

Guide to

the Institutional Review Board (IRB)

at the University of Nebraska–Lincoln



Who? What? When? Why? How?
of the IRB

1ST EDITION

This guide outlines the human subjects research review process at the University of Nebraska–Lincoln (UNL) and provides answers to the most common questions from the UNL research community. If you can't find the answer to your specific question, please contact Research Compliance Services at 402.472.6965 or nugrant-irb@unl.edu.



NOTE: Updates to this handbook will be posted at : <http://research.unl.edu/orr>

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UNL Organization Overview

What is Research Compliance Services (RCS)?

RCS focuses on five areas of compliance: Export Controls (EC), Conflict of Interest (COI), Responsible Conduct of Research (RCR), Research Misconduct (RM), and the Human Research Protection Program (HRPP). For purposes of this document, we will focus on the HRPP and specifically the Institutional Review Board (IRB) review process.

What is the Human Research Protection Program (HRPP)?

The HRPP is the centralized administrative office of the IRB. The IRB reviews all human subjects research conducted by UNL faculty, staff, and students in accordance with applicable federal regulations.

What is an Institutional Review Board (IRB)?

An IRB is defined as an administrative body composed of scientists, nonscientists and community members established to protect the rights and welfare of human research subjects recruited to participate in research activities.

Federal Agency Overview

What federal agencies oversee the protection of human subjects?

The Office for Human Research Protections (OHRP) and the Food and Drug Administration (FDA) are the primary agencies responsible for the oversight of human subjects research. These agencies are under the direction of the U.S. Department of Health and Human Services (HHS).

What is the Department of Health and Human Services?

HHS is the principal agency for protecting the health of all Americans. It is comprised of the Office of the Secretary and 11 operating divisions. The agencies perform a wide variety of tasks and services, for example, research, public health, food and drug safety, grants and other funding and health insurance.

For additional information regarding HHS please visit their website at <http://www.hhs.gov/>.

What is the Food and Drug Administration ?

The FDA is responsible for protecting public health by assuring that foods are safe, wholesome, sanitary and properly labeled; human and veterinary drugs, and vaccines and other biological products and medical devices intended for human use are safe and effective.

For additional information regarding the FDA please visit their website at <http://www.fda.gov/>.

What is the Office for Human Research Protections?

The OHRP provides leadership in the protection of rights, welfare, and wellbeing of subjects involved in research conducted or supported by HHS.

For additional information regarding the OHRP please visit their website at <http://www.hhs.gov/ohrp/>.



Federal Regulations that Govern the Protection of Human Subjects

What set of federal regulations does each federal agency implement and oversee?

The OHRP implements Title 45A – Department of Health and Human Services; Part 46-Protection of Human Subjects. (45 CFR 46)

The FDA follows a separate and distinct set of federal regulations. Title 21, Chapter 1-Food and Drug Administration, DHHS; Part 50-Protection of Human Subjects. (21CFR 50)

Does 45 CFR 46 have a specific name?

45 CFR 46 is also referred to as the “Common Rule”.

Why is it called the Common Rule?

It is called the Common Rule because several federal department and agencies have agreed to follow 45 CFR 46 in the protection of human subjects in research as a common regulation.

What agencies have agreed to follow the Common Rule?

- Department of Agriculture
- Department of Energy
- National Aeronautics and Space Administration
- Department of Commerce
- National Institute of Standards and Technology
- Consumer Product Safety Commission
- Agency for International Development (USAID)
- Department of Housing and Urban Development
- Department of Justice
- National Institute of Justice
- Department of Defense
- Department of Education
- Department of Veteran Affairs
- Environmental Protection Agency
- Department of Health and Human Services
- National Science Foundation
- Department of Transportation
- Central Intelligence Agency

Federal Regulations that Govern the Protection of Human Subjects

Are there other regulations that investigators need to follow?

Yes, even though departments and agencies have pledged to follow the Common Rule, many have additional regulations that apply to human subjects research.

NOTE: Specific state laws may affect research design as well.

How does OHRP know that UNL and all affiliated researchers are following the Common Rule?

UNL has established a Federalwide Assurance (FWA) with OHRP that specifies UNL will review ALL human subjects research projects in accordance with the Common Rule (45 CFR 46).

The following are the OHRP registration numbers for UNL's FWA and IRB:

