1. PURPOSE

To outline submission requirements and processes when seeking Aurora Health Care's (AHC) Institutional Review Board (IRB) review or review by an external IRB, or a determination by AHC'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 4.2.b) of AHC System Policy #811 – *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) Determination

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

b) Complete the *HSR Determination Form* if there is uncertainty as to whether your activity is "human subject research."

c) Submit the completed form via email to irb.office@aurora.org for a determination.

5.2 Exempt Human Subject Research

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

b) Obtain Research Administrative Preauthorization (RAP).

c) Complete the *Exempt Application* via Cyber IRB (see *Cyber IRB* guidance) or email to irb.office@aurora.org.

5.3 Request to Rely on an External IRB

a) Review *IRB Reliance for Multi-center Research Guidance* to determine if your activity is eligible for review by an external IRB. If ceding criteria are not met, contact centralIRB.office@aurora.org to request a waiver of the ceding criteria. The waiver request should include a statement that study does not meet the current ceding criteria, and include a copy of the protocol. 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 Research Administrative Preauthorization (RAP).

Complete a *Request to Rely on an External IRB* form and submit the form with supporting documents as outlined on the form via email to centralIRB.office@aurora.org.

c) Upon receipt of approval 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 IRB Reliance for Multi-center Research* guidance for studies that will include the use of Legally Authorized Representative.

d) Once activity is approved by external IRB, submit a copy of the approval to the RSPP office at centralIRB.office@aurora.org.

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

a) Obtain Research Administrative Preauthorization (RAP).

b) Submit an email to the RSPP office at irb.office@aurora.org requesting that AHC's IRB serve as the IRB of Record. The email should include:

i) Title of study

ii) Copy of protocol

iii) Name of Aurora researcher requesting review

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

v) Description of Aurora's role in the research

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

vii) Date by which IRB review is desired

c) Upon receipt of RSPP confirmation for AHC'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 Research Administrative Preauthorization (RAP).

b) Complete the *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 Creating a Research Informed Consent Document* and *Combined Informed Consent and Authorization Template* as a guide.

d) If the activity involves children, develop an assent form using the age-appropriate *Assent Template*

e) Submit the completed application along with supporting documents as outlined on the form via Cyber IRB or email to irb.office@aurora.org.

5.6 Compassionate Use/Expanded Access (not research)

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

b) Complete *Expanded Access Application*.

c) Develop a consent form using the *Expanded Access Consent Template* as a guide

d) Submit the completed application along with supporting documents as outlined on the form via Cyber IRB or email to irb.office@aurora.org.

5.7 Humanitarian Use Devices (not research)

a) Review *Use of HUDs* guidance.

b) Complete the *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 Cyber IRB or email to irb.office@aurora.org.

5.8 Emergency Use (not research)

a) Review *Emergency Single Time Use of an Investigational Article (Drug, Device, Biologic)* guidance to determine if the situation under consideration qualifies as an Emergency Use. 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 RSPP Office indicates that the convened board will not be able to meet and provide prior approval for the emergent use:

i) Prepare an informed consent document using *Emergency Use Consent Template* as a guide and submit to the RSPP Office via email to irb.office@aurora.org for review prior to emergency use.

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.

iii) Obtain written informed consent if possible. If not feasible, the physician responsible for administering the investigational agent and an Independent Physician should certify, prior to the use if possible, on the *Emergency Use – Exception from Informed Consent Certification* form that specific conditions, as noted on the certification form, have been met.

If, in the physician's opinion, immediate use of the investigational product is required to preserve the patient's life, and if 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 situation must then be reviewed and evaluated by a physician who is not

involved in the patient's care (an Independent Physician), and this individual should certify that the above listed conditions were met by also signing the *Emergency Use – Exception from Informed Consent Certification*.

iv) Within 5 days of use of the investigational agent, complete an *Emergency Use Report* and submit the report, along with the *Emergency Use – Exception from Informed Consent Certification* (if applicable), to the RSPP Office via email to irb.office@aurora.org.

v) Submit an *IRB Application* per section 5.5 of this SOP if anticipating a subsequent use of the same investigational product by the same physician.

5.9 Other Requirements

a) COI and Training. Prior to submission, investigators/key personnel listed on a human subject research applications (with the exception of key personnel in Exempt research) are required to:

i) Complete a significant interest disclosure questionnaire as required by AHC system policy #269 – *Conflict 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*?

Cyber IRB

Exempt Research

IRB Reliance for Multi-center Research

Guidance for Creating an Informed Consent Document

Expanded Access Consent Template

	Emergency Single Time Use of an Investigational Article (Drug, Device, Biologic) AHC system policy #269 – *Conflict Of Interest In Research - Individual* 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 50.25 21 CFR 56.104 21 CFR 56.111 AAHRPP Elements
PRIOR REVIEW / REVISION DATES:	