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 None

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 is required

6.1.3 The Staff Member should prepare a report to be sent to OHRP (*see Addendum B for example*)

6.1.3.1 **For an unanticipated problem involving risk**, the following information must be included:

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 Any applicable federal award number(s)

6.1.3.1.6 A detailed description of the problem

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

6.1.3.2 **For serious or continuing non-compliance**, the following information must be included:

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 Any applicable federal award number(s)

6.1.3.2.6 A detailed description of non-compliance

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

6.1.3.3 **For suspension or termination**, the following information must be included:

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 Any applicable federal award number(s)

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

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

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.

6.2 ***IRB Chair Responsibilities***

6.2.1 **After** the draft report is received from the IRB Staff Member, the IRB Chair should promptly (within days) email the report to OHRP at IRPT.OS@hhs.gov (*see Addendum C for example*).

6.2.2 If the investigation is still ongoing when the initial report is sent to OHRP, the IRB Chair should promptly report any follow-up information or corrective action plans on the same email chain.

6.3 ***OHRP Responsibilities***

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

7 MATERIALS

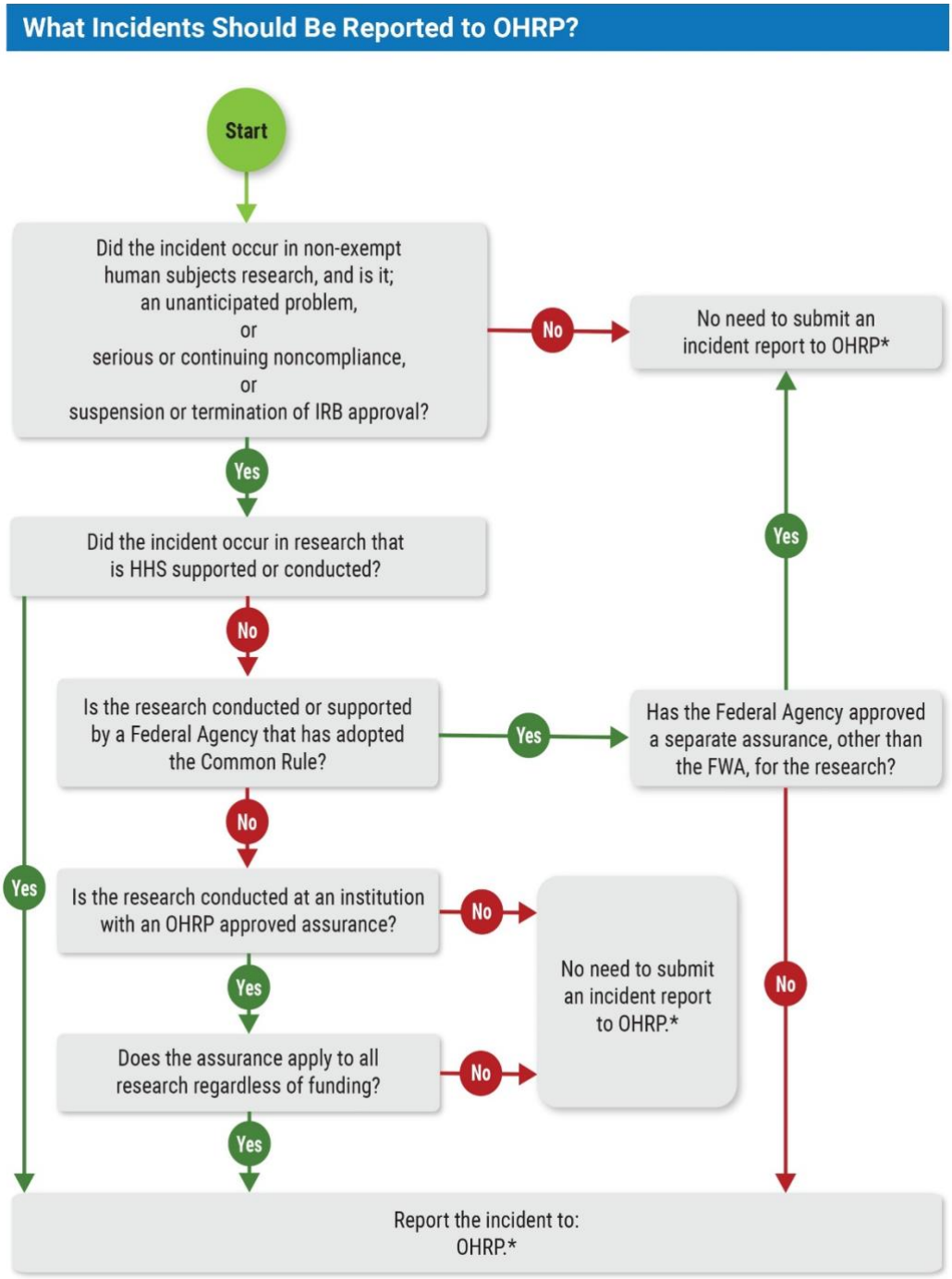
7.1 None

8 REFERENCES

8.1 OHRP Website: Reporting Incidents

8.2 45 CFR 46.108

ADDENDUM A
Decision Chart



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

ADDENDUM B
Report Example

MEMORANDUM/INCIDENT REPORT

From: LSUHSC-NO Institutional Review Board (FWA00002762)

To: Office of Human Research Protections

From: Jawed Alam, PhD, MBA
Executive Director, Office of Research Services
Institutional Review Board Chair

Date: [Date]

RE: **Title**:
Principal Investigator:
IRB #:
Award Number:

On [Date of Incident], the LSUHSC IRB was made aware of [Description of Incident].

As a result of this incident, [Description of Action Plan] or [The IRB approval for this study has been terminated.] or [The IRB approval for this study is suspended until further review is completed. All study activities will be halted.]

ADDENDUM C
Email Example

Subject: [Type of Incident] for [Short Title] Study – LSUHSC New Orleans

To Whom It May Concern-

The Louisiana State University Health Sciences Center – New Orleans IRB has just become aware of [Type of Incident] for the [Title], [Award/Grant #]. A detailed report is attached.

At this time, the LSUHSC-NO IRB is still investigating this incident and will follow-up with OHRP as more information becomes available.

Sincerely,