1.0 Purpose
The purpose of this SOP 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/orr/irbatunl.shtml](http://research/orr/irbatunl.shtml)). 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](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/orr](http://research.unl.edu/orr)).

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, biosketches, 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 protocol number, which includes the project ID, will be provided to the PI when the protocol is approved. This protocol number will be the identifier of the protocol for the life of the study.

All applications submitted for IRB review are screened by the IRB 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, Supervising Investigator, and other Participating Personnel) are currently CITI certified (required training in the protection of human participants - see HRPP policy # 3.009).

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.

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

Administrative Approval:

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<tr>
<th>Dan R. Hoyt, Ph.D.</th>
<th>Kimberly Andrews Espy, Ph.D.</th>
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<tr>
<td>IRB Chair</td>
<td>Associate Vice Chancellor for Research</td>
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1.0 Purpose
The purpose of this SOP 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 continuing 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 performance sites 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 approvable 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 clearly.

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 Confidentiality Certificate (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. 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 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).

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. **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.

6. **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.

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 conflict of interest of the principal investigators, which has been reviewed by the Conflict of Interest in Research Committee (COIRC) (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 of the investigator, which are judged by the IRB to be material 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 principal investigator. 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 in Research Officer.

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. A UNL staff member may be listed as the only project investigator.

4. For student projects, a UNL faculty member must be listed as the secondary investigator/advisor. A staff member or 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 performance 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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