AAH RSPP GUIDANCE
Administration of Significant Interest Disclosures

PURPOSE
Advocate Aurora Health (AAH) has established system policies (2302: COI in Research – Individual; 2307: COI in Research – Institutional) to ensure any Significant Interests (SI) held by Investigators/key personnel, AAH Research Leaders, IRB members, RSPP office staff or the institution do not create unmanaged conflicts in human subject research (HSR) conducted at AAH. Although the SI disclosure process and COI management is overseen by the AAH Compliance and Integrity department, this document outlines the processes that the RSPP office takes in the administration of SI disclosures of individuals associated with the human subject research at AAH.

Note the SI disclosure requirements included in AAH system policy 2302 and 2307 for investigators/key personnel and the organization pertain to those research studies overseen by the Advocate Aurora IRB as well as those HSR studies conducted at AAH, but ceded to an external IRB for oversight.

Definitions of Italicized words can be found in the AAH RSPP Glossary.

GUIDANCE
Who needs to complete a Significant Interest disclosure?
As indicated in system policy, RSPP staff, IRB members, investigators/key personnel, Research Leadership and others (e.g. consultants to the IRB) involved in the review, conduct or oversight of research conducted at AAH must disclose Significant Interests as defined by system policies. Per organizational policy, most individuals must disclose on an annual basis and within 30 days of discovering or acquiring a new SI.

Potential consultants to the IRB must complete, in a ‘just-in-time’ manner, the RSPP Consultant Conflict of Interest statement, prior to review of a research study for the IRB. If a potential consultant reports any SI related to the research, he/she may not act as consultant for the IRB on that study.

Although the Principal Investigator is asked in the RSPP submission application if he/she is aware of any SI (individual or institutional) related to the study that is being submitted, the RSPP office also checks for any related SI disclosures as part of the intake process of all HSR applications.
What needs to be disclosed?
AAH system policies 2302 and 2307 outline significant interests that must be reported on the Research SI Questionnaire (referred to from this point forward as ‘SI Disclosure Questionnaire’). Disclosures are made using the software program(s) dictated by the AAH Compliance & Integrity Department.

How are RSPP, IRB members and researcher SI disclosures managed by the RSPP?

RSPP Staff/IRB members
Any RSPP team member or IRB member who discloses a SI will not be able to review any research in which his/her interest is related. The RSPP Director will manage this process.
- RCAs in the RSPP office are asked to document his/her lack of related interests on IRB review checklists.

IRB members who disclose a SI will not be allowed to review or vote on research actions in which his/her SI is related. The RSPP Director or his/her delegate will manage this process.
- Members are reminded at the start of every convened IRB meeting of the need to recuse from the meeting when related research actions are being reviewed by the IRB.
- IRB members who review expedited actions for the IRB are reminded, prior to beginning their review, that they are not allowed to hold an interest related to the research.

Investigators/Key personnel
As part of the RSPP intake process for a new HSR application or Change request adding new key personnel, the RSPP office checks to ensure that all individuals listed as key personnel have a current SI Disclosure Questionnaire on file with the AAH Compliance & Integrity Department as required by system policy 2302.
- The RSPP office will withhold from review any new HSR application or Change form until all key personnel have completed a SI Disclosure Questionnaire.
- If any potential key personnel are not current in submission of a SI Disclosure Questionnaire, the submitter has the option of removing the individual from the application, and adding him/her back to the approved study using the appropriate Change process once the SI Disclosure Questionnaire is completed.

What is the RSPP process for reviewing SI disclosures
As part of their review, the RSPP Office conducts “relatedness” checks for any individual named as key personnel on the study, as well as the institution. This involves the RSPP staff reviewing the SI disclosures made by proposed key personnel as well as disclosures provided by AAH Compliance & Integrity department for the institution against specifics of the research study.
- AAH Compliance & Integrity department has created a SI Relatedness guidance document and form outlining the conditions under which a disclosed significant interest is ‘related to the research’.
- The SI Relatedness form is completed by the RSPP staff and forwarded to the AAH Compliance & Integrity department (Research Compliance Officer/RCO). The RCO
adjudicates the SI and determines if it rises to the level of a conflict of interest (COI) that must be managed by the institution.

