 Aurora Health Care®	Research Subject Protection Program SOP	NO:	11
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**1. PURPOSE**

To outline requirements and processes for Investigator and Key Personnel education and training.

**2. SCOPE**

This SOP applies to all human subject research (exempt and non-exempt) at Aurora Health Care AHC facility or utilizing AHC patients or their individually identifiable data.

**3. DEFINITIONS**

See Glossary

**4. APPLICABLE POLICY STATEMENTS**


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

**5. PROCEDURES**

**5.1 Initial Training**

a) *What is Required and When*

- i) Investigators and Key Personnel listed on human subject research submission for exempt or non-exempt human subject research must complete Collaborative Institutional Training Initiative (CITI) education modules. This education must be completed prior to submitting a study or Change form to the IRB for review. See *Instructions for CITI Training*.
- ii) Additional training may be mandated by Aurora Research Institute, the study's Principal Investigator, and/or study sponsor.
- iii) Training is not required for those engaged solely in non-research activities (i.e., clinical use of a Humanitarian Use Device, clinical Expanded Access use and Emergency Use of an investigational agent for clinical purposes). Clinicians should familiarize themselves with requirements related to these activities by reviewing RSPP guidance on the relevant topic.

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b) *Documentation & Monitoring of Training*

- i) Documentation of training occurs electronically upon completion of the CITI modules. No action on the part of the Investigator or Key Personnel is required.
- ii) RSPP Team Member will review initial training documentation to ensure completion prior to accepting an application for IRB review. Investigators and Key Personnel who do not complete initial training will not be approved to engage in human subject research.


**5.2** Ongoing Training

a) *What is Required and When*

- i) Renewal CITI training is required every three years. See *Renewal Instructions for CITI Training*.
- ii) Additional training may be mandated by Aurora Research Institute, the study's Principal Investigator, and/or study sponsor.

b) *Documentation & Monitoring of Training*

- i) Documentation of training occurs electronically upon completion of the CITI modules. No action on the part of the Investigator or Key Personnel is required.
- ii) RSPP Team Member will remind Investigators and Key Personnel of the need for completion of renewal training two months prior to CITI training expiration. Multiple attempts (by phone and email) will be made by the RSPP Office to contact the Investigator or Key Personnel within the two month time period.
- iii) When an Investigator or Key Personnel does not complete the required renewal training by the CITI expiration date, the RSPP Director or Team Member will notify the individual, a member of ARI leadership, and the PI(s) of all open research studies on which the individual participates, that the individual will be removed from participation after 5 business days if the refresher CITI training remains incomplete. The notification to the study PI and ARI leadership will include instruction on the need for replacing the individual, relative to the needs of the research, with someone who is properly trained, so as to not place enrolled subjects at

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increased risk of harm. If the RSPP office is notified by the PI or ARI leadership that enrolled subjects will be placed at increased risk of harm by the removal of the noncompliant Investigator or Key Personnel, the Institutional Official will be consulted and an action plan devised.

- iv) If, after 5 business days, the CITI refresher training remains incomplete, and the RSPP Office has not received notification that removal of the noncompliant individual will cause an increased risk of harm to enrolled subjects, the RSPP Office will complete a *Changes* form removing the individual from all open research studies on which he/she participates. The change will be approved by the RSPP Director or other IRB member. The change will be documented in the RSPP database, and the approved form provided to the individual, the study PI(s), and a member of ARI leadership. The noncompliant Investigator or Key Personnel will only be approved for participation in human subject research following completion of the required refresher CITI training.
- v) If the noncompliant individual is a study PI, the RSPP Office will immediately notify ARI of the need to replace the PI or close the study within 30 days. If this does not occur within 30 days, the issue will be scheduled for convened IRB or expedited review, as appropriate. The IRB or expedited reviewer will consider the effect of an absent PI on subject safety and study integrity and will make a determination as to how long the study may continue without a PI.

**5.3 Retention**

RSPP team members will retain all training records in accordance with AHC system #223 - *Record Retention, Storage and Destruction*


**CROSS REFERENCES:**

RSPP SOPs: #1 – *Initial Submission*

#3 - *Post-Approval Responsibilities & Submissions*

RSPP Guidance - *IRB Reliance for Multi-center Research*

AHC System Policy #811 – *Research Involving Humans or Their Identifiable Data or Biospecimens*

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**OWNER:**

Director, Research Subject Protection Program

**REFERENCES:**

AAHRPP Elements I.1.E. and III.2.A.; Standard I-2

**PRIOR REVIEW /  
REVISION DATES:**