### PURPOSE

* 1. This procedure establishes the process for IRB staff members for reporting any suspected non-compliance with HIPAA Privacy Rule, to the LSUHSC-NO Privacy Officer in the Office of Compliance Programs.
  2. The process begins when a member of the IRB Office Staff determines there is substantial reason to believe that an instance of HIPAA non-compliance may have occurred as applied to human subjects research.
  3. The process ends when the Office of Compliance determines the event to be resolved and issues a determination regarding the suspected HIPAA non-compliance reported by the IRB Office Staff.

### REVISIONS FROM PREVIOUS VERSION

### None

### POLICY

* 1. LSUHSC-NO requires its health care components, facilities and providers, including but not limited to health sciences schools, IRBs and/or Privacy Boards established thereunder, hospitals, physician/faculty practices, and clinics to comply with the HIPAA Privacy Rule when conducting research involving individually identifiable health information for human subjects.
  2. The IRB should notify the Privacy Officer immediately upon discovery of a Breach or suspected Breach of Protected or Restricted Information so that LSUHSC-NO may take appropriate steps to mitigate any harm that may possibly occur [LSUHSC CM-53].

### DEFINITIONS

* 1. HIPAA: - Health Insurance Portability and Accountability Act: Standards for Privacy of Individual Identifiable Health Information [45 CFR Parts 160 and 164]
  2. Non-Compliance: Failure to follow the regulations, or the requirements or determinations of the IRB.
  3. Research - A systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge.
  4. Research databases – A collection of health information or data that is maintained over time, where access to the data is controlled and multiple individuals may use the information for a variety of objectives. Data stored in a database may be identifiable or coded.
  5. Suspension of IRB Approval: An action of the IRB, IRB designee, Institutional Official, or designee of the Institutional Official to temporarily or permanently withdraw IRB approval of some or all research procedures short of a Termination of IRB Approval. Suspended studies remain open and are subject to continuing review.
  6. Termination of IRB Approval: An action of the IRB, IRB designee, Institutional Official, or designee of the Institutional Official to permanently withdraw IRB approval of all research procedures. Terminated studies are permanently closed and no longer require continuing review.

### RESPONSIBILITIES

* 1. Specific responsibilities for IRB Office Staff, IRB Chair, and Privacy Officer are described throughout this document.

### PROCEDURES

#### IRB Office Staff Responsibilities

* + 1. Upon receipt of any suspected HIPAA Privacy Rule non-compliance involving the misuse of PHI, the IRB Office Staff member will:
       1. Report whatever information is available at that time to the LSUHSC-NO Privacy Officer in the Office of Compliance Programs. This should be done immediately and prior to conduct of an IRB investigation.
       2. Notify the IRB Chair of the potential issue simultaneously.
    2. The IRB Office Staff member should then begin an investigation in order to better understand the possible explanation and circumstances for what appears to be a HIPAA issue and thus, likely an IRB regulatory issue.
       1. Any additional information which might help to resolve the investigation, should be passed on to the Privacy Officer and IRB Chair in a timely fashion.
       2. The IRB Office Staff member should continue the investigation until all necessary information has been collected, while keeping such documents secure.
    3. After (or before) completion of the investigation, the IRB Office Staff member will obtain permission from the Privacy Officer to continue with further action in order to resolve the non-compliance associated with the IRB-approved protocol.
       1. A suspension or termination of IRB approval by the IRB, IRB designee, Institutional Official, or designee of the Institutional Official may be considered in consult with the IRB Chair.
       2. It may be appropriate to prepare an initial report to OHRP and indicate that a follow-up or final report will follow by either a specific date, when the investigation has been completed, or when a corrective action plan has been implemented. This should be done in collaboration with the IRB Chair. *See HRP-2101 for the Standard Operating Procedure for the IRB reporting incidents to OHRP*.
  1. **Privacy Officer Responsibilities**
     1. After receiving and evaluating the initial report from an IRB Office Staff member, the Privacy Officer will respond in writing and will either state that the report was adequate or request additional information in order to make a determination as to whether a serious breach has occurred or a lesser issue of HIPAA Privacy non-compliance is appropriate.
     2. The Privacy Officer is responsible for providing in writing a determination as to the final analysis of the information provided in conjunction with the suspect HIPAA non-compliance.

1. **MATERIALS**

7.1 None

1. **REFERENCES**

8.1 [LSUHSC Office of Compliance Programs](https://www.lsuhsc.edu/administration/ocp/)

8.2 [LSUHSC CM-53 HIPAA Privacy Policies](https://www.lsuhsc.edu/administration/cm/cm-53/)

8.3 [HIPAA Privacy Rule](https://www.hhs.gov/hipaa/for-professionals/privacy/index.html)

8.4 [SOP HRP-2101 Reporting Incidents to OHRP](https://www.lsuhsc.edu/administration/academic/ors/irb/irb_sops.aspx)