AAH RSPP GUIDANCE
Human Subject Research Training/Education

PURPOSE
All individuals involved in Human Subject Research (HSR) have an obligation and responsibility to protect the rights and welfare of human subjects. Training of Research Subject Protection Program (RSPP) staff, Investigators/Key Personnel, research staff, and Institutional Review Board (IRB) members is critical if the RSPP is to fulfill its mandate to protect the rights and welfare of research subjects in a consistent manner throughout the research community at Advocate Aurora Health (AAH).

Note the HSR training/education requirements included in this guidance for investigators/key personnel pertain to those research studies overseen by the Advocate Aurora IRB as well as those studies that rely on IRB oversight of an external IRB.

Note all of the individuals who are required to complete HSR training/education must also complete a Significant Interest disclosure as outlined in AAH system policy 2302 [Conflicts of Interest in Research-Individual]. Separate educational requirements are part of the COI/Significant Interest disclosure process. See RSPP Guidance: Management of Significant Interest Disclosures for more information.

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

GUIDANCE
Who needs to complete HSR training/education?
RSPP staff, IRB members, investigators/key personnel, research staff and others charged with responsibility for reviewing and overseeing human subject research shall receive training, as appropriate, in the regulations, guidelines, ethics and policies applicable to human subject research.

What initial training/education is required of IRB members?
The RSPP Director establishes the education and training requirements for individuals involved in HSR at AAH.

Prior to appointment to the IRB, committee members are to complete an initial orientation which includes the following:

- Completion of an IRB Member Agreement/Confidentiality Statement
- HSR training via the Collaborative Institutional Training Initiative (CITI) program
- Overview of the IRB Member Connection
New members are asked to observe at least one IRB meeting before functioning as an IRB member.

A letter of IRB committee member appointment will not be provided to the individual until member training and other requirements are completed. If the new member has not completed required materials within 60 days of new member orientation, the RSPP Director will be notified and a reminder sent to the new member by the RSPP Office. If the new member does not complete the required materials within 90 days of orientation, the RSPP Director, and Institutional Official (IO) will be alerted, and a decision made on the engagement of the new member in the IRB process.

IRB Chairs, in addition to the IRB Committee Member training, must also complete the CITI course related to their role as an IRB Chair.

**What initial training/education is required of the Institutional Official?**
The IO, in addition to the IRB Committee Member training, must also complete the CITI course related to their role as IO as well as the training tutorial offered by the Office for Human Research Protections (OHRP).

**What initial training/education is required of RSPP staff?**
Newly hired RSPP staff must complete the following shortly within on-boarding to the RSPP:
- CITI course for RSPP Staff
- Compliance and HIPAA: Internet based training found on the AAH Learning Connection

Newly hired staff who do not complete the required training will be placed in a performance improvement plan under the supervision of the RSPP Director. Such action will be used in consideration of the team member’s annual performance review.

In addition to the above, new RSPP staff will also receive an overview of the following:
- Review of Job Description
- AAH Structure Overview
- Ethical Obligations Including the Belmont Report
- Federal Regulations
- SOPs and Form
- Levels of IRB review Including Full Committee, Expedited, Exempt, Not Human/Not Research
- HIPAA Forms
- Continuing Reviews, Changes, UPIRSOs, Noncompliance, New Information
- Other Review types (HUD, Expanded Access, Emergency)
- Agenda and Minutes
- Confidentiality Agreement
What initial training/education is required of investigators/key personnel on the study team?

Investigators/Key Personnel on the study team must complete the following:

- CITI course for HSR – The AAH RSPP has created two CITI courses for HSR: Biomedical Research course and Social Behavioral course. Investigators/Key Personnel must complete the CITI course that most closely aligns with the type of HSR being conducted. Because these two courses differ in content, if an individual is listed as an investigator/key personnel on more than one research study and the studies are of different disciplines, the individual may ultimately need to complete both CITI courses.

- Education/training as dictated by AAH or Advocate Aurora Research Institute (AARI) [e.g. ICH GCP training, PHS education for individuals involved in federally funded research] and others (including sponsor or funding agency).

Note all individuals listed as key personnel on the delegation log of a study submitted to the RSPP for review must be current in their education requirements before the RSPP will accept and begin the RSPP Research Intake process. Individuals who are not current may be removed from the delegation log by the PI/study team and added to the approved research study once his/her training is complete. The PI/study team will use the Change in Previously Approved Research process (see RSPP SOP 9) or Changes in Exempt Research (see RSPP SOP 3).

How long is HSR training/education valid?

