

**Reporting of Unanticipated
Problems, Suspensions,
Terminations, and Non-Compliance**

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POLICY:

- I. The UIC OPRS promptly reports to applicable institutional officials, funding sources, agency heads and regulatory agencies determinations by the IRB that an event represents:
 - A. A reportable unanticipated problem involving risks to subjects or others as determined by the IRB;
 - B. A serious or continuing non-compliance with federal regulations or the requirements or determinations of the IRB; or
 - C. A suspension or termination of IRB approval.
- II. This policy fulfills DHHS, VA and FDA regulations for incident reporting at 45 CFR 46.103(b)(5), 38 CFR 16.103(b)(5) and 21 CFR 56.108(b).
- III. UIC has reporting obligations under this policy for nonexempt human subjects research when UIC is engaged in the research or one of the UIC IRBs is the IRB of record or has oversight for the proposal.
- IV. For multi-center trials, UIC has no reporting obligations for unanticipated problems, serious or continuing non-compliance or suspension or termination of approved research occurring at non-UIC or non JBVAMC sites, except when UIC/JBVAMC serves as the lead site, coordinating center or sponsor of the research.
- V. The reporting requirements in this policy are not necessarily applicable to administrative holds and lapses in IRB approval.
- VI. The UIC has elected on its FWA not to apply the Common Rule and subparts B, C, and D to research which is not federally conducted or supported. UIC therefore does not report the events listed in Section I. to OHRP when the research is not federally conducted or supported.
- VII. Responsibility for implementing and coordinating the procedures described in this policy lies with the Director of OPRS.

PROCEDURES:

I. Preparation of the Report.

- A. The IRB Chair and Assistant Director notify the Director of OPRS promptly following a determination by the IRB of a reportable unanticipated problem involving risks to subjects or others, serious or continuing non-compliance with federal regulations or the requirements or determinations of the IRB, or suspension or termination of IRB approval.
- B. The IRB communicates its determination to the PI as described in the UIC HSPP policies: *Administrative Hold, Suspension or Termination of IRB Approval, Handling Complaints and Allegations of Potential Non-Compliance with Human Subject Protection Regulations*; and *Unanticipated Problems and Other Events Requiring Prompt Reporting*. This communication is copied to the Director of OPRS, Assistant Director of Quality Assurance/ Quality Improvement, Academic Department Head,, other relevant UIC oversight committees (e.g., investigational drug service, Institutional Biosafety Committee, radiation safety, cancer center), JBVAMC R&D Committee (if JBVAMC is a performance site), EC (if UIC IRB#4), NU OPRS (if NU is a performance site), relevant IRB and the UIC OPRS protocol file.
- C. The IRB staff provides the OPRS Director with a copy of the materials reviewed by the IRB and IRB meeting minutes.
- D. Based on the materials provided, the Director of OPRS evaluates the reporting requirements for the incident and, when verified, prepares a letter that contains the following information:
 1. Name of the institution conducting the research;
 2. Title of the research project and/or grant proposal in which the incident occurred;
 3. Grant/contract number, if DHHS-supported research;
 4. Name of test article and corresponding IND or IDE number, if applicable;
 5. Name of the PI on the protocol;
 6. Number assigned by the IRB for the research project and number of any applicable federal award(s);
 7. The findings of the IRB or organization and reasons for the findings;
 8. Detailed description of the unanticipated problem, noncompliance, or suspension or termination;
 9. Actions the institution is taking or plans to take to address the incident and reasons for the actions (e.g., revise protocol, suspend subject enrollment, revise informed consent, etc.);
 10. Plans for any further investigation or action (if applicable); and
 11. An indication of whether or not a follow-up or final report will be sent by the earlier of a specified date, completion of an investigation or implementation of a corrective action plan.
- E. A draft of the letter is provided to the IRB Chair, Associate Director for Research Compliance and HPA (only if this individual is not the same person as the OPRS Director) for review and comment.