FWA: 00002258

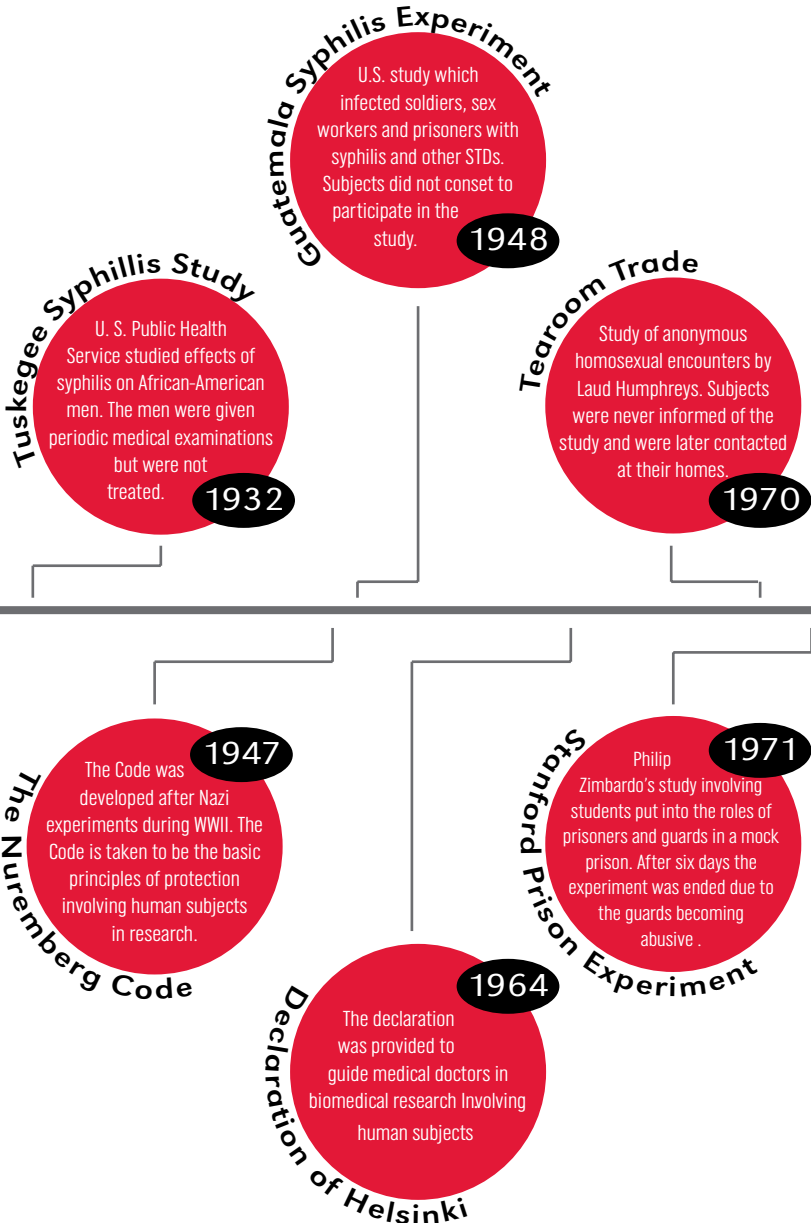
IRB: 00000672

NOTE: The FWA and IRB registration numbers are specific to UNL. Each Nebraska University campus operates under separate FWAs and IRBs.



Why is an IRB necessary?

There are several historical events causing the formation of an IRB and unfortunately also current events that continue to illustrate the need for an IRB.





Frequently Used IRB Terminology



NOTE: the following definitions are based upon human subjects research terminology.

Research

Research is a systematic investigation that involves a prospective plan which incorporates data collection, either quantitative or qualitative. Data analysis is conducted to answer a research question or objective that will either develop a theory or contribute to generalizable knowledge. This knowledge may be applied to populations outside of the specific study population and/or inform policy.

Quality Improvement or Evaluation

Quality Improvement or Evaluation is defined as an activity that is specifically initiated with a goal of improving the performance of a practice in relationship to an established standard.

For example, the Research Compliance Services office may choose to conduct a survey among UNL investigators to obtain feedback for program evaluation and improvement.

Human Subject

A human subject or a respondent is a living individual that provides data to an investigator through intervention, interaction and/or identifiable private information.

Project

The project would be considered to include all steps that the investigator would undertake to go from theory to publication, or the long-term process. This is commonly confused with the term protocol.

Protocol

The protocol would include logistical procedures, documents, scripts, and templates that will be reviewed by the IRB and subsequently followed by the investigator to conduct the project.

Form

The term form is used to describe the application that will be completed by the investigators to submit for IRB review. Forms would include the new protocol, continuing review, and change request.

Minimal Risk

Minimal risk is defined as the probability and magnitude of harm or discomfort anticipated in the research and is not greater than those risks ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.

De-identified

The term de-identified indicates that the data does not contain information that would link a participant's identity with the data collected.

UNL Human Subjects Research Review

Who reviews human subjects research affiliated with UNL?

UNL's IRB reviews all human subjects research protocols.

Who determines if an IRB review is required?

The RCS staff will initially make the determination if IRB review is required.



NOTE: The investigator should not determine whether IRB review is required. If you are unsure that your project would require review, please contact the RCS office at 402.472.6965.

When is it required?

IRB review should ALWAYS be sought before the research has begun.

Who are the IRB members?

The IRB consists of rotating faculty and staff from varying disciplines, backgrounds and expertise. The IRB also includes community members.

Does federal regulation dictate an IRB membership?

Yes, as listed within 45 CFR 46, an IRB must contain at least five members of various backgrounds, at least one community member not affiliated with the institution, and at least one non-scientist.

Research Category Review

Are there different categories in which the IRB can review a protocol?

Yes, the IRB will review protocols within three different categories:

- Exempt**-less than minimal risk
- Expedited**-minimal risk
- Full Board**-greater than minimal risk



NOTE: UNL's IRB will review each project based upon the protocol and may change the review level at any point during the project if the IRB sees fit based upon 45 CFR 46.



Exempt

What is Exempt (EX) Research?

Exempt research involves less than a minimal risk level and may not be subject to all federal regulations. However, this research may still be subject to all applicable state laws and institutional policies.

What types of research could be reviewed under the Exempt category?

- 1) Research conducted in established or commonly accepted educational settings involving normal educational practices.
- 2) Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior to obtain non-sensitive data.
- 3) Research involving elected or appointed officials and all identifying information remains confidential for the life of the data.
- 4) Research involving the collection or study of EXISTING public and/or unidentifiable materials.



