cannot earn extra credit for research activities completed by another person.
2. Students who are required to perform research worker activities (i.e., recruiting subjects, conducting interviews) to obtain extra credit, will have to complete the CITI short course researcher worker training prior to engaging in the research activities.

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|  <p>HRPP POLICIES AND PROCEDURES</p> <p>Research Compliance Services Human Research Protections Institutional Review Board</p> | <p>Policy # 6.001</p> <p>Title: <u>Certification of Review to Funding Agencies</u></p> <p>Section: <i>Funding Agencies</i></p> <p>Date: April 1, 2008</p> |
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1.0 Purpose

The purpose of this policy is to describe the process of certification of review to funding agencies.

2.0 Policy

It is the policy of the IRB that certification of review will be sent to funding agencies in full accordance with regulations at Health and Human Services 45 CFR §46 and all other applicable funding agency/sponsor regulations and/or policy.

2.1 Grant Application Covered by One IRB Protocol

When an investigator submits either a grant application involving human participants to Office of Sponsored Programs or receives notification for example, from National Institutes of Health of a fundable score, the investigator must identify the IRB number, which will cover the human participants activities described in the grant application. If the title on the IRB protocol on file does **not** match the title of the project listed on the grant application, the investigator should submit to the IRB a “Request for Change” in protocol with either of the following:

A. Addition of a second title (the title on the grant application) to the IRB protocol

OR

B. Substitution of the new title

Regardless of which option is selected by the investigator, Office of Sponsored Programs will not process a funded grant unless there is an IRB number. (Under special circumstances, Office of Sponsored Programs may waive this requirement with appropriate justification). Office of Sponsored Programs is required to ensure that IRB review and approval of the grant application’s human participant activities has been obtained by the investigator prior to any protocol activity. The IRB, in turn, will compare the grant application with the IRB application.


It is acceptable for consent document(s) to have a lay title rather than scientific title. However, this should be documented for the record in the IRB application.

2.2 Grant Application Covered by Two or More IRB Protocols

In a situation where the human participant activities portion of a grant application is covered by two or more IRB numbers, the Office of Sponsored Programs and the IRB will not require matching titles. However, the submission must specifically identify the IRB protocol, which covers each application section of the grant application.

2.3 Commercially Sponsored Contracts

It is preferable that titles match between all documents (i.e., contract, protocol, consent document(s), and IRB application). The sponsor's protocol number may be included in the protocol title; however, the IRB discourages inclusion of sponsor names in protocol titles.

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|  <p>HRPP POLICIES AND PROCEDURES</p> <p>Research Compliance Services Human Research Protections Institutional Review Board</p> | <p>Policy # 7.001</p> <p>Title: <u>Random Compliance Reviews</u></p> <p>Section: <i>Random Compliance Review</i></p> <p>Date: November 1, 2010</p> |
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1.0 Purpose

The purpose of this policy is to describe the Random Compliance Reviews Program.

2.0 Policy

It is the policy of the IRB that Random Compliance Reviews will be conducted in accordance with regulations at Health and Human Services 45 CFR §46.

2.1 Quality Improvement Assessment Program

The IRB Random Compliance Review Program has been developed to reflect the vision, purpose, and mission of the Institution and the HRPP.

The Quality Improvement Assessment Program is designed to be proactive, non-punitive, and focused on education of investigators, staff, and students about ethical and regulatory responsibilities in the conduct of human participant research. The focus of the program will encompass the IRB review system and IRB documentation.

2.2 Goal of Compliance Reviews

- A. Demonstrate the commitment of the Office of Research Responsibility to the safety, rights, and welfare of human subject research participants by verifying the implementation of approval research protocols.
- B. Conduct reviews that are designed to assist researchers and their staff by:
 1. Verifying compliance with approved research protocols;
 2. Identifying areas in their research operations where there could be unrecognized potential for non-compliance with regulatory standards;
 3. Recommending best practices approaches to minimize risks for study participants.
- C. Identify standards of excellence and potential areas for improvement in order to enhance the quality of human subjects' research protections at the University of Nebraska-Lincoln
- D. Design training materials and programs to identify and promote best practices approaches to the research community at the University of Nebraska-Lincoln.

2.3 Elements of Compliance Reviews

- A. Review of IRB project records to include:
 1. Verification that IRB project personnel list matches current personnel;
 2. Confirm current Human Subject training certification for all key personnel;

3. Verify current Responsible Conduct of Research training (where required);
 4. Assure compliance with IRB requirements for change/continuation requests.
- B.** Request the following information from the investigator, to be checked against currently approved protocol and IRB files:
1. The current recruitment documents and procedures;
 2. The consent procedures and consent/assent forms in use;
 3. Storage of research documents and data;
 4. List of personnel who have access to data;
 5. Any unexpected and/or adverse events;
 6. If appropriate, amount and documentation procedures for research subject payments
- C.** Based upon complexity of research protocol, examination of the IRB files, and the response provided by the investigator, the compliance review may also involve an on-site visit by an HRPP staff member. Onsite visits would be conducted using the following procedures:
1. Prior notification of the visit;
 2. Scheduling the visit time with the investigator;
 3. Informing the investigator of the specific records (e.g. consent forms) or procedures (e.g., data storage and security) that could be reviewed during the visit.

2.4 Selection of Studies

- A.** Research protocols to be reviewed will be selected randomly from each level of review. At least four of the reviews will be full board protocols, four expedited, and four exempt. Investigators who have a positive compliance review in the prior year will be removed from the sampling frame for the following year.
- B.** The HRPP staff will conduct a minimum of 12 compliance reviews annually. If any systematic problems are identified, additional reviews may be conducted to insure broad compliance. This might involve additional reviews of protocols associated with a specific investigator and/or research administrative unit.
- C.** Investigators may request a compliance review.


2.5 The Review Process

- A.** Investigators will be notified in advance of the selection of their project for a compliance review.
- B.** The initial review will be conducted on IRB project files by staff in the HRPP office, and will be completed within one week of the investigator notification.
- C.** Upon completion of the internal record review, investigators will be notified of any identified concerns (e.g., human subject training not up-to-date for key personnel) and will be asked to complete a form to provide responses to the topics identified in 2.B. The investigator will have two weeks to respond to the questions and any concerns identified in the initial review. Investigators may request an extension of the time to respond.

- D. After review of the investigator responses, and verification against project records, a follow-up on-site visit may be requested. If this visit is requested, the investigator will be advised in writing and the procedure outlined in 2.C. will be followed.
- E. Upon completion of the review, the HRPP office will issue a report of findings from the compliance review. The outcome of this review will fall into one of four categories:
 - 1. No issues
 - 2. No compliance issues, but best practices advice to better document/improve selected aspects of the research protocol
 - 3. Minor compliance issues, included required corrective actions
 - 4. Major compliance issues. Depending on the nature of the issues identified, this may require suspension of the research and reporting to the appropriate university and federal office.

2.6 Review of the HRPP Program

- A. The components of the HRPP program will be reviewed quarterly by members of the HRPP Program. Each group of people will complete the HRPP Quality Improvement Checklist once per year. The following components will be reviewed:
 - 1. Communication process
 - 2. Review process
 - 3. Review Timelines
 - 4. IRB Meetings
 - 5. Outreach Activities
 - 6. OHRP Regulations.
- B. The quarterly evaluation of the program will allows for continuous improvements to be made throughout the course of the year. The following people reviewing the program
 - 1. IRB Chairperson
 - 2. IRB Members
 - 3. RCS Manger
 - 4. RCS Staff
- C. The results of the reviews will be shared with the IO prior to implementing any program changes.

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|  <p>HRPP POLICIES AND PROCEDURES</p> <p>Research Compliance Services Human Research Protections Institutional Review Board</p> | <p>Policy # 8.001</p> <p>Title: <u>Students as Researchers</u></p> <p>Section: <i>General Requirements and Guidelines</i></p> <p>Date: May 27, 2015</p> |
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1.0 Purpose

The purpose of this policy is to describe requirements for research conducted by students.

2.0 Policy

It is the policy of the IRB that research conducted by students will adhere to the regulations set forth in 45 CFR §46 as well as the ethical standards contained in the Belmont Report. Students for the purpose of this policy include undergraduate, graduate, or post-doctoral trainee.

2.1 Introduction

Student participation in the research process is a valuable learning experience. The IRB supports this academic endeavor and has developed a specific policy to guide students and their advisor(s).

2.2 Classroom and Clinical Practica

Classroom and clinical practica (usually in the form of course-related exercises or evaluation projects and/or directed studies) are designed to provide students an opportunity to practice various research methods such as interview, observation and survey techniques, measurement of behavior (e.g., reaction time, speech, problem solving) as well as data analysis. Typically such projects are quite limited in scope, are not considered systematic investigations designed to develop or contribute to generalizable knowledge, and are not undertaken with that goal in mind. For example, a student may interview a peer when the interview does not involve any sensitive, personal information. Such projects should not put the participants at more than minimal risk, and the data must be recorded anonymously by the students (e.g., with no names, social security numbers, or any other codes that can be linked to a list of names). These projects are considered "classroom exercises", are not systematic investigations designed to develop or contribute to generalizable knowledge, and are not subject to review by the IRB. They do not require review unless the student is conducting research involving human participants (that is, the activity is a systematic investigation designed to develop or contribute to generalizable knowledge) and the student is interacting or intervening with living individuals to obtain information about those individuals or collecting private identifiable information about living individuals. If the student anticipates publishing the results or presenting at a professional meeting, consultation with the IRB should be obtained prior to beginning the activity.

2.3 Research Projects (Directed or Independent)

"Any research conducted by students, graduate, undergraduate or post-doctoral trainees that does not fall under the definition of a classroom or clinical practicum, which uses human beings as participants and, which is a systematic investigation

designed to develop or contribute to generalizable knowledge, must be reviewed and approved by the IRB. This includes, but is not limited to, all independent undergraduate research projects and honors theses, masters' theses and dissertations that involve research involving human participants.

Recognizing the time constraints imposed on projects that must begin and be completed within a single semester, the IRB will make every effort to work with instructors to process proposals promptly. However, instructors must plan for and allow adequate time for the review process (approximately a week to a month, depending on the particular human participant issues raised by the proposed research). The later in the term a proposal is received, the more difficult it will be to accomplish the review in time for the projects to be completed during the current semester. It is very strongly urged that instructors submit proposals within the first three weeks of the semester for projects that must be completed during the current semester. In some cases, when students in a course are all using similar methods of recruitment and data collection, instructors may submit an aggregate proposal. Student research projects may be submitted to the IRB for consideration as *exempt* research if they meet federal exemption criteria such as research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior in which data is collected anonymously (e.g., with no names, social security numbers, or any other codes that can be linked to a list of names) or otherwise qualifying under exemption category 2 of the federal regulations. The course instructor must submit exemption requests to the IRB.

All non-*exempt* student research projects must be submitted for regular IRB review. Projects requiring *expedited review* are reviewed when they are submitted. Projects requiring full review by the IRB need to be submitted by the first of the month and will be reviewed at that month's meeting.

2.4 Responsibilities of Student Advisors for all Student Research Projects

Faculty advisors as well as student researchers must have completed CITI training to conduct research with human participants, even if they are not currently conducting research with human participants.

It is the responsibility of faculty advisors to determine when an undergraduate or graduate student project does not meet the definition of a practicum and must be reviewed by the IRB. However, the advisor must have completed CITI training as noted above to be authorized to make this decision.

It is the responsibility of faculty advisors to ensure that research practica and *exempt* research activities are conducted according to the ethical standards of the relevant discipline.

When student research activities are not practica, it is the responsibility of faculty advisors to assist students in preparing review materials for the IRB and to ensure that the research is conducted in accordance with UNL's agreement with the federal government and with applicable UNL policy.

2.5 Potential Practicum Problems

Students engaged in the process of learning research techniques understandably want to focus on compelling or real-life issues. In the process of reviewing student research, however, the IRB has found topics and subjects that raise concerns for the well-being of the participants and students themselves. Projects collecting data about illegal activities, those which could cause emotional distress in the participants, those which would place the students at risk if confidentiality were breached, and those with children as participants, need to be constructed with special care.

While practica are not under the purview of the IRB, the staff of the IRB is available for consultation with students and for class presentations regarding issues of the protection of the rights and welfare of human participants. It is important to note that data collected as practica cannot at a later date normally be used for presentation at conferences, publications, or doctoral dissertations.

2.6 Activities Requiring IRB Review

“**All** research involving human participants must be reviewed and approved by the IRB” (see HRPP policy [# 3.001](#) for definition of research involving human participants). This directive includes research conducted by students.

To determine if the activity meets the definition of research, the investigation must “be a systematic investigation designed to develop or contribute to generalizable knowledge”. If the results of the investigation will be, or has the potential to be, published or presented through oral presentations, abstracts, or posters *outside* of the campus of UNL, the definition of research might be indicated. Accordingly the research, if it involves human participants, is subject to IRB review.

However, if the results of the investigation will be limited to, publications, oral presentations, posters, or abstracts solely on the UNL campus, and relatedly are not systematic investigations designed to develop or contribute to generalizable knowledge, IRB review might not be required.

UNL students enrolled in graduate programs are required to have IRB approval for thesis or dissertation research projects involving human participants.

2.7 IRB Application and Review

There is not a special IRB review process for student research. The student researcher is expected to follow all current IRB policies and procedures for IRB initial approval, continuing review, change requests, and other protocol matters. All deadlines and time frames will remain the same as for other researchers falling under the jurisdiction of the IRB.

Key personnel for research conducted by students may include:

- A.** *The student as PI.* It is the student’s responsibility to carry out all of the obligations of a PI.
- B.** *The student’s advisor as a Supervising Investigator.* It is the responsibility of the advisor to supervise the student’s research project and provide necessary advice concerning IRB requirements and applicable federal regulations. Faculty who assign or supervise research conducted by students or staff have an obligation to consider carefully whether those individuals are


qualified to safeguard adequately the rights and welfare of participants and have been properly trained in human research protection.

C. *Other applicable Supervising Investigators and/or participating personnel.*

2.8 Training in the Protections of Human Participant Requirements

The IRB requires that all key study personnel involved in the conduct of human participant research be certified by completion of the web-based training program (CITI). All students conducting research requiring IRB review must complete CITI training prior to IRB approval of the research. This includes *exempt* research. (See HRPP policy [# 3.010](#) for further information.)

Students participating in classroom projects that *do not* require IRB review are *not* required to complete CITI training. However, some colleges, departments, and sections may adopt internal requirements for all students to complete CITI training.

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|  <p>HRPP POLICIES AND PROCEDURES</p> <p>Research Compliance Services Human Research Protections Institutional Review Board</p> | <p>Policy # 8.002</p> <p>Title: <u>Epidemiological Research Guidelines</u></p> <p>Section: <i>General Requirements and Guidelines</i></p> <p>Date: April 1, 2008</p> |
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1.0 Purpose

The purpose of this policy is to describe the guidelines required when conducting epidemiological research.

2.0 Policy

It is the policy of the IRB that all epidemiological research will be performed in accordance with the regulations set forth in 45 CFR §46.

2.1 Introduction

Epidemiological research is defined as the collection and analysis of medically relevant data about individuals or groups to determine the causes, distribution, and control of diseases in populations.

Some epidemiological research requires access to many sources of Protected Health Information (e.g., medical records, databases, disease registries, and hospital discharge records). As a result the greatest risk associated with this research is breach of confidentiality and privacy. While the HIPAA Privacy Rule is not intended to obstruct epidemiological research, the investigator must understand and follow specific rules in order to meet the HIPAA Privacy Rule regulations as well as minimize the risks.

2.2 Development of the Protocol

During the development of an epidemiological research protocol, the investigator must consider several questions and be prepared to justify the responses in the IRB Application. Consideration of these questions will aid the investigator in meeting the requirements of the Privacy Rule, Health and Human Services regulations at 45 CFR §46, as well as all applicable IRB requirements:

- A. What is the purpose of the research and what data is required to achieve the purpose of the research?
- B. Will retrospective (already existing) or prospective (collected in the future) data be used in the study?
- C. Where will the data come from (e.g., medical record review, databases, registries or clinical interaction with participants)?
- D. Will the research involve banking of data for future use or for purposes that are not integral to the current research?
- E. Does, or will, the collected data contain Protected Health Information or other information that can be directly, or indirectly, linked to a participant? If yes, why will the link to a participant be required and how long will the identifiers be retained?

- F. Does the investigator have ethical access to the data (e.g., through a treatment relationship with potential participants or through control of an existent database)?
- G. Does the research have the potential to collect data on the participant (e.g., proband) and other related individuals (e.g., family members) identified by the participant or through other means (e.g., surveys and questionnaires)?

2.3 Protected Health Information

A. Identifiers

The Privacy Rule states that only the *minimum Protected Health Information necessary to achieve the research objective* can be used. Where it has been determined that participant identifiers are crucial to the research, the investigator must list the identifiers to be used and provide justification for their use (see HRPP policy [# 10.001](#) for a list of the identifiers.)

B. Limited Data Set

In cases where the investigator provides justification for a need to maintain subject links to the data, the use of a Limited Data Set should be considered (see HRPP policy [# 10.002](#) for further information.)

The investigator who is using the Limited Data Set **cannot** maintain the linked code. At UNL, the Director will normally maintain such codes. To obtain a Limited Data Set the investigator must complete a UNL Data Use Agreement (<http://research/orr/forms.shtml>). This will identify the investigator as the recipient of the Limited Data Set, how the data may be used and disclosed by the investigator, and provide assurances that the data will be protected.

During consideration of the application, the IRB will determine if the use of the limited data set meets the HIPAA and Health and Human Services requirements for waiver of informed consent.

C. De-Identified Data Set

If the data has been de-identified, the IRB will consider one of two (2) review options:

1. The IRB may determine that this qualifies for exemption under Health and Human Services regulations at 45 CFR §46.101(b) (see HRPP policy [# 4.001](#) for a listing of the research categories that qualify for exemption.)
2. The research is not considered human participant research, therefore it is not subject to Health and Human Services regulations at 45 CFR §46.

2.4 Informed Consent

Informed consent must be obtained from the participant, unless the IRB approves a waiver or alteration.

2.5 Waiver or Alterations of Informed Consent

While protection of patient privacy and confidentiality is the primary goal of the HIPAA regulations, it is understood that situations may arise where obtaining informed consent may be impractical (e.g., research conducted on existing databases or repositories where no contact information is available). In these cases, HIPAA and Health and Human Services regulations have provided for IRB waiver or alteration of informed consent, if approved by the full IRB.

The following criteria must be met (see HRPP policy [# 9.006](#)):

- A. The use or disclosure of Protected Health Information involves no more than minimal risk.
- B. An adequate plan to protect participant identifiers from improper use and disclosure must be presented to the IRB (e.g., data is coded or linked and the codes are stored separately).
- C. An adequate plan to destroy participant identifiers at the earliest opportunity must be presented to the IRB (unless there is a health or research justification for retaining the identifiers or required by law).
- D. Using the “reasonable person standard”, the alteration of waiver of informed consent will not adversely affect the rights and welfare of the individuals.
- E. The research cannot practicably be conducted without the waiver or alteration of informed consent and justification is provided.
- F. The research cannot be conducted without access to and use of the Protected Health Information. The objectives and validity of the study must provide justification for the use of specific Protected Health Information.
- G. Whenever appropriate, the participants will be provided with additional pertinent information after participation.

2.6 Participant Recruitment

All participant recruitment activities must be approved by the IRB (see HRPP policy [# 3.011](#)).

IRB approval of the recruitment plan is particularly important in situations where the investigator requests that a participant identify family members (or other applicable individuals) that might qualify for the study. It is important to note that the investigator has ethical access only to the enrolled participant, not those individuals identified by the participant. The investigator, or specialist, may not directly contact the family members (or others) without permission of those individuals.

The IRB recommends where possible the following recruitment plan be utilized:

The participant may be asked if they have family members that might qualify for the study. Rather than request the names and contact information, the investigator should ask the participant to speak with family members about the project. The participant may be provided an IRB-approved informational brochure or letter to give to the family member. The brochure/letter should provide information on whom to contact for further information. Alternately, it would be appropriate to provide self-addressed stamped postcards to the participant to hand out to family members. Interested family members (or others) could indicate their interest by returning the card with names and contact numbers filled in. In both cases, contact would be initiated by individuals expressing an interest in the study.