- IRB Member’s CITI certification is valid for three years. After that, IRB Members must complete the Refresher IRB Member course in CITI.
  - Failure to complete the CITI IRB Member Refresher course will result in the individual’s inactivation as an IRB member. The individual may not be scheduled for attendance at IRB meetings nor conduct review actions for the IRB during this time.

- The IO’s CITI certification is valid for three years.

- RSPP staff CITI certification is valid for two years. After that, RSPP staff must complete the RSPP Staff – Refresher course in CITI.
  - Failure to complete the CITI RSPP Staff Refresher course will result in the individual being placed in a performance improvement plan under the supervision of the RSPP Director. Such action will be used in consideration of the team member’s annual performance review.
  - The individual will not be allowed to conduct review actions for the RSPP during the time that his/her CITI certification has expired.

- Investigators/Key Personnel CITI certification is valid for three years. After that, investigators/key personnel must complete the Research Renewal course in CITI.
  - The CITI program notifies investigators/key personnel when his/her certification is to expire. As a courtesy, the RSPP office will also notify investigators/key personnel of the expiration of his/her CITI certification.
Failure to maintain valid HSR training/education certification in CITI will require the individual to be removed from all research studies conducted at AAH – this includes research ceded to an external IRB for oversight.

Upon expiration of CITI certification, the RSPP will ask the PI/study team to remove the investigator/key personnel who is noncompliant. If the investigator/key personnel is not removed from all active research studies conducted at AAH within 7 calendar days of notification by the RSPP, the RSPP Director and/or the Institutional Official will be notified. Leadership within AARI will also be notified as needed. As a last resort, the RSPP office will remove the noncompliant individual from the research study, providing the PI/study team with a copy of the Change form.

- At the time of processing the Change form, the noncompliant individual will no longer have the authority to conduct HSR at AAH. Upon completion of the HSR CITI renewal course, the individual may be added to the research study using the Change process (above). If the individual conducts HSR without IRB approval, this must be reported as an incident of Noncompliance (per RSPP SOP 7).

Is continuing education required?
In addition to the CITI certification discussed above, the IO, IRB members and RSPP office staff are required to complete continuing education.

- IRB Members must complete a total of 18 continuing education points during his/her three-year term (6 CE points per year).
  - Options for continuing education (along with respective points) are noted on the IRB Member Connection. Other options will be considered by the RSPP Director on an individual basis.
  - Failure to complete the required IRB member continuing education will be taken into account during consideration of IRB member reappointment.
  - At times, options for continuing education may be provided to members via RSPP office communication. This includes the provision of monthly IRB Advisor newsletter, OHRP/FDA guidance pertinent to current issues, etc. Some continuing education may also be done during IRB meetings. IRB members in attendance during the meeting will be automatically provided the appropriate CE points. Alternate IRB members and those members who were missing from the meeting, will be provided CE points if he/she notifies the RSPP office that the provided materials were reviewed.

- RSPP staff: administrative support staff are required to complete 24 continuing education points per year; Research Compliance Analysts are required to complete 40 points per year.
  - Points can be attained by viewing webinars, reading the monthly IRB Advisor, journal articles/newsletters or attending workshops and conferences pertinent to his/her area of responsibility.
At the end of the calendar year, the RSPP Director will review the tracking sheet to determine that appropriate continuing education has been completed. Individuals who do not complete the required training will be placed in a performance improvement plan under the supervision of the RSPP Director. Such action will be used in consideration of the team member’s annual performance review.

• The institutional official is required to complete the same amount of continuing education as the IRB Members.

Is my HSR training documented by the RSPP office?
All HSR training and continuing education is monitored, documented and records kept on file in the RSPP Office.

What Resources are available to obtain educational material?
• RSPP/IRB Website
• RSPP Newsletter (distributed to the research community quarterly) addressing changes and updates to processes, reminders about regulations and FDA guidance that may be pertinent to HSR. Archived editions are available on the RSPP/IRB website.
• AAH system policies on HSR
• AAH RSPP SOPs, guidance, forms and policy documents
• Code of Federal Regulations
• FDA FAQs and Guidance documents
• OHRP Guidance Documents and Decision Charts
• PRIM&R website
• Ethical Guidelines including: Nuremberg Code, Declaration of Helsinki, The Belmont Report
• IRB Member Connection

REQUIREMENTS
• AAHRPP Accreditation Standards/Elements: I.1.E, II.2; I.6.B (COI education)
• AAH System Policy: 2302
• AAH RSPP SOPs: 3, 7, 9
• AAH RSPP Guidance: Administration of Significant Interest Disclosure