

SOP: RR 408 Version No: 04 Effective Date: 2/10/11	EXTERNAL REPORTING	Supersedes Document Dated: 12/3/10
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1. POLICY

Steering Committee approved 10/17/11

In accordance with 45 CFR 46.103(b)(5) and 21 CFR 56.108(b), IRBs must establish “written procedures for ensuring prompt reporting to the IRB, appropriate institutional officials, and the department or agency head of (i) any Unanticipated Problems Involving Risks To Subjects or Others or any serious or continuing noncompliance with this policy or the requirements or determinations of the IRB; and (ii) any suspension or termination of IRB approval.” This policy outlines the procedures for ensuring the prompt reporting of the above to the IRB, applicable institutional officials, sponsors, appropriate regulatory agencies, and applicable others.

Specific Policies

1.1. IRB action

Once the IRB has taken action related to Unanticipated Problems Involving Risks To Subjects Or Others (SOP RR 403); Serious Or Continuing Noncompliance (SOP CO 601); or has suspended or terminated approval of research (SOP 407), the following will occur:

1.1.1. The RSPP Manager prepares, in consultation with the IRB Chair, a letter containing the following information:

- (i) The nature of the event(s);
- (ii) The findings of the IRB;
- (iii) Actions taken by the IRB;
- (iv) Reasons for the IRB’s actions; and
- (v) Plans for continued investigation or action.

1.1.2. A copy of the letter will be sent to the following as appropriate:

- (i) Investigator;
- (ii) Institutional Official, who notifies Administration as necessary;
- (iii) Federal agencies
 - (1) Office for Human Research Protections (see *Guidance on Reporting Incidents to OHRP* dated May 27, 2005);
 - (2) Food and Drug Administration (FDA), if the study is subject to FDA regulations (see FDA’s reporting of suspension and termination of IRB approval web site); and/or

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(3) Other federal agencies when the research was subject to those agencies' requirements, and they require reporting separate from that to OHRP;

(iv) Sponsor or contract research organization;

(v) Medical Staff Office or Chief Medical Officer;

(vi) The Chief Privacy Officer, if the event involved unauthorized use, loss or disclosure of PHI;

(vii) Department of Clinical Research, when the research is conducted under a contract with a pharmaceutical or device company; and

(viii) The external site where the Aurora IRB serves as the IRB of record.

(ix) NCI CIRB Administrator if the study is one that the NCI CIRB has oversight.

1.1.3. A copy of the letter is included in the next IRB meeting packet as an informational item.

1.2. Timing of report

The RSPP Manager will ensure that reporting is completed within 30 days of the recognition of the event as being reportable.

2. SCOPE

These policies and procedures apply all research submitted to the Aurora IRB.

3. APPLICABLE REGULATIONS, GUIDELINES AND STANDARDS

45 CFR 46.103(b)(5)

45 CFR 46.113

21 CFR 56.108(b)

21 CFR 56.113

Guidance on Reporting Incidents to OHRP (www.hhs.gov/ohrp/policy/incidreport_ohrp.html)

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FDA guidance on reporting *Suspension or Termination of IRB Approval*
(www.fda.gov/oc/gcp/irbterm.html)

AAHRPP Elements II.2.F. and II.2.G.

4. REFERENCES TO OTHER APPLICABLE SOPS

This SOP affects all other SOPs.