**Human Subject Research Guidelines**

**Institutional Review Board for the Protection of Human Subjects in Research**

Guidelines and Procedures for Handling Human Subject Research Proposals

Lincoln University IRB Guidelines

CITI PROGRAM Human Subjects Research Training

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**Statement of Ethical Principles**Lincoln University seeks to ensure that activities related to human subject research, regardless of funding source, will be guided by the ethical principles set forth in *The Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects*.

**Who Must Submit Proposals to the IRB**
In accordance with Federal Government Regulations; Lincoln University has established an Institutional Review Board to ensure the protection of human subjects in research projects.  **All researchers intending to work with human subjects must** **submit an application to the IRB prior to the start of research activities.** Human subject research includes any study involving human subjects, including survey questionnaires.  All human subject studies are subject to IRB review regardless of the purpose, extent, context, or source of funding for the study.  Class projects and studies that do not receive any external funding also require IRB review.  Research initially undertaken without the intent of using human subjects, which later propose to do, so, must comply with these procedures.  Researchers from other institutions wishing to conduct studies on students, faculty or staff at Lincoln University must submit an application to the Lincoln University IRB even if an IRB review was completed at their home institution (in accordance with Protection of Human Subjects, 45 CFR 46, part 46.114).

**Researchers from other institutions**: Human subject researchers who are not Lincoln University students, faculty or staff, must submit an Unaffiliated Investigator Agreement Form with their application for IRB review (see Investigators Unaffiliated with Lincoln University below).

**All research, including that conducted by students and professors in the classroom, is subject to IRB review.  Types of research that require IRB review are:**

**- Questionnaires/inventories administered in class by the professor or another** **researcher**

**- Observational research of behavior in a laboratory or field setting**

**- Experimental research that requires manipulation of subjects**

**Researchers who plan to conduct human subject research that they believe is exempt from IRB review** **must submit a full application to the IRB prior to conducting research activities**.  Federal regulations state that only the IRB may determine whether a research activity is exempt from full review (see below Exempt Research).

For information about the Federal Law concerning human subject research, click this link to the [Office for Human Research Protections](http://www.hhs.gov/ohrp) (OHRP) at the U.S. Department of Health and Human Services.

**Submission Procedures**

**Faculty Research**For **faculty research,** e-mail submission of the research protocol, questionnaires to be administered, and proposed Informed Consent Forms must be submitted at least four (4) weeks prior to the initial decision date desired.  A copy of the Proposal Cover Sheet (available at the Lincoln University IRB website) must accompany the proposal.  Faculty and Staff researchers must obtain the signature of their immediate supervisor (Department Chair) on the Proposal Cover Sheet.  The IRB will complete initial reviews of faculty research projects within four weeks of their submission.

**Student and Classroom Research Projects**Proposals for **student research projects** and **classroom projects** must be submitted via e-mail two (2) weeks prior to the initial decision date desired.  This proposal should include a brief description of the research protocol, questionnaires, and the proposed Informed Consent Forms.  Proposals for student research projects and classroom projects must be submitted by the Faculty Advisor.  The signature of the advisor is required on the Proposal Cover Sheet.  Approval of the Department Chair is also required prior to the submission of a student research proposal.  The Department Chair must indicate approval on the Proposal Cover Sheet.  **The IRB will attempt to complete initial reviews of student research within** **two weeks of the time of their submission.**

**Human Subjects Training Requirement**All students, faculty, and staff who submit proposals to the IRB also must submit a copy of the Human Subjects Assurance Training certificates for training modules 1-3 to document that they are informed of their responsibilities to protect the subjects they wish to study.  This training is available on-line and must have occurred within the past 3-years of the date a proposal is submitted to the IRB.  All three modules must be completed and certificates of completion printed with your name on them.  These certifications are available if you log-in to the CITI PROGRAM <https://www.citiprogram.org/> website.

