RETROSPECTIVE CHART REVIEW GUIDANCE AND INSTRUCTION

This application is designed for students, nurses, physicians and any other person who wants to use existing data for research purposes or presentation to any outside body or entity. Those purposes may include but are not limited to fulfilling class projects, presentations outside of Legacy and publications. The use of internal data, whether directly from the medical records or from data sets created for other purposes, requires institutional approval through the Institutional Review Board.

Attached you will find:

1. Retrospective Chart Review Application Form
2. Retrospective Chart Review Instructions
3. Explanation of the HIPAA Privacy Requirements
4. Explanation of the HIPAA Security Requirements
5. Instructions for HIPAA Training through CITI

**Retrospective Chart Reviews** evaluate patient data that is **existing** at the time the project is submitted to the IRB for initial review. In contrast, **Prospective Chart Reviews** evaluate patient data that does not yet exist at the time the project is submitted to the IRB for initial review. This application is just for those studies requesting already existing data.

**HIPAA** **PRIVACY AND SECURITY 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 **Institutional Review Board (IRB).** The IRB is a federally mandated committee tasked with protecting the rights and safety of research subjects by providing oversight for an institution’s research involving human subjects. The IRB must review all research involving human subjects prior to its initiation, including clinical trials, behavioral testing and the use of patient data.

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. Investigators are also required to complete relevant human subject CITI training. The submission document should be sent to the IRB Administrator at the address below and will serve as the approval document when it is returned to the investigator with a signature from the Chair of the Legacy IRB. All requests should be sent as a pdf e-mail attachment to:

Paul Newton, JD, CIP

Research Regulatory Specialist, Sr.

pwnewton@lhs.org

503.413.5355

**RETROSPECTIVE CHART REVIEW APPLICATION FORM AND APPROVAL DOCUMENT**

1. **Principal Investigator:**
2. **Other personnel involved in the project**:
3. **Project Title**:
4. **Description of Project**:
5. **Date Range**:
6. **Number of Charts**:
7. **Data Source**:
8. **Protected Health Information (PHI) to be collected:**
9. **Non-PHI Information to be collected**:
10. **Data Protection:**

**CITI Training:** Attach certificate of CITI training for all individuals listed in this application.

­­­­­­­­­­­­­­­­­Principal Investigator Signature Date

By signing this document the Principal Investigator assures that this study could not be practicably done without a waiver of patient authorization, that this disclosure poses no more than minimal risk to the privacy of the patient and the information requested is the minimum necessary to accomplish the goals of the study. I assure that I will not be contacting the patients whose charts I am reviewing and that I will maintain the confidentiality of those records described in this application.

Administrative Signature Date

For physicians this signature should be the signed by the Chair/Chief of the Legacy Medical Division/Section most affected by the study. For student or nursing projects, this signature should be that of the Director of the service most affected. By signing this document the Chair/Chief or Director assures that study is relevant to the goals and objectives of the practice of medicine at Legacy Health.

IRB Approval Signature Date

By signing this document the IRB Chair (or their designee) provides a waiver of HIPAA authorization to conduct this retrospective chart review.

**Instructions for Requesting Medical Records for Research Purposes**

1. **Principal Investigator -** Name, Title (MD, RN, PhD, etc.), Address (office) and Institutional affiliation (employee of Legacy, member of the Medical Staff, resident, non-affiliated):
2. **Other personnel involved in the project** - same details as Principal Investigator, name, title, institutional affiliation
3. **Project Title** - descriptive title and attach the protocol if available
4. **Description of Project** - abstract (not to exceed 1 page) should include the condition under study, the hypothesis being tested, key health questions being asked and brief description as to how the data will be analyzed
5. **Date Range –** specify the dates of the charts to be reviewed month and year
6. **Number of Charts** - state exact or approximate number of charts and explain how the sample size was determined
7. **Data Source** - Epic, lab, imaging, financial, hospital or clinic, etc.
8. **Protected Health Information (PHI) to be collected -** see HIPAA Privacy for full list of PHI; if no PHI write N/A and explain under what circumstances the data was de-identified
9. **Non-PHI Information to be collected** – include a specific list of all other data needed from the medical records for this project
10. **Data Protection –** how will data be stored and protected whether on a Legacy computer (list the W number), an encrypted device or laptop provided by Legacy IT, paper in a locked cabinet and whether data will be transferred from a Legacy computer to a laptop; state at what point PHI is no longer needed and will be destroyed; check HIPAA Security for details. If data was previously de-identified, refer to circumstances explained under #8.

Submit application with the Principal Investigator’s Signature and the appropriate Administrative signature.

### HIPAA PRIVACY

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.

Keep those requirements in mind when filling out the application.

**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 a 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 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.

**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) 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.

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.**

Please note: 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.

### HIPAA SECURITY

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
* 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 access to the records will be logged for accountability purposes
* Review of records will be conducted in a physically secure environment
* Records will only be available in a “read-only” format and will not be duplicated from the original medium of conveyance
* Access to electronic records will “screen lock” after 15 minutes of idle time
* When records are no longer necessary, they will be destroyed or de-identified in a secure manner such that they are not recoverable and then notify the IRB administrator that such destruction has occurred.

**Access Security Requirements:**

1) 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. Assistance and tools are offered by sending an email to Infosec@lhs.org.

2) Access to records will only occur in a physically secure environment, (ie. 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.

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).

3) 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.

4) In those instances where Legacy computers will not be used, the Principal Investigator must contact Information Security at infosec@lhs.org 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.

<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.