2.7 Research Involving the Development of a Database


There are two separate activities to consider in the development of a database. Each is considered a separate research activity under the HIPAA regulations and will require IRB-approved informed consent (authorization), unless the IRB grants a waiver or alteration to the informed consent requirement:

- A. The use or disclosure of Protected Health Information for *creating* a research database or repository.
- B. The use or disclosure of Protected Health Information in the database for a *future* research purpose.
- C. **Creation of a Research Database or Repository**

During consideration of an IRB application to create a research database or repository, the IRB must consider:

 1. Will the database maintain Protected Health Information? If yes, what is the investigator's justification?
 2. Will informed consent (authorization) be required, or does the database meet the qualifications for waiver or alteration of informed consent? In most cases, if the database involves collection of data through direct intervention or interaction with the participant, the IRB will require informed consent.
 3. Has the investigator provided sufficient assurance that the Protected Health Information in the database will not be used or disclosed for future research without IRB approval prior to use?
- D. **Future Research Using a Database**

Creation of a database for the purposes of research **does not** mean the database can be used for any future research without specific IRB approval of the proposed study. Therefore, use of a database for research not specifically approved by the IRB requires submission of an application and approval by the IRB prior to use for future research. At that time, informed consent requirements will be based on the Protected Health Information present in the database, prior informed consent of the subject to authorize the placement of Protected Health Information in the database, the purpose of the research, and prior IRB waiver or alteration of informed consent.

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|  <p>HRPP POLICIES AND PROCEDURES</p> <p>Research Compliance Services Human Research Protections Institutional Review Board</p> | <p>Policy # 8.003</p> <p>Title: <u>Exercise Protocol Guidelines</u></p> <p>Section: <i>General Requirements & Guidelines</i></p> <p>Date: April 1, 2008</p> |
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1.0 Purpose

The purpose of this policy is to describe the guidelines required when conducting studies that include exercise.

2.0 Policy

It is the policy of the IRB that all exercise studies will be conducted in accordance with regulations at Health and Human Services 45 CFR §46.

2.1 Introduction

The American College of Sports Medicine published guidelines in 2000 for use in studies involving exercise testing and prescriptions. These guidelines have been recognized as setting national standards. The guidelines, adopted by the IRB for research protocols involving exercise, reflect the American College of Sports Medicine 2000 guidelines and requirements of 45 CFR §46. These guidelines are largely based upon the following criteria:

- A. Intensity of exercise.
- B. Age of participant.
- C. Apparent health status of participant.
- D. Apparent fitness/activity level of participant.

The aforementioned criteria, in turn, determine health screening, monitoring, physician oversight and the type of IRB review (e.g., *expedited continuing vs. full board*). The IRB reserves the right to rule in exception to the exercise guidelines if necessary.

2.2 Health Screening

Appropriate participant health screening is required prior to the initiation of any maximal or sub-maximal intensity exercise test or program. Physician approval is required for participants that are at higher risk. A questionnaire may be administered by qualified study personnel to participants that are at lower risk. This questionnaire should be submitted with the IRB Application.

2.3 Maximal Exercise Procedures

A. Cardiovascular Endurance

Cardiovascular endurance exercise procedures that are higher in intensity than 90% of maximal heart rate or 85% of maximal oxygen uptake or heart rate reserve maximum are regarded as maximal exercise and are considered in the category, which requires review by the full IRB.

The following table should be used to determine how to classify a particular participant and which requirements must be met:

| | Participant 1 | Participant 2 | Participant 3 | Participant 4 | Participant 5 |
|---------------------------------------|----------------------|-------------------------|----------------------|-------------------------|-------------------------|
| Health Status | Apparently Healthy | Apparently Healthy | Apparently Healthy | Apparently Healthy | Unhealthy |
| Exercise Status | Active | Active | Sedentary | Sedentary | Active or Sedentary |
| Age, yr | < age 35 | > age 35 | < age 35 | > age 35 | < or >age 35 |
| Review | <i>Full Board</i> | <i>Full Board</i> | <i>Full Board</i> | <i>Full Board</i> | <i>Full Board</i> |
| Health Professional Attendance | None | Physician, R.N. or P.A. | None | Physician, R.N. or P.A. | Physician, R.N. or P.A. |
| Health Screening | Questionnaire | Physician approval | Questionnaire | Physician approval | Physician approval |
| Subject Monitoring | Heart rate | Heart rate EKG | Heart rate | Heart rate EKG | Heart rate EKG |

B. Muscular Strength/Endurance

Muscular strength/endurance exercise procedures using maximal (e.g., one-to-five) repetitions require full IRB approval regardless of participant health, activity level, and/or age.

Isokinetic exercise testing programs (e.g., Biodex) at slow movement speeds are considered in this category.

Scientific justification will be required to support the use of exercises that are considered high risk. These exercises include, but are not limited to:

1. Squat.
2. Dead Lift.
3. Clean and Jerk.
4. Overhead Press.
5. Any equivalent of the above.

The following table should be used to determine how to classify a particular participant and, which requirements must be met:

| | Participant 1 | Participant 2 | Participant 3 | Participant 4 | Participant 5 |
|---------------------------------------|----------------------|-----------------------------|----------------------|-----------------------------|-------------------------|
| Health Status | Apparently Healthy | Apparently Healthy | Apparently Healthy | Apparently Healthy | Unhealthy |
| Exercise Status | Active | Active | Sedentary | Sedentary | Active or Sedentary |
| Age, yr | < age 35 | > age 35 | < age 35 | > age 35 | < or >age 35 |
| Review | <i>Full Board</i> | <i>Full Board</i> | <i>Full Board</i> | <i>Full Board</i> | <i>Full Board</i> |
| Health Professional Attendance | None | None or IRB Ruling | None | None or IRB Ruling | Physician, R.N. or P.A. |
| Health Screening | Questionnaire | Questionnaire or IRB Ruling | Questionnaire | Questionnaire or IRB Ruling | Physician approval |

2.4 Moderate Exercise Procedures

A. Cardiovascular Endurance


Cardiovascular endurance exercise procedures that are lower in intensity than 90% of maximal heart rate or 85% of maximal oxygen uptake or heart rate reserve maximum are regarded moderate exercise and are considered in this category.

The following table should be used to determine how to classify a particular participant and the requirements, which must be met:

| | Participant 1 | Participant 2 | Participant 3 | Participant 4 | Participant 5 |
|---------------------------------------|-----------------------------|----------------------|-----------------------------|-----------------------------|-------------------------|
| Health Status | Apparently Healthy | Apparently Healthy | Apparently Healthy | Apparently Healthy | Unhealthy |
| Exercise Status | Active | Active | Sedentary | Sedentary | Active or Sedentary |
| Age, yr | < age 35 | > age 35 | < age 35 | > age 35 | < or >age 35 |
| Review | <i>Expedited continuing</i> | <i>Full Board</i> | <i>Expedited continuing</i> | <i>Full Board</i> | <i>Full Board</i> |
| Health Professional Attendance | None | None | None | None | Physician, R.N. or P.A. |
| Health Screening | Questionnaire | Questionnaire | Questionnaire | Questionnaire or IRB ruling | Physician approval |
| Subject Monitoring | Heart Rate | Heart Rate | Heart Rate | Heart Rate | Heart Rate EKG |

2.5 Other Exercise Procedures

Investigators intending to use exercise procedures not addressed in these guidelines should compare the proposed exercise to the most closely related category and classification. Attention should be given to the intensity of the exercise, the age of the participant, the apparent health status of the participant, and the apparent fitness/activity level of the participant. Finally, the appropriateness of the exercise should be considered in relation to these factors.

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|  <p>HRPP POLICIES AND PROCEDURES</p> <p>Research Compliance Services Human Research Protections Institutional Review Board</p> | <p>Policy # 8.004</p> <p>Title: <u>Research Conducted in Foreign Countries</u></p> <p>Section: <i>General Guidelines & Requirements</i></p> <p>Date: August 25, 2015</p> |
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1.0 Purpose

The purpose of this policy is to describe the guidelines for research conducted in foreign countries.

- 1.1 The Principal Investigator (PI) is a faculty member, staff, student, or other representative of the Institution, and the research is conducted at the international site by the PI.
- 1.2 The PI is a faculty member, staff, student, or other representative of the Institution and the research is conducted under the direction of the PI by external investigators unaffiliated with the Institution.

2.0 Policy

It is the policy of the IRB that all research in foreign countries will be conducted in accordance with the regulations at Health and Human Services 45 CFR §46. The IRB will review all human subjects research being conducted in foreign countries regardless of the foreign institution's IRB or Ethics Committee approval system.

2.1 Non-federally funded research

Non-federally funded research that is conducted in a foreign country is subject to all of the IRB requirements except that IRB requirements can be waived in consideration of the culture and local customs of the country in which the research is conducted. Investigators who seek a waiver of **any** IRB requirements must provide appropriate justification to the IRB.

- A. Any justifications for waivers of IRB requirements based on claims of local practices or customs will be independently verified with the foreign institution and/or appropriate governmental agency, or consultant when applicable.

2.2 Federally funded research

Federally funded research that is conducted in a foreign country is subject to all of the IRB requirements with exceptions granted in accordance with the federal (model) policy and OHRP guidance.

According to the model policy for the protection of human participants and OHRP requirements, when federally funded research takes place in foreign countries, a FWA must be filed. However, procedures normally followed in the foreign countries to protect human participants may differ from those set forth in the model policy. In these circumstances, a department, or agency head, must determine that the procedures prescribed by the foreign institution afford protections that are at least equivalent to those provided in

the model policy. If the procedures meet these criteria, the department or agency head may approve the substitution of the foreign procedures in lieu of the procedural requirements provided in the model policy.

- 2.3 The PI assumes overall responsibility for the safe and proper conduct of the research in full compliance with all applicable U.S. regulations, country specific laws/regulations, local IRB (e.g., IEC, REB, REC) requirements and UNL HRPP Policies. The PI is also responsible for conducting the research with consideration of all local customs and cultural requirements, as documented in the approved protocol.

3.0 IRB Requirements

Research that includes collaboration with an international institution must provide assurance to the IRB that all of its activities related to human participant research, regardless of funding source, will be guided by the ethical principles in one of the following documents:

- A. The Declaration of Helsinki (as adopted in 1996 or 2000).
- B. The Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects of Research of the U.S. National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research.
- C. Other appropriate international ethical standards recognized by federal departments and agencies that have adopted the US Federal Policy for the Protection of Human Subjects. A copy of these standards must be provided by the institution.

In addition, the IRB requires confirmation of IRB approval (or equivalent) from the foreign site, a copy of the protocol, and a copy of the informed consent document.

- 3.1 When non-exempt research is conducted at an international site by the Institution's faculty, staff, students, or other representative of the Institution, the following apply:
 - A. Review and approval of the research will be required by both the (1) UNL IRB, and (2) any local IRB at the international site which has review and oversight jurisdiction over the research, where applicable.
 - B. Protections of human subjects at the international site must be at least equivalent to 45 CFR 46 Subparts B and D as applicable.
 - C. International research involving prisoners may only be permitted if the following can be documented:
 1. There must be clear and overwhelming evidence that the research meets all criteria for IRB approval of research (see policy #3.004),
 2. There must be clear and overwhelming evidence that the research meets all criteria for IRB approval research under Subpart C within 45 CFR 46 (See policy #5.003)
 3. Institutional Official approval.

- 3.2 The IRB will consider the following items when reviewing international research.
- A. The qualifications of the PI and research personnel to conduct research in the specific country.
 - B. The consent process and consent documents are appropriate for the languages of the subjects and communication with the subject population. Arrangements are considered to communicate with the subjects throughout the research.
 - C. Verification that the PI has in place a process handling:
 - 1. Modifications to the research. The IRB and investigators should consider as many contingencies as possible when research is reviewed and approved.
 - 2. Complaints, noncompliance, protocol deviations, and unanticipated problems involving risk to subjects or others.
 - 3. Post-approval monitoring of the research.
 - D. IRB mechanisms for communicating with the PI and research personnel when they are conducting the research in other countries.

4.0 Verification of International Research Standards


The IRB will maintain links to information resources that provide information on foreign country regulations on human subjects research. The DHHS Office for Human Research Protection (OHRP) maintains the *International Compilation of Human Research Protections*. The Compilation lists the laws, regulations, and guidelines for over 50 foreign countries.

This Compilation is maintained in electronic format, with direct web links to each country's regulatory organizations, laws, and other resources that establish local standards. OHRP provides this Compilation to assist researchers and IRBs in verifying that research studies are complying with local laws and customs.

The Compilation can be accessed on the OHRP website:

<http://www.hhs.gov/ohrp/international/index.html>

If legal information is not available via the OHRP Compilation, additional resources will be sought, for example from general counsel or a consultant when applicable.

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|  <p>HRPP POLICIES AND PROCEDURES</p> <p>Research Compliance Services Human Research Protections Institutional Review Board</p> | <p>Policy # 8.005</p> <p>Title: <u>Community-Based Participatory Research</u></p> <p>Section: <i>General Guidelines & Requirements</i></p> <p>Date: November 1, 2010</p> |
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1.0 Purpose

The purpose of this policy is to describe the guidelines for community-based participatory research.

2.0 Policy

It is the policy of the IRB that all community-based participatory research will be conducted in accordance with the regulations at Health and Human Services 45 CFR §46.

2.1 Definition of community-based participatory research

Community-based participatory research (CBPR) is a research paradigm that attempts to make research a more inclusive and democratic process by fostering the development of partnerships between communities and academics to address community-relevant research priorities. The CBPR paradigm emerged from research with autonomous indigenous communities, particularly American Indian tribes, but has expanded to a broader scope. Broadly, communities in this research domain represent population groups with social structures, common customs, and acknowledged leadership. These ‘communities’ may include nations, cultural groups, small indigenous communities and some neighborhood groups.

Some of the unique elements of CBPR include; 1) active engagement and shared decision-making of community members and academic researchers, 2) involvement of community approval and representation in the research approval, design, and implementation, 3) integration of community social action, social change, priorities with the scientific objectives of the academic researchers, and 4) consideration and respect for the rights of the community in all aspects of the research.

2.2 Special considerations in the IRB review of community-based participatory research

In CBPR human protections are not just about individuals but the respect, beneficence and justice for the community. As such, the IRB review process requires documentation of access and approval to conduct research in communities (refer to questions 5-7 on page 1 of the IRB New Protocol Form).

Most communities do not have the equivalent of an IRB, and even those with some formal ethics review process typically do not have an established FWA. As such, the UNL IRB cannot use a formal collaboration agreement to address the dual processing of human subjects protections at the community and university levels. Rather, we have established the following additional review guidelines for

CBPR informed by the recommendations of the Community-Campus Partnerships for Health (CCPH):

- A. IRB Review of CBPR add the principle of “respect for communities” or “respect for cultures” as a criteria for assessing the proposed research;
- B. Written consent of the community must be obtained prior to the IRB approval of a CBPR study;
- C. If the study is not approved by the community, individual informed consent may not be used as an alternative to gaining community approval.

2.3 Community-based participatory research resources


There are a number of resources available to guide and aid university investigators in the design and implementation of CBPR.

Guidance for investigators:

- A. An annotated listing of CBPR articles, reports and websites was prepared by Community-Campus Partnerships for Health for the Robert Wood Johnson Clinical Scholars Program.
http://depts.washington.edu/ccph/pdf_files/rwjcs-cbpr-resources.pdf
- B. CBPR: Engaging Communities as Partners in Health Research
<http://depts.washington.edu/ccph/guide.html#CommPap200>
- C. Agency for Health Care Research and Quality commissioned literature review on CBPR approaches
<http://www.ahrq.gov/clinic/evrptpdfs.htm>

Resources for the IRB:

- A. CCPH, in collaboration with the Tuskegee University National Center for Bioethics in Research and Health care have created a series of training sessions on the relationship of CBPR and University IRBs
<http://depts.washington.edu/ccph/irbcalls.html>
- B. The IRB has experience in evaluation of CBPR research and maintains representation on the board of both community members and investigators who have experience with CBPR practices.
- C. The IRB has access to investigators on campus who have expertise in conducting CBPR and may be called upon by the IRB to provide expert consulting for specific community studies.

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|  <p>HRPP POLICIES AND PROCEDURES</p> <p>Research Compliance Services Human Research Protections Institutional Review Board</p> | <p>Policy # 8.006</p> <p>Title: <u>Enhancing Understanding of Participants, Prospective Participants, and the Community.</u></p> <p>Section: <i>Education and Outreach</i></p> <p>Date: November 1, 2010</p> |
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1.0 Purpose

The purpose of this policy is to describe the methods used to enhance the understanding of participants, prospective participants, and the community.

2.0 Policy

It is the policy of the IRB that all current and future potential participants understand the research being conducted at the University of Nebraska-Lincoln.

2.1 Printed Resources Available for Distribution

A. Research Compliance Services Brochure

The *Are you Thinking About Conducting Research with Human Subjects or their information?* Brochure provides a brief overview of human subjects research.

B. OHRP Becoming a Research Volunteer Brochure

It's Your Decision brochure distributed by OHRP offers an explanation of being a participant in research and provides questions that research participants should ask prior to participating in a research study. This document can be accessed on-line at

<http://www.hhs.gov/ohrp/education/brochures/3panelfinal.pdf>

2.2 Web Resources

A. Links to the Brochures

Print documents are posted on the Office of Research Responsibility website making them available to everyone.

B. Contact Information for Research Compliance Services

Contact information is provided to allow those interested to contact Research Compliance Services to:

1. Discuss problems, concerns, and questions.
2. Obtain information.
3. Offer input.

People will be responded to on a case by case basis depending on the nature of the comment or concern. The Research Compliance Services Director may respond to the person. If the question is not serious in nature, the Research Compliance Services staff will respond to the person. If the person has indicated that there has been a problem related to research conducted by a person affiliated with UNL, the principal investigator will be contacted to address the issue. The individual will remain anonymous.

C. Presentations will be made available via Adobe or Power Point on the

RCS website for the community to view.

D. CITI Training

Anyone interested may register and complete the CITI training to learn more about human subjects research.

3.0 Evaluation of Outreach Activities


Outreach Activities will be evaluated on an annual basis. Once per year the following members of the Human Research Protection Program (HRPP): the IRB Chairperson, members of the IRB Full Board Committee, the Research Compliance Services (RCS) Director, and Members of the RCS staff will evaluate the program.

3.1 The HRPP Quality Improvement Checklist will be used to evaluate the program on various aspects including Outreach.

A. An evaluation report will be compiled based on responses to the Checklist. This report will be shared with the RCS staff and the IO.

B. Improvements will be made quarterly based on the outcome of the Evaluation.

C. By completing the checklist annually by various people affiliated with the HRPP, program improvements will be made throughout the year.

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|  <p>HRPP POLICIES AND PROCEDURES</p> <p>Research Compliance Services Human Research Protections Institutional Review Board</p> | <p>Policy # 9.001</p> <p>Title: <u>Required Elements for Informed Consent Documents</u></p> <p>Section: <i>Informed Consent</i></p> <p>Date: July 27, 2016</p> |
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1.0 Purpose

The purpose of this policy is to describe the required elements for informed consent documents.

2.0 Policy

It is the policy of the IRB that the IRB shall ensure that informed consent is documented in accordance with and to the extent required by Health and Human Services 45 CFR §46.116, unless documentation is waived by the IRB as provided in Health and Human Services 45 CFR §46.109(c) and §46.117.

2.1 Introduction

The IRB shall require that information given to participants as part of informed consent is in accordance with Health and Human Services regulations at 45 CFR §46.116. The IRB may require that information, in addition to that required by regulations, be given to participants when in the IRB's judgment the information would meaningfully add to the protection of the rights and welfare of participants in accordance with Health and Human Services 45 CFR 46. §109(b). The IRB has authority to observe or have a third party observe the consent process and/or the conduct of research [45 CFR §46.109(e)]. Guidelines through the use of a template are available to assist all investigators to meet requirements of the federal regulations and IRB (available through the HRPP website, <http://research.unl.edu/researchresponsibility/human-research-protections-programirb-forms-policy-and-guidance-page/>).

