1 PURPOSE:

1.1 This procedure establishes the process for reporting mandatory IRB reporting to the Food and Drug Administration (FDA).

1.2 The process begins when a Reportable New Information application is received by a member of the IRB Office Staff and determined to meet the criteria required for reporting to FDA. **OR** When an IRB analyst discovers information that indicates an incident or events have occurred which requires reporting to the FDA.

1.3 The process ends when FDA has determined the reporting of the event to be adequate.

2 REVISIONS FROM PREVIOUS VERSIONS

None

3 POLICY:

Under 21 CFR 56.113, the IRB shall have the authority to suspend or terminate approval of research that is not being conducted in accordance with the IRB's requirements or that has been associated with unexpected serious harm to subjects. Any suspension or termination of approval shall include a statement of the reasons for the IRB`s action and shall be reported promptly to the investigator, appropriate institutional officials, and the Food and Drug Administration. 21 CFR 56.108(b) requires that the IRB follow written procedures for ensuring prompt reporting to the IRB, appropriate institutional officials, and the Food and Drug Administration of:

3.1 Any unanticipated problems involving risks to subjects or others; any serious or continuing non-compliance with FDA regulations, and any suspension or termination of IRB approval; or

3.2 Any instance of serious or continuing noncompliance with these regulations or the requirements or determinations of the IRB; or.

3.3 Any suspension or termination of approval shall include a statement of the reasons for the IRB`s action and shall be reported promptly to the investigator, appropriate institutional officials, and the Food and Drug Administration.

3.4 The reporting requirements apply to all non-exempt human subjects' research if the project is funded by a non-HHS federal agency or commercial/industry sponsor or involves human subjects' research that involves a drug, device or biologic that is FDA regulated.

4 DEFINITIONS

4.1 Reportable New Information: Information that becomes known during the course of a research study that will need to be reported to the IRB in a timely, meaningful way so that research participants can be protected from avoidable harms. This information may be Unanticipated Problems Involving Risk to Subjects or Others (UPIRSOs) and/or Non-compliance.

4.2 Unanticipated Problem Involving Risks to Subjects or Others: Any information that is (1) unanticipated and (2) indicates that subjects or others are at increased risk of harm.

Is unexpected (in terms of nature, severity, or frequency) given the procedures described in the research protocol documents (e.g., the IRB-approved research protocol and informed consent document) and the characteristics of the human subject population being studied.

Is related or possibly related to participation in the research (in this Instruction, possibly related means there is a reasonable possibility that the incident, experience, or outcome may have been caused by the procedures involved in the research).

Suggests that the research places human subjects or others at a greater risk of harm (including physical, psychological, economic, or social harm) than was previously known or recognized, even if no harm has actually occurred.

4.3 Serious Non-Compliance: failure to comply with regulations, university policies, or the requirements/determinations of the IRB, when, in the judgment of the institution, such failure substantially increases risks to subject welfare/safety, subject rights, or data integrity. Serious noncompliance may also involve compromising the effectiveness of LSUHSC's human subject research protection program

4.4 Continuing Non-Compliance: A pattern of Non-Compliance that suggests the likelihood that, without intervention, instances of Non-Compliance will recur, a repeated unwillingness to comply, or a persistent lack of knowledge of how to comply

4.5 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.

4.5 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.

5 RESPONSIBILITIES

5.1 Specific responsibilities for IRB Office staff and IRB Chair are described throughout this document.

6 PROCEDURES

6.1 **IRB Office Staff Responsibilities**

6.1.1 Upon receipt of a RNI application, the assigned IRB Office Staff Member, a voting or alternate member of the IRB conducting a designated member review, will determine if the incident is:

6.1.1.1 An unanticipated problem involving risk to subjects or others;

6.1.1.2 Serious or continuing non-compliance with 45 CFR Part 46 or the requirements of the IRB; or,

6.1.1.3 A suspension or termination of IRB approval by the IRB, IRB designee, Institutional Official or designee of the Institutional Official.

6.1.2 If the incident falls into one or more of the reportable categories, the Staff Member should alert the IRB Chair or ORS Compliance Manager that reporting to FDA is possibly required

6.1.3 The Staff Member should prepare and submit an email to one of the appropriate contacts listed below once it is confirmed that the incident is reportable.

6.1.3.1 When reporting suspensions or terminations of IRB approval, please include the IND or IDE number, the full name of the research protocol, the name(s) of the clinical investigators, and the reason(s) for the suspension or termination. These reports should be submitted via e-mail. Submit information to the contacts listed below.

6.1.3.1.1 Please report suspension or termination of IRB approval; unanticipated problems involving risks to human subjects; or serious or continuing noncompliance with the regulations or the requirements or determination of the IRB to one of the following contacts:

For Drug Products:
Office of Scientific Investigations
Email: CDER-OSI-GCPReferrals@fda.hhs.gov
Phone: (301) 796-3150

For Biologics Products:
Email: CBERBIMONotification@fda.hhs.gov
Bioresearch Monitoring Branch

For Device Products:
Phone (301) 796-5490
Fax: (301) 847-8136
Email: bimo@cdrh.fda.gov

6.1.3.1.2 Please report suspension or termination of IRB approval; unanticipated problems involving risks to human subjects; or serious or continuing noncompliance with the regulations or the requirements or determination of the IRB to the appropriate agency liste above and include the following information:

- Name of the Institution
- Title of the research project or grant proposal
- Name of the principal investigator
- IRB protocol number
- IND/IDE/510(k) Number if applicable
- Name of submitter should be listed as Compliance Manager.
- Any applicable federal award number(s)
- A detailed description of the problem
- Actions taken by the institution or plans to address the problem
- Return email used should be listed as IRBOffice@lsuhsc.edu
  Phone number listed as the phone line: (504) 568-

6.1.3.2 It may be appropriate to prepare an initial report to FDA 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.

6.1.3.3 The IRB Staff Member is responsible for updating the FDA and the IRB Chair as information becomes available until the report is considered resolved by FDA.

6.2 IRB Chair/Compliance Manager Responsibilities

6.2.1 After notification of the potentially reportable incident by IRB Staff Member, the IRB Chair or Compliance Manager will evaluate the incident and the IRB Staff member's determinations. The Chair or Compliance Manager will make a final determination whether or not the incident is required to be reported by the Staff Member to FDA.

6.3 FDA Responsibilities

6.3.1 After receiving and evaluating an incident report from an institution, FDA will acknowledge receipt and respond in writing and will state either that the report was adequate or request additional information.

7.0 REFERENCES

7.1 FDA Website: Mandatory IRB Reporting

7.2 21 CFR 56.108(b)