LOYOLA UNIVERSITY HEALTH SYSTEM

LOYOLA UNIVERSITY CHICAGO

External Database Procedures
PRO-011 012 qm 9-27-18
Effective date: 01/OCT/2018

I. PURPOSE AND SCOPE

The purpose of this Standard Operating Procedure (SOP) is to establish procedures for studies utilizing large publically available databases (e.g., HCUP, NSQIP, MBSAQIP), and to foster a compliant environment that adheres to applicable federal regulations and institutional polices.

This SOP applies to applicable clinical research studies conducted at Loyola University Chicago (LUC) and Loyola University Medical Center (LUMC) and covers the responsibilities of the Principal Investigator (PI) and study team members, including resident projects with a faculty PI.

II. DEFINITIONS

DATABASE: a structured set of data, also referred to as dataset or data file.

STUDY TEAM: Principal Investigator (PI) and faculty, staff, students and trainees as delegated by PI that are identified on the research protocol and approved by IRB.

III. PROCEDURES:

a. An investigator (the PI) is responsible for reviewing the organization's requirements for obtaining and using the dataset.
b. If the organization requires purchase of the dataset:
    1. The PI is responsible for the purchase and oversight of the data to be used at LUC and LUMC.
    2. The PI is responsible for reviewing the purchase agreement or terms of the purchase to identify requirements for data use, such as data use agreements (DUAs) and training.
    3. The PI signs the purchase agreement if it only requires signature by an investigator. If the purchase agreement requires signature by the institution (LUC or LUMC), the agreement is to be submitted through the Research Channel to Office of Research Services (ORS). See SOP Contract Review and Negotiation.
c. If the organization requires a DUA for use of the data:
    1. The PI signs the DUA if it only requires signature by an investigator. If the DUA requires signature by the Institution (LUC or LUMC), the DUA is to be submitted through the Research Channel to ORS. See SOP Contract Review and Negotiation.
    2. If required by the organization, Study Team members sign DUAs before accessing the data.
    3. The PI is responsible for maintaining copies of all DUAs. If the organization does not provide copies of signed DUAs, the PI maintains documentation from the organization that DUAs were received.
    4. The DUAs or documentation of the DUAs are to be included in the project's IRB submission.
    5. If study team members are added Initial IRB approval, the study team member's DUA or documentation of the DUA is to be submitted to the IRB with the request to add him/her to the IRB.

d. If the organization requires training before data is used:
   1. The PI is responsible for completing training and ensuring Study Team members complete training when required.
   2. The PI maintains training records.
   3. The PI includes training records with the IRB submission.
   4. If study team members are added initial IRB approval, the study team member's training record is to be submitted to the IRB with the request to add him/her to the IRB.

e. The data must be kept in a secure environment where access to the data is limited to those who have documentation of IRB Approval. Acceptable environments include the R:\ Drive or LUC shared drive. HSD Informatics, Joe Koral (jkoral@luc.edu 708-216-7904 is the technical contact for server and information security.

f. All research studies require IRB approval, exemption, or acknowledgement before initiation.
   1. Each project utilizing the dataset requires IRB approval. The research protocol must include a statement of "Intended Use" for the data that is project specific.
   2. The IRB will ensure DUA and training records are included with the application as required by the organization. If the organization does not require DUAs or training, the study team is encouraged to include documentation stating this with the IRB application.
   3. Once the project is approved by the IRB, the approval notice and research protocol may be used as verification that all institutional requirements for use of the data have been met. The requested data can then be released to or obtained by the investigator.

g. The Clinical Research Office (CRO) at LUC HSD is available to serve as a regulatory and statistical resource for interested study teams.. The CRO will assist in submitting for IRB approval or verify the project has obtained IRB approval prior to initiation of collaborating on research activities.

IV. REFERENCES AND ASSOCIATED DOCUMENTS AND FORMS

IRB Reference Guide for Research Investigators and Staff

MBSAQIP https://www.facs.org/quality-programs/mbsaqip/participant-use
NSQIP https://www.facs.org/quality-programs/acs-nsqip/participant-use
HCUP https://www.hcup-us.ahrq.gov/databases.jsp

V. APPROVALS

9-27-18

Colleen Fitzgerald, MD, MS — 9/26/18 Date
Medical Director, Loyola University Chicago Clinical Research Office

David Hecht, MD — 9/27/18 Date
Executive Vice President of Clinical Affairs, Loyola University Medical Center