1. PURPOSE

To outline submission requirements and processes when seeking Advocate Aurora Health's (AAH) Institutional Review Board (IRB) review or review by an external IRB, or a determination by AAH's Research Subject Protection (RSPP) Office.

2. SCOPE

This SOP applies to all initial submissions.

3. DEFINITIONS

See Glossary

4. POLICY

This SOP implements requirements at section IV.B.2 of AAH System Policy– *Research Involving Humans or Their Identifiable Data or Biospecimens*.

5. PROCEDURE

Identify the activity for which you are requesting RSPP or IRB review and follow the instructions for submission under the applicable header below. Also review and address items outlined in section 5.9 – Other Requirements, as applicable. Incomplete submissions will be returned to the sender.

5.1 Human Subject Research (HSR) and Research Engagement Determinations

a) Review the guidance on determining whether an activity is "human subject research."

b) Complete the RSPP *HSR Determination Form* if there is uncertainty as to whether your activity is human subject research or if AAH is engaged in human subject research.

c) Submit the completed form via AAH IRBNet for a determination. A project summary (smart form) in AAH IRBNet will also need to be completed.

5.2 Exempt Human Subject Research

a) Review exemption categories within the *Exempt Application* or *Exemptions* Guidance to assess whether the activity is likely to meet exemption criteria.

b) Obtain preauthorization from Research.

c) Complete the RSPP *Exempt Application* and submit it and all required documentation as noted on the application via AAH IRBNet.

5.3 Request to Rely on an External IRB

a) Review *Deferral/Ceding of IRB Oversight to an External IRB* Guidance to determine if your activity is eligible for review by an external IRB.

i) If ceding criteria are not met, send an email to irboffice@aah.org to request a waiver of the ceding criteria. **This must be done prior to submitting a Request to Rely form to the RSPP.**

ii) The waiver request should include:

1. a statement that study does not meet the current ceding criteria,
2. a copy of the protocol,
3. the name of the AAH PI,
4. and the proposed external IRB that will oversee the research study.

iii) If the waiver is granted continue with the steps of this section. If a waiver is not granted, continue with section 5.5.

b) Obtain preauthorization from AARI using their RAPR process/submission system.

c) Complete a RSPP *Request to Rely on an External IRB* form and submit the form with supporting documents as outlined on the form via AAH IRBNet.

d) Upon receipt of authorization from RSPP of the *Request to Rely on an External IRB*, submit the study to the external IRB using the external IRB's forms and instructions. Note special conditions in the *Deferral/Ceding of IRB Oversight to an External IRB* Guidance for studies that will include the use of Legally Authorized Representative, as well obligations of the PI/research team following approval of the study by the external IRB.

e) Once the activity is approved by the external IRB, submit a copy of the initial approval along with a Significant New Information form to the RSPP office via a new package in IRBNet [see AAH RSPP SOP #3 for more information].

5.4 Request for External Party to Rely on ACH's IRB

a) Obtain preauthorization from AARI using their RAPR process/submission system.

b) Submit an email to the RSPP office at irboffice@aah.org requesting that AHC's IRB serve as the IRB of Record. This should be done as soon as possible in the review process so that 1) the AAH RSPP is aware of the need; 2) we can start the IRB authorization process. The email should include:

i) Title of study

ii) Copy of protocol

iii) Name of AAH researcher requesting review

iv) Name of non-AAH individual or institution requesting review

v) Description of AAH's role in the research

vi) Description of non-AAH institution's role in the research

vii) Date by which IRB review is desired

c) Upon receipt of RSPP confirmation for AAH's IRB to serve as the IRB of Record, follow submission requirements outlined in this SOP for the applicable type of submission (e.g., exempt, non-exempt, compassionate use, etc.).

5.5 Non-Exempt Human Subject Research

a) Obtain preauthorization from AARI using their RAPR process/submission system.

b) Complete the RSPP *IRB Application* and attach all requested documents.

c) Unless a waiver of informed consent and/or waiver of HIPAA authorization is being requested, develop an informed consent and HIPAA authorization form using the RSPP guidance on *Informed Consent* and using the AAH IRB Combined Informed Consent and Authorization Template as a guide.

d) If the activity involves children, develop an assent form using an age-appropriate document using the AAH IRB Assent Template as a guide.

e) Submit the completed application along with supporting documents as outlined on the application form via AAH IRBNet.