2.2 Investigator Responsibilities

The investigator has a legal and ethical obligation to ensure that the prospective research participant has sufficient knowledge and comprehension of the elements of informed consent, meaning that the prospective research participant must be able to make an informed decision whether or not to participate in research. Obtaining informed consent should be seen as a communication process of explanation and not as an act of signing a form. As part of the process of obtaining informed consent, each element of consent should be explained carefully and simply to the prospective participant. In addition, the investigator should assess periodically the prospective participant's comprehension by asking appropriate questions. Ultimately, the investigator bears full responsibility for obtaining valid informed consent from the participant.

Investigators should be sensitive to the possible needs of an interpreter or translator for participants who do not speak English as a first language or who are hearing impaired.

2.3 Mail/Telephone Surveys

Mailed surveys that are completely anonymous can meet the informed consent requirement in one of two ways: a) they can be sent out with an accompanying cover letter and an informed consent form, or b) they can be sent out with an accompanying informed consent form but written in a cover letter format. If the second option is chosen, the return of the survey implies consent, which can be approved if the IRB grants an exemption determination or waives the requirement for documentation of the consent process. The letter would have to include notification of use of data, assurance of confidentiality, and phone numbers to contact in case of questions about participant's rights.

Some anonymous telephone interviews with adults can be handled in a similar way. It is preferred for the participant to receive a copy of the informed consent letter or form before the interview; however, in situations when that is not possible, information typically given on an informed consent form (notification of use of the data, assurance of confidentiality, phone numbers to contact in case of questions, etc.) can be included in an oral script that is read to participants to obtain oral consent. Oral scripts must be submitted to the IRB for review and approval before the study is conducted.

2.4 Required Elements for Informed Consent Documents

The following are the required elements that must be present in all consent documents.

The consent form must be:

- A.** Approved by the IRB and include the elements of informed consent required by Health and Human Services 45 CFR §46.117 and 46.117(b)(1);
- B.** Signed by the participant or the participant's legally authorized representative [Health and Human Services 45 CFR §46.117(a)]; unless the IRB has waived the requirement for document of the consent process in, which case a cover letter may be used as an informed consent document; and
- C.** A copy must be given to the participant or legally authorized representative [Health and Human Services 45 CFR §46.117(a)].

The agreement, written or oral, entered into by the participant, may not include language through which the participant is made to waive, or to appear to waive, any legal rights, or to release the investigator, the sponsor, UNL, or its agents from liability for negligence.

Informed consent should be appropriate to the research and participant population being studied.

- D.** Informed consent shall include the following elements:
 - 1.** A statement that the study involves research [Health and Human Services 45 CFR §46.116(a)(1)];
 - 2.** An explanation of the purposes of the research [Health and Human Services 45 CFR §46.116(a)(1)];
 - 3.** The expected duration of the participant's participation in the research [Health and Human Services 45 CFR §46.116(a)(1)];

4. A description of the procedures to be followed [Health and Human Services 45 CFR §46.116(a)(1)];
5. Identification of any procedures which are experimental [Health and Human Services 45 CFR §46.116(a)(1)];
6. A description of any reasonably foreseeable risks or discomforts to the participants [Health and Human Services 45 CFR §46.116(a)(2)];
7. A description of any benefits to the participant or to others which may reasonably be expected from the research [Health and Human Services 45 CFR §46.116(a)(3)];
8. A disclosure of appropriate alternative procedures or courses of treatment, if any that might be advantageous to the participant [Health and Human Services 45 CFR §46.116(a)(4)];
9. A statement describing the extent, if any, to which confidentiality of records identifying the participant will be maintained [Health and Human Services 45 CFR §46.116(a)(5)];
10. For research involving more than minimal risk, an explanation as to whether any compensation is available if injury occurs; whether any medical treatments are available if injury occurs; and, if so, what they consist of, or where further information can be obtained [Health and Human Services 45 CFR §46.116(a)(6)];
11. An explanation of whom to contact for answers to pertinent questions about the research and who to contact in the event of a research related injury to the participant. [Health and Human Services 45 CFR §46.116(a) (7)]. A contact phone number for the PI and the Supervising Investigator must be provided;
12. A statement of whom to contact concerning questions about research participants rights, for example, "Please contact the University of Nebraska-Lincoln Institutional Review Board at (402) 472-6965 to voice concerns about the research or if you have any questions about your rights as a research participant."
[Health and Human Services 45 CFR §46.116(a)(7)]; and
13. A statement that participation is voluntary, that refusal to participate involves no penalty or loss of benefits to which the participant is otherwise entitled, and that the participant may discontinue participation at any time without penalty or loss of benefits to which the participant is otherwise entitled: for example "Participation in this study is voluntary. You can refuse to participate or withdraw at any time without harming your relationship with the researchers or the University of Nebraska-Lincoln, (include any other agency/institution you are working with), or in any other way receive a penalty or loss of benefits to which you are otherwise entitled." [Health and Human Services 45 CFR §46.116(a) (8)].

E. If appropriate to the research, indicate whether the informed consent process provides the following 7 additional elements of information 45 §CFR 46.116(b):

1. That some risks to subjects may be unforeseeable.
2. Outlines the circumstances where a subject's participation may be terminated by PI without regard to subject's consent.
3. Whether there are any costs for which subjects will be responsible.

4. The consequences of a subject's decision to withdraw (safety issues).
5. That new and significant findings, which may affect subject's willingness to continue, will be disclosed.
6. The approximate number of subjects involved in the research at the institution and nationally.
7. Checkboxes specifically denoting consent for optional or variable procedures only.

The IRB requires that information in addition to that required by Health and Human Services 45 CFR §46 be given to research participants when in its judgment the information would meaningfully add to the protection of the rights and welfare of participants (Health and Human Services 45 CFR 109):

8. The age of participants (under 19 require parental informed consent in Nebraska except those who are legally emancipated or who are otherwise able to consent to the procedures involved in the research).
9. Where research takes place.
10. When individuals with decisional impairments are potential research participants, the IRB may require the investigator to use techniques that would confirm that individuals did understand the consent process.
11. A statement about why the participant was selected.
12. The IRB may require the consent process be monitored or observed when individuals with decisional impairments are involved.
13. The IRB may require waiting periods prior to consenting.
14. The IRB may require an advocate or ombudsman oversee the consent process for individuals with decisional impairments.
15. The IRB may require procedural changes or additional protections for individuals with decisional impairments.
16. A statement that if the participant was or became pregnant, the particular treatment or procedure might involve risks to the embryo or fetus, which were currently unforeseeable.
17. Procedures for the orderly termination of participation by the participant.

2.5 Documentation of Consent Process

The consent process must be appropriately documented in accordance with Health and Human Services regulations at 45 CFR §46.117. (see HRPP policy [# 9.002](#)):

- A. The participant must initial the bottom of each page of the consent, or the consent form should say page ___ of ___ and formally provide their full signature, and date, at the end of the consent.
- B. For studies involving greater than minimal risk, a witness must also provide signature and date.
- C. The investigator's name and phone number must be listed at the end of the consent form.

2.6 Signed informed consent can be obtained by the following methods.

- A. Participant physically signs a piece of paper or an electronic form using a stylus. This could be returned hardcopy, via fax, or via email.

B. For studies involving an on-line consent process, a signatures must follow the Nebraska Administrative Code at Title 437, Digital Signatures Act and at Nebraska Revised Statute 86-611. For example the following could be used to include electronic signature:

1. Checking a box and entering their name to indicate the person agrees to participate. The on-line consent form should state: By clicking this box and entering your name, you are providing your electronic signature and you are agreeing to participate in this research.
2. The person types their name on the on-line form.

C. For email consent procedures, a signature can be:

1. The informed consent is included as an attachment to the email. The participant prints the form, signs the form, scans it, and emails the signed document back to the researcher.
2. The consent information is included in the body of the email or as an attachment to the email. The person responds to the email indicating they agree to participate.


If these methods are not used, a waiver of consent signature must be requested. The waiver is not required if the proposed research can be classified as Exempt.

Depending on the nature of the research, the risks involved, and the characteristics of the potential participants, the IRB may require one signature process over another.

2.7 Observation of the Consent Process

A. The IRB can observe the consent process where it determines that such observation will meaningfully contribute to the reduction of risk to the research participant. For example, situations with vulnerable populations where observation of the consent might minimize coercion or undue influence, or situations involving non-compliance with the consent process.

B. If the IRB decides that the consent should be observed, the investigator would be notified before such observation. The PI will be consulted collegially so that appropriate arrangements can be made for the observation to take place in a manner that is as unobtrusive as possible. HRPP staff would conduct the observation.

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|  <p>HRPP POLICIES AND PROCEDURES</p> <p>Research Compliance Services Human Research Protections Institutional Review Board</p> | <p>Policy # 9.002</p> <p>Title: <u>Development of the Informed Consent Document</u></p> <p>Section: <i>Informed Consent</i></p> <p>Date: August 25, 2015</p> |
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1.0 Purpose

The purpose of this policy is to describe development of the informed consent document.

2.0 Policy

It is the policy of the IRB that the informed consent document will be developed in accordance with regulations at Health and Human Services 45 CFR §46.

2.1 Stationery

When appropriate consent documents should be printed on UNL letterhead.

2.2 Specific Layout Instructions

All consent/assent documents should be submitted suitable for reproduction and easy readability by potential participants.

Lines requiring the participant, witness, or PI signatures should not be placed on a separate page without the presence of any of the preceding language required in that section of the informed consent.

Each page of the consent/assent document **must** include:

- A. The IRB protocol number in the upper right corner as labeled by the IRB (“IRB # _____”), date of approval of current consent form, and “valid until” date. Commonly, there are many versions or amendments to the original consent throughout the course of a study. This requirement will help the investigator and IRB track the most current version of the consent/assent documents.
- B. Page numbers (“Page _ of _”) at the bottom of each page OR
- C. “Participant’s Initials _____” at the bottom of each page.

2.3 Identification of Type of Consent and Assent

To easily identify the type of consent/assent document, one of the following labels should be placed at the top of the first page:

- A. **Adult Consent:** Utilized when enrolling competent adults (in Nebraska defined as individuals 19 years of age or older and individuals under 19 years of age who are legally emancipated or who are otherwise able to consent to the procedures involved in the research).

- B. *Parent or Legal Guardian Consent:*** Utilized when enrolling children (in Nebraska defined as individuals under 19 years of age except those who are legally emancipated or who are otherwise able to consent to the procedures involved in the research) in a research study.
 1. *Youth Assent:* To be used for children aged 13-18 years
 2. *Child Assent:* To be used for children aged 7-12 years
- C. *Proxy, Legally Authorized Representative, or Durable Power of Attorney Consent:*** Utilized when enrolling decisionally impaired adults.
 1. *Adult Assent:* Used when enrolling decisionally impaired adults.
- D. *Screening Consent:*** Used to obtain participant consent to allow study-related screening tests for potential enrollment in a study. Full study consent will follow.
- E. *Addendum Consent:*** Commonly used to obtain additional consent from participants for auxiliary studies (e.g., tissue banking). Also may be used to inform currently enrolled participants of new information pertaining to the research.
- F.** Alternative Forms of Communication, such as translation services, must be provided. However, UNL does not permit the use of a short form procedure when documented consent is required.

2.4 Identification of Study Personnel

The PIs and Co-Investigators, if any, listed in the IRB Application must be listed on the last page of the informed consent/assent document in accordance with Health and Human Services regulations at 45 CFR §46.111(a) (4) and §46.116(a) (7).

The following subheadings must be used (as appropriate):

- A.** Principal Investigator
- B.** Co-Investigators

A contact phone number for the PI and the Co- Investigator must be provided.

2.5 General Style of Written Consent Documents

The informed consent form should be written in the second person format throughout (e.g., you are invited to participate; you will be assigned, etc.). When combined with conditional language and the invitation to participate, utilization of the second person communicates that the investigator believes there is a choice to be made by the prospective participant. Utilization of the first person format may be interpreted as presumption of participant consent before consent has been legally obtained.

2.6 Parental, Legal Guardian, Proxy, and Durable Power of Attorney Consent Documents

Proxy consent documents should reflect that it is the minor, or other vulnerable participant, who is the participant in the study. The individual giving consent

(parent or legally authorized representative) is providing permission to allow the participant to participate in the study.

2.7 Adult, Youth, and Child Assent Documents

Assent documents should reflect the age, maturity and cognitive ability of the decisionally impaired adults, youth, and children that will be the participants of the trial.

For further information about:

- A. *Parental/legal guardian consent and youth/child assent, see HRPP policy [# 9.002](#).*
- B. *Proxy/DP consent and adult assent, see HRPP policy [# 9.002](#).*

2.8 Readability

The consent form must be written in simple enough language so that it is readily understood by the least educated of the participants to be involved. Generally, the level of language in the adult consent document should be around an eighth grade standard. Youth and child assent documents should be written in an age-appropriate style.

Medical and scientific terms should be avoided where possible. If medical jargon is used the lay terms should be used first and then the medical term included in parentheses.

Common units of measure should be used appropriate to the procedure or content.

It is recommended that the language consist of short, concise sentences arranged in relatively short simple paragraphs. Headers should be used to separate sections of the document for easier reading, particularly when describing what will happen during the study. Generally, abbreviations should not be used in the consent document that is, all words should be spelled out. The IRB may approve limited use of abbreviations where appropriate, as long as the acronym is spelled out the first time it is used.

2.9 Length

There are no restrictions on the length of the informed consent/assent documents. The informed consent form should be lengthy enough to explain the elements of consent adequately, but not so lengthy or detailed as to lose the attention of the participant or to cause confusion.


2.10 Format

- A. ***Exempt Research:*** If the research is *exempt*, but it is determined that a written informed consent is appropriate (e.g., an educational study requiring parental consent), a narrative consent form format may be used. In the narrative consent form, all necessary elements of consent should be present on the consent form, but the elements need not be identified by subheadings.

B. Research Involving Minimal Risk or Greater: If the research involves procedures, which are *minimal risk or greater*, the legalistic consent document format must be used (see HRPP policy [# 3.004](#) for a definition of minimal risk). The IRB has developed an informed consent document template that is designed to provide investigators guidance in the development of this form. The template is available on the HRPP website (<http://research.unl.edu/researchresponsibility/human-research-protections-programirb-forms-policy-and-guidance-page/>).

2.11 Exculpatory Language

The consent document must not contain any exculpatory language through which the participant or the participant's representative is made to waive, or appear to waive, any of the participant's legal rights. Additionally the consent document must not release, or appear to release, the research investigator, the sponsor, the Institution, or its agents from liability for negligence.

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|  <p>HRPP POLICIES AND PROCEDURES</p> <p>Research Compliance Services Human Research Protections Institutional Review Board</p> | <p>Policy # 9.003</p> <p>Title: <u>Telephone Consent</u></p> <p>Section: <i>Informed Consent</i></p> <p>Date: April 1, 2008</p> |
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1.0 Purpose

The purpose of this policy is to describe the guidelines governing telephone consent.

2.0 Policy

It is the policy of the IRB that telephone consent will be gained in accordance with the regulations at Health and Human Services 45 CFR §46.

2.1 Introduction

Whenever possible, consent should be obtained in person by an authorized investigator. However, the IRB recognizes that an alternative informed consent process may, at times, be necessary for the safety of the participant. Therefore, under extenuating circumstances, when it is in the best interests of the participant, the IRB may approve an alternative informed consent process (es) via telephone. IRB approval of a telephone consent process for nonexempt research requires a waiver of the requirement for written documentation of consent. The consent discussion needs to include all required elements of consent disclosure unless the IRB approves a waiver or alteration of the consent process.

2.2 IRB Requirements for Use of a Telephone Consent Process

The IRB will review the proposed method of consent based upon the nature of the study, the risk level, participant population needs and/or significance of the treatment related change. The proposed method of consent must be fully explained and justified in the IRB application (Section 7) or in the Description of Proposed Changes section of the Request for Change in Protocol Form.

The following describes IRB requirements for the use of telephone consent for re-consent for significant changes or disclosure of significant additional risks and re-consent for minor changes or disclosure of additional minor risks.

2.3 Re-consent by Telephone for Significant Changes or Disclosure of Significant Additional Risks

With appropriate scientific rationale and justification, the IRB may approve a telephone consent procedure to allow participant to be notified of significant new risks.


- A.** The consent document (revised consent form or addendum) must be provided to the participant for review prior to the telephone consent process. It is preferred that this be done by mail; however, fax is acceptable when necessary. No research interventions can be conducted until a signed copy (fax, digital copy, or original) of the consent form has been received by the investigator. An extra copy must be provided for the participant to keep for their records.

- B. A telephone call is scheduled. The minimum required participants in the consent process are the participant and investigator. Additional people may be involved in the call as appropriate.
- C. Each element of the consent document, which has been changed, must be explained to the participant, and the participant's comprehension should be assessed as necessary. For example, an investigator may ask the participant to provide a summary of the new information. The participant must be given the opportunity to ask questions. It may be necessary to extend the process over several days and include other individuals such as the participant's family members. The participant must be instructed in the signing of the consent form and must return the original signed document to the investigator by mail. *The participant must be re-consented in the presence of the investigator when he/she returns to research site for follow-up.*
- D. The alternative process of consent should be documented in the research record by indicating the reason for the alternative method used and date.

2.4 Telephone Re-Consent for Minor Changes or Disclosure of Additional Minor Risks

With appropriate justification, the IRB, under certain circumstances, may approve a telephone consent procedure for participants to receive notification of a minor new risk.

- A. The consent document (revised consent form or addendum) must be provided to the participant for review **prior** to the telephone consent process. It is preferred that this be done by mail; however, fax is acceptable when necessary. No research interventions can be conducted until a signed copy (fax, digital copy, or original) of the consent form has been received by the investigator. An extra copy must be provided for the participant to keep for his/her records.
- B. A telephone call is scheduled. Minimum required participants in the consent process are the participant and investigator. Additional people may be involved in the call as appropriate.
- C. Each element of the consent document, which has been changed, must be explained to the participant, and the participant's comprehension should be assessed as necessary. For example, an investigator may ask the participant to provide a summary of the new information. The participant must be given the opportunity to ask questions. The participant must be instructed in the signing of the consent form and must return the original signed document to the investigator by mail. The alternative process of consent must be documented in the research record by indicating the reason for the alternative method used, date, time, and personnel involved in obtaining and documenting consent.

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|  <p>HRPP POLICIES AND PROCEDURES</p> <p>Research Compliance Services Human Research Protections Institutional Review Board</p> | <p>Policy # 9.004</p> <p>Title: <u>Re-Consent/Assent Research Participants</u></p> <p>Section: <i>Vulnerable Populations and Special Classes of Participants</i></p> <p>Date: April 1, 2008</p> |
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1.0 Purpose

The purpose of this policy is to describe the process of re-consent/assent of research participants.

2.0 Policy


It is the policy of the IRB that the process of re-consent/assent of research participants will be conducted in accordance with the regulations at Health and Human Services 45 CFR §46.

The initial informed consent/assent document(s) signed by the participant at enrollment *remains in effect for the duration of the participant's participation* in the study **or** until the IRB approves a change in the consent/assent document(s), which requires re-consent/assent of participants.

Informed consent/assent, however, is an ongoing *process*, not simply the document signed by the participant during enrollment in the research. In order to validate the voluntary nature of participation in research and exhibit respect for the individual, participants must be provided new information, which may affect their willingness to continue to participate in the research. Health and Human Services regulations at 45 CFR §46.116(b) (5), therefore, require investigators to inform participants of any important new information that is germane to the participant's willingness to continue participating in the study.

Each year, during the continuing review process, original consent/assent document(s) are submitted for review. Upon IRB re-approval of the study, the consent/assent documents are stamped with the "date approved" and "valid until" dates. The IRB **does not require re-consent** of previously enrolled participants at this time, **unless** the IRB approves a request for change during the continuing review process or identifies new information, which requires re-consent of the participants

Commonly, minor information (e.g., changes in personnel or administrative changes in the consent document) is provided to participants through verbal exchanges between the investigator and participant, without undergoing a formal re-consent procedure. Minor information is unlikely to affect a participant's willingness to continue participation in a study. However, significant new information, which requires re-consent/assent of participants must occur through use of IRB-approved, revised consent/assent document(s) or an addendum to the consent/assent form. For example, significant new information may include 1) changes in the duration of the study, or 2) major changes in the methods of the study.

