How to get approval of the IRB?
The investigator should follow the most recent Policies and Procedures (http://research.unl.edu/orr/forms.shtml) and submit an electronic request for review to the IRB Office providing a complete description of the procedures to be used in the research and identifying the research participants. These are reviewed for proper status and forwarded to the IRB, unless exempt. **Projects cannot be started before final approval by the IRB.**

Investigator Responsibilities
When IRB approval is received electronically by the investigator, it is his/her responsibility to follow the procedures that have been approved. If changes in procedures, number of subjects, location of research, etc. are needed, these changes must be approved by the IRB before they are started. It is the investigator's responsibility to provide a yearly update on the progress of the project and to inform the IRB at completion of the project.

UNL Human Research Protection Policies and Procedures are available online at:

http://research.unl.edu/orr/forms.shtml

If you have any questions, concerns, complaints, or suggestions about human research at the University of Nebraska-Lincoln, contact:

Dr. Daniel Vasgird
Director of Research Compliance Services

Human Research Protections Program
Office of Research Responsibility
209 Alexander Building-West
312 N. 14th Street
P.O. Box 880408
Lincoln, NE 68588-0408

Phone (402) 472-6965
Fax (402) 472-6048

Email: irb@unl.edu

Human Subjects

Institutional Review Board

University of Nebraska-Lincoln

Human Research Protections Program

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UNIVERSITY OF NEBRASKA-LINCOLN INSTITUTIONAL REVIEW BOARD (IRB)

What is the IRB?
The IRB is an administrative body established to protect the rights and welfare of human research participants.

The Department of Health and Human Services (DHHS) and the Food and Drug Administration (FDA) human subjects regulations are codified in Title 45 Part 46 of the Code of Federal Regulations (CFR). These are the regulations under which the IRB operates. This CFR requires that for an institution to be eligible for federal grant money, the institution must have an IRB and an assurance document approved by the National Institutes of Health.

IRB Administration
The Associate Vice Chancellor for Research is the Institutional Official for the IRB. The Research Compliance Services (RCS) Office coordinates the IRB. The UNL IRB is made up of faculty and community members.

All IRB applications are to be done online through the electronic NUgrant research administration system: https://nugrant.unl.edu

What research must be reviewed by the IRB?
All research projects involving human participants, conducted by UNL faculty, staff or students, must be reviewed. *Research,* for this purpose is defined as, a systematic investigation designed to develop or contribute to general knowledge. Research projects that fit under this classification include but are not limited to, surveys and questionnaires, personal interviews, physical testing, diagnostic sample collection, etc.

Kinds of Reviews
There are three levels of review. The level of review depends upon the vulnerability of the participant and the risks involved.

Exempt: This is research with less than minimal risk to non-vulnerable participants. Exempt reviews are handled in the RCS office for review, approval, and numbering. Research in this category is exempt from certain requirements, but not exempt from review.

Expedited: This involves research that is minimal risk to non-vulnerable participants. This research is reviewed by the IRB. The IRB Chair or Vice-Chair does the IRB review. The reviewer's comments are returned to the IRB office. If changes are requested, the IRB coordinator refers these to the investigator for consideration.

Full Board Reviews: Full board reviews are required for projects that involve vulnerable participants with minimal or greater risks to the participants. Two IRB members are asked to be the primary reviewers, however, all IRB members review each full board proposal prior to the IRB meeting. At the next IRB meeting this proposal is discussed by the entire board. If there are no problems with the proposal, the investigator is notified of approval. If there are recommendations for modifications, a letter is sent to the investigator requesting modifications. As soon as these are received and approved, a letter of approval is sent electronically to the investigator.

The IRB meets once a month. ***Projects should be in the IRB office by the first day of the month in which the project is to be reviewed.***

What does the IRB consider when evaluating a research proposal?
The main purpose of the IRB is the protection of human participants. We must consider three ethical values in each review: *Respect for Persons:* This involves making sure that the participant is informed and understands what is being asked of them as research participants, i.e. informed consent. *Beneficence:* This involves making sure that the benefits are worth the risks to which the participants are subjected. *Justice:* This mandates that the selection of participants is fair and just. These are judgment calls on the part of the IRB but we strive to be as fair as possible.