5.6 Compassionate Use/Expanded Access (not research)

a) Review the *Expanded Access* guidance to assess whether the activity qualifies as a non-research activity. If human subject research, submit as instructed under section 5.5.

b) Complete the RSPP IRB Application form.

c) Develop a consent form using the AAH IRB Expanded Access Consent Template as a guide.

d) Submit the completed application along with supporting documents as outlined on the form via AAH IRBNet.

5.7 Humanitarian Use Devices (not research)

a) Review *Use of HUDs* Guidance. If the use of the HUD is human subject research, submit as instructed under section 5.5.

b) Complete the RSPP *Request for Use of Humanitarian Use Device (HUD) for Non-Research Purposes*

c) Submit the HUD use request and supporting documents as noted on the submission form via AAH IRBNet.

5.8 Emergency Use (not research)

a) Review *Emergency Use of a Test Article* Guidance to determine if the situation under consideration qualifies as an Emergency Use. If possible. contact the RSPP Office to determine if a convened board meeting will be held prior to the use.

b) If the RSPP Office indicates that a convened board meeting will be held prior to the proposed emergent use, the use is not considered an Emergency Use. Follow instructions under section 5.6. Compassionate Use/Expanded Access.

c) If the use will occur during non-business hours or the RSPP Office indicates that the convened board will not be able to meet prior to the use:

i) Written informed consent is required per FDA regulations if feasible (see RSPP Guidance *Emergency Use of a Test Article* for more information). Prepare an informed consent document using the RSPP Emergency Use Consent Template as a guide (located in the AAH IRBNet Library Manager) and submit to the RSPP Office via AAH IRBNet for review prior to emergency use if possible.

ii) If time does not allow for RSPP Office review of the consent form, the physician administering the investigational article must ensure appropriate elements of informed consent as noted at 21 CFR 50.25 are included in the Emergency Use consent document.

iii) Obtain written informed consent. If not feasible, the physician responsible for administering the investigational agent and an Independent Physician should certify, prior to the use if possible, that specific conditions, as noted in the Guidance document, have been met. Certification will be collected on the RSPP Emergency Use Report (see section 5.8.c.iv below).

If, in the physician's opinion, immediate use of the investigational product is required to preserve the patient's life, and time is not sufficient to obtain an independent physician's determination prior to the use, the physician responsible for the emergency use may alone make the certification prior to administering the investigational product.
The use/conditions must be reviewed and evaluated by a physician who is not involved in the patient's care (an Independent Physician) after the use, and this individual will certify that the above listed conditions were met on the RSPP Emergency Use Report.

iv) Per this SOP and FDA regulations, within 5 days of the emergency use of the investigational agent, complete an *Emergency Use Report* and submit the report to the RSPP Office via AAH IRBNet.

v) Submit an RSPP *IRB Application* per section 5.5 of this SOP if anticipating a subsequent use of the same investigational product by the same physician (see RSPP Guidance *Emergency Use of a Test Article* for more information on this requirement).

5.9 Other Requirements

a) COI and Training. Prior to submission, investigators/key personnel listed on a human subject research application are required to:

i) Complete a significant interest disclosure questionnaire as required by AAH system policy #2302 – *Conflicts of Interest In Research-Individual*; and

ii) Complete appropriate human subject research education (see SOP #11: *Training & Education –Investigators & Key Personnel)*

CROSS REFERENCES:	RSPP SOP #11 - Education & Training – Investigator & Key Personnel RSPP Guidance: *Is My Project Research/Human Subject Research*? *Exemptions* *Deferral/Ceding of IRB oversight to an external IRB Informed Consent* *Emergency Use of a Test Article* AAH system policy #2302 – *Conflict Of Interest In Research - Individual* AAH system policy #2467 - *Research Involving Humans or Their Identifiable Data or Biospecimens*
OWNER:	Director, Research Subject Protection Program
REFERENCES:	45 CFR 46.104 21 CFR 50.25 21 CFR 56.104 21 CFR 56.111 AAHRPP Elements
PRIOR REVIEW / REVISION DATES:	6/8/22 (effective date 6/8/22)