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|  <p>HRPP POLICIES AND PROCEDURES</p> <p>Research Compliance Services Human Research Protections Institutional Review Board</p> | <p>Policy # 9.005</p> <p>Title: <u>Absence of Valid Consent: Re-Consent and Use of Data</u></p> <p>Section: <i>Informed Consent</i></p> <p>Date: April 1, 2008</p> |
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1.0 Purpose

The purpose of this policy is to describe the guidelines governing the re-consent and the use of data in the absence of valid consent.

2.0 Policy


It is the policy of the IRB that, in the absence of valid consent, re-consent and the use of data will adhere to the regulations at Health and Human Services 45 CFR §46.

The investigator has a legal and an ethical obligation to ensure that the prospective participant has sufficient knowledge and comprehension of the elements of informed consent prior to enrollment and during participation in research. This is accomplished through the initial and on-going process of informed consent.

If a participant enrolls and begins participation in a study without the presence of a valid informed consent document (e.g., the participant signed a wrong or outdated consent form), participant comprehension of the elements of informed consent and true informed decision making is called into question. The ethical principal of respect for persons demands that participants enter into research voluntarily and with adequate information.

If a participant enrolls in a study without valid informed consent, the principal investigator must immediately notify the IRB Chair and the participant and explain the situation. Additionally it may be necessary to refer to Policy 13.001 and/or 14.001. The PI should request that the participant re-consent to participate. If the participant agrees and the complete informed consent process is repeated, including signatures on the consent document and documentation of consent in the research record, data obtained during the period of invalid consent may be used with approval of the IRB.

If the participant refuses to consent, participation in the study must be halted immediately and the collected data cannot be used.

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|  <p>HRPP POLICIES AND PROCEDURES</p> <p>Research Compliance Services Human Research Protections Institutional Review Board</p> | <p>Policy # 9.006</p> <p>Title: <u>Waiver or Alteration of Consent</u></p> <p>Section: <i>Informed Consent</i></p> <p>Date: November 1, 2010</p> |
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1.0 Purpose

The purpose of this policy is to describe the situations in which the IRB may waive or alter the informed consent process and/or waive consent documentation.

2.0 Policy

It is the policy of the IRB that all requests for waiver or alteration of the informed consent process or consent documentation must undergo appropriate IRB review, and when waivers or alterations are granted, they are given based on Health and Human Services regulatory criteria at 45 CFR §46.111(a) (4) and (5), 45 CFR §46.116(a) to (e), 45 CFR §46.117(a) to (c).

3.0 Waiver of Documentation of Informed Consent

The Board, for some or all participants, may waive the requirement that the participant or the participant’s representative sign a written consent document per 45 CFR §46.117(c) if it finds:

- 3.1** That only the record linking the participant and the research would be a potential harm to the participant resulting from a breach of confidentiality. Each participant will be asked whether the participant wants documentation linking the participant with the research, and the participant’s wishes will govern; or
- 3.2** That the research presents no more than the minimal risk of harm to the participants, and involves no procedure for which written consent is normally required outside of the research context.

In cases in which the documentation requirement is waived, the IRB may require the investigator to provide participants a written statement regarding the research.

When the IRB considers waiving the requirement to obtain documentation of the consent process, the IRB should review a description of the information that will be provided to participants. When granting waivers of the requirement to obtain documentation of the consent process, the IRB should consider whether the investigator should provide participants with a written statement regarding the research.

4.0 Waiver or Alteration of Consent

The Board may waive the requirement for informed consent per 45 CFR §46.116(d) (or allow an alteration of some or all of the elements of informed consent) only if the Board finds that each of the following four elements are met. This is different than waiving the requirement of documentation of informed consent.

- 4.1** The research involves no more than minimal risk to participants; and

- 4.2** The waiver or alteration will not adversely affect the rights and welfare of the participants; and
- 4.3** The research could not practicably be carried out without waiver or alteration; and
- 4.4** Whenever appropriate the participants will be provided with additional pertinent information after participation (45 CFR 46.116(d)).

5.0 For research sponsored by the Department of Defense, the following guidelines will be followed:

5.1 The IRB may waive the consent process if the research participant(s) do not meet the definition of “experimental participant”.


5.2 If the research participant meets the definition of “experimental participant,” the waiver of consent shall not be granted by the IRB unless approval is obtained from the Secretary of Defense.

5.3 “Experimental participant” as defined in Department of Defense Directive 3216.02 shall include:

A. An individual participating in an activity for research purposes where there is an intervention or interaction for the primary purpose of obtaining data regarding the effect of the intervention or interaction (32 CFR 219.102(f), reference (c)). Examples of interventions or interactions include, but are not limited to a physical procedure, a drug, a manipulation of the subject or subject's environment, or the withholding of an intervention that would have been undertaken if not for the research purpose. This does not include:

- 1.** Activities carried out for purposes of diagnosis, treatment, or prevention of injury and disease in members of the Armed Forces and other mission essential personnel under Force Health Protection programs of the Department of Defense.
- 2.** Authorized health and medical activities as part of the reasonable practice of medicine or other health professions.
- 3.** Monitoring for compliance of individuals and organizations with requirements applicable to military, civilian, or contractor personnel or to organizational units. This includes such activities as drug testing, occupational health and safety monitoring, and security clearance reviews.
- 4.** Activities exempt under 32 CFR 219 (reference (c)).

The investigator must complete the section requesting a waiver in the informed consent process portion of the new protocol submission form.

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|  <p>HRPP POLICIES AND PROCEDURES</p> <p>Research Compliance Services Human Research Protections Institutional Review Board</p> | <p>Policy # 10.001</p> <p>Title: <u>Definition and Description of Protected Health Information Identifiers</u></p> <p>Section: <i>Protected Health Information & Research</i></p> <p>Date: April 1, 2008</p> |
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1.0 Purpose


The purpose of this policy is to define and describe Protected Health Information identifiers.

2.0 Policy

It is the policy of the IRB that the use of Protected Health Information will be in full accordance with regulations at Health and Human Services 45 CFR §46 and other applicable federal, state and local laws.

- 2.1** The Health Insurance Portability and Accountability Act (HIPAA) Privacy Rule was issued August 13, 2002, with a compliance date of April 14, 2003. The purpose of this rule is to provide additional protections of the privacy rights of participants involved in research. The HIPAA Privacy rule contains requirements designed to ensure that the Protected Health Information of research participants is appropriately used and/or disclosed during the conduct of research. UNL Student Health Services is a “covered entity” and, therefore, complies with HIPAA.
- 2.2** Protected Health Information is defined as any *individually identifiable health information*. Protected Health Information obtained by any means that is used or disclosed during the course of any research project at this Institution is subject to HIPAA. Only the minimum Protected Health Information necessary to achieve the research objectives can be used.
- 2.3** Individually identifiable Protected Health Information contains one or more of 18 *identifiers*. If **any** of the 18 identifiers are associated with the health information, then the information is considered “protected”. De-identification of Protected Health Information requires either:
- A.** Removal of all 18 identifiers, *or*
 - B.** Documentation by an expert statistician how he/she determined that the risk of participant identification using a subset of identifiers present is very small.
- 2.4 The 18 identifiers are:**
- A.** Names.
 - B.** Postal address information: street address, city, county, precinct, ZIP code (except specified combinations).
 - C.** All elements of dates (except year) related to an individual (e.g. birth, admission, discharge). For participants over 89 years of age, all elements of dates (including year) must be removed.
 - D.** Telephone numbers.
 - E.** Fax numbers.
 - F.** Electronic mail addresses.

- G.** Social Security numbers.
- H.** Medical Record numbers.
- I.** Health plan beneficiary numbers.
- J.** Account numbers.
- K.** Certificate/license numbers.
- L.** Vehicle identifiers and serial numbers, including license plate numbers.
- M.** Device identifiers and serial numbers.
- N.** Web Universal Resource Locators.
- O.** Internet protocols address numbers.
- P.** Biometric identifiers, including finger and voice prints.
- Q.** Full face photographic images [and any comparable images].
- R.** Any other unique identifying number, characteristic, or code.

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|  <p>HRPP POLICIES AND PROCEDURES</p> <p>Research Compliance Services Human Research Protections Institutional Review Board</p> | <p>Policy # 10.002</p> <p>Title: <u>Limited Data Set</u></p> <p>Section: <i>Protected Health Information & Research</i></p> <p>Date: April 1, 2008</p> |
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1.0 Purpose

The purpose of this policy is to describe the use of Limited Data Sets.

2.0 Policy


It is the policy of the IRB that the use of Limited Data Set will be in full accordance with regulations at Health and Human Services 45 CFR §46.

- 2.1** A researcher with IRB approval and a Data Use Agreement between the researcher and the covered entity can use and disclose Protected Health Information that contains a Limited Data Set without a HIPAA authorization or a waiver of consent granted by the IRB.

The limited data set must have all the identifiers removed, except the following:

- A.** A unique identifying number, characteristic or code (e.g., a registry or study number).
- B.** Elements of dates (e.g., birth).
- C.** Town, city, state, and ZIP code.

- 2.2** One of the advantages associated with the use of a Limited Data Set is that it is not subject to the HIPAA requirements of accounting for disclosure of Protected Health Information. Additionally, the limited data set also allows the maintenance of a linked code, which permits re-identification of an individual in the future should the need arise. However, the investigator who is using the Limited Data Set cannot maintain the linked code. The Director will maintain such codes.

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|  <p>HRPP POLICIES AND PROCEDURES</p> <p>Research Compliance Services Human Research Protections Institutional Review Board</p> | <p>Policy # 10.003</p> <p>Title: <u>Research Utilizing Medical Records</u> <i>Protected Health Information & Research</i></p> <p>Section: <i>Protected Health Information & Research</i></p> <p>Date: April 1, 2008</p> |
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1.0 Purpose

The purpose of this policy is to describe research utilizing medical records.

2.0 Policy

It is the policy of the IRB to use and disclose Protected Health Information in accordance with the HIPAA requirements and federal regulations pertaining to research found at Health and Human Services 45 CFR §46.

2.1 Definitions

- A. **Protected Health Information** is individually identifiable health information. Health information means any information, whether oral or recorded in any medium that:
 - 1. Relates to the past, present, or future physical or mental health or condition of an individual; the provision of health care to an individual; or the past, present, or future payment for the provision of health care to an individual.
- B. **De-Identified** Protected Health Information is the removal of all 18 identifiers from the health information (see HRPP policy [# 10.001](#) for a definition of the identifiers) or obtainment of a bio-statistical consult indicating there is only a “small risk” of re-identification of a participant.
- C. **Designated Record Set** means the medical records and billing records about individuals and records used to make decisions about individuals.
- D. **Authorized Investigators:**
 - 1. Any faculty member, student or staff member who is working with a person having ethical/legal access to Protected Health Information materials in a non-research context and who will assume responsibility for maintaining confidentiality safeguards as certified in writing.
- E. **Existing Medical Records:** “Existing” medical records is defined as medical records existing at the time of initial submission of the IRB application (e.g., date of the PI signature on the IRB application) and **not** when the IRB grants final approval and release of the study.
- F. **Non-Authorized Investigators:** Person(s) that do not fall within the definition of an authorized investigator shall be deemed a non-authorized investigator.

2.2 Access to Medical Records

Only authorized investigators listed by name in the IRB application shall have access to confidential records to be used for research purposes where participant identifiers are present.

Non-authorized investigators shall have access to confidential records to be used for research purposes with IRB and covered entity approval **only** when the following conditions are met:

- A. Approval is obtained to use the records from the covered entity (e.g., medical records department) **OR**
- B. The investigator has obtained informed consent/HIPAA authorization from the participant, **OR**
- C. **All** Protected Health Information has been de-identified in accordance with the requirements of HIPAA.

In all cases, the non-authorized investigator shall have received CITI training especially as it regards confidentiality and privacy.

2.3 **Exempt Research**

Research involving medical records is *exempt* provided the records utilized in the research are existing and the data are recorded in such a manner that participants cannot be identified (e.g., either all 18 HIPAA specified identifiers are removed or a bio statistical consult indicated there is only a “small risk” of re-identification of a participant).


2.4 **Non-exempt Research**

Research involving the study of medical records is not exempt if the investigator records the data in such a manner that participants can be identified either directly or through identifiers linked to the participant or if the study involves prospective collection of records.

If participant identifiers must be temporarily maintained in order to permit the investigator to identify additional records for inclusion in the study, informed consent/authorization is required unless the IRB may grant a waiver of informed consent in accordance with the following specific requirements of HIPAA and 45 CFR §46.116(d):

- A. Only the minimum amount of participant identifier data is recorded.
- B. The use or disclosure of Protected Health Information or data, which is not Protected Health Information involves no more than minimal risk.
- C. The alteration or waiver of informed consent will not adversely affect the rights and welfare of the participants.
- D. The research cannot practicably be carried out without the alteration or waiver.
- E. There must be an adequate plan to protect participant identifiers from improper use and disclosure.
- F. There must be an adequate plan to destroy the identifiers associated with Protected Health Information at the earliest opportunity, unless there is a health or research justification for retaining the identifiers or retention is required by law.

- G.** Whenever appropriate, the participants will be provided with additional pertinent information after participation.
- H.** If identifiers are recorded for the purpose of selecting a prospective participant population and the investigator intends to subsequently solicit informed consent to participate in a prospective study, specific guidelines must be followed regarding initial contact with potential participants. Contact with potential participants should originate with an individual who has the appropriate professional relationship with the potential participant (e.g., primary care physician, counselor, teacher, etc.). If an investigator does not have such a relationship, they should obtain assistance from someone who does. Once the appropriate professional has originated the contact, negotiation for informed consent can begin as with any other research protocol.

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|  <p>HRPP POLICIES AND PROCEDURES</p> <p>Research Compliance Services Human Research Protections Institutional Review Board</p> | <p>Policy # 10.004</p> <p>Title: <u>Review of Protected Health Information in Preparation for Research</u></p> <p>Section: <i>Protected Health Information & Research</i></p> <p>Date: April 1, 2008</p> |
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1.0 Purpose

The purpose of this policy is to describe the process of review of Protected Health Information in preparation for research.

2.0 Policy

It is the policy of the IRB that the review of Protected Health Information in preparation for research will be conducted in full accordance with regulations at Health and Human Services 45 CFR §46.


- 2.1** The HIPAA permits an investigator to review medical records containing Protected Health Information in preparation for a research project without obtaining an authorization or a waiver of consent from the IRB. To meet this requirement, the investigator, or other study personnel, must have an ethical-professional access to the Protected Health Information in the medical setting.

The investigator must file a request for access with the pertinent institution (e.g., UNL Student Health Center, local hospital or clinic). If the PHI is not contained within the medical record, the request should be filed with the IRB.

The investigator must certify:

- A.** The review of Protected Health Information will be conducted solely to determine the feasibility of a research project or for similar purposes in preparation for research.
- B.** The Protected Health Information may not be recorded, copied, or removed from the records repository in the course of review.
- C.** The Protected Health Information that is accessed is solely for research purposes.

If an investigator intends to record any Protected Health Information for the express purpose of contacting prospective research participants, the appropriate IRB application and associated informed consent documents must be submitted and approved by the IRB prior to the review of the medical records.

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|  <p>HRPP POLICIES AND PROCEDURES</p> <p>Research Compliance Services Human Research Protections Institutional Review Board</p> | <p>Policy # 11.001</p> <p>Title: <u>Continuing Review</u></p> <p>Section: <i>Continuing Review</i></p> <p>Date: March 30, 2015</p> |
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1.0 Purpose

The purpose of this policy is to describe the IRB's process for conducting continuing review.

2.0 Policy

It is the policy of the IRB that continuing review will be conducted in accordance with Health and Human Services regulations at 45 CFR §46.109(e) and OHRP guidance on continuing review (July 11, 2002).

Expedited continuing and *full board* protocols are approved for one year at a time and valid for up to five years but must be renewed annually by completion of a Continuing Review form.

In order for a study to continue without interruption, the IRB must re-review and approve the protocol **prior** to the IRB approval expiration date. Continuing Review has to occur as long as the research remains active for long-term follow-up of subjects, even when the research is permanently closed to the enrollment of new participants and all participants have completed all research-related interventions. Continuing review of research has to occur when the remaining activities are limited to collection of private identifiable information. If an investigator does not provide continuing review information to the IRB, or the IRB has not approved the protocol by the expiration date, the investigator will be instructed to stop all research activities, including recruitment, enrollment, interventions, and interactions, and collection of private identifiable data, and to stop all interventions and interactions on current participants, unless the IRB finds an over-riding safety concern or ethical issue involved such that it is in the best interests of individual participants to continue participating.

New enrollment of participants is not allowed after the expiration of IRB approval.

2.1 Risk Level

All human participant studies are subject to continuing review based on the level of risk as assessed by the IRB. Research approved previously by *expedited review* is considered eligible for *expedited review* at the time of its regular continuing review, if, during the course of the study, the risks of the study have not increased. Projects that were initially reviewed by the *full board* continue to receive *full board* review unless the IRB determined at the initial review during the *full board* meeting that the study meets the specific criteria for *expedited review*.

2.2 Continuing Review Submission Requirements

- A. It is the responsibility of the PI to submit the Continuing Review form, which must include informed consent/assent forms (updated as necessary) in sufficient time to allow the IRB to complete a substantive and meaningful review of the research, as well as provide the PI with a timely, written response prior to the expiration date indicated on the current IRB approval letter.
- B. The PI will receive three (3) IRB notifications (approximately 60 days prior to expiration of IRB approval, 30 days prior to expiration of IRB approval, and 15 days prior to expiration of IRB approval) if the Continuing Review form has not been submitted. The PI will also be notified on the date of project expiration.
- C. If the IRB, or *expedited reviewer(s)*, determines that a project requires review more often than annually, the investigator will be so notified at the time of initial review and/or at the time of continuing review. Factors which determine the frequency of continuing review are described in HRPP policy [# 3.010](#).

2.3 Pre-Review

The HRPP staff is responsible for pre-review of all protocols undergoing continuing review. At any time, HRPP staff may seek guidance and/or assistance from the RCS Director or IRB Chairperson/members as needed, during the pre-review process.

- A. The project is accessed via NUgrant. The IRB number, title(s) and the study personnel listing are checked for accuracy and training completion. The current continuing review form will be compared with the previous year's application, as well as other documents found in the protocol record as necessary, with particular attention paid to the types of consent documents. The reviewer(s) are provided with the complete protocol. When conducting review using the expedited procedure, the reviewer receives and reviews all submitted information including the complete protocol history. It is expected that primary and secondary reviewers perform an in-depth review of all pertinent documentation.
- B. The copy of the most recent consent document will be reviewed to determine if it was the appropriate version and used within the correct approval dates indicated in the IRB approval stamp.
- C. The new consent form(s) to be used during the next IRB approval period will be compared with the version last approved by the IRB to determine if the correct version of the consent form(s) has (have) been provided. In addition, the consent document will be closely checked for typographical or formatting errors and of any changes have been made to the consent document (without accompanying Request for Change in Protocol form)
- D. Discrepancies or omissions in the Continuing Review form will result in an email to the PI and SI requesting clarification and/or correction to appropriate forms. If the number of problems in the application are of such magnitude that IRB review is not possible, the full application and supporting documents will be sent back to the PI for revision and resubmission of the revised application and/or consent document(s).

- E. In situations of possible non-compliance, the RCS Director and IRB Chairperson as applicable will be notified. A complete review of the IRB project record will be performed by the HRPP staff to determine what further action should be taken in accordance with HRPP policy [# 14.001](#).
- F. For *full board* continuing reviews, copies of all correspondence (emails or letters) resulting from the pre-review process will be accessible via NUgrant to all IRB members. In addition, the HRPP staff will contact the assigned reviewers to inform them of unresolved problems or concerns.

