# News from the Advocate Aurora Health Research Subject Protection Program (RSPP) Institutional Review Board (IRB)

## June 2022

**Contents**

If you have questions about the transition to AAH IRB and the use of IRBNet, please reach out to the RSPP office at irboffice@aah.org.

### Association for the Accreditation of Human Research Protection Programs (AAHRPP) Accreditation Status

As you are aware, the Human Research Protection Program (HRPP) of AAH applied for reaccreditation with AAHRPP last year, with our site visit occurring in November 2021. As of March 15, 2022, AAH was once again awarded full AAHRPP accreditation status! AAHRPP accreditation is valid at AAH until September 2026.

Thank you again to everyone within the AAH HRPP who assisted in the preparation of the reaccreditation application and/or participated in the accreditation site visit. This is a noteworthy achievement as this is the first time that Advocate Health Care Network was included in the accreditation process.

### Important Information & Reminders

➢ The RSPP office has completed the **annual review of AAH RSPP SOPs.** Minor administrative changes were made to update processes and information regarding IRBNet. These revised SOPs have been posted to the AAH RSPP website.

REMEMBER, it is your responsibility to visit the AAH RSPP website to check that you are following current RSPP SOPs. NOTE that RSPP guidance documents are also located on the RSPP website.

NOTE that the Advocate IRB website has been retired.

➢ **The Advocate Health Network workspace in IRBNet was deactivated on May 27th**. All research studies that were historically accessed using the Advocate IRBNet workspace (including ceded studies) have been transferred to the AAH IRBNet workspace. This means that for all future actions in existing studies or submission of new studies (either ceded or to be overseen by the AAH IRB) you must use the AAH IRBNet workspace.

This transition to a single IRBNet workspace should eliminate any confusion as to which workspace you are to use when submitting your study package (post approval actions) or a new application. If necessary, you are still able to access prior Advocate IRBNet workspace submissions - those who were initially shared access will retain read-only access to submissions in the Advocate IRBNet workspace.

- ➢ **Submission Reminders/Tips**
  - ➢ **AAH RSPP/IRB forms** can <u>only</u> be found in the Forms and Templates section of the AAH IRBNet workspace. Required documents that must accompany any project/submission to the AAH RSPP will be outlined on each submission application and reiterated within the IRBNet submission instructions. There have been some minor changes to the AAH RSPP forms to denote the new Master Investigator Obligation Agreement (IOA). For each project/submission **always access the IRBNet Library for the most current version of all forms**. **Outdated versions of the forms will not be accepted.**

  - ➢ **RAPR authorization** is required to be uploaded in IRBNet with any new research submission (exempt, expedited, full or ceded research). Contact RAPR at <u>AAH-Research-Authorization-and-Protocol-Review@aah.org</u> with questions on their submission process.

    Remember that **RAPR authorization is not IRB approval**. You may **NOT** begin your research study on RAPR authorization alone. Submission and approval by the IRB is necessary to begin research activities at AAH.

  - ➢ **PI CVs** are required for research studies conducted at AAH. You must upload the PI's CV to IRBNet with the initial application to the RSPP, and when there is a change in PI for a study.

  - ➢ **Study Title/PI Change in IRBNet.** If a research study has a change in title and/or PI, the study team must revise this information in IRBNet at the time the Change form/package is submitted for approval/authorization. **This action cannot be completed by the RSPP Office.**

    Briefly, you may make this revision in IRBNet by taking the following actions:
    - o Search for the study in IRBNet;
    - o Select Project Overview;
    - o Once in Project Overview, select Edit and make your updates to the title or PI. Make these changes **BEFORE** submitting the Change form to the RSPP. If you do not make the change in title/PI before submitting the Change form in IRBNet, the RSPP office will unlock the package and you will be requested to make this change before the action is approved. Remember to re-lock the package in IRBNet so that the RSPP may continue their review.

    Feel free to review the IRBNet FAQs in the IRBNet Library for more information.

- ➢ **Remember that ALL projects must be electronically signed in IRBNet before submission to the RSPP.**
  - • The principal investigator must electronically sign/submit all NEW <u>research</u> submissions in IRBNet including ceded research submissions.
  - • Study personnel (regulatory specialists, study coordinators, etc.) can sign/submit post-approval research actions with the attestation that the PI is aware of the submission (captured on the IRB submission forms). It is the submitter's responsibility to make sure the PI is informed of the action.
  - • For HSR Determinations, the individual submitting the request may sign/submit the form in IRBNet. Please also remember that a Project Summary smart form is also necessary when submitting your HSR request.

