**Legacy Health IRB**

**Retrospective Chart Review Application – Version June 3, 2024**

**Form B Instructions**

Form B is the application for any proposed **retrospective chart review** at Legacy Health that uses patient or provider information from any source at Legacy. You may submit a separate written protocol that provides more detail about your project but it must contain at least the elements required by this application.

**All other or older application forms for a retrospective chart review submission to Legacy IRB review are obsolete as of June 2, 2024 for and should not be used, as their use will delay review and approval for your research project.**

**Submission Requirements**

The Form B application is designed for students, nurses, physicians and any other person who want to use **existing** data for research purposes. The use of internal data, whether directly from the medical records or from data sets created for other purposes, requires approval through the Legacy Institutional Review Board.

The Form B application, Protocol, 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 for IRB review and approval before the research can begin.

**Existing Data Only**

A protocol that requests to conduct a retrospective chart review is intended toevaluate patient data that is **existing** at the time the project is submitted to the IRB for initial review. It is not collecting data on *future* patients. Therefore, in using this application, you may only request permission to collect data from currently existing records at Legacy that you suspect might have useful data to answer a research question. If you intend to collect data from *future* patient records, do not use this application, as the approval criteria for prospective research requires a more extensive analysis of the request and may need to be reviewed by the full IRB. This application is just for those studies requesting already existing data at Legacy.

**Waivers of Consent or Authorization**

The Form B application assumes that you are requesting a **waiver of consent** and a **waiver of authorization for PHI** for review of subject charts. However, it is not automatic that a waiver of consent or authorization will be granted. You will need to provide a detailed justification for any waiver requests in **Domain 7** of the form. The IRB may determine that the requested waiver of consent or authorization is not ethical and may instead require that subjects be contacted and consented for access to their records. The IRB will inform you if a waiver of consent cannot be granted so that you can revise your project accordingly.

**Form B Application Domains:**

The Form B 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.

**Domain 4:** indicate the sponsor, funders and funding of the research. Provide name and contact information of the Legacy manager that provides permission for the research to be conducted.

**Domain 5:** provide details about the data to be collected from the existing charts, the number of charts anticipated, the date range of the charts (past to present only, no future charts), the location of the charts, and the name of the manager who controls access to the charts.

**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 waiving consent of subjects.

**Domain 8:** describe the 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.

**Domain 10:** review the assurances required and sign and date on the signature line. **This signature page can be sent as a pdf, but the application must be submitted as a word document.**

**HIPAA Privacy and Security**

**HIPAA** regulations affect any business which is involved in the delivery of health care including health care providers, hospitals, clinics, insurance companies, and community health information systems which are involved in handling and transmitting health care information. Those businesses are referred to as “covered entities.” HIPAA Privacy rules regulate the use and disclosure of Protected Health Information (PHI)by specifying that a Covered Entity can only use PHI for treatment, payment or health care operations, which may include activities such as quality projects or disclosures to public health authorities. All other disclosures of PHI by a covered entity must be otherwise permitted under the Privacy rules or the result of an individual’s direct written authorization or through a waiver of patient authorization granted by the IRB.For Retrospective Chart Reviews, Legacy requires that investigators submit applications to the IRB in order to qualify for a waiver of patient authorization and consent.

**Additional information regarding Waiver requests**

In submitting this request for Retrospective Chart Review you must either seek the signed written consent of each patient whose medical records will be used or your application must contain the following elements in order to obtain an IRB approved waiver of HIPAA authorization and consent:

* the research could not be practicably done without the waiver
* the use or disclosure of information involves no more than minimal risk to the privacy of the patient; and
* there is an adequate plan to protect the identifiers from improper use or disclosure.

The criteria can be satisfied by establishing this information:

* **“could not be practicably done without the waiver”:** Generally, consent is not sought when an individual is not readily available and/or there are a large number of charts being requested.
* **“No more than minimal risk”:** For chart reviews minimal risk is defined as data requested that does not represent an unusual risk to an individual’s privacy or that could affect their standing among their peer and community if there was a breach of data security. In addition, in those instances where unusually sensitive data is requested (such as records related to sexual activity, sexual orientation, illegal drug use or criminal activity) additional security safeguards may be requested or a waiver may not be appropriate. Highly sensitive data may be determined by the IRB to not meet the standard of minimal risk.
* **“adequate plan to protect the data”:** In those instances where researchers are gathering data that could identify the patient there needs to be a plan to destroy the identifiers at the earliest possible opportunity consistent with the research and an assurance that the information will not be reused or disclosed to any other person. Retrospective review of medical records must involve only data that existed prior to the request and there must be no intent to contact patients.

**Protected Health Information (PHI)**

Protected Health Information (PHI) is defined by HIPAA as information that could identify the patient. The investigator must first justify gathering that information and then submit a plan as to how and when the PHI would be de-identified or the entire data set destroyed. HIPAA requires that if less than 50 records are utilized for this project, a note should be entered into each of the electronic records or paper charts that it was used for research purposes.

PHI is specifically defined by HIPAA as including: patient name, birth date, admission date, discharge date, date of death, all ages over 89, postal address, telephone number, or other identifying number such as FAX number, e-mail address, SSN, medical records number, account number, license/certificate number, vehicle ID number, device ID or serial number, patient web URL or biometric ID (finger/voice prints, facial photographs) or any coded identifier.

**Access Security Requirements**

When data is gathered using electronic devices the following safeguards must be taken:

* For non-Legacy Health entities a current Business Associate and/or Confidentiality Agreement must be in place.
* All personnel accessing the records have names attached to the application i.e., be study staff.
* Access to records shall be limited to the named individuals by way of encryption and/or passwords.
* Records transmitted over an open network or stored on a portable medium such as CD/DVD-ROM, laptop, USB drive shall be encrypted.
* All medical records will be abstracted manually and will be de-identified when stored on a personal laptop or other computer If records are stored on a laptop, CD/DVD or thumb drive; provide an assurance that the laptop and any removable media are encrypted.
* Access to records will only occur in a physically secure environment, (i.e., hospital, your office, your home office, etc.). Access to records shall be restricted only to authorized personnel named above by means of encryption and password protection where appropriate.
* Laptop shall automatically “lock” after 15 minutes of inactivity.
* A strong password will be used of at least 8 characters in length combining letters, numbers and symbols.
* Review of records will be conducted in a physically secure environment.
* All access to the records will be logged for accountability purposes.
* Records will only be available in a “read-only” format and will not be duplicated from the original medium of conveyance.
* When records are no longer necessary, they will be destroyed or de-identified in a secure manner such that they are not recoverable.
* If records are shared with a third party complete a confidentiality agreement with the vendor and encrypt records copied to removable media (i.e. CD/DVDs, thumb drives, other).
* When records are no longer necessary, they will be securely destroyed or de-identified.
* When personnel named above are removed from project their access to the records will be blocked.
* In those instances where Legacy computers will not be used, the Principal Investigator must contact Information Security to assure appropriate protections are understood and in place.

**CITI Training**

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.

**QUESTIONS?**

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