- The AAH Compliance & Integrity department (Research Compliance Officer) returns any created management plan to the RSPP so that the IRB may review it as part of their consideration of approval of the research.
  - As indicated in the system policies, the IRB may add to, but not delete, any measures set forth by the AAH Compliance & Integrity department to manage the COI.
  - As part of the management plan, the AAH Compliance & Integrity department establishes a plan for monitoring compliance with the COI management plan.

In addition to initial review considerations, when an individual submits an annual and/or revised SI Disclosure Questionnaire to the AAH Compliance & Integrity Department, the RSPP reviews the individual's disclosures against all currently approved HSR on which that individual serves as key personnel. This process will determine if new COI management plans need to be created for the individual.

**What happens if the RSPP discovers that a key personnel on an approved study does not have a current SI disclosure on file?**

If the RSPP office discovers that an individual serving as key personnel on an open research study conducted at AAH does not have a current SI Disclosure Questionnaire on file with the AAH Compliance & Integrity Department, as indicated in system policy 2302, that issue will be immediately brought to that individual’s attention. In addition, the PI of any open research study on which the individual serves as key personnel will also be made aware.

- The noncompliant individual [and PI(s) of the respective open research studies] will be notified that he/she has 5 calendar days from the date of RSPP notification in which to comply with the system policy, and submit his/her SI Disclosure Questionnaire.
- If the noncompliant individual does not submit his/her SI Disclosure Questionnaire within the 5 calendar time period, the PI of any open research study on which the individual serves as key personnel will be requested to remove the individual from the research study.
- If the noncompliant individual is not removed from all open research studies within 14 calendar days from initial RSPP notification, the RSPP Director, Institutional Official and appropriate AAH leaders will be notified. The RSPP Director will take immediate measures to remove the noncompliant individual from all open research studies conducted at AAH.

Should the noncompliant individual be PI of an open research study, he/she will have 5 calendar days from initial RSPP notification to complete the SI Disclosure Questionnaire.

- If the noncompliant individual does not submit his/her SI Disclosure Questionnaire within the 5 calendar time period, the RSPP Director, Institutional Official, Advocate Aurora Research Institute (AARI) leadership, and appropriate AAH leaders will be notified. The
RSPP Director will take immediate measures to remove the noncompliant individual from all open research studies conducted at AAH.

- Institutional and AARI leadership will need to find someone to assume the PI role of all affected research studies, and contact study sponsors as needed.
- The IRB will consider the consequences to currently enrolled subjects of research being conducted without PI oversight, as well as take appropriate actions to suspend/terminate research activities as necessary.

The key personnel or PI may be returned to the research study, via the appropriate RSPP Change mechanism, once he/she has completed the necessary SI Disclosure Questionnaire.

If the research study is being overseen by an external IRB, per the terms of the executed IRB reliance agreement, the IRB of Record will be informed by the RSPP when a key personnel/PI on research conducted at AAH has been removed from a research study due to noncompliance with system policy 2302.

**Is education provided on the SI Disclosure process?**

Per system policy 2302, Advocate Aurora Health (typically the responsibility of the AAH Compliance & Integrity department) shall educate researchers on the requirements of the policy, researcher responsibilities regarding disclosure of SIs, and, when the researcher is engaged in Public Health Service (PHS) funded Research, regulation related to objectivity in research. Researcher’s education shall occur initially prior to engaging in HSR or PHS-funded research, at least every four years thereafter, and then as needed per policy.

- The RSPP will track the completion of PHS education, and will check key personnel completion as part of the RSPP intake process for PHS-funded research.

**REQUIREMENTS**

- AAH System Policy: 2302, 2307