NOTE: Exemption #2 does not apply if:

- The participant can be identified AND it would cause them harm to be identified.
- The research involves surveys, interviews or participant observation with children.
- The research involves observation of sensitive aspects of a participant's behavior.



NOTE: ALL data to be included within a secondary data analysis protocol must exist at the time in which the research starts. If data will be added through a future primary data collection process, the protocol cannot be reviewed at an Exempt review level.

- 5) Research involving the study of public benefit or service programs.
- 6) Research involving a taste and/or food quality or consumer acceptance study.

Expedited

What is Expedited (EP) research?

Expedited research involves no more than a minimal risk level.

What types of research are acceptable under the Expedited category?

- 1) Clinical studies of drugs and/or medical devices.
- 2) Collection of blood samples by finger stick, heel stick, ear stick, or venipuncture.
- 3) Prospective collection of biological specimens for research purposes by noninvasive means.
- 4) Collection of data through noninvasive procedures routinely employed in clinical practice, excluding procedures involving x-rays or microwaves.
- 5) 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).
- 6) Collection of data from voice, video, digital or image recordings made for research purposes.
- 7) Research on individual or group characteristics or behavior.
- 8) Research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation or quality assurance methodologies.



NOTE: An “Expedited” review level does not indicate that the review will be conducted faster than other projects.

Full Board

What Research is Reviewed under the Full Board (FB) Category?

Full Board research involves greater than minimal risk, may include vulnerable populations or cannot be reviewed by using an EX or EP category.

How are protocols reviewed during an IRB meeting?

The lead reviewers are assigned to each full board protocol based upon their expertise and they lead the IRB group discussion.

What does an IRB examine when reviewing a protocol?

The IRB must ensure that subject selection is equitable, coercion is minimized, risks and benefits are proportionately reasonable and the participant is informed appropriately.

Is a quorum required for an IRB to vote on a Full Board protocol?

Yes, a quorum (more than half of the members present) is required for a vote on a protocol. If quorum is not met; the meeting will be adjourned and the protocol will be placed on next month's agenda.



NOTE: To be eligible for review, all FB protocols must be submitted by the first business day of each month.

Not All Projects Require Approval

What projects are not required to be submitted for IRB approval?

- Class projects
- Pilot procedures that will not be included within the research analysis
- Quality improvement (QI) or evaluation projects.

What if the RCS office determines that a project does not require IRB review, can the data still be published?

Typically, QI or evaluation information can be published, but the results CANNOT be called research within publications. If the author wishes to establish this information as “research” then IRB approval would be required.

When should the RCS office be contacted to make this determination?

It is ALWAYS best to contact the RCS office before data collection has begun. IRB approval cannot be granted if the research has already started or been conducted.



NOTE: Theses and dissertations are not considered class projects. They must be reviewed by the IRB.

NUgrant: An Electronic Submission System

How is a human subjects research protocol submitted to the IRB for review?

Research protocols are submitted through UNL's electronic submission system, NUgrant.

Where can NUgrant be found?

<http://nugrant.unl.edu>.

What is used to login to NUgrant?

Blackboard login information will give access to NUgrant.

What if Blackboard login information is unknown?

If you do not know your Blackboard login information, you will be required to contact UNL's Your Help Center at <http://www.unl.edu/helpcenter/>

What if someone has never used the NUgrant system?

Start by creating an account when logging into the NUgrant system. NUgrant will ask the user to identify their role (more than likely investigator) and department.

Are NUgrant training sessions offered?

Yes, there are several training sessions offered throughout the academic year.

Where is information about the training sessions found?

Training session dates and times vary and are posted on the NUgrant login page or on the NUramp homepage at <http://research.unl.edu/nuramp/workshops.shtml>.



NOTE: Please contact the RCS office at 402.472.6965 to request additional information about training.



IRB Forms: The Application Phase

What forms are completed within NUgrant?

There are four forms that are reviewed during different stages of a project depending on the review level (EX, EP, FB): A New Project, Change Request, Continuing Review, and/or a Final Report form.

What information is included in each form?

New Project

The New Project form provides the overall information to the IRB about the participants, research methods, purpose, procedures, confidentiality of the data, informed consent process, and how the research results will be shared.

Change Request

The Change Request form provides specific details about procedural changes to the originally approved protocol. Changes may include introduction of a new measurement, removing a measurement, recruiting additional participants, increasing compensation, etc.



NOTE: A change request must not change the overall purpose of the originally approved protocol.

Continuing Review

The Continuing Review form provides a review of the previous year of the protocol, while summarizing any changes over the past year as well.

This form is not required for EX protocols.

Final Report

The Final Report form provides a brief summary of the research results to the IRB.

In addition, this form will provide detailed information regarding the total amount of participants that were involved, if there were any problems reported, and the finalized funding source of the project.

Problem Report

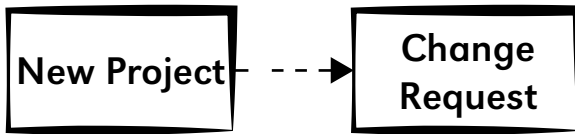
The Problem Report form is submitted directly to the RCS office and NOT through NUgrant. **This MUST be completed within 24 – 48 hours after an unforeseen event, adverse event, or unanticipated problem has occurred with the project.** Examples of possible “problems” could include injury of a participant, not following protocol procedures, a complaint from a participant, etc.



