1. PURPOSE

To outline processes for IRB review of Changes and communication of outcome of review.

2. SCOPE

This SOP applies to all non-exempt human subject research (HS 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. If review of a study has been ceded to an external IRB, the external IRB's policy on changes to previously approved research must be followed. Changes in Exempt research overseen by the Aurora IRB should follow the process outlined in RSPP SOP #3 – *Post Approval Responsibilities*. See also *Exempt* 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.

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 *Expedited Review* guidance for examples of minor changes.

4. POLICY

This SOP implements requirements at sections 4.2c), 4.2g)i) & ii), 4.2h)i) and 4.2j) of AHC System Policy #811 – *Research Involving Humans or Their Identifiable Data or Biospecimens*.

5. PROCEDURE

See section 1.1 for proposed Changes, section 1.2 for Changes made to eliminate apparent immediate hazard to subjects, section 1.3 for other Changes made without prior IRB approval,

and section 1.4 for Changes not implemented within 30 days of communication from the IRB Office noting approval of the change.

5.1 **Proposed Changes.** Upon receipt of submissions, the proposed change will be logged into the RSPP database for tracking purposes. The tracking number will be entered onto the submitted form.

a) Administrative Review.
Upon receipt of a Change form, RSPP team member(s) will review to determine whether additional information is needed. Based upon type of Change being proposed, the following may occur:

i) If new PI or change in study design or objectives, confirm receipt of RAP

ii) If addition of key personnel, confirm education and significant interest disclosure questionnaire are complete.

iii) Review the submission for completeness/conflicting information and request clarification, additional information/materials or revisions as deemed necessary

b) IRB Chair or designee (qualified IRB member) determines whether the request is a Minor Change that qualifies for expedited review.

i) If a Minor Change, review is conducted by the IRB Chair or designee (qualified IRB member) in accordance with *Expedited Review* guidance and *Criteria for IRB Approval* guidance.

RSPP Office will:

(a) document outcome of review on form;

(b) update RSPP database

(c) return completed form to submitter

(d) notify IRB members of actions taken via expedited review by listing on the IRB meeting agenda.

ii) Changes other than Minor:

(a) RSPP Team Member schedules the item for review at the next available convened IRB meeting following procedures listed in SOP #2 section 5.5c)-d).

(b) After the convened IRB meeting, if applicable, RSPP Team Member will communicate in writing any conditions of approval within two days of the meeting whenever possible. Upon receipt of responsive material, the individual designated by the IRB will review responsive material and grant final approval or defer to next IRB meeting if condition(s) cannot be met. (See guidance on *IRB Determinations, including Conditional Approval*).

(c) RSPP Office will document outcome/determination in meeting minutes and on submitted form, and update RSPP database. Completed form will be returned to submitter.

5.2 Changes Made to Eliminate Apparent Immediate Hazard to Subjects

Review and communication of outcome of review occurs in accordance with RSPP SOP #8 – *Review of Unanticipated Problems*.

5.3 Other Changes Made Without Prior IRB Approval

Review and communication of outcome of review of changes made without prior IRB approval and not made to eliminate apparent immediate hazard to subjects will occur in accordance with RSPP SOP #6 – *Review of Noncompliance.*

5.4 Changes Not Implemented Within 30 Days

IRB Chair or designee will:

a) review the report and determine whether additional action (e.g., placing a hold on study recruitment) or convened IRB review of the delay is needed; and

b) notify, in writing, the principal investigator, reporter and others as applicable, of the outcome of the review.

5.5 RSPP Office will retain a copy of the all materials submitted and/or distributed to IRB members as well as documentation and correspondence generated by the IRB or RSPP Office, in accordance with AHC record retention requirements as noted in AHC system policy #223 - *Record Retention, Storage and Destruction*

CROSS REFERENCES:

RSPP SOPs:#2 - *Review of Initial Submission*

#3 – Post Approval Responsibilities

#6 - *Review of Noncompliance*,

#8 - *Review of Unanticipated Problems*

RSPP Guidance – *Expedited Review*

Criteria for IRB Approval

IRB Determinations, including Conditional Approval

IRB Meeting Administrative Reference Guide

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(a)

45 CFR 46.103(b)(4)

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

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

PRIOR REVIEW / REVISION DATES: