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1. PURPOSE

To outline responsibilities and requirements after an Institutional Review Board (IRB) has issued approval of an activity or the Research Subject Protection Office has approved reliance on an external IRB.

2. SCOPE

This SOP applies to all submissions to the Aurora RSPP.

3. DEFINITIONS

See Glossary

4. POLICY

This SOP implements requirements 4.2a), 4.2g)-h) of AHC System Policy #811 – *Research Involving Humans or Their Identifiable Data or Biospecimens*.

5. PROCEDURE


5.1 Human Subject Research (HSR) Determination

No post-approval requirements or submissions exist unless the project changes in a way that affects the original determination. Contact the Research Subject Protection Program Office to discuss your change in project if uncertain.

5.2 Exempt Human Subject Research

The following must be submitted to the RSPP prior to implementation.

- a) Using the *Changes in Exempt Research* form, submit:
 - i) any changes in Investigator or Key Personnel or PI; and
 - ii) Substantial changes in study design/conduct.
 - iii) If the proposed change in study conduct or design is such that the study no longer meets the exemption criteria, submit a new *IRB Application* (see RSPP SOP #1 – *Initial Submission*). See RSPP SOP # 9 and *Exempt Research* guidance for information.

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- b) Final Report – Submit *Final Report* form when a study is complete and may be closed with AHC’s IRB. See *Final Report* guidance for information.

5.3 Relying on an External IRB

In addition to complying with the determinations and requirements of the external IRB and applicable AHC policies and AHC IRB procedures (see *IRB Reliance for Multi-center Research* guidance), submit the following to AHC’s [RSPP Central IRB Office](#):

- a) Noncompliance—Report events or occurrences meeting the definition of Noncompliance within the time frames and as directed in RSPP SOP #5 - *Noncompliance Submission Requirements*.
- b) UPIRSOs—Submit a copy of any unanticipated problem involving risks to subjects or others (UPIRSO) that is submitted to the external IRB if the UPIRSO occurred at an Aurora site. Submit to the RSPP Office at the same time reported to the external IRB.
- c) Re-approvals/Continuing Review Notices—Submit notification from the external IRB of study continuation which includes the re-approval date and the approval period. These should be submitted upon receipt.
- d) Changes in key personnel—Submit proposed additions or removal of investigators or key personnel before they are submitted to the external IRB using the *Changes in Key Personnel in Ceded Research* form. Wait for RSPP Office notification before submitting to external IRB.
- e) Study completion—Submit a *Final Report* (see section 5.5.f) of this SOP when the study is closed with the external IRB. This should be submitted within two weeks of study close out.


5.4 External Party Relying on ACH’s IRB

Follow the post-approval submission requirements outlined in the relevant section of this SOP based on the type of submission.

5.5 Non-Exempt Human Subject Research

Submit the following:

- a) Noncompliance – Report events or occurrences meeting the definition of Noncompliance within the time frames and as directed in RSPP SOP #5 – *Noncompliance Submission Requirements*.


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- b) Unanticipated Problems – Report events or occurrences meeting the definition of reportable Unanticipated Problems within the time frames and as directed in RSPP SOP # 7 - *Unanticipated Problems Submission Requirements*.
- c) Proposed Amendments/Changes – Obtain prior approval of any protocol amendments and/or changes to information/documents previously approved by the IRB in accordance with requirements noted in RSPP SOP #9- *Changes to Previously Approved Human Subject Research -Submission & Implementation Requirement*. Also see RSPP SOP #9 for the exception to prior approval for changes necessary to eliminate apparent immediate hazards to human subjects or others, and reporting obligations related to the exception and changes not implemented within 30 days of approval of a proposed amendment.
- d) Significant New Information – Submit *Significant New Information* form to the RSPP Office to report information that could impact the conduct or design of the research study but does not qualify as reportable Noncompliance, Unanticipated Problem or a Change to Previously Approved Human Subject Research. See *Significant New Information* Guidance for information. Significant New Information should be submitted within 14 working days of discovery or report to/from regulators.
- e) Continuing Review Reports – Submit upon and in accordance with request from the RSPP Office. Frequency is dependent on the stage of your study and risks to subjects as determined by the IRB. See *Continuing Review* guidance for additional information.
- f) Final Reports – Submit *Final Report* form when a study is complete and may be closed with AHC’s IRB. See *Final Report* guidance for more information.

5.6 Compassionate Use/Expanded Access (not research)
See section 5.5 above. The same submission procedures will be used for post-approval submissions for Compassionate Use/Expanded Access protocols.

5.7 Humanitarian Use Devices – (Not Research) – see also *HUD* guidance

- a) Changes to initial submission that involves the scope of use, physicians authorized to use the device, etc. – Submit as a Change (Section 5.5.c) of this SOP. Seek prior IRB approval before continued use of HUD at AHC.
- b) Medical Device Reporting (MDR) reports submitted to FDA, in accordance with 21 CFR Part 803, when Aurora’s IRB is serving as the IRB of record – Submit a copy of the submitted FDA report to the RSPP using the *Significant New*

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Information form (section 5.5.d) of this SOP) within 14 working days of reporting to FDA.

- c) Changes to the HUD status per the FDA (e.g. the HDE is rescinded or the device is cleared for use) – Submit using the *Significant New Information* form (section 5.5.d) of this SOP) within 14 working days of receipt of notification.
- d) Continuing Review Reports – Submit upon and in accordance with request from the RSPP Office. See also *Continuing Review* guidance for additional information.
- e) Notify the device manufacturer and the FDA of any withdrawal of IRB approval within five working days after being notified of withdrawal of approval.
- f) Final Report – Submit *Final Report* form when HUD will no longer be used at AHC as indicated in section 5.5.f) of this SOP.


5.8 Emergency Use (not research)

No post- approval requirements or submissions exist

5.9 Administrative (“voluntary”) Holds

If the PI decides to voluntarily place a research project on administrative hold either based on his/her judgment and/or in consultation with the Sponsor, FDA, or other entity. the PI must:

- a) Submit request for placement of the study or parts of the study (e.g. enrollment of new subjects) on administrative hold via the Change process indicated in section 5.5.c) of this SOP
- b) Include a rationale for the PI-initiated Administrative Hold and include any supporting documents
- c) Continue to submit reportable events as outlined in section 5.5. above, while on administrative hold
- d) Notify the IRB via the Change process (see section 5.5.c) of this SOP of the intent to resume research activities placed on hold prior to resuming these research activities.

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CROSS REFERENCES:

RSPS SOP #1 - *Initial Submission*

#5 - *Noncompliance Submission Requirements*

#6 - *Review of Noncompliance*

#7 – *Unanticipated Problems Submission Requirements*

#11 - *Education & Training – Investigator & Key Personnel*

RSPS Guidance: *Continuing Review*

Exempt Research

IRB Reliance for Multi-center Research

HUD

Final Report

Significant New Information

AHC system policy #811 - *Research Involving Humans or Their Identifiable Data or Biospecimens*

OWNER:

Director, Research Subject Protection Program

REFERENCES:

45 CFR 46.104

21 CFR 56.104

21 CFR 56.111

AAHRPP Elements

PRIOR REVIEW / REVISION DATES: