1 PURPOSE

1.1 This procedure establishes the process for reporting incidents to Office for Human Research Protections (OHRP).

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 OHRP.

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

2 REVISIONS FROM PREVIOUS VERSION

2.1 Includes the use of the OHRP Incident Report Online Form as required by OHRP.

3 POLICY

3.1 Any unanticipated problems involving risks to subjects or others; any serious or continuing non-compliance with Department of Health and Human Services (DHHS) regulations, 45 CFR Part 46, or determinations of the IRB approval; or any suspension or termination of IRB approval must be reported to OHRP promptly.

3.2 The reporting requirements apply to all non-exempt human subjects research that is (a) conducted or supported by HHS; (b) conducted or supported by any non-HHS federal department or agency that has adopted the Common Rule and is covered by a Federalwide Assurance; or (c) covered by a Federalwide Assurance regardless of funding

3.3 See *Addendum A* for a decision chart: What Incidents Should Be Reported to OHRP?

3.4 If the project is funded by a non-HHS federal agency or commercial/industry sponsor, other reporting requirements may apply in addition to OHRP.

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 UM'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.

4.6 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.

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 the categories, the Staff Member should alert the IRB Chair that reporting to OHRP is possibly required.

6.1.3 The Staff Member should prepare and submit an OHRP Incident Report Online Form once the Chair confirms he agrees with the determination that the incident is reportable.

6.1.3.1 **For an unanticipated problem involving risk**, the following information must be included in the on-line reporting application form:

6.1.3.1.1 Name of the Institution

6.1.3.1.2 Title of the research project or grant proposal

6.1.3.1.3 Name of the principal investigator

6.1.3.1.4 IRB protocol number

6.1.3.1.5 Name of submitter should be listed as IRB Chair

6.1.3.1.6 Any applicable federal award number(s)

6.1.3.1.7 A detailed description of the problem

6.1.3.1.8 Actions taken by the institution or plans to address the problem

6.1.3.1.9 Return email used should be listed as IRBOffice@lsuhsc.edu

6.1.3.2 **For serious or continuing non-compliance**, the following information must be included in the on-line reporting application form:

6.1.3.2.1 Name of the Institution

6.1.3.2.2 Title of the research project or grant proposal

6.1.3.2.3 Name of the principal investigator

6.1.3.2.4 IRB protocol number

6.1.3.2.5 Name of the person submitter should be entered as IRB Chair

6.1.3.2.6 Any applicable federal award number(s)

6.1.3.2.7 A detailed description of non-compliance

6.1.3.2.8 Actions taken by the institution or plans to address the non-compliance

6.1.3.2.9 Return email used should be listed as IRBOffice@lsuhsc.edu

6.1.3.3 **For suspension or termination**, the following information must be included in the on-line reporting application form:

6.1.3.3.1 Name of the Institution

6.1.3.3.2 Title of the research project or grant proposal

6.1.3.3.3 Name of the principal investigator

6.1.3.3.4 IRB protocol number

6.1.3.3.5 Name of the submitter should be entered as IRB Chair

6.1.3.3.6 Any applicable federal award number(s)

6.1.3.3.7 A detailed description of the reason for the suspension or termination

6.1.3.3.8 Actions taken by the institution or plans to address the suspension or termination

6.1.3.3.9 Return email used should be listed as IRBOffice@lsuhsc.edu

6.1.3.4 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.

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

6.2 ***IRB Chair Responsibilities***

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

6.3 ***OHRP Responsibilities***

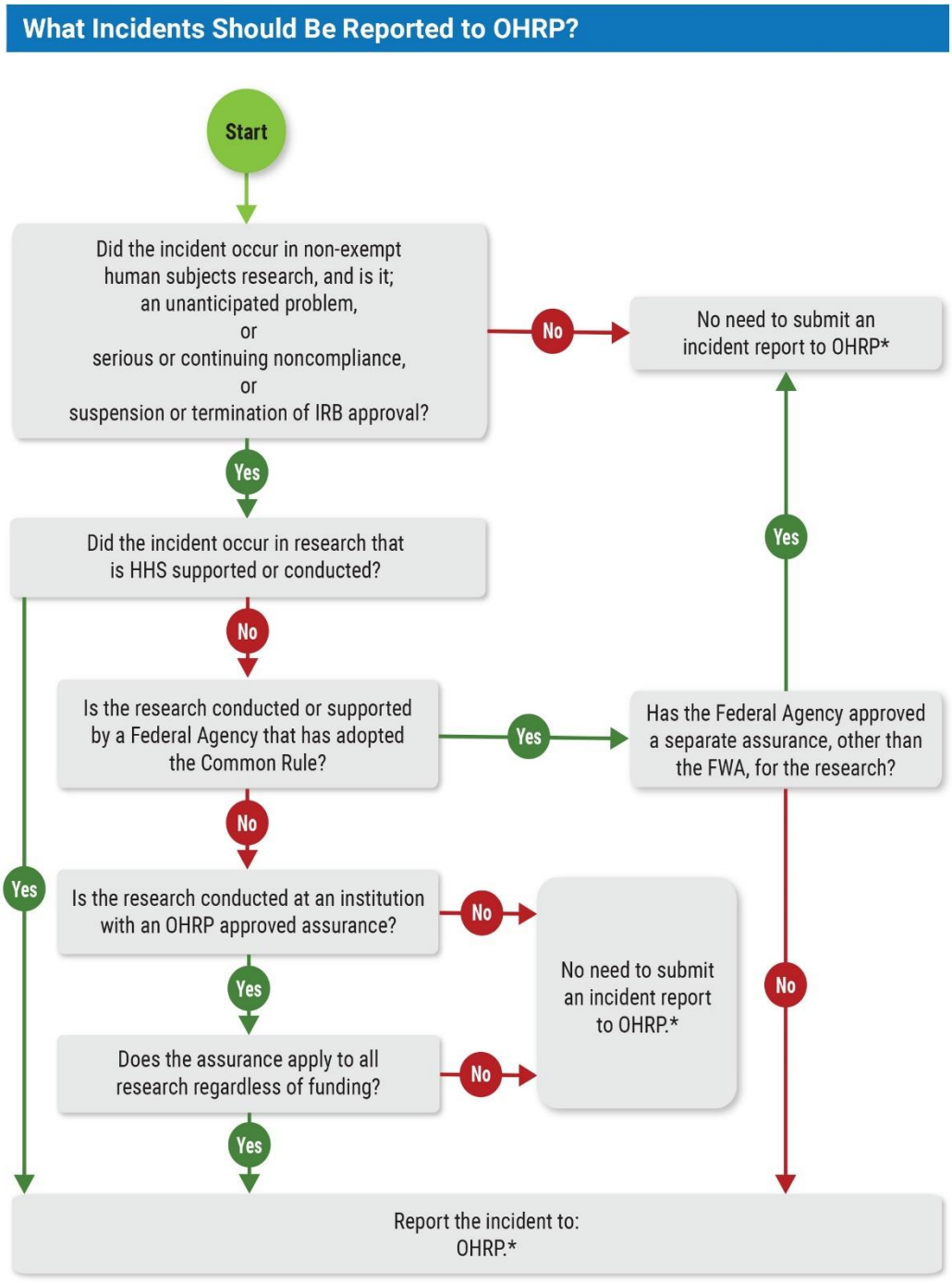
6.3.1 After receiving and evaluating an incident report from an institution, OHRP will respond in writing and will state either that the report was adequate or request additional information.

7 REFERENCES

7.1 OHRP Website: Reporting Incidents

7.2 45 CFR 46.108

ADDENDUM A
Decision Chart



* Other reporting requirements may apply, whether or not a report to OHRP is required.