2.4 Expedited continuing IRB Continuing Review Procedure.

- A. Continuing review forms which qualify for *expedited review* will be assigned to the IRB Chair or Vice Chair.
- B. In order to facilitate continuing review, an *Expedited* Continuing Review Reviewer Form Checklist is provided to *expedited reviewers*.
- C. The *expedited reviewer* will determine whether or not increased monitoring and/or more frequent continuing review is required in accordance with HRPP Policy [#3.010](#).
- D. IRB approval periods for projects reviewed by the *expedited* method begin as of the date of completion of the review. Approval periods cannot exceed one year. IRB approval therefore expires one year later, or sooner if the *expedited reviewer* sets a more frequent continuing review date. For example, if *expedited review* was completed on February 17, 2005, and the reviewer set an approval period of one year, IRB approval is valid until February 17, 2006. This means that IRB approval is in force until 11:59 pm February 16, 2006. As of midnight all research activity must cease unless IRB re-approval and full release has been granted.

All future and subsequent review periods are determined by the date of the most recent IRB Member review completion of the continuing review form. The approval period will not exceed 1 year or sooner if the expedited reviewer sets a more frequent review period.

2.5 Expedited review Actions.

- A. ***Re-approval and full release***
No modifications or clarifications are required. All of the criteria for IRB approval specified in Health and Human Services regulations at 45 CFR §46.111 are satisfied. The investigator will be notified of the re-approval in writing and is authorized to continue the study.
- B. ***Re-approval and full release (with minor clarifications)***
Minor clarification(s) or information concerning the protocol is necessary for completion of the record. This action is only taken when the clarification(s) is (are) minor and does not impact protection of human participants and/or the approvability of the consent document(s). The investigator will be notified of the re-approval in writing and asked to make the necessary modifications and return the materials before final approval for continuing review can be granted.

Failure to respond to the IRB continuing review clarification letter may result in the full IRB revoking approval of the study. In such a case, all research related activities must immediately cease, unless an extension is granted by

the IRB Chair in consideration of a written request from the PI. The IRB will be notified of all extensions granted by the IRB Chair.

HRPP staff is empowered by the IRB to review the Investigator's response in consultation with the IRB Chair as necessary and grant re-approval and full release.

C. Conditional approval, contingent upon Expedited reviewer acceptance of specific modifications/clarifications

The investigator will be notified in writing as to the nature of the required modifications/clarifications. During the remaining IRB approval period, the investigator is authorized to continue the research. When the investigator complies, in writing, with all requirements as determined by the *Expedited reviewer*, re-approval and full release will be granted.

If the PI fails to respond to the IRB's continuing review request letter within the remaining IRB approval period, the protocol has, or will be, classified as administratively closed. If IRB approval expires, all research-related activities must immediately cease, unless an exception is granted by the IRB Chair in consideration of a written request. The IRB will be notified of all exceptions granted by the IRB Chair.

D. Referred for full IRB review

IRB members assigned to perform an *expedited review* can refer the protocol for review by the full IRB.

2.6 Full IRB Review Procedure

- A.** If the research initially required full IRB approval, the Application for Continuing Review must also be approved by the full IRB. Unless at the initial approval it was determined that the project involves no greater than minimal risk and no additional risks have been identified then the application for continuing review can be reviewed as *expedited continuing*.
- B.** Applications for continuing review are scheduled for full IRB consideration at the monthly IRB meeting, if quorum can be obtained. Each attending member will receive, one week in advance, all continuing review applications and associated consent/assent documents to be considered at the meeting and have access to the complete protocol .IRB members are asked to review, as necessary, the complete IRB protocol record.
- C.** A primary reviewer will be assigned to perform a thorough review of the application. He/she will interact with the IRB staff involved in the pre-review as necessary, contact the investigator in order to resolve any concerns prior to the meeting, and review the protocol record at the meeting when necessary.
- D.** In order to facilitate continuing review, a *Full Board Continuing Review Reviewer Checklist* is provided to reviewers.
- E.** The primary reviewer will present to the full IRB the results of his/her review and any remaining concerns will be discussed by the members who are also expected to have reviewed the application and the consent/assent documents. Each protocol will be voted on separately in accordance with IRB policy (see HRPP policy [# 2.011](#)).

- F. The IRB will determine whether or not increased monitoring and/or more frequent continuing review is required in accordance with HRPP policy [#3.010](#).
- G. IRB approval periods for protocols reviewed by the *full board* begin as of the date of initial or continuing review. Approval periods cannot exceed one year, which is defined as one year from the date of IRB review. IRB approval, therefore, expires one year later, or sooner if the IRB sets a more frequent continuing review date. For example, if the IRB reviewed a protocol on February 17, 2005, and set an approval period of one year, IRB approval would be valid until February 17, 2006. This means that IRB approval is in force until 11:59 pm February 16, 2006. As of midnight all research activity must cease unless IRB re-approval and full release has been granted.

All future and subsequent review periods are determined by the date of the most recent IRB review completion of the continuing review form. The approval period will not exceed 1 year or sooner if the Board sets a more frequent review period.

2.7 Full IRB Actions

A. Re-approval and full release

No modifications or clarifications are required. All of the criteria for IRB approval specified in Health and Human Services regulations at 45 CFR §46.111 are satisfied. The investigator will be notified of the re-approval in writing and is authorized to continue the study.

B. Re-approval and full release (with minor clarifications)

Minor clarification(s) or information concerning the protocol is necessary for completion of the record. This action is only taken when the clarification(s) is (are) minor and does not impact protection of human participants and/or the approvability of the consent document(s). The investigator will be notified of the re-approval in writing and asked to make the necessary modifications and return the materials before final approval of continuing review can be granted.

Failure to respond to the IRB continuing review clarification letter may result in the full IRB revoking approval of the study. In such a case, all research related activities must immediately cease, unless an extension is granted by the IRB Chair in consideration of a written request from the PI. The IRB will be notified of all extensions granted by the IRB Chair. HRPP staff is empowered by the IRB to review the Investigator's response in consultation with the IRB Chair as necessary and grant re-approval and full release.

C. Conditional approval, contingent upon IRB Chair/Vice Chair acceptance of specific modifications/clarifications

This category is restricted to modifications/clarifications, which are not considered to be substantive in nature.

The investigator will be notified in writing as to the nature of the required modifications/clarifications. During the remaining IRB approval period, the investigator is authorized to continue the research. When the investigator

complies, in writing, with all requirements as determined by the IRB Chair/Vice Chair, re-approval and full release will be granted.

If the PI fails to respond to the IRB's continuing review letter within the remaining IRB approval period, the protocol has, or will be, classified as "administratively closed". If IRB approval expires, all research-related activities must immediately cease, unless an exception is granted by the IRB Chair/Vice Chair in consideration of a written request. The IRB will be notified of all exceptions granted by the IRB Chair/Vice Chair.

D. *Conditional approval, contingent upon full IRB re-review of specific modifications/clarifications.*

This category is restricted to modifications/clarifications, which are considered substantive in nature, but are not of sufficient magnitude to require a hold be placed on participant accrual. The PI will be notified in writing as to the nature of the required modifications/clarifications. During the remaining IRB approval period, the investigator is authorized to continue the research. When the investigator complies, in writing, with all requirements as determined by the full IRB at a convened meeting, re-approval and full release will be granted.

If the PI fails to respond to the IRB's continuing review letter within the remaining IRB approval period, the protocol has, or will be, classified as suspended. If IRB approval expires, all research-related activities must immediately cease, unless an exception is granted by the IRB Chair in consideration of a written request. The IRB will be notified of all exceptions granted by the IRB Chair.

E. *Tabled with re-review by the full IRB*

This action is taken when the IRB has identified significant concerns related to participant safety and/or conduct of the study. All research-related activities must immediately cease, unless an exception is granted by the IRB Chair in consideration of a written request. The IRB will be notified of all exceptions granted by the IRB Chair.

The IRB must receive a satisfactory response from the PI regarding any necessary modifications and/or clarifications of the protocol and/or consent document(s) within *thirty (30) business days*. Failure to respond to the IRB continuing review letter within the designated time period may result in termination of the study.

F. *Decline to Complete Review*

This category is restricted to applications, which are deficient and preclude the IRB from performing a substantive and meaningful review. The investigator will be instructed in writing to revise the application in accordance with IRB requirements. During the remaining IRB approval period, the investigator is authorized to continue the research.

If the PI fails to respond within the remaining IRB approval period, the protocol will be classified as suspended "approval expired. If IRB approval

expires, all research-related activities must immediately cease, unless an exception is granted by the IRB Chair in consideration of a written request. The IRB will be notified of all exceptions granted by the IRB Chair.

G. Disapproved

The IRB has a serious concern regarding participant safety and/or compliance. The protocol will be suspended or possibly terminated and a report submitted to OHRP in accordance with HRPP policy [# 14.002](#). No new participants can be accrued. All research-related activities must cease and the full IRB will make a determination if currently enrolled participants may continue participation in the study. The Institutional Official and the PI's departmental chair will be notified.

2.8 IRB Re-Approval Notification and Release

Upon IRB re-approval of a research project, the PI will be sent a letter of re-approval and stamped/dated IRB-approved consent/assent forms. The stamp indicates the date of IRB re-approval and the "valid until" date. The "valid until" date is the last date that IRB approval is in effect. The letter provides a summary of investigator responsibilities and also reminds investigators that changes in research activity may not be initiated without IRB review and approval except when necessary to eliminate apparent immediate hazards to participants.

The re-approved consent/assent forms should be kept on file as the master copy (ies) and all outdated consent/assent forms must be destroyed as they are no longer valid.

Initial and amended informed consent documents signed by the participant remain in effect for the duration of the participant's participation in the study. Therefore, previously enrolled participants are *not* required to be re-consented each year following continuing review, *unless* the IRB approves a change during the continuing review process, which requires re-consent of participants (e.g., participant notification of new risks or changes in protocol.)

2.9 Lapse of Approval

If a PI fails to submit the continuing review form or respond to the IRB review letter in sufficient time to allow the IRB to complete its review and grant re-approval and full release before the end of the current IRB approval period, the protocol will be classified as expired-IRB approval no longer valid.

Notification of administrative closure is sent by email to the PI and any designated research personnel 60 days after the date of lapse of approval.

2.10 Final progress reports

When a project is completed, the PI must immediately notify the IRB by submitting the Final Report Form as the final progress report.

2.11 Five year re-application


Continuation of projects beyond five years requires submission of an Application for Continuing Review, informed consent/assent document(s), and answering the 5 year renewal questions on the continuing review form.

2.12 Ten-year protocol requirements

A. Projects that reach a 10 year approval period, with plans of future participant enrollment and data collection, will be required to submit a new project form. This will ensure that the research remains approved under current federal and institutional policies.

Investigators will need to submit a new project for review and approval prior to the expiration date. If the new project cannot be approved prior to the 10 year expiration date, investigators must submit a continuing review to keep the existing project open. These projects can be re-approved for a 90 day period to allow time for approval of the new project. The valid until date cannot be extended without continuing review approval by the expiration date.

D. Projects that reach a 10 year approval period with only plans of identifiable data analysis may be permitted to submit additional continuing review forms to maintain IRB approval.

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|  <p>HRPP POLICIES AND PROCEDURES</p> <p>Research Compliance Services Human Research Protections Institutional Review Board</p> | <p>Policy # 11.002</p> <p>Title: <u>Suspension and Termination</u></p> <p>Section: <i>Continuing Review and Suspension and Termination</i></p> <p>Date: April 27, 2016</p> |
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1.0 Purpose

The purpose of this policy is to describe the conditions under which suspension and termination apply and the process involved.

2.0 Policy

Suspension of IRB approval is a directive of the convened IRB, IRB Chair, or RCS Director to temporarily stop some or all previously approved research activities short of permanently stopping all previously approved research activities. Suspended protocols remain open and require continuing review. Termination of IRB approval is a directive of the convened IRB to permanently stop all activities in a previously approved research protocol. Terminated protocols are considered closed and no longer require continuing review.


2.1 The IRB Chair or RCS Director may suspend research to ensure protection of the rights and welfare of participants. Suspension directives made by the IRB Chair or RCS Director must be reported to and reviewed by the convened IRB. Research may only be terminated by the convened IRB. Terminations of protocols approved under expedited review must be made by the convened IRB.

2.2 When study approval is suspended by the convened IRB or an authorized individual, in addition to stopping all research activities, the Primary Investigator (PI) will notify any subjects currently participating that the study has been suspended. The convened IRB or individual ordering the suspension will consider whether procedures for withdrawal of enrolled subjects are necessary to protect the rights and welfare of subjects, such as: transferring participants to another investigator; making arrangements for care or follow-up outside the research; allowing continuation of some research activities under the supervision of an independent monitor; or requiring or permitting follow-up of participants for safety reasons.

2.3 When study approval is terminated by the convened IRB, in addition to stopping all research activities, the convened IRB will notify any subjects currently participating that the study has been terminated. The convened IRB will consider whether procedures for withdrawal of enrolled subjects are necessary to protect the rights and welfare of subjects, such as: transferring participants to another investigator; making arrangements for care or follow-up outside the research; allowing continuation of some research activities under the supervision of an independent monitor; or requiring or permitting follow-up of participants for safety reasons.

- 2.4** If follow-up of subjects for safety reasons is permitted/required by the convened IRB or individual ordering the suspension or termination, the subjects should be so informed that any adverse events/outcomes will be reported to the IRB and the sponsor.

- 2.5** It is the policy of the IRB that all applicable incidents will be promptly reported to OHRP and Department or Agency heads (if applicable) (see Policy 14.002.)

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|  <p>HRPP POLICIES AND PROCEDURES Research Compliance Services Human Research Protections Institutional Review Board</p> | <p>Policy # 12.001 Title: <u>Request for Change</u> Section: <i>Amendments to Approved Protocols</i> Date: June 2, 2014</p> |
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1.0 Purpose

The purpose of this policy is to describe the process for requesting changes to an approved protocol.

2.0 Policy

It is the policy of the IRB that review of all requests for changes in approved protocols will be conducted in full accordance with regulations at Health and Human Services 45 CFR §46.

2.1 Introduction

Any proposed change in a protocol which affects the human participants must be reviewed and approved by the IRB *prior* to implementation except when an immediate change is necessary to eliminate a hazard to the participants.

All change classifications will be confirmed through the designated reviewer process. If there is a concern or question about the classification, the HRPP staff will consult with the IRB Chairperson and if necessary the convened IRB. The following definitions of changes include but are not limited to only the examples provided.

3.0 Definitions of Changes

3.1 Informational

Informational changes (1) have no potential impact on the risks for research participants, and/or (2) clarify or provide only editorial updates to the protocol, informed consent form, or supporting documents.

A. Examples

1. Changes in researcher contact information
2. Deletion of study personnel (PI or SI)
3. Correction of typographical errors
4. Minor administrative changes in the protocol by the sponsor
5. Revision of wording that does not change content or meaning, but adds to the understandability/clarity of information provided to the participant
6. Addition of study sites

When submitting revised documents, the track changes function should be enabled to aide in the review process.

3.2 Minor

Minor changes may impact the research participant, but do not significantly affect the risks to the participant.

A. Examples

1. Addition of study personnel (PI or SI)
2. Addition/deletion of questionnaires or questionnaires items which are consistent with those previously approved and do not change the consent process.
3. Deletion of interventions
4. Addition/deletion of study procedures which are consistent with those previously approved.
5. Minor change in eligibility requirements
For example, increasing the age range in an adult population between the ages of 19-65 years by five to ten years.
6. Change in follow-up schedules
7. Revisions to the consent form which are not substantive in nature.
8. Additional communication to participants that do not present a significant concern such as adding one follow-up contact.
9. Decrease in compensation.
10. Increase in compensation that will not affect the voluntary nature of the project based on the population and potential increase in coercion.

When submitting revised documents, the track changes function should be enabled to aide in the review process.

3.3 Major

Major changes are classified as minimal risk revisions or major risk revisions.

Minimal risk means the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.

Major risk revisions involve more than minimal risks to research participants. These changes reflect a major-risk change in the direction of the study that may substantially change the purpose or goals of the study.

A. Examples

1. Adding a substance which may be intended for participant ingestion, changing dosages, or frequency of administration
2. Addition of a study phase
For example, the project includes pre- and post- phase and a three month follow-up will be added.
3. Changing the treatment
4. Revising eligibility requirements
For example, including a vulnerable population that is not consistent with those previously approved.
5. Addition of study procedures that are not consistent with those previously approved.

For example, moving from paper and pencil survey administration to on-line survey administration would generally be seen as a major change.

6. Addition/deletion of questionnaires or questionnaires items which are not consistent with those previously approved. For example, study asks about educational goals and motivation, but the researcher now wants to include data about impacts of sexual activity on education.
7. Addition or increase in compensation that will affect the voluntary nature of the project based on the population and potential increase in coercion.
8. Substantive revisions to the informed consent forms, which would likely incorporate changes 1-7 above.

When submitting revised documents, the track changes function should be enabled to aid in the review process.

3.4 Significant Changes

In some cases there are significant changes that require immediate implementation in order to decrease risk to participants and require full disclosure to the participants immediately. These changes may include: addition of a major risk resulting from a reported adverse event or other major changes enacted to reduce risk to participants. Significant changes which affect the safety to participants should be implemented immediately, but are required to be submitted to the IRB within 48 hours of implementation.

NOTE: Any proposed revision that substantively deviates from the original purpose and objectives of the project must be submitted as a new project.

4.0 Submission Requirements

Investigators must submit:

- A. IRB Request for Change in Protocol form on-line via NUgrant.
- B. Complete description of the changes requested.

The IRB files must contain a complete and accurate description of the research. Therefore, changes indicated in the Request for Change in protocol must be described clearly.

- C. Revised consent/assent document(s) (as appropriate).

Re-consent of current participants is dependent upon the nature of the change. Informational changes, such as revising the telephone number or correcting typographical errors, normally do not require re-consent. Minor changes may require re-consent of current participants depending on the nature of the change. The PI must provide a plan, as necessary, for notification of current participants. Re-consent of current participants is normally required for major changes, such as changing the treatment or revising eligibility requirements.

For significant changes, re-consent of current participants utilizing the revised IRB-approved consent document or addendum is required. A witness is required during the re-consent process.

The revised consent document that will be used to consent new participants and to re-consent current participants must be submitted for review as part of the change request.

- D. When a change in protocol is the result of a new or revised grant application, a copy of the complete grant narrative must be submitted.

5.0 IRB Review

As a Request for Change in Protocol form is received in the RCS office, the HRPP staff will conduct a pre-review and document the requests to determine the appropriate review process as described below.

- A. Administrative changes are reviewed in the HRPP office using the exempt review process. If the change requires additional information prior to approval, the HRPP office will communicate with the researcher(s) directly.

- B. Exempt Research. For exempt research, both minor and major changes will be reviewed by the HRPP staff to ensure that the proposed changes do not affect the exempt status of the research. If the status is not affected, the changes will be reviewed to determine that the original goal of the research has not changed and the risk has not increased. If the exempt status is affected by the nature of the change, the change request will be forwarded to the expedited or full board review process.

- C. Expedited Research

- 1. Minor Changes

- For research initially approved as Expedited, minor changes will be reviewed by HRPP staff, who have been designated by the IRB Chairperson to process these reviews. The HRPP staff will communicate any necessary revisions directly to the PI. The HRPP staff have the authority to submit the requested revisions to one of the expedited reviewers or the IRB Chairperson if there are concerns regarding the nature of the requested changes.

- Changes in expedited research which are minor changes must be documented as being classified as a minor change.

- 2. Major Changes

- For research initially approved as Expedited, major changes will undergo a pre-review conducted by HRPP staff. Once the HRPP staff person has determined that the change request is complete, the request will be submitted to one of the designated expedited reviewers. The reviewer may request additional revisions prior to approval of the change. The designated reviewer has the authority to

request that the revision be reviewed by the convened IRB if the revisions affect the risk level of the research.

When conducting the review of an expedited change request, the reviewer has access to and reviews all submitted information including the complete protocol history via NUgrant. The reviewer(s) complete the Institutional Review Board – Change in Protocol checklist to determine whether the modifications meet the criteria allowing review using the expedited procedure, and if so, whether the research with the proposed modifications meets the regulatory criteria for approval. (HRPP Policy 2.009).