**Investigators Unaffiliated with Lincoln University**Human subject researchers who are not affiliated with Lincoln University (individuals who are not Lincoln University students, faculty or staff) **must** submit to Lincoln University IRB review prior to conducting any research activity or subject recruitment at Lincoln University. IRB approval from your home institution does not substitute for review by the IRB and does not influence the independent review that will be conducted by the Lincoln University IRB. The research protocol, questionnaires to be administered, and proposed Informed Consent Forms must be submitted  by e-mail at least four (4) weeks prior to the initial decision date desired. Researchers not affiliated with Lincoln University also must submit an Unaffiliated Investigator Agreement Form with their application for IRB review. **Approval of a human subject research proposal by another IRB does not assure approval by the Lincoln University IRB.**

Investigators unaffiliated with Lincoln University who submit proposals to the Lincoln University IRB also must submit copies of the Human Subjects Assurance Training certificates for training modules 1-3 to document that they are informed of their responsibilities to protect the subjects they wish to study.  This training is available on-line and must have occurred within the past 3-years of the date a proposal is submitted to the IRB.  All three modules must be completed and certificates of completion printed with your name on them. These certifications only are available if you log-in to the [CITI](http://ohrp-ed.od.nih.gov/CBTs/Assurance/login.asp) PROGRAM <https://www.citiprogram.org/> website.

**E-mail Submission**

All IRB applications must be submitted by e-mail and must conform to the following requirements:

A cover sheet, the entire proposal and all materials submitted as part of the application must be sent as a **single PDF document** attached to an e-mail to the Human Subjects Administrator. Proposals consisting of multiple separate documents will delay review or will simply be returned to the proposer without review.

Electronic submissions to the IRB will be acknowledged within 2 days of receipt with an e-mail from the IRB Administrator.

Proposals to the IRB must be submitted to:

Name and contact information for Lincoln IRB personnel

All materials submitted will be stored in the office of the Lincoln University IRB Administrator, \_\_\_\_\_\_\_\_\_\_\_\_\_\_ who will initially forward proposals to the IRB chair (or co-chairs) to determine whether the proposal requires full IRB review.  If the IRB chair determines that a full review is required, the staff will distribute proposals and related materials to the Principal Reviewer (PR) and all IRB members.  The PR is an IRB member who will lead the review of the proposal.  Each IRB member will have responsibility for leading reviews of proposals.  Each proposal will be handled by a different PR on a rotating basis.

**Proposal Content**Generally, a proposal to the IRB for approval of a human subjects research project should consist of a brief description of the purpose of the study and its justification, but a complete copy of a submitted grant proposal is seldom necessary.

The following questions must be addressed in every proposal for IRB review:

What do you propose to do and why?

Who are you recruiting and how?
                        How many participants do you plan to recruit?
                        What are the criteria for recruitment?
                        How will you ensure that participation is voluntary?

What do you want subjects to do?
                        How much time will it take?
                        Where will it take place?
                        Will there be a follow-up activity?
                        Will participants be compensated and if so how?
                        If you plan to use a questionnaire, you must provide that in the proposal.
                        Do you plan to make an audio or video tape of participants?
                                    What is the purpose of such recordings?

How will you obtain Informed Consent?
                        Attach the Informed Consent Form you propose to use

What are the risks to participants?
                        If you think there are no risks, think again.
                        How will risks to participants be minimized?
                        Will participant responses be anonymous?

What are the benefits to participants?

**IRB Review of Proposals**Expedited Review: The Lincoln University Institutional Review Board does not have authority to conduct expedited reviews.  All proposals will be subject to a full review by the IRB.

Full Review:  Full reviews will be conducted in accordance with the guidelines provided by the Office for Human Research Protections (OHRP) of the US Department of Health and Human Services (Protection of Human Subjects, 45 CFR 46, part 46.109).  Copies of the proposal will be sent to each IRB member for full review.  A review meeting of the IRB will be held approximately one week after a proposal is sent to IRB members.  The PR will lead the discussion of the proposal at meetings of the IRB.  The PR will complete a full review form that reports the decision of the IRB and advises the principal investigator of required changes to the protocol or consent forms.  A completed full review form will be sent to the Human Subjects Administrator who will retain a copy and forward it to the principal investigator.  Annual and ongoing reviews of revised proposals and consent forms will be led by the same PR.  The IRB Chairperson and PR will sign the Notification of Approval and submit the same to the Human Subjects Administrator who will retain a copy and forward it to the principal investigator.

**Exempt Research**Exempt Research:  Some research activities with human subjects are exempted from Full IRB Review, but that determination can only be made by the IRB chairperson in accordance with Federal regulations (45CFR46, part 46.101).  If proposed human subjects research is found to be exempt from full review, the IRB Chairperson will sign a Notification of Approval, indicating that the research is exempt, and submit that form to the Human Subjects Administrator who will retain a copy and forward it to the principal investigator.

