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1. PURPOSE

To define Changes, detail submission requirements for all Changes to research overseen by Advocate Aurora Health’s (AAH) IRB and explain expectations for implementation of approved changes.

2. SCOPE

This SOP applies to all non-exempt human subject research (HS Research) conducted by researchers on staff at or affiliated with AAH, conducted at any AAH facility, or utilizing individually identifiable data of AAH patients.

Changes in research ceded to an external IRB should follow the external IRB’s policy. Certain Changes (for example changes in key personnel, study title, use of Legally Authorized Representative (LAR), inclusion of individuals with Limited English Proficiency (LEP), etc) must be submitted to the AAH RSPP. See RSPP SOP #3 – *Post Approval Responsibilities*, and RSPP Guidance: *Deferral/Ceding of IRB Oversight To An External IRB*.

Changes in Exempt research overseen by the AAH IRB should follow the process outlined in RSPP SOP #3 – *Post Approval Responsibilities*. See also RSPP guidance: *Exemptions* guidance.

3. DEFINITIONS


Changes in approved research includes modifications, additions or deletions to study documents or study plans/processes that were reviewed and approved by the IRB or require IRB review and approval. This includes but is not limited to changes (including administrative changes) to the written protocol, IRB submission form (e.g., number and type of subjects to be included in the study, changes in individuals engaged in the research, etc.), consent form, data collection forms, recruitment process, informed consent process, or other study documents and processes requiring IRB approval, and premature completion of a study.

Minor Changes in previously approved research are changes that:

- a) do not involve an increase in risk that is more than minimal;
- b) do not affect the regulatory criteria for approval;
- c) do not affect the rights and welfare of subjects; and
- d) in which all added procedures fall into categories (1)-(7) of research that may be reviewed using the expedited review procedure (45 CFR 46.110(a)).

See RSPP guidance: *Expedited Review* for examples of minor changes.

4. POLICY

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This SOP implements requirements at sections IV.B.3, IV.B.7.a) &b), IV.B.8.a) and IV.B.10 of AAH System Policy– Research *Involving Humans or Their Identifiable Data or Biospecimens*.

5. PROCEDURE

See section 5.1 for proposed Changes, section 5.2 for Changes made to eliminate apparent immediate hazard to subjects, section 5.3 for other Changes made without prior IRB approval, and section 5.4 for Changes not implemented within 30 days of communication from the RSPP Office noting approval of the change.

5.1 Proposed Changes


- a) What and When to Submit
 - i) Submit any proposed Change that may have an impact upon subject safety or the risk-benefit analysis of the study within thirty (30) days after notification of the proposed Change from the sponsor or lead PI of a multi-center study, or after a local PI determines that a Change is necessary.
 - ii) Submit all other Changes within ninety (90) days after notification/determination that a Change is necessary.
- b) How to Submit

Submit proposed Changes using a *Changes to Previously Approved Human Subject Research* form. This form should be submitted using AAH IRBNet.
- c) When to Implement Changes
 - i) Implement Changes as soon as possible after IRB approval but no later than 30 days after receipt of written communication of IRB approval from the RSPP Office.
 - ii) See section 5.4 below if Changes cannot be implemented within 30 days of receipt of written communication of IRB.

5.2 Changes Made to Eliminate Apparent Immediate Hazard to Subjects

- a) When to Report

Report to RSPP within 5 working days of initiation of the Change, whenever possible.

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b) How to Report

Report Changes made to eliminate apparent immediate hazard to subjects in accordance with RSPP SOP #7 - *Unanticipated Problems Submission Requirements*.

5.3 Other Changes Made Without Prior IRB Approval

Report Changes made without prior IRB approval and not made to eliminate apparent immediate hazard to subjects in accordance with RSPP SOP #5 – *Noncompliance Submission Requirements*.

5.4 Changes Not Implemented Within 30 Days of Approval

a) When to Report

Report changes that cannot be implemented within 30 days of receipt of IRB approval communication from the RSPP Office prior to the end of the 30 day period.

b) How to Report

Report via IRBNet using [Significant New Information form](#) to the RSPP Office. Include:

- i) the reason(s) for the delay in implementation;
- ii) a summary of why the delay will not negatively impact currently enrolled or yet to be enrolled subjects or if there is a negative impact, what is being done to mitigate that impact; and
- iii) a proposed implementation date.


CROSS REFERENCES:

RSPP SOPs #3 – *Post Approval Responsibilities*

#5– *Noncompliance Submission Requirements*

#7 – *Unanticipated Problem Submission Requirements*

RSPP Guidance – *Expedited Review*

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Exemptions

Deferral/Ceding Of IRB Oversight To An External IRB

AAH system policy - Research Involving Humans or Their Identifiable Data or Biospecimens

OWNER: Director, Research Subject Protection Program

REFERENCES:

21 CFR 56.108(a)

45 CFR 46.108(a)(3)(iii)

OHRP Guidance on Written IRB Procedures (July 1, 2011)

AAHRPP Elements II.2.E.3. & II.2.F.3

PRIOR REVIEW / REVISION DATES: 10/7/21 (effective 11/3/21)