I. SCOPE

This SOP applies to requests for Loyola Medicine clinical patient data for research purposes.

Requests for Loyola Medicine financial data is addressed in research SOP PRO-014 Research use of financial information.

II. PROCEDURES

1. If the Principal Investigator (PI) or his/her designee ("Study Team") has direct access to a Loyola Medicine Electronic Health Record (EHR), they may abstract data directly from the EHR as permitted by an IRB-approved HIPAA waiver or IRB-approved HIPAA Authorization signed by the individual patient.
2. If a report or data abstract is needed from an EHR for the study, the Study Team requests the data through Loyola University of Chicago (LUC) Informatics or Loyola University Medical Center (LUMC) Clinical Research (LUMC CR). The PI is responsible for meeting IRB requirements before patient-level data is requested for research purposes.
   a. Requests for data from LUMC are submitted to LUC Informatics. The data request process is initiated through the Clinical Research Database (CRDB), which is accessible through Loyola Wired. Guidance on how to use the CRDB is available in the Documentation tab in the CRDB.
   b. Requests for data from Gottlieb Memorial Hospital or MacNeal Hospital are submitted to LUMC CR. The data request process is initiated through submission of the Loyola Medicine Research or QI Data Request Form, available on the Clinical Research department Spirit page: https://mytrinityhealth.sharepoint.com/sites/LM-ClinicalResearch.
   c. The Study Team may not request clinical data from Loyola Medicine administrators or other Loyola Medicine colleagues for research purposes.
3. The Study Team may only store the data on hardware (including laptops and USB drives) that is configured by LUC or Trinity Health and is encrypted. Any use of a USB drive for clinical data storage requires special permission.
4. The Study Team may only send or store the data on software or applications that are supported and approved by LUC or Trinity Health. The use of REDCap is strongly encouraged.
5. The Study Team may not share the data outside of LUC or Loyola Medicine without an executed agreement with the institution or party who intends to receive the data, or confirmation from Loyola Medicine that an agreement is not needed.

III. REFERENCES

1. 45 CFR Part 160, Part 162, and Part 164

IV. ASSOCIATED DOCUMENTS AND FORMS

1. Research SOP PRO-014 Research use of financial information
2. LUMC Policy COMP-004 Access to and Release of Patient Information – Research
3. LUMC Policy COMP-008 Accounting for Disclosures
4. Loyola Medicine QI or Research Data Request Form

V. APPROVALS

Allison M. Fitzgerald 6/25/2021
~~LUMC Chief Integrity Officer~~ Date
Medical Director, Clinical Research Office

Jim B Kiss 6/29/2021
~~Medical Director, Clinical Research Office (or designee)~~ Date
LUMC Chief Integrity Officer

Revision History

Effective Date	Summary of Changes
1/July/2019	Initial version
1/July/2021	Split out the source of LUMC data from the source for Gottlieb and MacNeal data