

**Loyola University Medical Center
Institutional Review Board for the Protection of Human Subjects**

The following information and template are to be used when submitting a request to conduct retrospective chart and or material review studies.

Retrospective chart/existing materials reviews;

- a) requires protocol, IRB application, review and approval;**
- b) Conditions of approval will be:**

1. You are bound by the usual and customary medical, legal and ethical considerations governing the confidentiality of the medical record.
2. The data you collect may not be sold or given to any third party outside the scope of this submission unless it is to a journal for publication. Data to a journal for publication must be de-identified.
3. The chart reviewed is to be identified on the data collection form by a unique code number and the master list kept under lock and key. If you are not collecting data elements that can directly or indirectly identify the chart reviewed then this requirement is not relevant.
4. The link of the patient to the project is to be destroyed when it is no longer necessary.

- c) Waiver of consent and waiver of authorization**
- d) Show the approval letter to the keeper of the records.**

To waive consent, IRB must find:

1. The study is of minimal risk and qualifies for expedited review 45CFR46.110, b-1, HHS Secretary Category).
2. The requirement for consent is waived:
 - a) the research could not practicably be done without the waiver;
 - b) the waiver does not adversely affect the rights of the individual;
 - c) the research involves no more than minimal risk;
 - d) there is no information that would need to be provided to the individual.

(45CFR46.116, d1-4).

To waive authorization IRB must find:

3. The IRB finds that:

(A) The use or disclosure of protected health information involves no more than minimal risk to the individuals;

(B) The alteration or waiver will not adversely affect the privacy rights and the welfare of the individuals;

(C) The research could not practicably be conducted without the alteration or waiver;

(D) The research could not practicably be conducted without access to and use of the protected health information;

(E) The privacy risks to individuals whose protected health information is to be used or disclosed are reasonable in relation to the anticipated benefits if any to the individuals, and the importance of the knowledge that may reasonably be expected to result from the research.

(F) There is an adequate plan to protect the identifiers from improper use and disclosure;

(G) There is an adequate plan to destroy the identifiers at the earliest opportunity consistent with conduct of the research, unless there is a health or research justification for retaining the identifiers, or such retention is otherwise required by law;

(H) There are adequate written assurances that the protected health information will not be reused or disclosed to any other person or entity, except as required by law, for authorized oversight of the research project, or for other research for which the use or disclosure of protected health information would be permitted by this subpart.

PROTOCOL TEMPLATE

Title:

Principal Investigator:

Co-Investigator:

Clinical Research Nurse:

1. Purpose/rationale (appropriately referenced):

2. Objectives:

3. Methods and Material: indicate what will be reviewed and the criteria for pulling the charts for review and how you will know what charts to review. Examples: ICD-9 diagnostic codes, departmental database, etc.

4. The following data will be collected (INDICATE)

5. Plan to protect the identifiers from improper use and disclosure:

6. State when the identifiers will be destroyed:

7. Describe who will have access to the protected health information:

8. Describe the use of the data: (publication, presentation, etc).

9. Bibliography

Complete IRB application and attach (upload) protocol and data collection sheets.