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**Legacy Health IRB**

**INITIAL REVIEW APPLICATION –** **Version 7-1-2022**

**Form A Instructions**

Form A is the application for any proposed new study whether biomedical, social-behavioral, clinical investigation, outcomes, or pilot study that intends to enroll subjects at Legacy, whether the subject are Legacy patients, employees or othersat Legacy Health and/or that uses patient or provider information from any source at Legacy. The Form A application does not substitute for a written protocol that outlines your research in detail. A written protocol is **required** to be submitted for review and approval.

**Submission Requirements**

The Form A application is designed for all researchers who want to conduct a study at Legacy seeking relevant patient and/or provider data to answer a research question. This application assumes that you plan to consent subjects and seek to collect data prospectively. **If you are submitting a retrospective chart review study only and requesting a waiver of consent for all subject information, you may use “Form B: Retrospective Chart Review Application” for that kind of simple study.** Otherwise, you must use this form.

The Form A application, protocol, consent forms, all protocol related documents, subject materials, the Principal Investigator’s CV, and documentation of PI and study staff human subject research protection training (CITI or equivalent) must be submitted to irbsubmissions@lhs.org.

**All other forms for submission are obsolete as of August 1, 2022 for submission to Legacy IRB review and should not be used, as their use will delay review and approval for your research project.**

**Please note that one principal investigator (PI) is responsible for all aspects of the research.**  **Therefore, the PI is required to address all issues before the research can be considered for review.** The PI must sign the document attesting that the information is correct and reliable for the IRB to consider for review of the research. Co-Investigators on a study must file separate applications and make assurances that they are equally responsible for the conduct of the study.

**Form A Application Domains**

The Form A application consists of 10 Domains that must be filled out completely. Incomplete answers to Domain questions will delay review of the project you have submitted.

**Study Summary:** provide the basic information of the submission: title, PI name, submitter, date, documents to be reviewed.

**Domain 1:** Provide information about the PI, PI qualifications, and study staff, training and conflict of interests.

**Domain 2:** Describe the target subject population and justification of inclusion/exclusion criteria.

**Domain 3:** Specify the sites of the research and whether any research activity will not be at a Legacy site. Provide name and contact information of the Legacy manager that provides permission for the research to be conducted in their department or at their site.

**Domain 4:** Indicate the sponsor, funders and funding of the research.

**Domain 5:** Provide details about the type of research you are proposing.

**Domain 6:** Describe the risks of the study and the protections in place to guard against risks of harm.

**Domain 7:** Provide details about the consent of subjects or provide rationale for waiver requests.

**Domain 8:** Describe the type of data to be collected, protection of the data collected, the security of the data, how the data will be analyzed, and the plan for how a security breach will be handled.

**Domain 9:** List the documents you need/want the IRB to review and approve and submit them with the application form.

**Domain 10:** Review the assurances required and sign and date on the signature line.

**All questions on the application must be answered.** “N/A” is only an option where indicated.

If the contact information for the PI or main study contact provided in this form changes during the life of the study, you must provide the updated information to us.

The information provided in this submission form (addresses, phone numbers, contact names, payment information, etc.) will be used to produce your final Board Action Approval Document, approved regulatory documents and approved consent form.

**IRB REVIEW OF RISKS**

PI’s must obviously understand the nature of the risks of the proposed research but are not tasked to determine risk levels required for specific findings under the regulations; that is the task of the IRB. However, the PI must clearly understand where standard clinical care is being departed from in their proposed study and must outline all specific risks of the research in the consent form consistent with the protocol. Greater than minimal risk research will be re-reviewed at least once a year at continuing review. Minimal risk or low risk research will also be reviewed annually, but may be re-reviewed at longer intervals. In all cases, the IRB’s request for an update on the research will need to be promptly addressed.

This form must also be used for all deferral requests and requests for single IRB (sIRB) applications. See **Domain 4** for questions related to IRB deferral requests.

**DOCUMENTS REQUIRED FOR REVIEW**

Do not submit research without the documentation requested below, as it will only delay your review.

* **LRI Application (Form A):** No research request will be processed without use of this form. The form must be submitted and must be signed by the PI or an email from the PI may be used to indicate confirmation of the submission.
* **CURRICULUM VITAE (CV):** The PI’s CV must be dated and up-to-date.
* **PROTOCOL** or **RESEARCH PROPOSAL:** A protocol outlines the research plan in detail and must be a complete (untracked) version, recently dated, and naming only one principal investigator, the sponsor (if any), and the funding (if any).
* **Consent/ASSENT form(S):** Submit Consent/Assent forms or Information Sheets as Word files only. The submitted consent form should have been prepared using **Legacy Health Informed Consent Form Template** and must contain all required elements and Legacy required language for Legacy sites. If you are requesting a waiver of consent, you must submit documentation supporting the request to enroll subjects into your research without giving their consent. *See* **Domain 7** for the criteria that must be met for a waiver of consent or other waiver requests.
* **Research “Subject Materials”:** Other materials to be provided to the subjects which are not included in the protocol, such as advertisements, questionnaires, surveys, subject diaries, etc. must be submitted for review and approval. Unmodified standard validated instruments to be used in the research should be noted in the protocol but do not need to be submitted for separate review, but modified instruments or unique instruments must be submitted for review and approval.

