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**Human Subjects Research Protection**

**RELIANCE ON THE IRB OF ANOTHER INSTITUTION, ORGANIZATION, OR AN INDEPENDENT IRB**

**July, 2016**

**Lincoln University IRB**(LUIRB) may rely on an external IRB, meaning the IRB of another institution or organization, or an independent (commercial) IRB, for review and approval of human research if such reliance benefits LU, its investigators, and/or its research participants. Examples of when such reliance may be considered include: research in which LU as an institution has a conflicting interest; multi-site research in which LU employees are involved in minimal risk study activities only; Phase II, III or IV multi-site, industry-initiated, industry-sponsored research; and federally sponsored research for which a federally sponsored central IRB is duly constituted, or for federally sponsored research requiring the use of a central IRB.

The LUIRB Institutional Official or his/her designee has the ultimate authority regarding whether or not to rely on an external IRB. The Clinical Research Unit (CRU) that is responsible for oversight of a specific study may also determine whether or not to rely on an external IRB, provided the study meets the specific criteria below.

Certain phase I studies conducted in the LU Clinical Research Unit (LU CRU) may also be eligible for reliance on an external IRB.

### Types of Research that May Utilize External IRB Review

1. Phase II, III or IV research

LUIRB will consider relying on a qualifying external IRB for review of research studies that meet ALL of the following criteria:

* + Phase II, III or IV;
  + Industry-initiated protocols;
  + Industry-funded;
  + Multi-site;
  + Already possess external IRB approval from an AAHRPP-accredited IRB located in the U.S.

1. Other research

LUIRB will consider utilizing the services of a qualifying external IRB for review of research studies that meet ANY of the following criteria:

* + An institutional or individual conflict with the research has been determined by the Lincoln University Conflict-of-Interest Committee, the Institutional Official or the convened LU IRB;
  + LU employees are engaged in multi-site research involving only minimal risk study activities;
  + A federally funded or cooperative group study utilizing review by an AAHRPP-accredited IRB located in the US.

1. Research ineligible for use of an external IRB

Research that requires either of the following institutional reviews may **NOT** use an external IRB and must rely on the LU IRB:

* + Lincoln University Stem Cell Research Oversight Committee review;
  + Institutional Biosafety Committee review.

### Criteria for Selecting an External IRB

LUIRB will apply the following criteria in selecting an external IRB that qualifies to conduct the review of LU protocols:

* + The external IRB is currently registered with OHRP/FDA.
  + The external IRB is in good standing with OHRP/FDA (no recent warning letters, no open investigations).
  + For commercial IRBs: the commercial IRB is AAHRPP-accredited
  + For non-commercial IRBs: the IRB is AAHRPP-accredited or determined as part of the administrative review to meet Lincoln University standards
  + The external IRB is located within the U.S.

In accordance with OHRP Guidance, when DUHS relies on an external IRB for review and approval of human research, the relationship is documented with an IRB Authorization Agreement (IAA).

The IRB Authorization Agreement may be written to cover one research project, or to cover research projects on a case-by-case basis, or to cover a program of research. The agreement includes a description of the regulatory requirements for which each party will assume responsibility.

### eIRB Requirements

Lincoln University Principal Investigator must prepare an eIRB submission in the LU eIRB system and at Section 001 (Protocol Application Type) choose “External IRB Application”. The application will route through LUIRB and ancillary committee reviews as per the regular review pathway. Once LUIRB approval has been obtained, the study team will download all relevant study documents, prepare the external IRB submission, and submit the study to the external IRB.

Once external IRB approval has been obtained, the study team will upload all external IRB-approved study documents, including the notice of approval, into the eIRB to permit completion of the LUIRB approval process.

New studies arriving in the LU IRB via the external IRB application pathway will pass through IRB Administrator and will be assigned directly to a Chair/Vice Chair, the Executive Director or a designee to serve as the reviewer for administrative review. The reviewer will make reasonable efforts to complete their administrative review within 2 business day of notice of assignment.

A Notice of Administrative Review will be issued by the LU IRB. The expiration date of the Notice will be the expiration date issued by the external IRB.