- ➢ **Key personnel HSR training and Significant Interest Disclosure.** All Key Personnel (see RSPP glossary) listed on the IRBNet Personnel Delegation Log must have completed HSR training per RSPP SOP 11, as well as a Significant Interest Disclosure per system policy 2303, before the submission will be reviewed by the AAH RSPP.

- ➢ **Aligned Key Personnel.** Individuals who are not employed by AAH but who have clinical privileges at AAH and wish to participate in human subject research must have completed and on file a master Investigator Obligation Agreement (IOA). This agreement has been created by AAH Legal. Questions on whether this agreement has been executed or in the process for executing the agreement may be obtained by contacting the RSPP office.

- ➢ **Personnel Delegation Log.** Make sure that the information provided on this form is accurate – especially when indicating the employment status of the listed individual. The RSPP will use the information provided by you to determine whether other agreements (e.g. Investigator Obligation Agreement or IRB Reliance Agreement) are necessary for the individual to take part in the research study at AAH.

- **Continuing Reviews.** Study expiration reminders are ONLY sent from IRBNet. We have revised the dates that IRBNet sends reminders to **75, 45 and 15 days prior to expiration and the day of expiration.**

  It is the study team's responsibility to download the continuing review (CR) form from the IRBNet Library when submission of the CR to the AAH RSPP is required. Study teams are also responsible for ensuring that the CR form is submitted with ample time for the RSPP office to conduct a pre-review and schedule the study for convened board review (when necessary).

  To assist you in submitting CR applications with ample time for RSPP office and IRB review, recommended submission deadlines have been added to the IRB meeting dates found on the Meeting Schedule located on the [RSPP website](#). REMINDER that no research activities may be conducted if IRB approval/oversight has lapsed.

- **Human Subject Research (HSR) Determinations.** Per system policy 2467, the AAH RSPP is the only body that is authorized to make decisions on whether a project to be conducted at AAH is HSR. If you have questions as to whether your project is HSR, please download the HSR Determination form from the IRBNet Forms and Template Library, accurately complete the document, and then upload into IRBNet. RAPR authorization is not needed for HSR Determinations, but the submitter must complete the Project Summary in IRBNet by selecting the Project Summary 'wizard' in the New Project package. See IRBNet FAQs for more information on submitting the form.

  The study team must receive the RSPP determination **BEFORE** starting the project. For more information on what constitutes human subject research, please refer to the AAH RSPP Guidance on HSR Determination on the [RSPP website](#).

- **Study site authorization.** It is the responsibility of the study team to secure the authorization/agreement of each clinic/hospital department or facility taking part in the research prior to the start of research activities. This requirement is not only for studies overseen by the AAH IRB but for studies ceded to an external IRB.

  Research teams are no longer required to provide this department/facility authorization/agreement with the submission. However, documentation from each location should be retained by the study team in case of future audit. Failure to obtain such authorization/agreement from the clinic/hospital department or facility for participation in human subject research, would be an incidence of noncompliance.

- **IRB Review Fees**
  The RSPP office has recently reviewed our IRB Review Fee schedule and have increased the IRB review fees. The new fee structure will go into effect for those studies submitted on or after July 1, 2022. The new fee schedule has been posted to the [RSPP website](#).

- **Keeping PI informed of research actions in IRBNet**
  As the PI is ultimately responsible for the conduct of the study, he/she should be aware of all events related to the study. This means he/she should be aware of all Changes, Continuing Reviews, Significant New Information, Unanticipated Problem Reports and incidents of Noncompliance being reported in the study.

  The IRB will communicate outcome of IRB actions using IRBNet only, and therefore the PI will only be made aware of the outcomes via access to IRBNet. It is expected that the PI retain their IRBNet access for the life of the study at AAH so they are aware of IRB communications about the study.

- **Questions on IRBNet Use**
  If you have questions on how to use IRBNet, please review the FAQs located in the Forms and Templates Library section of IRBNet. We also have a recorded presentation available on the RSPP website. There are also IRBNet Energizers (short videos created by the IRBNet tech team) that can be viewed by users new to the IRBNet system. Please contact the RSPP Office and one of our Super-Users will be glad to assist you.

## AREA OF FOCUS – Changes Requested by the RSPP Office after Submission

If information is found to be missing in a submission sent to the RSPP, the office reviewer will unlock the package and ask for revisions to be made. A list of needed changes will be included in IRBNet (project email) as well as be sent to the email address entered into the system account. NOTE that necessary research personnel assessments (see below) are made by RSPP team members at study intake. Therefore, any changes in research personnel made after study intake are not taken into account by the RSPP unless we are notified of these changes.

- ➢ In order to make the review process as easy and expeditious as possible, please make sure to address all changes identified by the office reviewer. If all needed changes are not made, you will be asked again to make the needed changes. This will add time to the office review process.