II. Distribution.

A. The final correspondence is distributed from the Director of OPRS to the following:

1. IRB;
2. OHRP, when the research is covered by DHHS regulations;
3. Sponsor, including grant management and program officers of DHHS-supported research;
4. Other federal agencies when the research is overseen by those agencies and they require reporting separate from that to OHRP;
5. FDA, when research is FDA regulated;
6. IO;
7. HPA (if this is a separate individual);
8. Assistant Director of Quality Assurance/ Quality Improvement;
9. Associate Director for Research Compliance;
10. Department/Unit Head;
11. PI;
12. UIC Office of Research Services, when research is externally funded;
13. Other participating institutions, when the UIC IRB is the IRB of record or has oversight for the research (e.g., UIC is the lead site, coordinating center or sponsor for the research); and
14. JBVAMC ACOS for Research and Development, if JBVAMC is a performance site for the research.

B. Research performed at JBVAMC.

1. When the research is performed at the JBVAMC, a copy of the report is sent to the ACOS for R&D. The ACOS prepares a cover letter describing the reporting event and, for adverse events where the IRB takes substantive action or an unexpected death regardless of action taken, attaches form 10-0420.
2. The ACOS sends the report to the following institutional officials and agencies:
 - a) COS;
 - b) Medical Center Director;
 - c) Chair, R&D Committee;
 - d) VA Legal Counsel;
 - e) JBVAMC Privacy Office (if the report involves the unauthorized use of, loss or disclosure of individually identifiable patient information);
 - f) JBVAMC Information Security Officer (if the report involves violations of the information security requirements);
 - g) The Regional VA Office of Research Oversight (ORO RO);
 - h) The Office of Research and Development, if VA-funded;
 - i) VA Central Office, when the report involves an unanticipated problem involving risks to subjects or others that is an adverse effect;

- j) OHRP - The communication is sent even if the UIC IO or Director of OPRS has already notified OHRP. This duplication ensures that OHRP is notified as research at JBVAMC typically meets the criteria of being federally funded or conducted and, as such, falls under the purview of OHRP;
 - k) The IRB, as an information item in the agenda; and
 - l) Any "Common Rule" agency that is supporting or conducting the research when they require reporting separately from OHRP.
 - 3. To facilitate submission of the report to the Director of ORO RO, the Medical Center Director initials the report and sends it by express mail and e-mail or fax. When reporting adverse events to ORO, a copy of the IRB meeting minutes relevant to the adverse event accompany the report or are sent to ORO RO within 4 weeks of the IRB meeting.
 - 4. The timeframe for sending reportable adverse events to ORO RO is described in the UIC HSPP policy, *Unanticipated Problems and Other Events Requiring Prompt Reporting*.
- C. The ACOS reports suspensions or terminations of IRB approval to the IRB Chair
- D. With the exception of the duplicate notification to OHRP when JBVAMC is a performance site (above), UIC will not report to federal agencies already made aware of an incident (unanticipated problem involving risks to subjects or others, serious or continuing non-compliance, or termination or suspension) through reporting by the sponsor or another organization.

III. Timeline for Reporting.

- A. Reports to, OHRP, FDA and other federal agencies will be made promptly. The letter from the OPRS Director will be sent within 10 working days of the convened IRB's determination. In the event a situation requires extended time to investigate or resolve, a preliminary report will be sent and followed by a final report. In no event will a preliminary report to institutional officials, the supporting agency head, OHRP, or FDA be delayed beyond 30 days of the OPRS/IRB receiving notice of a reportable event.

REFERENCES:

[21 CFR 56.108\(b\)](#)
[38 CFR 16.103\(b\)\(5\)](#)
[45 CFR 46.103\(b\)\(5\)](#)
[OHRP, *Guidance on Reporting Incidents to OHRP*, May 27, 2005.](#)
[VHA Handbook 1200.5 \(7\)\(d\)](#)
[VHA Handbook 1058.1](#)

Version (#, date)	Replaces (#, date)	Summary of changes
2.0, 10/01/08	1.0, 04/17/07	Updated reporting requirements for protocols involving the Jesse Brown VAMC

2.1, 06/18/09	2.0, 10/01/08	Added Assistant Director of Quality Improvement/ Quality Assurance title.
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