 <b>AdvocateAuroraHealth</b> Research Subject Protection Program SOP	<b>NO:</b>	<b>3</b>
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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 Advocate Aurora Health (AAH) RSPP.

**3. DEFINITIONS**

See Glossary

**4. POLICY**

This SOP implements requirements IV.B.1., IV.B.7.-8. of AAH System Policy *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. All submissions are to be made via AAH IRBNet.

a) Using the RSPP *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) Using the RSPP *Noncompliance Reporting form*, report events or occurrences meeting the definition of Noncompliance within the time frames and as directed in RSPP SOP #5 - Noncompliance Submission Requirements.
- c) Using the RSPP *Unanticipated Problem Reporting form*, 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*.
- d) Final Report – Submit *Final Report* form when a study is complete and may be closed with AAH's IRB. See RSPP Guidance: *Study Closure & Researcher Record Retention* for information.

**5.3 Relying on an External IRB**

In addition to complying with the determinations and requirements of the external IRB and applicable AAH policies and AAH IRB procedures (see *Deferral/Ceding Of IRB Oversight To An External IRB* guidance), submit the following to the RSPP via AAH IRBNet using the forms indicated below.

- a) Initial Approval Notification—Submit documentation provided by the external IRB of study approval using the Significant New Information form in IRBNet. Initial Approval documentation should be submitted upon receipt, but **not later than 14 days after receipt**.
  - 1) Failure to supply the RSPP Office with the external IRB's initial approval documentation within 14 days of receipt requires the event to be reported as Noncompliance.
- b) Noncompliance occurring at an AAH site —Report events or occurrences meeting the definition of Noncompliance within the time frames and as directed in RSPP SOP #5 - *Noncompliance Submission Requirements* using the AAH RSPP Investigator Noncompliance form.
  - 1) Additionally, a copy of the external IRB's final determination on the incident should be uploaded into IRBNet using an AAH RSPP Significant New Information (SNI) form **immediately upon receipt** of the decision by the external IRB.
- c) UPIRSOs occurring at an AAH site—Submit a copy of any unanticipated problem involving risks to subjects or others (UPIRSO) that is submitted to the external IRB to the AAH RSPP. A copy of the external IRB's form – submitted to the IRB of record - should be submitted to the AAH RSPP via IRBNet using **AAH RSPP SNI form**. The SNI report should be submitted **at the same time the event is reported to the external IRB**.

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1) A copy of the external IRB's final determination on the incident should be uploaded into IRBNet using an AAH RSPP Significant New Information (SNI) form **immediately upon receipt** of the decision by the external IRB.

d) Changes to the previously submitted RSPP Request to Rely submission – including Changes in key personnel—Submit proposed revisions using the RSPP *Changes in Ceded Research* form **before the Changes are submitted to the external IRB**. Changes may not be initiated until you have received authorization from the AAH RSPP Office. See form for types of Change that must be submitted to the RSPP.

e) Study completion—Submit a *Final Report* form (see section 5.2.b of this SOP) when the study is closed with the external IRB. This should be submitted **within two weeks of study close out** with the IRB of record.


**5.4 External Party Relying on AAH'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:

- b) Noncompliance – Report events or occurrences meeting the definition of Noncompliance within the time frames and as directed in RSPP SOP #5 – *Noncompliance Submission Requirements*.
- c) 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*.
- d) 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 changes necessary to eliminate apparent immediate hazards to human subjects or others, and reporting obligations related to the event and changes not implemented within 30 days of approval of a proposed amendment.
- e) Significant New Information – Submit the RSPP *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

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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.

- f) Continuing Review Reports – Submit upon and in accordance with the notification sent via AAH IRBNet using the RSPP Continuing Review form. Frequency of the continuing review is dependent on the stage of your study and risks to subjects as determined by the IRB. See *Continuing Review* guidance for additional information.
- g) Final Reports – Submit the RSPP *Final Report* form when a study is complete and may be closed with AAH’s IRB. See *Study Closure & Researcher Record Retention* 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

- b) Changes to initial submission that involves the scope of use, physicians authorized to use the device, etc. – Submit as a Change (see Section 5..d) of this SOP). Seek prior IRB approval before continued use of HUD at AAH.
- c) Medical Device Reporting (MDR) reports submitted to FDA, in accordance with 21 CFR Part 803, when AAH’s IRB is serving as the IRB of record – Submit a copy of the submitted FDA report to the RSPP using the *Significant New Information* form (section 5.5.e) of this SOP) within 14 working days of reporting to FDA.
- d) 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.e) of this SOP) within 14 working days of receipt of notification. If the change in HUD status means that the device will no longer be used at AAH, you only need to submit a Final Report (section 5.7.g)).
- e) Continuing Review Reports – Submit upon and in accordance with the notification sent via AAH IRBNet using the RSPP HUD Continuing Review form. See also *Continuing Review* guidance for additional information.
- f) Notify the device manufacturer and the FDA of any withdrawal of IRB approval within five working days after being notified of withdrawal of approval.

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- g) Final Report – Submit *Final Report* form when HUD will no longer be used at AAH as indicated in section 5.5.g) 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:

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

**CROSS REFERENCES:**

<p>RSPP SOP #1 - <i>Initial Submission</i></p> <p>#5 - <i>Noncompliance Submission Requirements</i></p> <p>#6 - <i>Review of Noncompliance</i></p> <p>#7 – <i>Unanticipated Problems Submission Requirements</i></p> <p>#9 - <i>Changes to Previously Approved HS Research – Submission &amp; Implementation Requirements</i></p> <p>#11 - <i>Education &amp; Training – Investigator &amp; Key Personnel</i></p> <p>RSPP Guidance: <i>Continuing Review</i></p> <p><i>Exemptions</i></p>
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*Deferral/Ceding Of IRB Oversight To An External IRB*  
*HUD*  
*Study Closure & Researcher Record Retention*  
*Significant New Information*  
  
*AAH system policy - 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
- 21 CFR 56.803
- AAHRPP Elements

**PRIOR REVIEW / REVISION DATES:** 11/7/22 (effective 11/7/22)