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1. PURPOSE

To outline RSPP Office and Institutional Review Board (IRB) review processes and requirements after receipt of post-approval submissions.

2. SCOPE

This SOP applies to all post-approval submissions to the Aurora RSPP.

3. DEFINITIONS

See Glossary

4. APPLICABLE POLICY STATEMENTS

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

5. PROCEDURE


RSPP Office and IRB processes for review of post-approval submissions are detailed under the header for each type of submission.

5.1 Human Subject Research (HSR) Determination

Not applicable.

5.2 Exempt Human Subject Research

- a) Log the submission into the RSPP database for tracking purposes. The tracking number will be entered onto the submitted form.
- b) Upon receipt of *Change in Exempt Research* form, RSPP Team Member will review submitted information.
 - i) If a change in investigator/key personnel or PI, verify that human subject research education and Significant Interest questionnaire has been completed for added individual(s).
 - ii) If a change in study conduct or design, determine whether the research study will continue to meet exemption criteria. Will request PI to submit a

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new *IRB Application* (see RSPP SOP #1 – *Initial Submission*) as necessary.


- iii) RSPP acknowledgment will be returned to the submitter.
- c) Upon receipt of *Final Report*, confirm that all research activities have been completed and close the study in the RSPP database.
 - i) RSPP acknowledgment will be returned to the submitter.

5.3 Relying on an External IRB

Upon receipt of post-approval submissions related to studies relying on an external IRB, review of submissions will occur as noted below :

- a) Noncompliance—Review will be conducted in accordance with RSPP SOP #6: *Review of Noncompliance*.
- b) UPIRSOs—Review will be conducted to determine whether immediate action is necessary to alleviate apparent immediate risks to Subjects or Others. Verbally communicates immediate action required with PI, follows up in writing.
- c) Re-approvals/Continuing Review Notices—RSPP Office will review to ensure external IRB of record oversight remains in place. The continued approval and study status will be entered into the RSPP database.
- d) Changes in key personnel—RSPP Office will review the submitted *Changes in Key Personnel in Ceded Studies* form, and verify that new key personnel have completed the required human subject research training, significant interest disclosure questionnaire, and have appropriate medical staff privileges (if applicable).
 - i) RSPP database will be updated with new personnel.
 - ii) RSPP acknowledgment will be returned to the submitter.
- e) Study completion—RSPP Office will review submitted *Final Report*, and confirm that all research activities have been completed.
 - i) The study will be closed in the RSPP database.
 - ii) RSPP acknowledgment will be returned to the submitter.

5.4 External Parties Relying on AHC’s IRB

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Review of post-approval submissions from external parties relying on AHC’s IRB will occur in the same manner as post-approval submissions for research conducted by internal investigators. See applicable section (e.g., exempt, non-exempt, etc.) of this SOP.

5.5 Non-Exempt Human Subject Research


a) Administrative Review.

Upon receipt of submission, RSPP team member(s) will:

- i) Log the submission into the RSPP database for tracking purposes. The tracking number will be entered onto the submitted form.
- ii) Review the submission for completeness/conflicting information and request clarification, additional information/materials or revisions as deemed necessary.

b) See the type of non-exempt submission below for specific review procedures.

- i) Noncompliance—Noncompliance will be reviewed in accordance with RSPP SOP #6 – *Review of Noncompliance*.
- ii) Unanticipated Problems – Unanticipated Problems meeting immediate reporting requirements will be reviewed in accordance with RSPP SOP #8- *Review of Unanticipated Problems*.
- iii) Proposed Changes – Proposed changes, changes not implemented within 30 days of approval of a change request, and changes made to eliminate apparent immediate hazard to subjects will be reviewed in accordance with RSPP SOP #10 – *Review of Changes to Previously Approved Human Subject Research*.
- iv) Significant New Information
 - (a) RSPP team member will review submitted materials. Initial consideration will be given as to whether information should be reported as Noncompliance (RSPP SOP #5), Unanticipated Problem (RSPP SOP #7), or Change in Previously Approved Human Subject Research (RSPP SOP #9).
 - (b) If further review is necessary, route to IRB Chair or convened board.

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- (c) If convened board review is necessary, RSPP team member schedules the item for review at the next available convened IRB meeting following standard procedures for assignment of reviewers and distribution of meeting material;
 - (i) Convened IRB reviews and determines if action is required to address the significant new information;
 - (ii) RSPP Office documents decision in meeting minutes.
- (d) *Significant New Information* form is updated as to outcome of review. Decision communicated to submitter, Principal Investigator and others as applicable. RSPP database updated.
- v) RSPP Continuing Review Reports – Review of continuing review reports will undergo an administrative review, followed by expedited or convened IRB review, as applicable, in accordance with procedures described in RSPP SOP #2, section 5.5.b) or c), with the following exceptions:
 - (a) The *Continuing Review Checklist* will be used to document review. See *Continuing Review* guidance for additional information.
- vi) Final Reports
 - (a) RSPP Team Member(s) will confirm that all research activities have been completed. The study will be closed in the RSPP database.
 - (b) RSPP acknowledgment will be returned to the submitter.

5.6 Compassionate Use/Expanded Access (not research)


Review will occur as indicated in section 5.5 of this SOP dependent upon type of action.

5.7 Humanitarian Use Devices (not research)


Review will occur as indicated in section 5.5 of this SOP dependent upon type of action.

5.8 Emergency Use (not research)

Not applicable.

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- 5.9** Suspensions or Terminations of IRB Approval. In the event IRB Chair or convened IRB takes action to suspend or terminate research as a result of actions or activities described in *Suspension or Termination of IRB Approval* guidance, the IRB Chair or designee as appropriate, will:
- a) work with the PI and study team to determine and document any action necessary to protect the rights and welfare of currently enrolled subjects (see Suspension or Termination guidance)
 - b) verbally communicate action to the PI, and follow up in writing.
 - c) instruct the PI to report any adverse events or outcomes to the IRB upon termination or suspension of the research.
 - d) if an expedited action, inform the IRB of the termination or suspension via the meeting agenda.
 - e) if an action taken by the convened IRB, document the termination or suspension in meeting minutes.
 - f) IRB terminations or suspensions will be reported via written communication to regulatory agencies and institutional officials, and others as applicable, in accordance with the RSPP SOP #12 – *External Reporting*.
- 5.10** Administrative Holds
- a) The IRB Chair or designee will:
 - i) review the submitted form as a Change To Previously Approved Human Subject Research in accordance with RSPP SOP #10;
 - ii) consider whether the reasons for the hold should be reported as an Unanticipated Problem or Noncompliance. If determined to be a reportable Unanticipated Problem, as indicated in RSPP SOP #7 – *Unanticipated Problem Reporting Requirements*, or an instance of Noncompliance, as indicated in RSPP SOP #5, the PI/research team will be instructed to submit the action per the appropriate SOP.
- 5.11** 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*.

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**CROSS
REFERENCES:**

RSPS SOPs: #5 – *Noncompliance Submission Requirements*

#6 - *Review of Noncompliance Submission Requirements*

#7 - *Unanticipated Problem Reporting Requirements*

#8- *Review of Unanticipated Problems*

#10 – *Review of Changes to Previously Approved HS Research*

#12 – *External Reporting*

RSPS Guidance: *Continuing Review*

AHC system policy 140 - Use and/or Disclosure of Protected Health Information for Research

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:

45 CFR 46.104; 111

21 CFR 56.104; 111

AAHRPP Elements

**PRIOR REVIEW /
REVISION DATES:**