**REQUIRED DOCUMENTS REQUIRED FOR DRUG OR DEVICE TRIALS**

**UNDER FDA JURISDICTION**

**For drugs and biologics,** provide a copy of each of the following:

* **Investigator’s Drug Brochure**: This is a sponsor document that outlines the scientific background of the drug being used in the study. The IRB must be able to review this background material.
* **Investigational New Drug (ind) number documentation:** This documentation must come from the sponsor or FDA verifying whether an IND is required for the research. If an IND is not required, provide the reason why in writing either in the protocol or in the application form and provide supporting documentation or rationale for an exemption under 21 CFR § 312.2(b).

**For device studies,** provide documentation of the status of the device under FDA requirements:

* **Unredacted FDA Letter** granting the Investigational Device Exemption (IDE).
* **Letter from the PI or sponsor** stating that the study is a **non-significant risk (NSR) device study** and the basis for that determination or conclusion. The IRB is required to determine whether the research qualifies as non-significant risk device study. Please note that a NSR determination does not mean that the study is minimal risk; the device may be non-significant risk while the study itself poses greater than minimal risks to subjects.
* **Documentation of why the investigation is exempt:** A device may be exempt fromIDE requirements under 21 CFR § 812.2(c) if the device has met premarket approval (PMA) or has 510(k) clearance.In each case, submission of the FDA letter showing PMA status or 510K status is required.
* **Humanitarian Use Device (HUD):** Physicians seeking approval to use a Humanitarian Use Device (HUD) on-label must provide the necessary documentation regarding the use of the HUD and to indicate what site will use the HUD. (See the FDA guidance titled “Guidance for HDE Holders, Institutional Review Boards (IRBs), Clinical Investigators, and Food and Drug Administration Staff Humanitarian Device Exemption (HDE) Regulation: Questions and Answers” for more information about requirements for use of HUDs.)

**QUALIFICATIONS AND TRAINING**

* **DOCUMENTATION OF HUMAN SUBJECT RESEARCH PROTECTION TRAINING:** Legacy IRB requires investigators to verify on the initial review submission form that the PI and each member of the research team has successfully completed training in human research subject protection. No exceptions will be made.

In order to understand the regulatory and historical knowledge to conduct research at Legacy Health you are required to complete Human Subjects CITI Training, an on-line training system.

CITI provides a research ethics education that is necessary to conduct clinical trials. Other equivalent training will be considered acceptable on a case-by-case basis in lieu of CITI. However, regardless of the type of training received, Legacy IRB requires that all research staff have training that includes ethical principles related to human subject protections, federal regulations for protection of human subjects, and Good Clinical Practice. Please note that HIPAA training or prior research experience by itself does not satisfy this requirement for training in human subject protection.

**CITI Training requirements**

Legacy requires the all individuals involved in a retrospective chart review complete the appropriate CITI training, an on-line training system managed by the University of Miami. The Collaborative Institutional Training Initiative (CITI) provides a research ethics education that is necessary to conduct medical research including retrospective chart reviews and better understand the requirements of the Institutional Review Board. Principal Investigators and all study staff must complete relevant human subject CITI training. The documentation of CITI training should be submitted along with the other items for review, and must be kept on file by the PI for proof of study staff training.

<http://www.citiprogram.org/>

1. Click on Register Here

2. Participating Institutions

 Select arrow and Scroll down to Legacy Health & Select

3. Select your Username & Password

 First & last name with no spaces

Create a password and Verify password

4. Enter your Name

5. Enter your email address and submit

6. Specify Department, your role in Research and submit

7. Under “My Learner Tools for Legacy Health” choose “Add a course”

8. Under Question 1 (Human Subjects Research) choose “Retrospective Chart Review”; Question 2 (Good Clinical Practice) choose “not at this time”; Question 3 (Laboratory Animal Welfare) no decision necessary; Question 4 (Conflict of Interest) choose “no”; Question 5 (Responsible Conduct of Research) choose “not at this time”.

9. Complete course and attach completion certificate with application.

The documentation of CITI training should be submitted along with the other items for review and must be kept on file by the PI for proof of study staff training.

**WHO TO CONTACT FOR FURTHER INFORMATION OR IF YOU HAVE QUESTIONS**

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**SUBMIT ALL IRB SUBMISSIONS TO:**

irbsubmissions@lhs.org