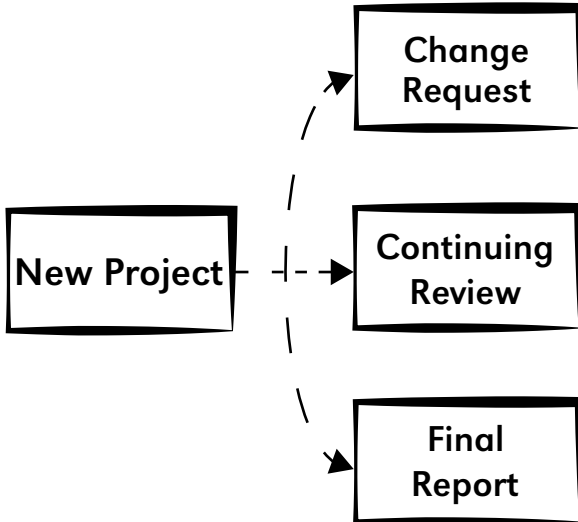
NOTE: A problem report must be submitted regardless of the review category.

IRB Forms: The Application Phase

Exempt Review




Expedited & Full Board Review



No Revisions Requested

How can I get a protocol to be approved with no revisions requested?


- Use clear, detailed and complete descriptions.
- Use lay terms and do not include scientific terms especially when describing the project's purpose and procedures.
- Upload all appropriate supporting documents.

 **NOTE: Each section of the protocol where a required document can be identified has been denoted with an asterisk (*) in pages 21-34 when specifically discussing a New Project form.**

- Obtain all appropriate approvals from outside institutions/ organizations/sites involved in the project prior to submission.

What supporting documents could be included within the protocol?

Advertisements, fliers, handouts, bulletin postings, reminders, email messages, phone scripts, invitations, postcards, thank you cards, informed consent documents, informed assent documents, private health information authorizations, all surveys, questionnaires, images, introductions, recruitment scripts, assessments, standardized assessments, funding applications, site permission letters, confidentiality agreements, etc.

 **NOTE: A general rule of thumb: Any document that the participant will see, use, hear, etc. will require review.**



New Project Submission via NUgrant

Pages 21-34 will discuss each section (1-9) of a New Project form..

The following information has been developed to provide direction and explanation of the IRB application process. Please understand that the IRB may request additional information.



NOTE: The following pages do not include all sections of a New Project form. If the following pages do not address a specific section that is still in question, please feel free to contact the RCS office at 402.472.6965.




Section 1

Project Information

Section 1 within a New Project form discusses basic logistical information about the project. For example, this page identifies the investigators, the estimated timeline of the project, any collaborating institutions and any funding associated with the project.

(1.1) Project Title

The title of the project should reflect the project's purpose. It should be included on all applicable documents.

 **NOTE: If the project is routed through the Office of Sponsored Programs, please match the title of the NUgrant proposal with the title of the NUgrant IRB protocol.**


(1.2 & 1.3) Investigators

As the project's principal or secondary investigator, it is your responsibility to ensure that ALL research procedures are conducted as described. To ensure that the proper guidance and supervision is provided on all IRB projects, a faculty member must be present as either the PI or SI on ALL student research.

This policy would still apply if you are a staff member and are conducting research as a student.

(1.5) Outside Entity

Generally, if a project involves an outside entity, approval or permission documentation to conduct research MUST be uploaded with the New Project form. *Please see page 36.*

 **NOTE: UNL has a strong collaborative relationship with the Lincoln Public Schools (LPS) District Evaluations and Assessment team. Protocols are reviewed by both institutions through the NUgrant system.**

Section 1 Project Information

(1.8) Present/Proposed Funding Source

The CURRENT funding source(s) is a very important piece of information for the IRB. The IRB reviews each protocol in accordance with specific funding agency regulations and policies.

(1.9 & 1.10) Project Start and End Dates

A project's start date indicates when the project will begin, not when the New Project form is created via NUgrant.

A project's end date is at the completion of data analysis using identifiable information.

(1.11) Multi-Institutional Study

Please list all institutions that will be involved within the research. This section identifies collaborative relationships among investigators and helps the RCS office in determining if an Authorization Agreement between IRBs can be formalized.



NOTE: UNL is not permitted to enter into Authorization Agreements with institutions that do not have a Federalwide Assurance on file with OHRP.
Please see page 6.



Section 2

Project Information Continued

Section 2 within a New Project form asks questions about the project's proposed methodology, the involvement of data sources, biological specimens and/or the possibility of the inclusion of elected officials. The following information is based upon the most common questions received by RCS regarding Section 2.

Some of these questions don't apply to my research. Do I still have to answer them?

Yes, this section is used by the NUgrant system to categorize the protocol (EX, EP, FB) before it is submitted to the RCS office.

What if the NUgrant categorization is not correct?

NUgrant conducts a preliminary categorization of the protocol based upon specific responses to protocol questions. Once the protocol is submitted to the RCS office, the assigned IRB Coordinator and/or the IRB will make the final category (EX, EP, FB) determination.

What if I don't answer some of these questions "right" the first time?

This section should be completed to the best of the investigator's ability. When the IRB begins the review process, this section can always be revised to be consistent with IRB requirements.



Section 3

Description of Participants

Section 3 within a New Project form seeks specific information about the potential participants. The IRB will base many of its considerations and determinations on the characteristics of the population. For example, a competent adult above the age of 19 is far less vulnerable than a child at the age of 10.