D. Full Board Research – Proposed changes

1. Minor Changes

For research initially approved as Full Board, minor changes will undergo a pre-review conducted by HRPP staff. Once the HRPP staff person has determined that the change request is complete, the request will be submitted to one of the IRB Chairperson, who will serve as the designated reviewer. The reviewer may request additional revisions prior to approval of the change. The designated reviewer has the authority to request that the revision be reviewed by the convened IRB if the revisions affect the risk level of the research.

2. Major Changes

For research initially approved as Full Board, major changes will undergo a pre-review conducted by HRPP staff. Once the HRPP staff person has determined that the change request is complete, the request will be submitted to the next scheduled convened IRB meeting. The full committee will review the change request. The IRB may request additional revisions prior to approval of the change request. If the changes affect the original scope of the research, a new protocol may be requested. Depending on the nature of revisions, the IRB has the authority to disapprove the requested changes.


All IRB members have access to all submitted materials for the review of modifications to previously approved research by the convened IRB via NUgrant. It is expected that primary and secondary reviewers will perform an in-depth review of all pertinent documentation. At the meeting, the primary reviewer presents an overview of the modifications and leads the IRB through the completion of the regulatory criteria for approval (HRPP Policy 2.009). All other IRB members will review the materials in enough depth to discuss the information at the convened meeting (HRPP Policy 2.009).

5.1 Change to Eliminate Immediate Risk Prior to IRB Approval

If a change is initiated without any IRB approval in order to eliminate immediate hazards to the participants or to provide essential information to the participants, the IRB must be notified as soon as possible, but no later than two (2) business days from the time the change was initiated. If the change was initiated for all participants, the IRB Request for Change in Protocol must be completed.

The investigator is authorized to implement changes without IRB approval in

order to eliminate apparent immediate hazards to participants. The IRB chair or designee has no authority to approve more than minor changes even if needed to eliminate immediate hazards to participants.

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|  | HRPP POLICIES AND PROCEDURES | Policy # 13.001 |
| Research Compliance Services Human Research Protections Institutional Review Board | | Title: <u>Unanticipated Problems Involving Risk and Adverse Events</u> Section: <i>Unanticipated Problems & Adverse Events</i> Date: April 1, 2008 |

1.0 Purpose

The purpose of this policy is to describe the procedure to ensure prompt reporting to the IRB, appropriate institutional officials, sponsor, coordinating center, and the appropriate regulatory agencies of unanticipated problems involving risks to participants or others.

2.0 Definitions

2.1 *Unanticipated Problems Involving Risk to Participants or Others.* This term is defined as an adverse event that is (1) unexpected, (2) serious, and (3) related or possibly related to participation in the research. Unanticipated problems also includes unexpected adverse events, regardless of severity, that the IRB determines represent risk to participants or others. Unanticipated problems also includes events that are not categorized as adverse events and are not directly related to an individual subject's participation in a study, but represent risk to participants or others.

Example: Events that could lead to a breach of confidentiality or privacy provisions such as the unanticipated loss or theft of files or that in anyway might subject the research participant to a higher degree of risk than anticipated in the research protocol.

2.2 *Adverse Event (AE).* This term is defined as any untoward physical or psychological occurrence in a human subject participating in research. An AE can be any unfavorable or unintended event including abnormal laboratory finding, symptom or disease associated with the research or the use of a medical investigational test article.

2.3 *Serious Adverse Event (SAE).* This term is defined as death; a life threatening experience; hospitalization (for a person not already hospitalized); prolongation of hospitalization (for a patient already hospitalized); persistent or significant disability or incapacity; congenital anomaly and/or birth defects; or an event that jeopardizes the subject and may require medical or surgical treatment to prevent one of the preceding outcomes.

2.4 *Unexpected Adverse Event (UAE).* This term is defined as any adverse event and/or reaction, the specificity or severity of which is not consistent with the informed consent, current investigator brochure or product labeling. Further, it is not consistent with the risk information described in the general investigational plan or proposal.

2.5 *Related.* An event is "related" if it is likely to have been caused by the research procedures.

2.6 Substantive Action. An action taken by an IRB that materially alters the substance and meaning of a protocol, informed consent form or process, or investigator status, including, but not limited to, restriction, suspension or termination of a study or investigator participation, and actions taken to prevent future occurrence(s) of the AE in research.

2.7 Unexpected Death. The death of a research subject in which a high risk of death is not projected, as indicated by the written protocol, informed consent form, or sponsor brochure. This definition does not include deaths associated with a terminal condition unless the research intervention clearly hastened the subject's death. A subject's death that is determined to be clearly not associated with the research is also not an "unexpected death" for purposes of the reporting requirements of these procedures.

3.0 Policy

It is the IRB's policy to comply with Health and Human Services regulations at 45 CFR §46.103(b) (5) (1) (i) to have policies and procedures that ensure reporting of all unanticipated problems involving risk to participants or others to the IRB, regulatory agencies, and institutional officials.

3.1 The following problems must be reported to the IRB within 48 hours using the Problem


Report form:

- A.** Any physical or psychological harm experienced by a participant, which in the opinion of the principal investigator, is both unexpected and related.
 - 1. Harm is "unexpected" when its specificity and severity are not accurately reflected in the consent document.
 - 2. Harm is "related to the research procedures" if in the opinion of the principal investigator, it is more likely than not to be caused by the research procedures or if it is more likely than not the event affects the rights and welfare of current participants.
- B.** Information that indicates a change to the risks or potential benefits of the research. For example:
 - 1. An interim analysis or safety monitoring report indicates that the frequency or magnitude of harms or benefits might be different from those initially presented to the IRB.
 - 2. A paper is published from another study that shows that the risks or potential benefits of your research might be different from those initially presented to the IRB.
- C.** A breach of confidentiality.
- D.** Change to the protocol taken without prior IRB review to eliminate an apparent immediate hazard to a research participant
- E.** Incarceration of a participant in a protocol not approved to enroll prisoners.
- F.** An event that requires reporting to the sponsor.
- G.** Sponsor imposed suspension.
- H.** Complaint of a participant.
- I.** Protocol deviation.

3.2 IRB review of external reported problems.

- A.** The IRB Chair reviews problem reports and determines whether each is an unanticipated problem involving risks to participants or others. If the report is an unanticipated problem involving risks to participants and others, it is referred to the convened IRB for review. The IRB Chair also considers whether each report involves noncompliance. If so, the noncompliance policy is followed. If the IRB chair determines that the report is neither an unanticipated problem involving risks to participants or others nor noncompliance, it is filed and no further action is taken.
- B.** The IRB Chair will take all actions necessary to protect human participants including suspension or termination of the study (HRPP Policy [# 14.001](#)). Investigators may also make changes to the research without prior approval by the IRB when necessary to eliminate apparent immediate hazards.
- C.** If referred for full IRB review, two (2) IRB reviewers are assigned to review the Report of Unanticipated Problem(s) or Adverse Event(s) Involving Risk. These members are provided and expected to review, in depth, copies of:
 - 1. The Report of Unanticipated Problem Involving Risk and all submitted supporting materials.
 - 2. The current consent document.
 - 3. The protocol application.
 - 4. The industry protocol (if one exists).
 - 5. The investigator's brochure (if one exists).
- D.** All IRB members are provided and are expected to review, be familiar with, and be prepared to discuss copies of:
 - 1. The Report of Unanticipated Problem(s) or Adverse Event(s) Involving Risk and all submitted supporting materials.
 - 2. The current consent document.
- E.** The primary reviewers present the event or problem and lead the discussion. The IRB discusses and votes on whether the event or problem represents an unanticipated problem involving risks to participants or others as defined above. If the IRB determines by majority vote that the event or problem represented an unanticipated problem involving risks to participants or others, the SOP on Reporting to Regulatory Agencies and Institutional Officials will be followed (see HRPP policy [#14.001](#) and [#14.002](#)). If the IRB determines that the problem is not an unanticipated problem involving risks to participants or others, the IRB determination overrules the determination of the chair and no further action is taken. The IRB determination of whether the problem is an unanticipated problem involving risks to participants or others is documented in the minutes.
- F.** The IRB considers the following actions on all reportable events or problems:
 - 1. No action.
 - 2. Modification of the research protocol.
 - 3. Modification of the information disclosed during the consent process.
 - 4. Additional information provided to past participants.

5. Notification of current participants (required when such information may relate to participants' willingness to continue to take part in the research).
6. Requirement that current participants re-consent to participation.
7. Modification of the continuing review schedule.
8. Monitoring of the research.
9. Monitoring of the consent.
10. Suspension of the research.
11. Termination of the research.
12. More information sought pending a final decision or
13. Referral to other organizational entities (e.g., legal counsel, risk management).

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|  <p>HRPP POLICIES AND PROCEDURES</p> <p>Research Compliance Services Human Research Protections Institutional Review Board</p> | <p>Policy # 14.001</p> <p>Title: <u>Noncompliance</u></p> <p>Section: <i>Compliance</i></p> <p>Date: April 1, 2008</p> |
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1.0 Purpose

The purpose of this policy is to: 1) define noncompliance, 2) describe categories of noncompliance, 3) describe procedures for reporting noncompliance to the IRB, 4) address IRB actions, and 5) reporting noncompliance to OHRP and Department or Agency heads.

2.0 Definitions

- 2.1 Noncompliance** is defined as the failure to comply with any Health and Human Services regulations, and/or IRB requirements. Noncompliance is assessed as non-serious, serious, or continuing.
- 2.2 Incident of noncompliance** is defined as a proven assertion of non-compliance.
- 2.3 Serious noncompliance** is defined as failure to comply with Health and Human Services regulations, and/or IRB requirements, which in the judgment of the convened IRB, places human participants at unacceptable risk, decreases potential benefits to participants, compromises the integrity of the HRPP, or results in non-disclosure of pertinent information to all participants thereby compromising informed consent.

Example 1: Use of an outdated consent document where the changes are material to the participant's consent and, therefore the participant was unable to make an informed decision (e.g., new information about risks).

Example 2: Failure to have the participant sign the consent form.

Example 3: Failure to submit a Request for Change prior to implementing a change and the change has impact on the risk/benefit relationship of the research and/or the informed consent (e.g., addition of blood draws).

Example 4: Conduct of a study after IRB approval expiration.

Example 5: Failure to obtain IRB approval of non-exempt research.

Example 6: Failure to report to the IRB an unanticipated problem involving risk to the participant or others, which impacts the risk/benefit relationship of the study and/or informed consent (e.g., a participant develops depression after a particular psychological technique is implemented and is not described in the informed consent form).

- 2.4 Continuing noncompliance** is defined as a pattern of noncompliance that, in the judgment of the convened IRB, suggests a likelihood that instances of noncompliance will continue without intervention. "Continuing noncompliance"

also includes failure to respond to a request to resolve an episode of noncompliance. "Continuing noncompliance" includes:

- A.** Multiple incidents of serious or non-serious noncompliance in a twelve (12) month period, which occurs in any one research protocol. The incidents of noncompliance may involve one specific issue or different issues.

Example: During a routine audit of the PI's research records, ten of fifty consent forms obtained during the last twelve months did not have a signed and dated investigator's signature.

- B.** Multiple incidents of serious or non-serious noncompliance in a twelve month period carried out by the same individual in multiple research protocols. The incidents of noncompliance may involve one specific issue or different issues.

Example: During a routine audit of the PI's research records for six studies, multiple protocol violations were identified, which included failure to record lab values, participants seen outside of window, participants signing outdated consent forms, and lack of re-consent of participants in a timely manner.

The IRB reserves the right to judge noncompliance as continuing in circumstances that do not meet the above definition.

2.5 Allegation of noncompliance is defined as an unproven assertion of noncompliance.

2.6 Serious allegation of noncompliance is defined as an unproven assertion of noncompliance with grave implications.

3.0 Policy

All members of the University community involved in human participant research are expected to comply with the ethical standards of professional conduct in accordance with federal and state regulations and UNL and IRB policies governing the conduct of research involving human participants. Therefore, it is the policy of the IRB that investigators and research staff must immediately report to the HRPP office any allegations or incidents of noncompliance.

All allegations or incidents of noncompliance will be promptly investigated in order to ensure ongoing adequate protection of the rights and welfare of research participants. Confidentiality will be preserved and due process utilized.

Serious or continuing noncompliance and suspensions or terminations of IRB approval must also be promptly reported to OHRP, and department or agency heads in accordance with HRPP Policy # 14.002.

3.1 Reporting Noncompliance

- A.** Investigators and research staff must report all allegations or incidents of noncompliance *immediately* to the HRPP office (402-472-6965).
- B.** A report of an allegation or incident of noncompliance can be submitted to the HRPP office via a letter, email, or telephone call from any source.

3.2 Procedure for Handling an Allegation of Noncompliance

- A. Receipt of the allegation of noncompliance will be documented.
- B. The investigator will be informed of all allegations of noncompliance.
- C. Confidentiality and compliance with policies and procedures will be maintained at all times.
- D. The Chair and Director will investigate the allegation of noncompliance to determine whether it is true or has no basis in fact. If the Chair and Director are unable to conduct the investigation on their own, others may be requested to assist.
- E. If the Chair and Director determine that the allegation of noncompliance has no basis in fact, this determination is communicated to the investigator and no other action is taken. If the Chair and Director determine that the allegation of noncompliance is true, the Institutional Official is informed and it is handled below as an incident of noncompliance.

3.3 Procedure for Handling an Incident of Noncompliance

- A. Receipt of the incident of noncompliance will be documented.
- B. The investigator will be informed of all incidents of noncompliance.
- C. Confidentiality and compliance with policies and procedures will be maintained at all times.
- D. The Chair and Director will investigate the incident of noncompliance to determine whether it is serious or continuing. If the Chair and Director are unable to conduct the investigation on their own, others may be requested to assist.

3.4 Procedure for handling an incident of noncompliance determined by the Chair and Director to be neither serious nor continuing.

- A. Receipt of the incident of noncompliance will be documented.
The investigator will be informed of all incidents of non-compliance.
- B. Confidentiality and compliance with policies and procedures will be maintained at all times.
- C. The Chair and Director will investigate the incident. If Chair and Director determine the incident to be neither serious nor continuing, then the investigator and the IRB will be informed of the determination by letter or email. It will be filed and no further action taken.

3.5 Review by the Convened IRB of Noncompliance Determined by the Chair or Director to be Serious or Continuing.

- A. The IRB Chair and Director reviews and determines that an allegation or incident on non-compliance is serious or continuing. The Chair is charged with internal review of any incident of allegation or noncompliance.
- B. The IRB Chair and Director will take all actions necessary to protect human participants including suspension of the study.
- C. All findings of serious or continuing non-compliance referred to the IRB will be reviewed at a convened meeting. All IRB members are provided with and expected to review, be familiar with, and be prepared to discuss copies of:
 1. All documents relevant to the allegation
 2. The last approval letter from the IRB
 3. The last approved IRB protocol; and
 4. The last approved consent document.

Two IRB reviewers are assigned to review the incident or allegation in depth.

The primary reviewers present the event or problem and lead the discussion. The IRB discusses and votes on whether it represents serious or continuing noncompliance. If the IRB incident or allegation is serious the SOP on Reporting to Regulatory Agencies and Institutional Officials will be followed (See HRPP policy [#14.001](#) and [# 14.002](#))

D. At this stage, the IRB may:


1. Find that there is no issue of non-compliance;
2. Find that there is noncompliance that is neither serious nor continuing and an adequate corrective action plan is in place;
3. Find that there is serious or continuing non-compliance and approve any changes proposed by the IRB Chair and Director
4. Find that there may be serious or continuing non-compliance and direct that a formal inquiry (described below) be held; or
5. Request additional information.

E. If there is a finding of serious or continuing non-compliance, the following actions can be considered for any corrective action plan:

1. Increase monitoring of the study by the IRB Specialist
2. Required interim reports from PI.
3. Reported internal audits be conducted by the PI and/or study personnel.
4. Monitoring of the consent process by the IRB Specialist or IRB members.
5. More frequent continuing review.
6. Disclosure to the participant information which may affect the participant's willingness to continue in the study.
7. Required additional training of the principal investigator and or/study personnel in the protection of human participants.
8. Suspension of the study.
9. Termination of the study.
10. Suspension of all principal investigator's studies pending the completion of an audit.
11. Recommendation of the IO that a letter of reprimand be placed in the principal investigator's personnel file or the file of other study personnel.
12. Recommendation to the IO that the principal investigator's privilege to conduct research be suspended for a specific period of time or terminated.
13. Recommendation to the IO that the principal investigator's employment or employment of specific study personnel be terminated.
14. Recommendation to the IO that the case be referred for further action or investigation by the Professional Conduct Committee.
15. Recommendation to the IO that whistleblower protection is needed for the complainant.

3.6 Reporting noncompliance to federal agencies.

All noncompliance determined by the Chair and Director to be serious or continuing noncompliance will be reported to OHRP, and Federal Department or Agency Heads in accordance with HRPP Policy [# 14.002](#).

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|  <p>HRPP POLICIES AND PROCEDURES</p> <p>Research Compliance Services Human Research Protections Institutional Review Board</p> | <p>Policy # 14.002</p> <p>Title: <u>Reporting Incidents to OHRP or Department and Agency Heads</u></p> <p>Section: <i>Compliance</i></p> <p>Date: April 27, 2016</p> |
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1.0 Purpose

The purpose of this policy is to describe the procedure to ensure prompt reporting to OHRP or Department and Agency Heads as applicable: 1) unanticipated problems involving risk to the participants or others, 2) serious or continuing noncompliance, and 3) suspensions or terminations of approved research by the IRB.

2.0 Definitions

- 2.1 Unanticipated problems involving risks to participants or others** are defined as any problem that (1) was unforeseen and (2) indicates that the research procedures caused harm to participants or others or indicates that participants or others are at increased risk of harm.
- 2.2 Serious noncompliance** is defined as failure to comply with any Health and Human Services regulations, and/or IRB requirements that places human participants at unacceptable risk or results in non-disclosure of pertinent information to all participants thereby compromising informed consent.
- 2.3 Continuing noncompliance** is defined as: 1) multiple incidents of serious or non-serious noncompliance in a twelve (12) month period, which occurs in any one research protocol, or 2) multiple incidents of serious or non-serious noncompliance in a twelve (12) month period carried out by the same individual in multiple research protocols. The incidents of continuing noncompliance may involve one specific issue or different issues.
- 2.4 Suspension or termination of IRB approval of research** is defined as a mandatory directive to the investigator in writing to suspend or terminate some or all research activities conducted under an IRB-approved protocol. Such directives may be issued as a result of decisions made by either the full IRB at a convened meeting or by the IRB Chair or Institutional Official in order to eliminate apparent immediate hazards to the participants or others.
- 2.5 Internal study hold** is defined as a mandatory directive by the IRB to the investigator in writing to suspend further participant accrual on an IRB approved protocol. Such directives may be issued when the IRB has a concern about unresolved adverse event or serious problem reports, or other issues, which impact participant safety.
- 2.6 External Study Hold** is defined as a mandatory directive by the sponsor or cooperative group, to the investigator in writing to suspend further participant accrual on an IRB approved protocol. Such directives are usually issued for planned study holds to evaluate reported problematic therapeutic techniques.

3.0 Policy

It is the policy of the IRB that the following incidents will be promptly reported to OHRP and Department or Agency heads (if applicable) in accordance with Health and Human Services regulations at 45 CFR §46.103(b) (5) or to other federal agencies when the research is overseen by those agencies: 1) any unanticipated problem involving risk to the participant or others, 2) any serious noncompliance, 3) any continuing noncompliance, 4) any suspension or termination of IRB approval.. In general, the reporting requirements apply to all nonexempt human subjects research that is 1) conducted or supported by HHS; 2) conducted or supported by any non-HHS federal department or agency that has adopted the Common Rule and is covered by an FWA; or 3) covered by an FWA regardless of funding source.²

Reporting to OHRP and other relevant federal agencies unanticipated problems involving risk to the participant or others, which occur at institutions not under the jurisdiction of the IRB are the responsibility of the external institution.

