

SOP: 308
REPORTING TO REGULATORY AGENCIES
AND INSTITUTIONAL OFFICIALS

1. POLICY

This policy addresses the reporting requirements of the IRB to regulatory agencies when serious or continuing non-compliance, unanticipated problems involving risks to participants or others, and 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, Unanticipated Problems Involving Risks to Participants or Others and Protocol Deviations; and SOP 411, Suspension or Termination of IRB Approval.

Specific Policies

1.1 Notification. The IRB Chair or designee, the IRB Quality Improvement Coordinator, or the Director of Compliance shall notify the HRPP Director 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, OHRP, FDA, ORA and/or other sponsors/agencies as applicable. At the HSC campus, 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.

For research being conducted at the VA, the HRPP Director shall also notify the VA Research and Development Office; the Regional VA Office of Research Oversight; the VHA Privacy Officer if the report involves the unauthorized use, loss, or disclosure of individually identifiable patient information; and the VHA Information Security Officer if the report involves the violation of information security requirements. For VA research that expires because continuing review is not completed, the IRB shall notify the sponsoring agency, private sponsor, Office of Research and Development, Office of Research Oversight, or other Federal agencies, as appropriate.

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

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 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. The Director of Compliance and IRB Chair may be consulted for guidance in preparing the letter/report. The HRPP Director shall approve the letter/report.

2. SCOPE

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

3. RESPONSIBILITY

- 3.1 The HRPP Director 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 and IRB staff are responsible for notifying the HRPP Director and/or IRB Chair or designee regarding alleged serious or continuing non-compliance and/or unanticipated problems involving risks to participants or others.
- 3.3 The IRB Chair or 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 as per SOP 407, Unanticipated Problems Involving Risks to Participants or Others.
- 3.5 The HRPP Director or designee is responsible to notify the sponsoring agency, private sponsor, VA Office of Research and Development, Office of Research Oversight, or other Federal agencies, as appropriate for VA research that expires because continuing review is not completed.

4. APPLICABLE REGULATIONS AND GUIDELINES

45 CFR 46.103
21 CFR 56.108

5. REFERENCES TO OTHER APPLICABLE SOPS

SOP 903, Non-compliance/Scholarly Misconduct
SOP 407, Unanticipated Problems Involving Risks to Participants or Others and Protocol Deviations
SOP 411, Suspension or Termination of IRB Approval.

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, the IRB Chair or designee, IRB Staff, or Director of Compliance immediately notifies the HRPP Director.
- 7.2 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
 - OHRP, when the research is covered by DHHS regulations
 - FDA, when research is FDA-regulated.
 - VA Research and Development Office
 - VA Regional Office of Research Oversight

- VA Central Office, if the unanticipated problem involving risks to participants or others is an adverse event
- VHA Privacy and/or Information Security Officer when the report involves violations of VA information security requirements.
- The report will be distributed to the IRB to which the research is assigned
- Other federal agencies when the research is subject to those agencies and those agencies require reporting separate from that to OHRP.
- Office of Research Administration

7.3 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

7.4 At the HSC Campus, 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.

7.5 The HRPP Director is responsible for drafting and distributing follow-up communication with applicable federal and Institutional Official, as needed.

APPROVED BY: _____

DATE: 09/01/2009

NEXT ESTABLISHED REVIEW DATE: MAY 2012