1. PURPOSE

To outline external reporting requirements when human subject research has the oversight of the Advocate Aurora Health's (AAH's) 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 AAH, conducted at any AAH facility, or utilizing individually identifiable data of AAH patients.

3. DEFINITIONS

See Glossary.

4. POLICY

This SOP implements requirements at section IV.B.7 and IV.D.2.k) of AAH System Policy– *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 AAH IRB approval (see section 5.9 of RSPP SOP #4), or reports of Unanticipated Problems Involving Risks To Subjects or Others (RSPP SOP #8), and Serious or Continuing Noncompliance (RSPP SOP #6) that occur at an AAH site is required to be made to OHRP and (as needed) FDA 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 AAH PI, AAH IRB and appropriate AAH institutional officials, including Research Compliance Officer, Research leadership, 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/institution for which AAH 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.

c) Reports to OHRP must be submitted using the online incident reporting form (https://www.hhs.gov/ohrp/compliance-and-reporting/guidance-on-reporting-incident/index.html - mandatory 02 January 2022).

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 AAH IRB is not the IRB of record, AAH RSPP will rely on the external site to report to appropriate federal agencies and to the AAH RSPP, as described in the executed 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 – *AAH 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* AAH system policy #2467 - *Research Involving Humans or Their Identifiable Data or Biospecimens* OHRP Guidance: Reporting Incidents to OHRP (2011) -updated to include mandatory online reporting as of 02 January 2022
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 II.2.G.
PRIOR REVIEW / REVISION DATES:	10/7/21 (effective 11/2/21)