(3.2) Special Groups Checkbox

Please mark only those groups that will be intentionally recruited for inclusion within the protocol. (e.g. pregnant women should not be marked because there could coincidentally be a pregnant woman taking a survey about teaching instruction)

(3.5) Participant Characteristics

Describe each population separately. For example, if the research will include parents and their children, the parent population should be described separately from the child population.

(3.6) Access to the Population

Describe in detail the ability to obtain access to the population included within the research.

Be aware of any potential conflicts of interest or coercive recruiting techniques that could be present. For example, the IRB generally discourages the direct recruitment of one's own students.

(3.8) Persons Assisting with the Research

Describe the training that research personnel will undergo to conduct the research.



NOTE: It is a common error to answer section 3.8 with the perspective of the participant in mind. This should be answered with a description of the research personnel training process (i.e. CITI, weekly meetings, training sessions, etc.).

(3.9) Additional group exclusionary criteria

Describe any populations that will be excluded from the research and provide a scientific justification to support the exclusion. This section should not include additional primary sample population exclusionary criteria; all primary sample population criteria should be included within section 3.5.

Section 4

Unique Research Methodology or Data Sources

Section 4 within a New Project form describes the project’s methodology. The following “tips” can be used to provide a detailed description within each section.

(4.1) Audio-recording

Audio-recording can change the anonymous vs. confidential dynamic within the research procedure. If you are including audio-recording procedures within the research, please be sure to include a description of this within the informed consent form (ICF). The ICF should allow the participant to clearly agree or disagree to audio-recording procedures. This can be accomplished by including a check-box system within the ICF.



NOTE: Research cannot be both anonymous and confidential; however, research could be confidential and then become anonymous if identifiers are removed and reported in summarized form.

(4.2) Web-based research

Describe the software or survey company that will be used to conduct the research along with answering each specific question within this section.

Each software package is unique and some programs even let the user choose additional services. For example, some services allow paid or free use of their product and the level of security can vary widely.

(4.3) Protected Health Information*

The National Institutes of Health (NIH) define Protected Health Information or “Private” Health Information (PHI) as information that is obtained about a participant through a covered entity such as a medical facility, insurance company, etc. Section 4.3 should specify each piece of information that will be obtained from the person’s medical record.

A PHI Authorization (or medical release form) is required to also be completed by the participant prior to any information being obtained from the participant’s file. A template of this form can be found at <http://research.unl.edu/orr>.



NOTE: If health information is obtained through a self-disclosure process, the information obtained is NOT considered PHI due to the source of the information.


A waiver of authorization, typically in medical chart review projects, can also be obtained if specific justifications and requirements can be met. If you would like to request a waiver of PHI Authorization, please contact RCS at 402.472.6965 for additional information.

Section 4

Unique Research Methodology or Data Sources

(4.4) Genetic Data, Sampling and Analysis

Describe an exact description of the process, purpose and its justification for the inclusion of genetic data and sampling. For example, why is genetic information of the given population important to be able to achieve the project's objectives?

 **NOTE: If genetic information will be obtained, the research must be in compliance with all applicable regulations under the Genetic Information Nondiscrimination Act of 2008.**

(4.6 & 4.7) Photography & Video-recording


Provide specific details regarding the content of the pictures and videos that are intended to be included within the research process. For example, will the participant's face be included? Will the images include facility content? When and how will the photos and/or videos be destroyed?

Also, please describe if the photos or video-recording will be used during the data reporting or publication process.

(4.8) Secondary Data

The IRB must review research involving the use of secondary data, specifically when the data is not publicly accessible.

If the data is NOT publicly accessible a full description is required to include all data fields that will be accessed. In some cases, a data use agreement may be required.

 **NOTE: Defining public accessibility is tricky. For example, if you can Google the information or find it in a public library then the data is most likely public.**

(4.9) Biological Samples

Describe the types of samples that will either be primarily collected from the participant or collected from a third-party vendor. Also, describe if the samples will be identifiable or de-identified.

Include a description of the sample analysis process. For example, where will the sample will be analyzed? How will the sample be transported? Will the sample be identifiable to the person conducting the analysis?

Section 5

Purpose, Methods & Procedures

Section 5 within a New Project form provides a detailed description of the project's overall purpose, scientific support and methods used to achieve a research hypothesis.

(5.1) Purpose

Provide a brief literature review and scientific justification in lay terminology regarding the purpose of the research.

(5.2) Methods and Procedures*

Describe in detail all research procedures that each population included within the protocol will complete. Such procedures could include assessments, measurements, interviews, surveys, observations, etc. Please upload all applicable supporting templates/documents within section 9 of the New Project form.



NOTE: Sections 5.1 and 5.2 should always be written with the use of lay terminology. (i.e. scientific jargon should be omitted)

(5.3) Participant Time Requirement

Describe the time required for each method and procedure, while also including an overall time requirement.

(5.4) Reminders*

Describe the process that will be followed when conducting a reminder follow-up with the participant. Specifics should include how many reminders will be sent and if reminders will only be sent to non-responders or if they will be sent to the entire sample.

Template documents/scripts of reminder communication should be uploaded within section 9 of the New Project form.

Section 6

Recruitment, Benefits & Risks

Section 6 within a New Project form describes the participant recruitment process, the benefits and risks of the research.

(6.1) Names and Contact Information

Describe how and why you have access to the participant population. Again be aware of any conflict of interest that may exist with the access or any coercive recruitment techniques as described on page 31.



NOTE: Include necessary documentation of all required permissions to access the population.