Once the study is underway, all approved amendments and their approval notices issued by the external IRB must be uploaded into the eIRB system. The Lincoln University Principal Investigator must submit all continuing renewals in eIRB no later than five days prior to the expiration date, for administrative review by a Chair/Vice Chair, the Executive Director, or a designee. The continuing renewal approval notice issued by the external IRB must be attached to the submission in eIRB.

Reminders of the impending LU expiration date will be sent to the study team by the eIRB system.

In particular, any Safety Events, including serious adverse events, protocol deviations/violations or unanticipated problems involving risks to subjects or others that involve LU personnel or LU research participants must be reported promptly to the LU IRB using the eIRB’s Safety Event reporting mechanism. The report must include the review of the external IRB and any corrective actions issued by that IRB. Upon completion of its review, the LU IRB may require additional corrective actions.

### Responsibilities of the Investigator/Study Team

The investigator/study team may not add any procedures to the sponsor’s protocol (e.g., additional biopsies, storage of biological specimens for future research at LU, additional laboratory or imaging studies). Such activities can only be undertaken by submitting those investigations as a separate study through the LU IRB. In addition, the investigator/study team is responsible for indicating all required institutional reviews (e.g., Radiation Safety, OCRC, DOCR) in the appropriate section(s) of the eIRB submission.

1. Initial review

The LU investigator will provide the LU IRB with a copy of:

* + The letter of approval from the external IRB;
  + The final approved protocol and informed consent;
  + The entire grant, if applicable, exclusive of appendices;
  + Relevant Investigator’s Brochure(s) and package insert(s);
  + Advertisements;
  + All surveys, questionnaires, phone scripts, and other participant materials;
  + Approved waivers of consent and/or HIPAA Authorization;
  + Any other documents considered by the external IRB in making its determination to approve the study.

1. Continuing review

The LU investigator will provide a copy of:

* + The continuing review approval letter from the external IRB;
  + The final approved protocol and informed consent;
  + The Progress Report;
  + Any other documents considered by the external IRB in making its determination to approve the study.

1. Modifications or amendments

The LU investigator will provide a copy of:

* + The proposed modification or amendment;
  + Documentation from the external IRB of approval of the modification or amendment;
  + The external IRB-approved modified or amended protocol, consent form or other study documents.

1. Unanticipated Problems Involving Risks to Subjects or Others (UPIRTSOs)
   * Any unanticipated events involving risks to subjects or others that involve Lincoln personnel or research participants must be reported according to Duke policy in addition to the guidelines of the external IRB. As soon as the document is available, the external IRB’s resolution of the UPIRTSO must be provided to the LUIRB. All other UPIRTSOs should be reported to the LUIRB with the next periodic continuing review.
2. Closure of the study
   * Once research is completed, the LU investigator must submit a final report in the eIRB to close the study.

### Responsibilities of the CRU

The CRU having oversight of the specific study will follow its regular processes for the review and approval of a LU research study, including review of scientific merit, resources and all financial aspects of the study.

### Responsibilities of the External IRB

1. For studies conducted or supported by any federal department or agency that has adopted the Federal Policy for the Protection of Human Subjects, known as the Common Rule, the external IRB will comply with the terms set forth in the Code of Federal Regulations at 45 CFR 46 (including Subparts A, B, C, and D), unless the research is otherwise exempt from these requirements, or the department or agency conducting or supporting the research has determined that the research shall be covered by a separate assurance.

For clinical investigations regulated by FDA under section 505(i) or 520(g) of the Federal Food, Drug, and Cosmetic Act (21 U. S. 6. 355(i)), the external IRB will apply FDA human subjects regulations. These regulations include, but are not limited to, Protection of Human Subjects (21 CFR 50), Institutional Review Boards (21 CFR 56), Investigational Drugs (21 CFR 312), Investigational Devices (21 CFR 812), and Application for FDA Approval to Market a New Drug (21 CFR 314).

For all other research involving human participants the external IRB will be guided by the Code of Federal Regulations at 45 CFR 46 when providing equivalent protections.

