SOP 308: Reporting to Regulatory Agencies and Institutional Officials

1. POLICY

This SOP addresses the reporting requirements of the IRB to regulatory agencies when serious or continuing non-compliance, unanticipated problems involving risks to participants or others, or suspension/termination of IRB approval occurs. Noncompliance, unanticipated problems, and suspension/termination are described in detail in SOP 903: Non-compliance/Scholarly Misconduct; SOP 407: Protocol Deviations and Unanticipated Problems; and SOP 411: Suspension or Termination of IRB Approval.

Specific Policies

1.1 Notification

1.1.1 The HRPP Director shall be notified when non-compliance, unanticipated problems involving risks to participants or others, or suspension/termination of IRB approval occurs.

The HRPP Director shall notify the Director of Compliance, the University Senior Vice President and Provost or designee, the HSC VPR, OHRP, FDA, the University Controller, ORA/ORS, Legal Counsel, and/or sponsors/agencies as applicable. The HRPP Director is responsible for distributing the written communication to the Senior Vice President and Provost or designee, prior to distribution to any outside agency.

Maximum time from the recognition of a reportable event and reporting the event to the appropriate external authorities is generally thirty (30) University business days.

1.1.2 For reporting requirements of non-compliance, unanticipated problems involving risks to participants or others, unanticipated serious adverse events, and suspension/termination of IRB approval in VA research projects, see 603A: Veterans Affairs Medical Center.

1.1.3 Any determinations of unanticipated problems involving risk to participants or others, serious or continuing noncompliance, and suspension or termination of DoD-supported research must be promptly (no longer than within 30 days) reported to the DoD human research protection officer.

1.2 Contents of the Letter/Report

The HRPP Director shall include in the written communication details regarding how the event was discovered, the IRB or IRB Chair or IRB designee response to the event, the investigator response to the event, and the IRB plan for monitoring the outcome of the event.

1.3 Approval of the Letter/Report

The HRPP Director or designee shall draft the letter/report regarding serious or continuing non-compliance, unanticipated problems involving risks to participants or others, and suspension/termination of IRB approval. For the NC the Director of Compliance and for HSC the HSC VPR, Legal Counsel, and IRB Chair may be consulted for guidance in preparing the letter/report. The HRPP Director and University Privacy Official shall approve the letter/report.

2. SCOPE

This SOP refers to reporting to outside agencies/entities only. For internal communication procedures, consult SOP 903:Non-Compliance/Scholarly Misconduct; SOP 407: Protocol Deviations and Unanticipated Problems; and SOP 411: Suspension or Termination of IRB Approval.

3. RESPONSIBILITY

3.1 The HRPP Director or designee is responsible for drafting letters to external agencies as described in Section 1.1 above regarding serious or continuing non-compliance, unanticipated problems involving risks to participants or others, and suspension/ termination of IRB approval.

3.2 The Director of Compliance for the NC and the HSC VPR for HSC, and IRB staff are responsible for notifying the HRPP Director and/or IRB Chair or IRB designee regarding alleged serious or continuing non-compliance and/or unanticipated problems involving risks to participants or others.

3.3 The IRB Chair or IRB designee is responsible for reporting to the convened IRB any suspension/termination of IRB approval.

3.4 The Investigator is responsible for notifying the IRB of unanticipated problems involving risks to participants or others, maintaining accurate documentation, and investigating and following up all possibly related serious and unexpected harm to participants, per SOP 407: Protocol Deviations and Unanticipated Problems.

4. APPLICABLE REGULATIONS AND GUIDELINES

45 CFR 46.103

21 CFR 56.108

5. REFERENCES TO OTHER APPLICABLE SOPS

SOP 407: Protocol Deviations and Unanticipated Problems

SOP 411: Suspension or Termination of IRB Approval

SOP 603A: Veterans Affairs Medical Center

SOP 903: Non-compliance/Scholarly Misconduct

6. ATTACHMENTS

None

7. PROCESS OVERVIEW

7.1 When serious or continuing non-compliance, unanticipated problems involving risks to participants or others, and/or suspension/termination of IRB approval occurs, including but not limited to the IRB Chair or IRB designee, IRB Staff, or for the NC the Director of Compliance and for HSC the HSC VPR immediately notifies the HRPP Director.

7.2 The HRPP Director is responsible for distributing the written communication to the Senior Vice President and Provost or designee, prior to distribution to any outside agency. The HRPP Director is responsible for drafting and distributing follow-up communication with applicable federal agencies and the Institutional Official, as needed.

7.3 The HRPP Director drafts written communication within 30 business days to be distributed to applicable federal and institutional officials, which may include but are not limited to:

- IRB
- Director of Compliance
- Senior Vice President and Provost
- HSC Vice President for Research
- Institutional Official
- OU Legal Counsel

- University Privacy Official
- OHRP, when the research is covered by DHHS regulations
- FDA, when research is FDA-regulated
- The report will be distributed to the IRB to which the research is assigned
- Other federal agencies when the research is subject to the authority of those agencies and those agencies require reporting separate from that to OHRP.
- Office of Research Administration/Office of Research Services
- Controller

7.4 The letter shall include the following:

- Investigator name
- IRB number and project title
- Applicable grant number(s)
- Nature of the event
- IRB or QI Audit findings
- IRB actions and rationale
- Investigator actions and preventative measures
- Plan for continued evaluation

APPROVED BY: _____ DATE: 09/09/2016

NEXT ESTABLISHED REVIEW DATE: AUGUST 2018