(6.2) Recruiting Participants*

Describe each recruitment strategy and upload all applicable supporting templates/documents.

(6.3) Research Benefits

Describe the potential research benefits to both the participant and society but do not overstate the benefits as this may cause participant confusion. If there are no direct benefits to the research participant, it is okay to state there are no direct benefits.

(6.5) Medical Availability

Describe the availability of medical accessibility if needed. This section should be consistent with the risks that are stated within section 6.4 of the protocol. For example, if there are no known risks, it is okay to state that medical resources are not applicable.



NOTE: If medical resources are required to be offered on account of the content of the research and population included, the resources should be relevant and local to the participant.



Section 6.6

Incentives & Compensation

Section 6.6 within a New Project form requests information regarding the incentive and/or compensation that will be offered during the research process. Research participation should be “revenue neutral”; however, compensation can be considered to offset the cost of a participant’s time, effort, transportation, etc. required for the research to be conducted.

(6.6) Description of Compensation

The specific amount and type of payment (i.e. cash, gift card, check, extra credit, research credit, etc.) to be made must be included. Generally, incentives or compensation should not affect the participant’s ability to reasonably decide to participate.

Student Extra Credit

The IRB encourages the amount of extra credit to be less than 2 percent of the overall possible course points. An alternative activity for extra credit must be offered to all students to allow the same opportunities for those who do not wish to participate in the research.

Lotteries

Lotteries are becoming a widely used incentive for participation. If a lottery would be included specify the odds of winning the lottery and a date of when the winner will be notified within the protocol and the informed consent form.



NOTE: The alternative activity must be equal in time and effort to participation in the research.

Section 6.6 Incentives & Compensation

Federal or State Funded Projects

UNL must also adhere to all record-keeping requirements of federal, state or grantor agencies. In doing so, proper documentation of incentive or compensation records must be recorded for all payments made to research participants.

NOTE: This would also include all UNL funds such as layman awards, department funds, etc.

If a single payment for research incentive or compensation is greater than 50 dollars, the participant's social security number will be required to be collected.

Payment receipt templates are available on the Office of Research Responsibility's website at <http://research.unl.edu/orr/>.

NOTE: Compensation is NOT considered a research benefit and should not be included within benefit descriptions.



Section 7

Participant Consent

Section 7 within a New Project form discusses the process that will be followed to obtain a participant's consent. A voluntary consent process is one of the most important processes of the research procedures and one of the pillars that an IRB strives to maintain. The consent process should always be thought of as a discussion between an investigator and a research participant.

(7.2) Conducting the Consent Process*

NOTE: Obtaining consent from a participant should be thought of as a process and not just a form.

An investigator has an obligation to ensure that the participant fully understands all elements of the project before they provide their consent.

All personnel involved in a consent process must be included within the project personnel list and all applicable supporting consent templates/documents should be uploaded within section 9 of the protocol application.

(7.5) Coercion or Undue Influence

Describe any pre-existing relationship(s) between an investigator and the participant, and what processes will be followed to minimize possible participant coercion.

(7.6 & 7.7) Consent Language

Appropriately translated versions of all documents will be required to be uploaded via NUgrant if a language other than English will be used during the research procedures.

NOTE: Please contact the RCS office at 402.472.6965 if the language being used is not a written language or you are unable to secure translated documents.



Section 7.9

Consent Waiver

(7.9) Consent Waiver

If a waiver request is applicable to the protocol, provide a clear justification as to why consent, assent or an element of consent/assent such as signature will be requested to be waived by the IRB.

(7.9.a.) Type of Consent Waiver

Specify what type of consent waiver will be requested. For example, will a waiver of parental consent, child assent, or consent signature be requested?

(7.9.b.) Rights of the Participant

Specify if the participant will be required to waive any rights (i.e. legal, personal, etc.) if the IRB would grant a waiver.

Also, specify if the participant could be harmed (i.e. physically, emotionally, etc.) if the waiver is granted. For example, if parental consent is waived, could a participating minor be in a vulnerable position to not fully understand the procedures and research implications?

(7.9.c.) Research Feasibility

Describe why the population should be included within the research. For example, what characteristics does the population possess that if excluded it would compromise the validity of the research?

Also, this section should explain why the consent, assent, or element of consent cannot be obtained.

(7.9.d.) Additional Information

Specify if the participant will be provided additional project-related information. For example, a debriefing process immediately following the procedures or a follow-up process after the project analysis is complete are ways in which the participant could receive additional information.

Section 8

Confidentiality & Data

Section 8 within a New Project form discusses the procedures used to maintain confidentiality or anonymity within the research. Throughout this section it is important to note that there are differences between confidentiality and anonymity. If someone would be able to trace the responses back to the participant, then the investigator should maintain the participant's confidentiality. If people, including the investigators, do not interact with the participant or collect identifying information about them, then the investigator would maintain the participant's anonymity.

(8.1) Confidentiality

Describe the maintenance of the data in terms of confidentiality. This should also be specific to the research protocol. For example, if you are conducting an online survey, then the records would typically be maintained in an online secure server that is password protected. Likewise, if paper records are maintained, the files would be kept in a locked office accessible to only the investigators.

(8.2) Identified During Data Collection

There are many research projects where the investigator knows the identity of the participant. An investigator should maintain a participant's confidentiality throughout the project. This section should reflect as such.



NOTE: A participant is considered identifiable if a list linking names and participant ID codes is maintained separate from the data.