- 3.1** The IO is responsible for the prompt submission of all required written reports to OHRP, and/or Department or Agency heads.
- 3.2** The IO may notify OHRP verbally in advance of a written report when the incident is particularly serious.
- 3.3** All required reports will be submitted no greater than 30 business days from the time the full IRB makes a final determination concerning the incident.
- 3.4** If the study is conducted or funded by any Federal Agency other than DHHS that is subject to “the Common Rule, the report is sent to OHRP or the head of the agency as required by the agency.
- 3.5** Information to be included in written reports:
 - A.** Name of the institution.
 - B.** Protocol number and the number of any applicable federal award(s).
 - C.** Name of the principal investigator on the protocol.
 - D.** Title of the research project and/or grant proposal in which the problem occurred.
 - E.** Detailed description of the problem.
 - F.** Actions the institution is taking or plans to take.
 - 1.** If the report is related to an unanticipated problem, the actions could include: revise the protocol, suspend subject enrollment, terminate the research, revise the informed consent document, inform enrolled subjects, increase monitoring of subjects, etc.
 - 2.** If the report is related to serious or continuing noncompliance, the actions could include: educating the investigator, educate all research staff, educate the IRB or institutional official, develop or revise IRB written procedure, suspend the protocol, suspend the investigator, conduct random audits, etc.
 - 3.** If the report is related to suspension or termination of the research, the actions could include: investigating alleged noncompliance, educate the

² See the OHRP Flowchart What Incidents Should be Reported to OHRP at <http://www.hhs.gov/ohrp/compliance/reports/index.html>.

investigator, educating all research staff, require monitoring of the investigator or the research project, etc.


3.6 Notification of Reporting

Copies of the letter sent to the OHRP and any necessary supporting documents must be provided to:

- A.** The individual(s) directly responsible for the noncompliance.
- B.** The PI.
- C.** The IO.
- D.** The Federal sponsor.
- E.** Other appropriate individuals as determined by the IO, the HRPP Staff or the IRB, such as the Department Chair or Head.

3.7 OHRP review of incident reports

- A.** OHRP will assess the adequacy of the actions taken by the institution. OHRP will determine if the actions taken will ensure that the incident will not happen again.
- B.** OHRP recommends, if appropriate, that the corrective action plan be implemented institution wide.
- C.** OHRP will respond to reports in writing either acknowledging the report as adequate or will request more information.
- D.** Reports must be sent as a PDF or Word document to IRPT.OS@hhs.gov.

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|  | HRPP POLICIES AND PROCEDURES | Policy # 14.003 |
| Research Compliance Services Human Research Protections Institutional Review Board | Title: <u>Audits by Outside Agencies</u> | Section: <i>Compliance</i> |
| | Date: April 1, 2008 | |

1.0 Purpose

The purpose of this policy is to describe audits by outside agencies.

2.0 Policy

It is the policy of the IRB that the IRB will cooperate with audits by outside agencies in full accordance with regulations at Health and Human Services 45 CFR §46.

2.1 Audit of the IRB by the Food and Drug Administration, OHRP, Department Of Defense or National Institutes of Health Cooperative Group

When an IRB staff member or IRB officer is contacted by a representative from a federal agency or a National Institutes of Health cooperative group for an audit of the IRB, the following actions must be taken:

- A. Ask for the reason for the visit, if this has not already been provided.
- B. Inquire what documents and information they will require during the investigation.
- C. Immediately contact the Director and the IRB Chair/Vice Chair.
- D. An email confirming the visit will be sent to the Director, the IRB Chair/Vice Chair, IRB Administrator and staff, and the IO.
- E. When the auditor(s) arrives, ask to see the auditors' identification and business card for name and agency affiliation. Additionally, if the investigation is being conducted by a federal agency, the auditor may provide a copy of the memo from headquarters detailing the reason for the visit.
- F. During the visit, the Director, IRB Administrator and Chair should be available to the auditor. A written record of the study files that are reviewed and documents photocopied must be kept.
- G. During the closing interview it is preferable that the IRB Chair, the Director and IRB Administrator be present. If the IRB Chair and/or the Director are not available, the IRB Administrator can participate alone or request the IRB Specialist join the interview. The IRB Administrator will note all issues identified by the investigation and the action proposed by the auditor (if applicable).
- H. If the Director is unable to attend the exit interview, the IRB Administrator will provide a summary of the results of the interview and required actions resulting from the investigation. If necessary, all individuals involved in the investigation will meet with the Director for debriefing.
- I. Following the discussion with the Director, the IRB Administrator will immediately send an email to the individuals named in #4 above providing a synopsis of the investigation and the preliminary results presented at the closing interview. Special emphasis will be placed on those areas where deficiencies were found that require attention.

- J. The IRB Chair and Vice Chair, the Director, and the IRB Administrator will meet within five (5) days following the investigation to propose a corrective action plan to address deficiencies found during the investigation. The full IRB will be notified of the investigation and action plan. The full IRB may modify the plan as necessary.
- K. The IRB Administrator will notify by email all principal investigators whose study files were examined during the investigation. Results from the audit that are pertinent to the specific study will be discussed. Following receipt of the official letter from the regulatory agency, the Principal Investigator will also be notified of areas of concern related to his/her study.
- L. The IRB will normally receive a report of the results of an audit. Where there are identified areas of concern or sanctions placed, the IRB Chair, Director and other appropriate UNL officials will respond to the agency.

2.2 OHRP For-Cause Investigation of Noncompliance and Not-For-Cause Compliance Oversight Evaluation

If the IO receives notification from OHRP that OHRP has initiated a for-cause investigation of noncompliance or a not-for-cause compliance oversight evaluation, the IO, together with the IRB Chair, Director, and other appropriate institutional officials will respond immediately and appropriately with an action plan to address the matter.

2.3 Audits of Investigator's Records by Outside Agencies

When a PI is contacted by a representative from any federal agency, sponsor, or other entity for an investigation or audit of a research protocol, the IRB must be notified of the visit. If the visit is pre-planned, an email may be sent to the IRB Administrator. If it is a no-notice investigation or audit, the IRB Administrator should be called as soon as possible. The following information must be provided to the IRB:


- A. The IRB # and protocol title.
- B. The name of the governmental agency, sponsor, or other entity.
- C. Name of the investigator.
- D. The dates of the visit.
- E. The type of visit:
 1. routine surveillance/monitoring visit.
 2. "for cause" investigation.
 3. other: _____.

Following the investigation or audit, the IRB must be notified by the Principal Investigator of any compliance issues identified during the exit interview. If the investigation or audit revealed conditions or practices that are of significant departure from the federal regulations with potential for sanctions, the IRB Chair must be immediately notified by telephone. If the IRB Chair is not available, the IRB Administrator should be informed. This information will be relayed to the Director and other appropriate UNL officials as soon as possible and HRPP policy [# 14.003](#) will be implemented as necessary.

A copy of the official letter detailing the results of the investigation must be provided to the IRB. If the investigation or audit revealed areas of concern, the

Principal Investigator must provide the IRB with a copy of the response with particular emphasis on the corrective action plan.

The full IRB will be given all information and will determine what action is necessary, including reporting noncompliance to OHRP and Food and Drug Administration.

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|  <p>HRPP POLICIES AND PROCEDURES</p> <p>Research Compliance Services Human Research Protections Institutional Review Board</p> | <p>Policy # 15.001</p> <p>Title: <u>Human Research Compliance with Department of Education Regulations</u></p> <p>Section: <i>Department of Education</i></p> <p>Date: July 28, 2015</p> |
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1.0 Purpose

The purpose of this policy is to outline ethical standards and practices of the Human Research Protection Program (HRPP) in accordance with Department of Education regulations.

2.0 Policy

It is the policy of the HRPP to comply with all Department of Education Policies and procedures and with the Family Educational Rights and Privacy Act (FERPA). The University of Nebraska – Lincoln will comply with all processes and guidelines when conducting any research funded by the Department of Education.

3.0 Definitions

- 3.1** Research or experimentation program or project means any program or project that is designed to explore or develop new or unproven teaching methods or techniques.
- 3.2** Children are persons enrolled in research not above the elementary or secondary education level, who have not reached the age of majority as determined under state law.

4.0 The IRB will follow these guidelines when processing parental/student consent for the release or non-release of any student records for research. This responsibility may be delegated to the IRB or another individual or component of the University of Nebraska - Lincoln (e.g., a FERPA committee).

4.1 An educational agency or institution may disclose personally identifiable information from an education record of a student without consent if the disclosure is to organizations conducting studies for, or on behalf of, educational agencies or institutions to:

- A.** Develop, validate, or administer predictive tests.
- B.** Administer student aid programs.
- C.** Improve instruction.

4.2 A school district or postsecondary institution that uses this exception of non-consent is required to enter into a written agreement with the university or investigator conducting the research that specifies:

- A.** The determination of the exception.
- B.** The purpose, scope, and duration of the study.
- C.** The information to be disclosed.
- D.** That information from education records may only be used to meet the purposes of the study stated in the written agreement and must contain the

current requirements in 34.99.31(a)(6) on re-disclosure and destruction of information.

- E.** That the study will be conducted in a manner that does not permit personal identification of parents and students by anyone other than representatives of the university with legitimate interests.
- F.** That the university is required to destroy or return all personally identifiable information when no longer needed for the purposes of the study.
- G.** The time period during which the university must either destroy or return the information.

4.3 Education records may be released without consent under FERPA if all personally identifiable information has been removed including:

- A.** Student's name and other direct personal identifiers, such as the student's social security number or student identification number.
- B.** Indirect identifiers, such as the name of the student's parent or other family members; the student's or family's address, and personal characteristics or other information that would make the student's identity easily traceable; date and place of birth and mother's maiden name.
- C.** Biometric records, including one or more measurable biological or behavioral characteristics that can be used for automated recognition of an individual, including fingerprints, retina and iris patterns, voiceprints, DNA sequence, facial characteristics, and handwriting.
- D.** Other information that, alone or in combination, is linked or linkable to a specific student that would allow a reasonable person in the school community, who does not have personal knowledge of the relevant circumstances, to identify the student with reasonable certainty.

5.0 University of Nebraska – Lincoln will follow these guidelines when conducting research that will comply with the Protection of Pupil Rights Amendment:

5.1 No student shall be required, as part of any research project, to submit without prior consent to surveys, psychiatric examination, testing, or treatment, or psychological examination, testing, or treatment, in which the primary purpose is to reveal information concerning one or more of the following:

- A.** Political affiliations.
- B.** Mental and psychological problems potentially embarrassing to the student or his or her family.
- C.** Sex behavior and attitudes.
- D.** Illegal, anti-social, self-incriminating and demeaning behavior.
- E.** Critical appraisals of other individuals with whom the student has close family relationships.
- F.** Legally recognized privileged and analogous relationships, such as those of lawyers, physicians, and ministers.
- G.** Religious practices, affiliations, or beliefs of the student or student's parent.
- H.** Income, other than that required by law to determine eligibility for participation in a program or for receiving financial assistance under a program.

5.2 All instructional material – including teachers' manuals, films, tapes, or other supplementary instructional material – which will be used in connection with any

research or experimentation program or project must be available for inspection by the parents or guardians of the children engaged in such research.

6.0 University of Nebraska – Lincoln will follow these guidelines when reviewing any IRB protocol when prior consent is used.

6.1 Prior consent means:


- A.** Prior consent of the student, if the student is an adult or emancipated minor; or
- B.** Prior written consent of the parent or guardian, if the student is an un-emancipated minor. Schools and contractors obtain prior written parental consent before minor students are required to participate in any Department of Education-funded survey, analysis, or evaluation.

7.0 Policies and procedures include that for research funded by the National Institute on Disability and Rehabilitation Research, when an IRB reviews research that purposefully requires inclusion of children with disabilities or individuals with mental disabilities as research participants, the IRB must include at least one person primarily concerned with the welfare of these research participants.

8.0 For research not funded by the US Department of Education but being conducted in conjunction with the University of Nebraska – Lincoln, the IRB will follow these guidelines:

8.1 The IRB must verify compliance with U.S. Department of Education regulations that schools are required to develop and adopt policies in conjunction with parents regarding the following:

- A.** The right of parents to inspect, upon request, a survey created by a third party before the survey is administered or distributed by a school to students.
- B.** Arrangements to protect student privacy in the event of the administration of a survey to students, including the right of parents to inspect, upon request, the survey, if the survey contains one or more of the same eight items of information noted above.
- C.** The right of parents to inspect, upon request, any instructional material used as part of the educational curriculum for students.
- D.** The administration of physical examinations or screenings that the school may administer to students.

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|  <p>HRPP POLICIES AND PROCEDURES</p> <p>Research Compliance Services Human Research Protections Institutional Review Board</p> | <p>Policy # 15.002</p> <p>Title: <u>Human Research Compliance with Environmental Protection Agency Regulations</u></p> <p>Section: <i>Environmental Protection Agency</i></p> <p>Date: November 1, 2010</p> |
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1.0 Purpose

The purpose of this policy is to outline ethical standards and practices of the Human Research Protection Program (HRPP) in accordance with Environmental Protection Agency regulations.

2.0 Policy

It is the policy of the HRPP to comply with all Environmental Protection Agency regulations when conducting research in conjunction with the protection of human health and the environment within Title 40 CFR.

3.0 The IRB will not approve the following when conducting research with pregnant women and children:

3.1 Research involving the intentional exposure of pregnant women, nursing women, or children to any substance.

- A.** EPA requires application of 40 CFR 26 Subparts C and D to provide additional protections to pregnant women and children as participants in observational research, i.e., research that does not involve intentional exposure to any substance.

4.0 The IRB will follow these guidelines when conducting research with observational behavior:

4.1 The IRB will review and approve observational research involving children that does not involve greater than minimal risk only if the IRB finds that adequate provisions are made for soliciting the assent of the children and the permission of their parents or guardians, as set forth in 40 CFR 26.406.

4.2 The IRB will review and approve observational research involving children that involves greater than minimal risk but presenting the prospect of direct benefit to the individual participants if the IRB find and documents that:


- A.** The intervention or procedure holds out the prospect of direct benefit to the individual participant or is likely to contribute to the participant's well-being.
- B.** The risk is justified by the anticipated benefit to the participants.
- C.** The relation of the anticipated benefit to the risk is at least as favorable to the participants as that presented by available alternative approaches.
- D.** Adequate provisions are made for soliciting the assent of the children and permission of their parents or guardians, as set forth in 40 CFR 26.406.

5.0 The University of Nebraska – Lincoln in conjunction with EPA policy will require submission of IRB determinations and approval to the EPA Human Subjects Research Review official for final review and approval before the research can begin.

6.0 For research not conducted or supported by any federal agency that has regulations for protecting human research participants and for which the intention of the research is submission to the EPA, the EPA regulations protecting human research participants apply, including:

6.1 EPA extends the provisions of the 40 CFR 26 to human research involving the intentional exposure of non-pregnant, non-nursing adults to any substance.

6.2 EPA prohibits the intentional exposure of pregnant women, nursing women, or children to any substance.

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|  <p>HRPP POLICIES AND PROCEDURES</p> <p>Research Compliance Services Human Research Protections Institutional Review Board</p> | <p>Policy # 15.003</p> <p>Title: <u>Human Research Compliance with Department of Justice Regulations</u></p> <p>Section: <i>Department of Justice</i></p> <p>Date: July 28, 2015</p> |
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1.0 Purpose

The purpose of this policy is to outline ethical standards and practices of the Human Research Protection Program (HRPP) in accordance with Department of Justice regulations.

2.0 Policy

It is the policy of the HRPP to comply with all Department of Justice regulations when conducting research within the Bureau of Prisons and/or when conducting National Institute of Justice-funded research.

2.1 Implementation of programmatic or operational initiatives within the Bureau of Prisons made through pilot projects are not considered to be research.

3.0 The IRB, investigators, and research staff must follow the requirements outlined in 28 CFR 512 when conducting research within the Bureau of Prisons.

3.1 Adequate research design must contribute to the advancement of knowledge about corrections and all research proposals will be reviewed by the Bureau Research Review Board.

3.2 The project must not involve medical experimentation, cosmetic research, or pharmaceutical testing.

3.3 The research design must be compatible with both the operation of prison facilities and protection of human participants.

3.4 The investigator must observe the rules of the institution or office in which the research is conducted.

3.5 Investigators who are not employees of the Bureau must sign a statement in which he or she agrees to adhere to the provisions of 28 CFR 512.

3.6 At least once a year, the researcher shall provide the chief, Office of Research and Evaluation, with a report on the progress of the research.

3.7 At least 12 working days before any report of findings is to be released, the researcher shall distribute one copy of the report to each of the following: the chairperson of the Bureau Research Review Board, the regional director, and the warden of each institution that provided data or assistance. The researcher shall include an abstract in the report of findings.

- 3.8** In any publication of results, the researcher shall acknowledge the Bureau's participation in the research project.
- 3.9** The researcher shall expressly disclaim approval or endorsement of the published material as an expression of the policies or views of the Bureau.
- 3.10** Prior to submitting for publication the results of a research project conducted under the subpart, the researcher shall provide two copies of the material, for informational purposes only, to the Chief, Office of Research and Evaluation, Central Office, Bureau of Prisons.
- 4.0** Research taking place within the Bureau of Prisons must adhere to the following participant recruitment and compensation methods:
- 4.1** The researcher must assume responsibility for actions of any person engaged to participate in the research project as an associate, assistant, or subcontractor to the researcher.
- 4.2** The selection of participants within any one organization must be equitable.
- 4.3** Incentives may not be offered to help persuade inmate participants to participate. However, soft drinks and snacks to be consumed at the study site may be offered.
- 4.4** Reasonable accommodations such as nominal monetary compensation for time and effort may be offered to non-confined study participants who are both:
- A. No longer in the Bureau of Prisons custody; and
 - B. Participating in authorized research being conducted by Bureau employees and contractors.
- 4.5** A non-employee of the Bureau may receive records in a form not individually identifiable when advance adequate written assurance that the record will be solely as a statistical research or reporting record is provided to the agency.
- 4.6** Except as noted in the consent statement to the participate, the investigator must not provide research information that identifies a participate to any person without that participant's prior written consent to release the information. For example, research information identifiable to a particular individual cannot be admitted as evidence or used for any purpose in any action, suite, or other judicial, administrative, or legislative proceeding without the written consent of the individual to whom the data pertain.
- 4.7** Except for computerized data records maintained at an official Department of Justice site, records that contain non-disclosable information directly traceable to a specific person may not be stored in, or introduced into, an electronic retrieval system.
- 4.8** If the investigator is conducting a study of special interest to the Office of Research and Evaluation (ORE) but the study is not a joint project involving

ORE, the investigator may be asked to provide ORE with the computerized research data, not identifiable to individual participants, accompanied by detailed documentation. These arrangements must be negotiated prior to the beginning of the data collection phase of the project.

5.0 All research receiving National Institute of Justice (NIJ) funding must:

5.1 Have a Privacy Certificate approved by the NIJ Human Subjects Protection Officer.

- A. Under a privacy certificate, investigators and research staff do not have to report child abuse unless the participant specifically acknowledges with signature to allow child abuse reporting.


5.2 Have Employee Confidentiality Statements signed by all investigators and Research staff. These Statements must be maintained by the Principal Investigator (PI).

5.3 Have a confidentiality statement on the consent form stating that confidentiality can only be broken if the participant reports immediate harm to participants or others.

5.4 Have the following elements of disclosure included in the informed consent document:

- A. Identification of the investigators
- B. Anticipated uses of the results of the research.
- C. A statement that participation is completely voluntary and that the participant may withdraw consent and end participation in the projects at any time without penalty or prejudice (the inmate will be returned to regular assignment or activity by staff as soon as practicable).
- D. A statement regarding the confidentiality of the research information and exceptions to any guarantees of confidentiality required by federal or state law. For example, an investigator may not guarantee confidentiality when the participant indicates intent to commit future criminal conduct or harm himself or herself or someone else, or, if the participant is an inmate, indicates intent to leave the facility without authorization.
- E. A statement that participation in the research project will have no effect on the inmate participant's release date or parole eligibility.

5.5 A copy of all data must be de-identified and sent to the National Archive of Criminal Justice Data, including copies of the informed consent document, data collection instruments, surveys, or other relevant research materials.

