IRB Review of Reportable Events

PURPOSE

It is the purpose of this policy to describe the procedures to ensure appropriate Institutional Review Board (IRB) review of reportable events and notification of appropriate institutional officials, sponsor, coordinating center and the appropriate regulatory agencies of unanticipated problems involving risks to participants or others.

Review Process

Event reports and accompanying information will be screened for completeness by Human Research Protection Program (HRPP) staff, who will make an initial determination about whether the event represents a possible unanticipated problem involving risks to subjects or others. These events will be forwarded to the IRB Chair, or designee with relevant IRB expertise for review. All other event reports will be reviewed by the expedited procedure.

Reports of events that do not meet the requirements for prompt reporting may be withdrawn.

Expedited Review

Event reports and accompanying information will be forwarded by HRPP staff to the IRB Chair or one of the experienced members with relevant expertise designated by the Chair for expedited review. The Chair or designee will determine if the report raises new concerns about risks and will recommend further review by the convened IRB if necessary, for a final determination. The IRB Chair or Vice-Chair will consider the rights and welfare of participants when suspending, terminating, or modifying research.

If during expedited review the event is determined not to be an unanticipated problem involving risks to subjects or others, the reviewer will make any necessary recommendations for action (see below), which will be communicated to the Investigator by the IRB. Modifications proposed by the Investigator or IRB reviewer that represent minor changes will also be reviewed by the expedited procedure. IRB members will be informed of these expedited reviews.

Convened Review

Suspensions and terminations imposed by someone other than the convened IRB must be reported to and reviewed by the IRB. Reports of events determined by HRPP staff or expedited
IRB review to present possible unanticipated problems involving risks to subjects or others will be forwarded to the IRB for convened review. Modifications proposed by the Investigator or IRB reviewer that represent more than minor changes will also be reviewed by the convened IRB. The Chair, Vice-Chair, or other member with relevant expertise will serve as the primary reviewer. Copies of the reports, all other information provided by the investigator, and current consent documents (or verbal scripts) with any proposed changes will be included in the review materials for the IRB members. Sections from the protocol, previous event reports, and other relevant information or reference materials may also be reviewed, as applicable.

The complete protocol record will be available to any IRB member prior to and during the convened IRB meeting.

By convened review the IRB will determine whether the event is an unanticipated problem involving risks to subjects or others and if further action is necessary. Action(s) will be based on the nature of the event, degree to which research participants are placed at risk, occurrence of previous problems, etc. The IRB will consider the rights and welfare of participants when suspending, terminating, or modifying research.

**IRB Actions**

The types of actions that the IRB may consider for any event include, but are not limited to:

- Modification(s) of the research protocol or procedures;
- Modification(s) of the consent process or consent form;
- Provision of additional information should be provided to current research participants (required when such information may relate to their willingness to continue in the research);
- Provision of additional information should be provided to past research participants;
- Reconsent of Current research participants;
- Additional follow-up/monitoring is required for current and/or past research participants;
- Monitoring of the research (including audits) or consent process;
- Education or mentoring for the Principal Investigator and/or research staff;
- Additional reporting is required, including modification of the continuing review schedule;
- Additional resources are needed to support the Investigator’s research activities;
- Limitations (e.g., restriction to co-investigator status) on the Investigator’s research activities;
- Suspension or termination of the research; and
- Referral to other appropriate University process (e.g., misconduct review).

The IRB’s determination and action(s), including votes taken, will be recorded in the meeting minutes. The requirements for quorum and majority apply. Investigators will be notified in writing of the IRB’s decisions regarding events determined not to represent unanticipated
problems involving risks to subjects or others following approval of the meeting minutes by the IRB Chair or Vice-Chair. Suspended IRB approval may be reinstated, as appropriate, based on the outcome of the convened review. Investigators (and others) will be notified of IRB actions regarding events determined to be unanticipated problems involving risks to subjects or others as described below.

If the IRB determines that the event was an act of non-compliance, then the IRB Chair will make a report of non-compliance to the Institutional Official, and if the non-compliance involves the Veterans Affairs Medical Center (VAMC), to the VAMC Research and Development, in accordance with Policy Number VII.03 Investigating Allegations of Non-Compliance in Human Subjects Research.

Institutional Reporting

If the IRB determines that an event is an unanticipated problem involving risks to subjects or others, or if the IRB suspends or terminates approval of research that is associated with unexpected serious harm to subjects, the Investigator(s), IRB, Institutional Official, and the Investigator(s)’ Dean and Department Chair (or equivalent) will be notified of the reasons for the IRB’s action in writing by HRPP staff within 14 days of the determination. OHRP, FDA (as applicable for FDA-regulated research), the sponsor or any other sponsoring federal Department or Agency, and others (e.g., Sponsored Research Services) as necessary, in accordance with the University of Cincinnati’s Federalwide Assurance, will be notified in writing within 30 days. The content of the report will conform to OHRP requirements for incident reporting.

For VAMC research, the director will report to the VAMC Research and Development Office and the regional VAMC Office of Research Oversight, the VAMC Information Security Office, or the VAMC Privacy Officer.
- Any unanticipated problems involving risks to participants or others
- Unauthorized use, loss or disclosure of individually identifiable patient information
- Violations of VAMC information security requirements
- Any noncompliance
- Any suspensions or terminations
- Corrective actions

For VAMC studies, reporting of unauthorized use, loss or disclosure of individually identifiable patient information or portable media must be made within 1 hour (of discovery of the event) to the employee’s supervisor, VAMC police, VAMC Privacy Officer and Research Compliance Officer.
Applicable Regulations, Document(s):
45 CFR 46.103(b)(5)
21 CFR 56.108(b)(1)
IRB Procedure # 320 Review of Reportable Events
Guidance for Clinical Investigators, Sponsors, and IRBs Adverse Event Reporting to IRBs
Improving Human Subject Protection, DHHS, FDA, January 2009
VHA Handbook 1058.01 (May 21, 2010)
VHA Handbook 1200,05 (October 15, 2010)

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<td>July 2009</td>
<td>M. Linke</td>
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<td>J. Gerlach</td>
<td>Add timeframe for reporting loss of Protected Health Information - for VA studies.</td>
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