OFFICE OF THE VICE CHANCELLOR FOR RESEARCH

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

Version: 2.5; Date: 12/15/2016
Approved by: Human Protections Administrator, Director of OPRS, and Executive IRB Chair
AAHRPP REF #: 173
AAHRPP Elements: I.5.D., II.2.F., II.2.G., III.2.D.

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 sites, except when UIC serves as the lead site, coordinating center or sponsor of the research, or central or single IRB role.

V. The reporting requirements in this policy are not necessarily applicable to administrative holds.

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 Human Protections Administrator.

PROCEDURES:

I. Preparation of the Report. Human Protections Administrator (HPA) 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.
   A. 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*.
   B. The IRB staff provides the HPA with a copy of the materials reviewed by the IRB and IRB meeting minutes.
   C. Based on the materials provided, the HPA 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.

II. Distribution.
   A. The final correspondence is distributed from the Human Protections Administrator 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. Department of Defense (DoD) component Human Research Protections Officer (if DoD funded);
7. IO;
8. Director of OPRS;
9. Associate Director for Compliance;
10. Department/Unit Head;
11. PI;
12. 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

B. Research reviewed by CHAIRb
   1. The policy and processes described above are consistent with research reviewed by CHAIRb; however, the CHAIRb Portal must be utilized to access the submission documents.
   2. The distribution list can be found in the *CHAIRb Operations SOP.*

C. 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 (e.g., lead or coordinating center), unless CHAIRb is the IRB of record.

III. Timeline for Reporting.

A. Reports to, OHRP, FDA and other federal agencies will be made promptly. The letter from the HPA 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.

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.

2.2, 7/13/11	2.1, 06/18/09	Updated reporting to JBVAMC to reflect revised Handbook 1058.01 vs May 2010
2.3, 5/31/12	2.2, 7/13/11	Inclusion of role of Executive Chair and DoD requirements.
2.4, 02/25/16	2.3, 5/31/12	Removal of JBVAMC/IRB #4 items. Addition of research reviewed by CHAIRb.
2.5, 12/15/16	2.4, 02/25/16	Addition of hyperlinks. Removal of Executive Chair involvement.