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|  <p>HRPP POLICIES AND PROCEDURES</p> <p>Research Compliance Services Human Research Protections Institutional Review Board</p> | <p>Policy # 15.004</p> <p>Title: <u>Human Research Compliance with Department of Defense Regulations</u></p> <p>Section: <i>Department of Defense</i></p> <p>Date: June 23, 2016</p> |
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1.0 Purpose

The purpose of this policy is to outline ethical standards and practices of the Human Research Protection Program (HRPP) in accordance with Department of Defense regulations.

2.0 Policy

It is the policy of the HRPP to comply with all federal regulations when conducting, reviewing, approving, overseeing, supporting, or managing Department of Defense-sponsored human participant research. In order to ensure compliance with these regulations, the HRPP staff will review the current Department of Defense regulations at 32 CFR 219, directives, and instructions at the time of initial and continuing protocol review, as applicable including but not limited to, DoD Directive 3216.02 for the protection of human subjects in research conducted or supported by the DoD, DoD Instruction 6200.02 for the application of FDA rules, and SECNAV Instruction 3900.39D for the application of Navy requirements in the protection of human subjects.

- 2.1** IRB members and HRPP staff regularly receive training that provides information necessary to facilitate the performance of assigned responsibilities. In addition, all personnel involved in conducting human participation research are required to complete training in the protection of human participants prior to engaging in human research activities. (See HRPP policy # 3.009 and # 2.004)

Individual Department of Defense (DoD) sponsored research components may require additional specific requirements. Researchers should contact their DoD project coordinator to ensure adherence to any unique requirements.

2.2 Communicating DoD specific requirements

- A.** If the DoD sends a contract with specific requirements, the Office of Sponsored Programs (OSP) will review the contract.
- B.** OSP then communicates these requirements to both the HRPP and the investigators.
- C.** OSP, HRPP, and the investigators work together to make sure the requirements are met.

3.0 DoD sponsored human research must adhere to the following directives:

- 3.1** Substantive amendments to approved research must undergo scientific review prior to IRB review (see HRPP policy # 3.006).
- 3.2** Surveys performed on DoD personnel must be submitted, reviewed, and

approved by the DoD after the research protocol is reviewed and approved by the IRB.

- 3.3** When conducting multi-site research, a formal agreement between organizations is required to specify the roles and responsibilities of each party.
- 3.4** The IRB must determine that the informed consent form includes provisions for research-related injury follows the requirements of the DoD component.

4.0 Investigators conducting research in foreign countries must:

- 4.1** Have permission to conduct research in that country by certification or through a local ethics review; and
- 4.2** Follow all local laws, regulations, customs, and practices.

5.0 Risk Evaluation

- 5.1** When evaluating risk, the phrase “ordinarily encountered in daily life or during the performance of routine physical or physiological examinations or tests” in the definition of minimal risk (section 32 CFR 219.102(i) of Reference (c)) shall not be interpreted to include the inherent risks certain categories of human subjects face in their everyday life. For example, the risks imposed in research involving human subjects focused on a special population should not be evaluated against the inherent risks encountered in their work environment (e.g., emergency responder, pilot, soldier in a combat zone) or having a medical condition (e.g., frequent medical test or constant pain). (DoD Directive 3216.02(b)).

6.0 For research involving greater than minimal risk (as defined in 32 CFR 219.102(i), reference (c)) an independent medical monitor shall oversee a Data and Safety Monitoring Plan. In some instances, the IRB may require the development of a Data and Safety Monitoring Plan for research involving no more than minimal risk, if appropriate (see HRPP policy # 3.010).

- 6.1** The independent medical monitor shall be appointed by name.
- 6.2** The research monitor has the authority to:
 - A.** Stop a research study in progress
 - B.** Remove individuals from study.
 - C.** Take any steps to protect the safety and wellbeing of participants until the IRB can assess the situation.

7.0 When research involves U.S. military personnel, the following procedures shall be followed in order to protect military research participants in order to minimize undue influence:

- 7.1** Officers are not permitted to influence the decision of their subordinates.

- 7.2** Officers and senior non-commissioned officers may not be present at the time of recruitment.
- 7.3** Officers and senior non-commissioned officers have a separate opportunity to participate.
- 7.4** When recruitment involves a percentage of a unit, an independent ombudsman shall be present.
- 7.5** When research involves U.S. military personnel, policies and procedures require limitations on dual compensation:
 - A.** An individual shall not receive pay or compensation for research conducted during duty hours.
 - B.** U.S. military personnel may be compensated for research if the participant is involved in the research when not on duty.
- 8.0** The following guidelines will be followed when considering approval of waived consent:
 - 8.1** The IRB may waive the consent process if the research participant(s) do not meet the definition of “experimental participant”
 - 8.2** If the research participant meets the definition of “experimental participant,” the waiver of consent shall not be granted by the IRB unless approval is obtained from the Secretary of Defense.
 - 8.3** “Experimental participant” as defined in Department of Defense Directive 3216.02hall include:
 - A.** An individual participating in an activity for research purposes where there is an intervention or interaction for the primary purpose of obtaining data regarding the effect of the intervention or interaction (32 CFR 219.102(f), reference (c)). Examples of interventions or interactions include, but are not limited to a physical procedure, a drug, a manipulation of the subject or subject's environment, or the withholding of an intervention that would have been undertaken if not for the research purpose. This does not include:
 - 1. Activities carried out for purposes of diagnosis, treatment, or Prevention of injury and disease in members of the Armed Forces and other mission essential personnel under Force Health Protection programs of the Department of Defense.
 - 2. Authorized health and medical activities as part of the reasonable practice of medicine or other health professions.
 - 3. Monitoring for compliance of individuals and organizations with requirements applicable to military, civilian, or contractor personnel or to organizational units. This includes such activities as drug testing, occupational health and safety monitoring, and security clearance review.

4. Activities exempt under 32 CFR 219 (reference (c)).

9.0 The IRB shall maintain a complete set of materials relevant to the review of the research protocol for a period of time sufficient to comply with legal and regulatory requirements, Sponsor requirements, and organizational policies and procedures.

9.1 Contingent on the terms and conditions of the DoD award, the IRB may submit a copy of these materials to the DoD for archiving.

10.0 For any DoD-supported researcher, the following items must be met.

A. The following information shall be promptly reported (according to the process described in Policy #14.002 Reporting Incidents to OHRP or Departmental and Agency Heads) to the DoD human research protection officer:

1. When significant changes to the research protocol are approved by the IRB.
2. The results of the IRB continuing review.
3. Change of reviewing IRB.
4. When the organization is notified by any Federal department, agency, or national organizations that any part of an HRPP is under investigation for cause involving a DoD-supported research protocol.

B. If consent is to be obtained from the experimental subjects' legal representative, the research must intend to benefit the individual participant.

1. The determination that research is intended to be beneficial to the Individual experimental subject must be made by the IRB.


11.0 Reporting Non-compliance to the DoD

11.1 Incidents of noncompliance will be reviewed according to HRPP Policy 14.002.

11.2 All noncompliance determined by the Chair or Director to be serious or continuing noncompliance will be reported to OHRP and the DoD.

A. Per the process described in Policy #14.002, the IO will send a formal letter to the OHRP Director of Compliance Oversight and the DoD. The letter must include the following:

1. Identification of the protocol.
2. Funding of the protocol (federally or non-federally funded, commercially sponsored).
3. Timeline and description of noncompliance.
4. Copy of the IRB application and applicable consent document(s).
5. Applicable reports from IRB consultants.
6. Other documentation pertaining to the event.
7. Correction action plan approved by the full IRB.

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|  <p>HRPP POLICIES AND PROCEDURES</p> <p>Research Compliance Services Human Research Protections Institutional Review Board</p> | <p>Policy # 15.005</p> <p>Title: <u>Human Research Compliance with the Department of Energy Regulations</u></p> <p>Section: <i>Department of Energy</i></p> <p>Date: November 1, 2010</p> |
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1.0 Purpose

The purpose of this policy is to outline ethical standards and practices of the Human Research Protection Program (HRPP) in accordance with the Department of Energy principles for the protection of human subjects involved in Department of Energy research.

2.0 Policy

It is the policy of the HRPP to comply with all Department of Energy (DOE) regulations when conducting research in the physical sciences in conjunction with human subjects.

3.0 In addition to traditional biomedical and clinical studies, such Department of Energy human subject research includes but is not limited to the following:

3.1 Research using humans to examine devices, products, or materials with the express purpose of investigating human-machine interfaces or evaluating environmental alterations when humans are the subjects being tested;

3.2 Research using personally identifiable bodily materials such as cells, blood, tissues, urine, or hair, even if the materials were collected previously for a purpose other than the current research;

3.3 Research that collects and uses personally identifiable information such as genetic information or medical and exposure records, even if the information was collected previously for a purpose other than the current research;

3.4 Research that collects personally identifiable data, surveys, or questionnaires through direct intervention or interaction with individuals; and

3.5 Research that searches for generalizable knowledge about categories or classes of subjects (e.g., linking job conditions of worker populations to hazardous or adverse health outcomes).

4.0 Department of Energy human subject research do not include the following:

4.1 Research that hopes to improve the safety or execution of procedures that apply to routine occupational activities;


4.2 Research for occupational health surveillance of DOE Federal and contractor employees to determine apparent departures from typical health status and not for the purpose of obtaining generalizable knowledge; and

4.3 Research that involves employee surveys used as management tools to improve worker or contractor performance as long as the identity of the participant is protected.

5.0 The IRB will review and approve the “DOE Requirements Checklist” to verify Department of Energy funded research involving human subjects are in compliance with the following:

5.1 Protection of human subjects in compliance with the protection of personally identifiable information (PII).

5.2 Protection of human subjects in compliance with CFR 46 subparts A, B, and C.

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|  <p>HRPP POLICIES AND PROCEDURES</p> <p>Research Compliance Services Human Research Protections Institutional Review Board</p> | <p>Policy # 15.006</p> <p>Title: <u>Sponsored Research</u></p> <p>Section: <i>Sponsored Research</i></p> <p>Date: July 28, 2015</p> |
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1.0 Purpose

The purpose of this policy is to describe the requirements for human subjects research in a sponsored research project.

2.0 Policy

It is the policy of the HRPP that in sponsored research, both the Sponsor and the Institution have obligations to protect research participants and ensure that the research is conducted in accordance with the Institution's ethical standards in full compliance with all applicable HRPP policies, federal regulations for protection of human subjects, and applicable state regulations.

3.0 Definitions


- 3.1 **Sponsor** is defined as the company, federal agencies, non-federal agencies, or individual donors providing financial or other support for a research study.
- 3.2 **Contract** is defined as a study agreement executed between the Sponsor and the Institution and signed by authorized representatives of each of the parties.

4.0 Procedures

- 4.1 Contracts are received and reviewed by the UNL Office of Sponsored Programs (OSP).
- 4.2 While OSP can provide the appropriate excerpts from the Contract, the appropriate HRPP staff members have access to review all applicable documents within the Sponsored Programs NUgrant module which could include contracts or study agreements. These documents are reviewed in conjunction with the detailed study protocol, the IRB application, and consent documents in order to ensure consistency and compliance with the Institution and HRPP policies.
- 4.3 The Contract between the Sponsor and the Institution may address the following obligations when appropriate:
 - A. The Institution will comply with the detailed study protocol, HRPP policies, and all applicable federal regulations.
 - B. The Sponsor's responsibility, if any, for the payment of medical care for research participants who experience a research related injury is clearly defined and this statement of responsibility is consistent with the compensation in case of injury clause found in the consent document.

- C. The Sponsor's responsibility, if any, to provide medical care for research participants who experience a research related injury is clearly defined and this statement of responsibility is consistent with the compensation in case of injury clause found in the consent document. If the Sponsor is not providing medical care, the contract needs to clearly state who will.
 - D. Indemnification language must not compromise the rights and welfare of research subjects.
 - E. Contracts cannot include a financial bonus or financial penalty specifically linked to subject recruitment efforts (see Policy X (compensation)).
 - F. Direct personal payments or other form of compensation from the Sponsor to investigators and other study personnel is not permitted.
 - G. The Sponsor, or their agent of record (e.g., CRO), will have a plan in place to notify the Institution/PI of the results upon completion of the study when the findings may directly affect the safety or medical care of subjects. The PI will, in turn, notify the subjects.
 - H. The Sponsor will send data and safety monitoring plans and reports to UNL. Contracts or other funding agreements specify the time frame for providing routine and urgent data and safety monitoring reports to the organization as indicated in the data and safety monitoring plan approved by the IRB.
 - I. There is no prohibition for retention of a copy of the data generated during the study at UNL or other study sites under the jurisdiction of the UNL IRB.
 - J. There are no restrictions on publication of the results of the research which violate the University of Nebraska, Board of Regents Policy.
 - K. The Sponsor will promptly report (within 30 days) to UNL any findings that could:
 - 1) Affect the safety of the participants.
 - 2) Influence the conduct of the study or alter the IRB's approval to continue the study.
 - L. Specify a time frame after closure of the study during which the sponsor will communicate such findings (e.g. two years). The timeframe will be based on each individual study.
- 4.4** OSP and appropriate HRPP staff interact with sponsors, investigators, and legal counsel to resolve identified issues and concerns.
- 4.5** If the IRB has already reviewed the project and the Contract requires a major modification of the IRB application and/or consent form(s), the IRB will re-review the study.
- 4.6** The IRB will not issue a final release of commercially sponsored research until OSP has a fully executed Contract.
- 4.7** RCS will be notified by OSP when the Contract is fully executed.
- 4.8** RCS will notify OSP when the IRB has issued final approval and release of the research.

- 5.0** When the grant or contract agreement includes human research activities that will be conducted by investigators who are not employees or agents of the Institution, a subcontract is executed between the Institution and the collaborating institution. The subcontract includes the requirement for the collaborating institution to assure compliance with federal regulations for the protection of human subjects in research and to provide documentation of current and ongoing IRB approval.
- 6.0** Sponsored programs will not authorize a release of funds until all compliance checks have been addressed. This includes IRB, Export Control, Conflict of Interest, Biosafety, and Radiation Safety.
- 7.0** FDA Regulated Research
The UNL IRB does not review FDA regulated research. If a UNL investigator proposes to conduct FDA regulated research, the protocol will be reviewed by the UNMC IRB. (See Policy 1.001, Item 2.4 and Policy 1.006, Item 2.6).
- 7.1** UNMC does charge a fee to sponsors for review. Appropriate language will be included in the contracts to collect the fees from the sponsors.

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|  <p>HRPP POLICIES AND PROCEDURES</p> <p>Research Compliance Services Human Research Protections Institutional Review Board</p> | <p>Policy # 16.001</p> <p>Title: <u>Institutional Conflict of Interest Management</u></p> <p>Section: <i>Institutional Conflict of Interest</i></p> <p>Date: November 1, 2010</p> |
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1.0 Purpose


The purpose of this policy is to describe the process to identify and manage financial conflicts of interest of the university related to the Human Research Protection Program (HRPP) of university covered persons as defined in University of Nebraska Board of Regents Policy 3.2.8.

2.0 Policy

It is the policy of the HRPP to manage, reduce or eliminate financial conflicts of interest that interfere with human research taking place at the University of Nebraska-Lincoln (UNL) in compliance with University of Nebraska Board of Regents Policy – 3.2.8.

2.1 Research Compliance Services will review disclosures that describe outside activities and interests made by researchers, as well as the responses to the conflict of interest questions for all researchers that pertain to each active IRB protocol. This information is reviewed along with reports detailing outside activities of researchers involving start-up companies provided by NUtech Ventures, Inc., a separate non-profit corporation directly responsible for negotiating commercialization activities for the university regarding real, potential or perceived conflicts of interest.

2.2 Should there be any investigators or project personnel with a conflict of interest or associated with a company in which NUtech Ventures has an equity position, the Chair of the Conflict of Interest in Research Committee (CIRC) along with the Chair of the Institutional Review Board will be notified. A management plan will be developed to manage, reduce or eliminate the perceived, potential or real conflict of interest by the CIRC in accordance with the UNL Conflict of Interest in Research Policy. The researcher and the Chair of the Institutional Review Board may attend this meeting to provide input in the development of this plan regarding human subjects protections. In addition, the Chair of the CIRC may attend the IRB meeting where the protocol is reviewed in order to explain the background of the individual conflict of interest, provide greater detail regarding the management plan, and to address any concerns. The IRB then will vote to determine whether the management plan ensures independence of the conduct of human participant research from the interests of the researchers. If the vote is negative, the plan will be referred back to the Conflict of Interest in Research Committee for further modification, until a management plan that is acceptable to the CIRC and IRB is developed.

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|  <p>HRPP POLICIES AND PROCEDURES</p> <p>Research Compliance Services Human Research Protections Institutional Review Board</p> | <p>Policy # 16.002</p> <p>Title: <u>Institutional Conflict of Interest</u></p> <p>Section: <i>Conflict of Interest</i></p> <p>Date: May 3, 2011</p> |
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1.0 Purpose

The purpose of this policy is to describe the management of Institutional Conflict of Interest for the University of Nebraska-Lincoln as it relates to human subjects research.

2.0 Ownership and/or Equity Interests

2.1 NUtech Ventures, Inc. (NUtech), a separate non-profit corporation directly responsible for negotiating commercialization activities the university. NUtech maintains a service contract with University of Nebraska-Lincoln, University of Nebraska-Kearney and University of Nebraska-Omaha campuses to manage the Intellectual Property processes for each campus. The UNL Chancellor and Vice Chancellor for Research and Economic Development have seats on the NUtech Board of Directors. NUtech prepares annual reports detailing ownership interests retained by NUtech (on behalf of the University) for the HRPP office. When NUtech sells the equity interests in business entities related to university research the proceeds are distributed to the university as per the distribution agreements.

As per the University of Nebraska Board of Regents Policy, each campus is responsible for reducing, eliminating or managing the institutional conflicts of interest that pertain to any equity interests that relate to the conduct of research by UNL researchers. The UNL Conflict of Interest in Research Committee (CIRC), administered by Research Compliance Services, reports to the Vice Chancellor for Research & Economic Development and is responsible for reducing, managing or eliminating these potential or actual Institutional Conflicts of Interest. CIRC is responsible for developing appropriate institutional management plans to address potential or actual conflicts of interest. Because NUtech is an independent entity, there are relatively few avenues for “institutional” conflicts (i.e., those held by NUtech and not UNL) to influence the conduct of human subjects research, as these interests are already separate by definition. In his service on the NUtech Board of Directors, the Vice Chancellor for Research & Economic Development can provide input regarding potential impact on human participant research to the Directors and Officers of NUtech prior to its entering into any agreements that transfer equity to NUtech. Furthermore, the Deans and department chairs review and approve institutional conflict of interest plans developed by the CIRC, assuring that equity interests held by NUtech cannot influence the conduct of human subject research.

2.2 All senior university administrators are required to disclose their financial interests to the Nebraska Accountability and Disclosure Commission through the University of Nebraska Office of General Counsel, which is responsible for oversight of the disclosure and management of outside interests and activities of senior

administrators. If a senior administrator has a financial interest that relates to the conduct of research, the Office of General Counsel coordinates management with the cognizant campus officials and Research Compliance Services. Section 1.10.1 of the Board of Regents Bylaws requires employees to conform to the following guidelines:

- A.** Make certain that no outside activities interfere with the discharge of University obligations
- B.** Not have any substantial financial or personal interest in business transactions of the Corporation

2.3 The University Nebraska system (of which UNL is one of four campuses), has a separate incorporated foundation, NU Foundation, which is responsible for accepting and administering gifts on the behalf of the four campuses. The NU Foundation has well trained legal staff who determine whether donations meet the definition of a gift according to IRS regulations (i.e., have no deliverables, reporting milestones, or specified outcomes) before the donation is accepted and are responsible for managing any potential institutional conflicts associated with these donations. Foundation payout distributions as indicated in the gift to the campus are handled by UNL's Sponsored Programs office, a unit of the Office of Research with whom Research Compliance Services coordinates already for the management of conflicts of interest for sponsored research, which ensures that the same rigorous conflict of interest standards and processes are applied.