(8.6) Reportable Data

Describe how the data will be reported (e.g. aggregate form or specifically identifying participants) and how the results will be used. For example, the results could be used as a class project, thesis, scientific journal, conference presentation, publication, etc.



Section 9

Attachments & Comments

Section 9 within a New Project form should include all documents that will be seen, heard, or used by the participant during the course of the research project from the recruitment phase to the debriefing phase, if applicable.

Many common documents that are required to be reviewed by the IRB would include but are not limited to the following items:

- **Advertisements**
- **Fliers**
- **Handouts**
- **Bulletin Postings**
- **Reminders**
- **Email Messages**
- **Phone Scripts**
- **Invitations**
- **Postcards**
- **Thank You Cards**
- **Informed Consent Documents**
- **Informed Assent Documents**
- **Private Health Information Authorizations**
- **Surveys**
- **Questionnaires**
- **Images**
- **Introductions**
- **Recruitment Scripts**
- **Assessments**
- **Standardized Assessments**
- **Funding Applications**
- **Site Permission Letters**
- **Confidentiality Agreements**

Routing an IRB Form

What is the next step after completing a form?

Each form must be “routed” to the RCS office for IRB processing. The routing process will be completed in Step 2 of the NUgrant protocol.

How do I access step 2 or start routing the form?

The routing process can be accessed through two different areas via NUgrant:

- Click on “Step 2” when on the IRB New Project form page
- Click on “Routing Signatures” under the workflow steps on the left-hand side of the form summary.

How is an IRB form routed?

To route the form, the primary and secondary investigator, if applicable, will be required to approve and electronically sign the form.

How is a form electronically signed?

NUgrant login information will again be used during this process to sign the form.



NOTE: Before signing an application and routing it to the RCS office for IRB review, each investigator should review the protocol application and ensure that all information included is clear, concise and accurate.

What if the second person signing the form would like it revised?

There are two options during the routing process. Either the investigators can approve the project and it gets submitted to the RCS office or revisions can be requested.



NOTE: If revisions are requested during the routing step, the applicable investigator will be notified via email.

What happens after the routing process has been completed?

The IRB review process will begin within seven days of the RCS office being notified via email upon the date of the form’s submission.

Outside Entities

Do I need to get approval from outside entities prior to UNL IRB approval?

Yes, approval documentation from the appropriate signatory official(s) will need to be included with the form prior to submission.

What should be included in the approval documentation?

The approval document should be on company/organization/institutional letterhead. Documentation should include specific statements to illustrate that the organization fully understands what they are being asked to perform or provide.

What if the research will be conducted within the LPS District?

The LPS District reviews all UNL research applications via NUgrant. If working with LPS, please complete and submit your New Project form via NUgrant.



NOTE: For additional information regarding LPS review please refer to the LPS District approval help document on the ORR's website at <http://research.unl.edu/orr>.

What if I am collaborating with another University that has their own IRB? Do I need to get their IRB approval as well?

First, the research team should determine who the lead researcher or Primary Investigator will be. When this has been established please contact the RCS office at 402.472.6965 to discuss the appropriate process.

Project Personnel & Assistants

Are there other items that are required in addition to the New Project form to obtain IRB approval?

Yes, the following items will be required to be completed before the RCS office will process IRB approval.

- All personnel must be listed on the project summary page.
- All personnel must have the appropriate human subjects research training. *Please see page 39.*
- All personnel must complete a project specific conflict of interest disclosure. *Please see page 41.*

Who would be a personnel member?

Any member of the research team who interacts with a participant, obtains informed consent, has access to identifiable data, or analyzes collected data should be identified as a personnel member.

Who would be an assistant?

Assistants are anyone who needs to have access to the IRB protocol via NUgrant. This person may or may not be a personnel member depending on their role.



NOTE: An assistant can view, add or edit any information within the IRB protocol.

Project Personnel & Assistants

How is the personnel list updated?

From the project summary page, click the “Add Personnel” button. A personnel member can be deleted from the personnel list by also clicking on the “Remove” button

When should the personnel list be updated?

The personnel list should be updated each time there is a change in personnel.

What if there are more than two individuals who are considered lead investigators?

Any personnel member can be added as an assistant within the project to provide them full access to the project within the NUgrant system.



Human Subjects Research Training (CITI)

How do investigators complete human subjects training?

UNL uses the Collaborative Institutional Training Initiative (CITI), a web-based program, to provide an educational access to the federally required human subjects training curriculum at www.citiprogram.org.

Who needs to complete CITI training?

All investigators conducting human subjects research are required to complete the proper CITI training course. This includes faculty, staff, students and any unaffiliated collaborators.

What course is required and when?

Most UNL investigators will complete the Group 2 Social/Behavioral module, but it is required that a **BASIC** course is completed before a refresher course.

How does UNL's RCS office know when human subjects training has been completed?

CITI completion records are accessed regularly through the CITI website and updated manually within the NUgrant system.

Are investigators required to take a human subjects training course annually?

No, each course (basic and refresher) is valid for three years, and is required to be completed and/or updated prior to IRB approval for any form submitted via NUgrant.



NOTE: If your record has not been updated within the NUgrant system within 5 days of completion, it is your responsibility to find out why this is currently listed as not valid. You may have completed the wrong course.

Human Subjects Research Training (CITI)

What modules are offered via CITI?

Each module includes a basic and a refresher course.

