1. PURPOSE

To outline external reporting requirements when human subject research has the oversight of the Aurora Health Care's (AHC) Institutional Review Board (IRB).

2. SCOPE

This SOP applies to all non-exempt human subject research conducted by researchers on staff at or affiliated with Aurora Health Care, conducted at any AHC facility, or utilizing individually identifiable data of AHC patients.

3. DEFINITIONS

See Glossary.

4. POLICY

This SOP implements requirements at section 4.2.g) and 4.4.b)xi) of AHC System Policy #811 – *Research Involving Humans or Their Identifiable Data or Biospecimens*.

5. PROCEDURE

5.1 What to Report

a) Regulated research

i) Reports of suspensions and terminations of IRB approval (see section 5.9 of RSPP SOP #4), Unanticipated Problems Involving Risks To Subjects or Others (RSPP SOP #8), and Serious or Continuing Noncompliance (RSPP SOP #6) is required to be made to OHRP and FDA (as needed), and federal agencies/departments per federal regulation [45 CFR 46.108(a)(4)(i-ii) and 21 CFR 56.108(b)].

ii) Reports are also to be sent to the PI, IRB and appropriate institutional officials, including Research Compliance Officer, ARI leader, and the Institutional Official.

iii) Additionally, and as needed, reports may be sent to:

- Sponsor of the research (if other than above) or contract research organization
- An external site for which Aurora IRB serves as the IRB of Record

- Chief Privacy Officer if the event involved unauthorized use, loss or disclosure of PHI

b) Un-regulated research

i) Same as outlined in 5.1.a) with the exception that reporting to OHRP, FDA and federal agencies/departments is not required.

5.2 How to Report

a) Reports are drafted by the RSPP Director or designee, with assistance from the IRB Chair and Research Compliance Officer, as needed.

b) Each report includes (but is not limited to) the following information:

- Name of the institution (e.g., university, hospital, foundation, school, etc.) conducting the research;
- Title of the research project and/or grant proposal;
- Name of the principal investigator on the protocol;
- Number of the research project assigned by the IRB and the number of any applicable federal award(s) (grant, contract, or cooperative agreement);
- A detailed description of the incident/problem;
- The actions the institution is taking or plans to take to address the incident/problem, ie. the corrective and preventative action plans. This can include, but is not limited to: revision of the protocol/informed consent document, informing enrolled subjects, suspending subject enrollment, terminating the research, educating the investigator, and/or research staff, conducting random audits, requiring monitoring of the investigator or the research project, etc.

5.3 When to Report

a) Reports will be distributed no later than 30 days of IRB review and determination.

b) For a more serious incident, reporting may occur within days (initial report), with a follow-up or final report sent at a later date or when the investigator has completed or correction action plan has been implemented.

c) For incidents occurring at another site in multi-center or collaborative research for which the Aurora IRB is not the IRB of record, Aurora RSPP will rely on the external site to report to appropriate federal agencies and to the Aurora RSPP, as described in an IRB Authorization Agreement or other applicable agreement.

5.4 RSPP Office will retain submitted materials and documentation of determinations in accordance with AHC record retention requirements as noted in AHC system policy #223 - *Record Retention, Storage and Destruction*.

CROSS REFERENCES:	RSPP SOP # 4, 6, 8 RSPP Guidance: *External Reporting* AHC system policy #223 - *Record Retention, Storage and Destruction* AHC system policy #811 - *Research Involving Humans or Their Identifiable Data or Biospecimens*
OWNER:	Director, Research Subject Protection Program
REFERENCES:	21 CFR 56.108 45 CFR 46.103 OHRP "Guidance on Reporting Incidents to OHRP" (06/20/2011) AAHRPP Element
PRIOR REVIEW / REVISION DATES:	