LOYOLA
UNIVERSITY
HEALTH SYSTEM

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UNIVERSITY
CHICAGO

Research Use of
Financial Information
PRO-014
Effective date: 01/Mar/2019

I. SCOPE

Financial Information is considered business confidential by Trinity Health. Financial information includes hospital or clinic claims, cost data and reimbursement information.

Financial Information to be utilized for a research study requires a different approval process than protected health information. This approval process proceeds in parallel with IRB review. No data should be released for research purposes by anyone except as described in this SOP.

II. PROCEDURES

1. LUMC Clinical Research ("LUMC CR") reviews research use and disclosure of financial data further described in Sections 2-4 below as part of the LUMC Institutional Review Operational Assessment.
    a. The criteria listed in this SOP will be used to evaluate the intended use of financial data for research.
    b. LUMC CR will communicate approvals or disapprovals to the Principal Investigator or his/her designee ("Study Team").
    c. Study Teams should indicate clearly in the research protocol what financial data elements are to be obtained for the study. It must be clear in the protocol that financial data will be utilized. Otherwise, LUMC CR will not be notified to initiate the approval process and the data release may be in violation of Policy. LUMC CR will confirm the study's IRB submission describes the use of financial data and aligns with the data request. Data will not be released for research purposes without IRB approval.
    d. Financial information is not to be released for research purposes without documentation of approval from LUMC CR.

2. With LUMC CR approval, **copies of claims and claims data** may be released outside of LUMC for research purposes under the following conditions:
    a. Redacted claims may be provided to third parties if approved by LUMC CR.
    b. During the Operational Assessment, LUMC CR reviews the protocol to confirm the data is necessary to meet the endpoints of the study and documents the assessment.
    c. If the request is determined to be not justifiable, LUMC CR informs the Study Team.
    d. To request a claim:
        (1) The third party requests the information from the Study Team.
        (2) The Study Team ensures the request is in accordance with the protocol and the IRB approval.
        (3) The Study Team sends a request to LUMC CR with the following supporting information:
            (a) Patient medical record number and date of birth
            (b) Patient study ID
            (c) Date(s) of service for which claims are requested
            (d) The location of the encounter: inpatient, emergency room, or outpatient
        (4) LUMC CR confirms the request is approved and then forwards the request to the Revenue Integrity Research Billing Team.
        (5) Revenue Integrity prints the requested claims and scans/emails them to LUMC CR.
        (6) LUMC CR redacts confidential information in the claim, including:
            (a) HIPAA identifiers
            (b) Patient's insurance provider
            (c) Providers

The claim will contain the revenue codes, descriptions, CPT codes, charges, and diagnosis codes if requested by the Study Team and if in accordance with IRB approval.
(7) LUMC CR sends the redacted claims to the Study Team to provide to the third party.

3. With LUMC CR approval, **reimbursement** information may be used for research under the following conditions:
   a. Data is provided by LUC HSD Informatics after review and approval by LUHS Finance for data integrity and accuracy.
   b. Private payer reimbursement information cannot be used for research purposes.
   c. Medicare reimbursement is publically available. The Study Team may obtain it directly from the Medicare website or request it from LUC HSD Informatics.
      (1) To obtain Medicare reimbursement data from the Medicare website, see:
          (a) Physican Fee Schedules
          (b) Hospital Outpatient Fee Schedules
          (c) Clinical Lab Fee Schedule
          (d) Drugs

4. With LUMC CR approval, **cost** information may be used for research under the following conditions:
   a. Data is provided by LUHS Finance.
   b. If the study involves clinical data as well as cost data, Study Teams are to obtain and validate the clinical component of their data from LUC HSD Informatics first.
      (1) LUC HSD Informatics defines the cohort for which LUHS Finance would provide the cost data.
      (2) The data set should include the hospital account record ("HAR") for each inpatient or hospital-based outpatient encounter of interest, or guarantor and date of service for each outpatient encounter of interest. Cost data is reported by the HAR or guarantor.
      (3) Note: If both data sets are requested concurrently, they may not align. This may result in re-work and delays in obtaining a complete final data set or affect the integrity of the data set.
   c. To request the data, the Study Team completes a Decision Support data request form; https://app.smartsheet.com/b/form/1f913da780d249d2bac4f3e6bfa80fad.
   d. Cost data may be presented internally (e.g. grand rounds). Copies of the data may not be shared in paper or electronically with anyone outside of the Study Team.
   e. Cost data may not be published or presented externally. In some cases, exceptions may be made with the review and approval of LUHS Finance of the proposed presentation.
   f. Cost data for discharges including inpatient, emergency room, observation care, and surgical cases are available from the Illinois Department of Public Health (http://www.dph.illinois.gov/topics-services/prevention-wellness/patient-safety-quality/discharge-data)

III.   REFERENCES

1. LUMC Policy COMP 0024 Data Request Policy
2. SOP PRO-003 LUMC Operational and Financial Assessment of Research
3. 45 CFR 164.514

IV.   **APPROVALS**

_____   1/28/19
Senior Vice President, Finance (or designee)   Date

_____   2/1/19
LUC Medical Director, Clinical Research Office (or designee)   Date