1. The external IRB will make available to LUIRB relevant minutes of its meetings and any other documents related to the review, approval and continuing oversight of the research study.
2. The external IRB will provide prompt notification of all actions, requirements and determinations it makes related to the participation of LU in the research study.
3. When the LU IRB is serving as the IRB-of-Record for another institution, it will likewise carry out the responsibilities specified in this section.

### Responsibilities of LU

1. LU will assign a Chair/Vice-Chair, the Executive Director, or a designee to serve as the reviewer to perform an administrative review of the research protocol and the external IRB's decisions and determinations to ensure that:
   * The LU investigators and staff conducting the research are appropriately qualified;
   * The study is consistent with LU policies;
   * Other applicable institutional approvals, such as Investigational Drug Pharmacy, Radiation Safety, and, where applicable, Conflict-of-Interest Committee have been obtained before research begins;
   * Those actions and determinations made by the external IRB meet LU standards for initial review, continuing IRB review, or review of amendments to previously approved research;
   * No concerns about local context are present;
   * The consent form complies with LU standards and requirements;
   * The consent form contains applicable LU standard language;
   * The external IRB is AAHRPP accredited or is determined as part of administrative review to meet Lincoln’s standards.

The reviewer will be guided by a reviewer checklist (Attachment A). The expiration date for administrative review will be set by the reviewer, working with the IRB Board Specialist, to match the expiration date established by the external IRB.

1. Promptly report to the external IRB and, as applicable, to the Office for Human Research Protections (OHRP), Food and Drug Administration (FDA), study sponsor and to all other appropriate agencies and individuals:
   * Any UPIRTSO declared by the LU IRB to be related to the research reviewed by the external IRB;
   * Any serious or continuing noncompliance with the determinations of the LUIRB related to the research reviewed by the external IRB;
   * Any suspension or termination of approval declared by LU related to the research reviewed by the external IRB.
2. Make available to the external IRB relevant minutes of meetings and any other documents related to the LU monitoring or oversight of this research study, or the declaration by the LU IRB of a UPIRTSO, serious or continuing noncompliance, or any suspension or termination described in B. above.

### Determinations Resulting from Administrative Review

LU retains the authority to accept the external IRB’s approval, or to make minor changes through the LU administrative review, or to require review by a convened LU IRB.

1. The Reviewer will either:
   * Accept the external IRB approval;
   * Accept the external IRB approval with minor modifications; or
   * Not accept the external IRB approval in which case the investigator may either withdraw the study or have it referred to a convened LU IRB for review.
2. If all conditions described in this policy have been adequately addressed, the investigator will be sent written notification (Notice of Administrative Review) by the LU IRB that the external IRB approval is affirmed.

### References:

FDA Information Sheet, Non-Local IRB Review, (1998)

OHRP Guidance, IRB Knowledge of Local Research Context, August 27, 1998 [Updated July 21, 2000]

# ATTACHMENT A

## Reviewer Checklist for LU-Specific Requirements

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| **I.** | 1. | **Consent Form Language**  ‘Invite to participate’ language eliminated |
|  | 2. | HIPAA core elements (LU-specific language is not needed if all core elements |
|  | 3. | are present.)  Statements concerning waiver of legal rights eliminated |
|  | 4. | Ownership of samples: replace “will own” with “will assert all rights to” |
|  | 5. | GINA language (LU or equivalent) when appropriate |

### YES/NO

1. LU-specific genetic language or equivalent (e.g., incidental findings) when appropriate
2. Compliance with LU policy on “Mandatory State Reporting Requirements”
3. Compliance with LU policy on “State Law Terms and Principles Applicable to Human Subjects Research”
4. Compliance with LU policy on “The Use of the Legally Authorized Representative in Research Involving a Vulnerable Population of Adult Subjects”
5. Appropriate contraceptive language for subject population and study drug(s)
6. Serum pregnancy test at screening if pregnancy is an exclusion
7. Drug interaction language
8. Inclusion of external IRB contact information for participants’ rights

### II. Submission Form/Research Summary

1. Consent process described in submission form
2. Privacy/confidentiality described in submission form
3. Data analysis methodology described in summary