**Federal-wide Assurance of Protection of Human Subjects (FWA)**Lincoln University IRB has a currently valid Federal wide Assurance of Protection of Human Subjects.   The IRB is authorized to approve human subject research supported with funds from federal agencies.  Researchers whose IRB application is for a federally funded proposal must indicate the federal agency from which funds are sought on the Proposal Cover Sheet.  Principal Investigators are responsible for ensuring that IRB instructions are followed, that problems with human subject research are promptly reported to the IRB, and that refinements, changes, or any modification to research protocols are reported to the IRB prior to their use in research.  Institutions at which human subject research is not conducted in compliance with Federal regulations are subject to the loss of all federal funding.

**Notification of Approval**Following review by the IRB for initial or continuing approval, written notification will be sent to the principal investigator by Lincoln University IRB Administrator.  Written notification will clearly indicate either approval or non-approval.  When a proposal is not approved, the IRB will provide a statement of the reasons for its decision, provide the principal investigator with an opportunity to respond in writing and typically will provide instructions to principal investigators on proposal modifications that would increase the likelihood of approval upon resubmission.  **However, the IRB is not obliged to approve any research proposals that may present risks to human subjects, regardless of the proposed benefits foreseen by the principal investigator.**

**IRB approvals only are made in writing and have duration no greater than 12 months.** Federal government agency grants typically require IRB approval documentation communicated directly to the granting agency by the Human Subjects Administrator. It is the responsibility of the principal investigator to provide the IRB with the contact information for their granting agency Program Director, in writing, when such documentation is needed.

**Criteria for IRB approval**In order to approve research, the IRB must determine, within its sole discretion, that the following requirements are satisfied: (1) there are no unnecessary risks to subjects; (2) the risks to subjects are reasonable; (3) the selection of subjects will be equitable; (4) informed consent will be sought and appropriately documented; (5) adequate provision has been made for monitoring data collection to ensure safety of subjects; (6) adequate provision has been made to protect the privacy of subjects; and (7) when subjects are likely to be vulnerable to coercion or undue influence, additional safeguards have been included.

**Conditions of IRB Approval**IRB approval of a proposed study is limited to the specific study described in the proposal reviewed by the IRB.  Approval is limited to 12 months.  An extension of IRB approval for an additional 12 month period requires that the principal investigator notify the IRB of the following information (1) number of subjects seen, (2) location and number of consent forms obtained, (3) adverse reactions encountered and corrective measures taken, and (4) any changes in the research protocol.  Proposals for extensions for an additional 12 month period may be submitted no later than two months prior to the start of the second 12 month period.  Researchers must report to the IRB any changes made to protocols, questionnaires, or informed consent forms during a study **prior** to the initiation of such changes.  Changes in protocols, questionnaires, or informed consent forms must be approved by the IRB **prior** to use with human subjects, except when such change is necessary to eliminate apparent immediate hazard to the subjects.  If any such immediate changes are made, the IRB must be immediately notified and approval of the change must be sought.  Any incident in which a human subject is injured must be reported immediately to the IRB.  In all cases, researchers must report to the IRB on the status to their project at the end of each 12 month approval period or at shorter intervals as specified by the IRB.

Projects that pose a high level of risk to human subjects or that have had problems complying with IRB requirements in the past may be subject to continuing reviews at intervals more frequent than 12 months and/or verification of research activities by individuals other than the principal investigator.

**Termination of Approval**The IRB has the authority to suspend or terminate approval of any research that is not being conducted in accordance with these guidelines or that is associated with unexpected serious harm to the subjects.  When approval is either suspended or terminated, the IRB will provide the principal investigator with a statement of the reasons for its decision.

**Watchdog Function of IRB Administrator**The following circumstances will result in immediate reporting to Lincoln University IRB, the Senior Vice President for Academic Affairs, the Director of Sponsored Programs, the Office for Human Protections (OHRP) at the U.S. Department of Health and Human Services, and to the relevant funding and regulatory agencies specific to a given research project:

1. Serious or continued noncompliance with Federal Regulations or the Morehouse College IRB requirements.

2. Suspension or termination of IRB approval.

3. Unanticipated problems involving risks to research subjects or others.

**Record Keeping**Copies of all proposals submitted, IRB review results, and minutes of IRB meetings will be stored in the IRB Administrator Office.  All correspondence between the IRB and human subject researchers will be handled by IRB Administrator Office.  All records will be retained for at least 3 years after the completion of each approved research project (in accordance with the guidelines in the Protection of Human Subjects, 45 CFR 46, part 46.115).

Copies of the Protection of Human Subjects guidelines are available at the Office of the Lincoln University IRB Administrator located in Room 118 and the Office of Sponsored Programs located in the Wright Hall.

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