Group 1: Biomedical Investigators and Key Personnel

- Research with a medical base

Group 2: Social/Behavioral Research Investigators and Key Personnel

- Research with a social behavioral base

Limited Research Worker

- This module is intended for those whom are ONLY providing data entry or transcription services within the project procedures. No graduate level students and faculty members should complete this training.

Responsible Conduct of Research (RCR)

- This module is ONLY optional and will NOT satisfy the human subjects research training requirement. Nor will it satisfy the UNL RCR training program for National Science Foundation (NSF) requirements.
- Undergraduate students, graduate students and post-doctoral fellows may be required to complete an RCR training course through UNL's Blackboard system if paid from NSF supported projects. If this is required each student will be notified to complete this course.



NOTE: The Basic course in each module is required to be completed prior to any refresher courses.

Conflict of Interest

What is a conflict of interest and why is reporting a requirement?

A conflict of interest is any situation that may have a real or perceived influence on the research results. The IRB requirement will specifically ask about any financial interest or conflict of commitment that you may have that is specific to the IRB project under review.

NOTE: Salaries or wages from grant funding is a typical procedure and is not considered a conflict of interest. Conflict of interest reporting is required based upon UNL policy, UNL HRPP policy, and state and federal regulations.

For additional information regarding conflict of interest, please visit the Research Compliance Services' webpage at <http://research.unl.edu/orr/conflict.shtml>.



Review Timelines

How long does it take to receive an IRB approval?

Approval time varies depending on the number of protocols under review, the quality of the protocol submitted and the amount and content of the revisions that were requested.

- **Exempt Review** typically requires three weeks for a determination.
- **Expedited Review** typically requires four weeks with review conducted by one member of the IRB.
- **Full Board Review** typically requires at a minimum one month for review by the convened IRB.

How long does it take for communication from the RCS office?

Typically, communication is received within seven days of each step in the IRB review process.

What is a “status”?

A status indicates where the form is at within the review process. (e.g. submitted to RCS office)

When can I tell a new status was posted?

Each status will have a timestamp associated with it within the NUgrant system pinpointing the date in which each status was completed.

When a form is listed at a “revisions requested” status, how much time is allowed to complete the required revisions?

New Project form revisions are allowed fourteen days for re-submission.

This deadline will shift based upon the form that is under review. For example, continuing protocol forms are allowed seven days for re-submission.



NOTE: Approval timelines may fluctuate depending on the time of year the protocol was submitted, the quality of the protocol submitted, and the quantity of information presented within the protocol.

Please be aware that the RCS office is busiest during the academic year and this may cause delay in the approval of your project based upon the volume of protocols that are currently being reviewed.

Post IRB Approval

How is a notice of IRB approval communicated?

An approval email will be sent to the Primary and/or Secondary Investigator, if applicable. In addition, the official approval letter will be available upon signature from the appropriate official.

Where will the official approval letter appear?

The form's official approval letter can be found in the "Form Messages" and is typically available within one week of approval being processed by the RCS office.

Where will stamped informed consent documents appear?

After the form is approved, the stamped versions of the consent/assent documents are available within the form files.

Does NUgrant provide reminders for important dates to remember?

Yes, the NUgrant system will send automatic reminders for many important dates based upon a project's review level including:

- A reminder 30 days before your CITI training expires. *Please see page 39-40.*
- A reminder 60 days, 30 days and 7 days prior to the lapse of an Expedited or Full Board project's valid-until date.

A continuing review protocol should be approved prior to the lapse of the valid-until date. Please allow at least three weeks for review and approval of a continuing protocol.



NOTE: Although, the NUgrant system does provide "reminders", it is the investigator's responsibility to keep all requirements updated throughout the life of the project.



Quick Reference, Templates & Contact Information

Document Templates

The Office of Research Responsibility's website houses templates to help create documents for your protocol. You can find these templates at <http://research.unl.edu/orr/forms.shtml>.

Contacts and supplemental resources

Research Compliance Services

- 402.472.6965
- <http://research.unl.edu/orr/humansubjectsresearch>

Conflict of Interest (*see page 41*)

- <http://research.unl.edu/orr/conflict>

Research Misconduct (Falsification, Fabrication, or Plagiarism)

- <http://research.unl.edu/orr/misconduct>

Institutional Animal Care Program (IACP) and/or the Institutional Animal Care and Use Committee (IACUC) (any protocols involving animals)

- 402.472.4486
- <http://research.unl.edu/orr/iacp.shtml>

Institutional Bio-Safety Committee (IBC) (any protocols that use genetic cell lines, blood pathogens or samples such as DNA)

- 402.472.9554
- <http://ehs.unl.edu/committees/#ibc>

Export Control Program (ECP) (any protocols that will conduct research with or in countries that are sanctioned by the US; or international travel)

- 402.472.6965
- <http://research.unl.edu/orr/exportcontrol>

Department of Health and Human Services (DHHS)

- <http://www.hhs.gov/>

Office of Human Research Protections (OHRP)

- <http://www.hhs.gov/ohrp/>.

National Institutes of Health

- <http://www.nih.gov/>

Collaborative Institutional Training Initiative (CITI)

- <https://www.citiprogram.org/>

UNMC- /Nebraska Medical Center/ IRB

- <http://www.unmc.edu/irb/>

UNK IRB

- http://www.unk.edu/academics/gradstudies/irb/Institutional_Review_Board/

Notes

This handbook has been developed for use as an educational tool and quick reference document. Please contact the Research Compliance Services office at 402.472.6965 with any additional questions.



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