- ➢ Make sure that you re-lock the submitted package after you have made the necessary changes. **If you do not re-lock the package, the RSPP will not be informed that the revised package is ready for review**. The package will sit idle until you re-lock the package. The RSPP cannot re-lock packages for you.

- ➢ If you must make changes that are not part of the Office reviewer's request, please inform the reviewer of the extra changes that were made. You may do this by adding a message (project email) to IRBNet prior to re-locking the package. For example, often a submitter will make changes to a Personnel Delegation Log without the RSPP reviewer being aware. This is problematic because these late additions to the key personnel log will not undergo the necessary scrutiny that is required of the IRB or our reliance agreement in the case of studies ceded to an external IRB (see below).

> Per FDA guidance (*Guidance for IRBs, Clinical Investigators, and Sponsors: IRB Responsibilities for Reviewing the Qualifications of Investigators, Adequacy of Research Sites, and the Determination of Whether an IND/IDE is Needed*, August 2013), federal research regulations, RSPP SOPs and system policies for research, and our reliance agreements with other institutions, it is required that the IRB/AAH ensures that all research key personnel approved for study participation 1) are appropriately trained - including having completed necessary institutional HSR training requirements; 2) have been vetted for COIs; and 3) that the individual is appropriately qualified to conduct the research by training and experience.

> In summary, in order to make the necessary assessments, the RSPP office must know about any changes – especially to research personnel.

## SOP Spotlight – SOP 3: Post-Approval Responsibilities & Submissions

The purpose of SOP 3 is to outline responsibilities and requirements after an Institutional Review Board (IRB) has issued approval of an activity or the RSPP Office has approved reliance on an external IRB.

- ➢ Please take a moment to review this important SOP that outlines what post-approval requirements are needed for Human Subject Research (HSR) Determinations, Exempt Human Subject Research, Relying on an External IRB, External Party Relying on AAH's IRB, Non-Exempt Human Subject Research, Compassionate Use/Expanded Access (not research), Humanitarian Use Devises (not research), Emergency Use (not research), and Administrative ("voluntary") holds.

**REQUEST FROM THE RSPP OFFICE**

The RSPP continues to receive applications/packages that have numerous issues. Missing or inaccurate information not only causes a delay in the review and approval of your research study, but it may also cause a delay in the review of other people's submissions. Please take care when submitting packages to the RSPP.

Below are a few of the common issues:
- o Personnel Delegation Logs that only include the last name of key personnel. Please include full names on the logs.
- o Incorrect employee status on the delegation logs. Aligned employees are NOT employed by AAH.
- o Un-responded to questions on the RSPP applications
- o Missing documents

As part of the RSPP review process, a RSPP team member will provide you with a list of items/information that is missing from your application. Please do your part and check your work before you hit the submit button to ensure you have a complete submission. This will save not only you but the RSPP time, and get your submissions approved a lot faster.

## Upcoming 2022 AAH IRB Meeting Dates

The AAH IRB regularly meets on the 1st Wednesday (W) at 11:30am and the 3rd Tuesday (T) at 7:00am. If there is no business that warrants convened board consideration, the meeting may be canceled.

- o 07/06/2022 (W)
- o 07/19/2022 (T)
- o 08/03/2022 (W)
- o 08/16/2022 (T)
- o 09/07/2022 (W)
- o 09/22/2022 (T)

The 2022 IRB meeting schedule is located on the RSPP website and is also posted in the IRBNet Library. Please note, the schedule is subject to change as necessary.

## IRB Help Information

Individuals from either Wisconsin or Illinois that have questions or comments about IRB processes or submissions in IRBNet should not hesitate to contact us at IRBOffice@aah.org. This is a great way to ensure that you get in touch with the appropriate individual in the AAH RSPP office. Using the group box will typically get you a timelier response.
If there is a topic that you would like addressed in a future newsletter, please send a detailed description of the topic to IRBOffice@aah.org. Past editions of the RSPP newsletter can be found on the RSPP website.

## Notice: Significant Interest Disclosures

Per AAH System Policy 2302, Investigators/key personnel must update their annual disclosure within 30 days of discovering or acquiring a new significant interest (SI), and Investigators/key personnel have an obligation to notify appropriate reviewing bodies (including the IRB) and funding agencies of significant interests they believe are related to a project on which they are named. Significant Interests are those related to a research project that could directly and significantly affect a covered party's designing, conducting, or reporting of the research or Aurora's conduct, review, and/or oversight of the research.

Currently, SI disclosure questionnaires are available through Policy Tech at Aurora, or Qualtrics at Advocate. Please contact the RSPP office if you have questions on how to access the questionnaire to process a new or changed Significant Interest. In addition, if you wish to notify the IRB of a Significant Interest that you hold and you believe is related to a study on which you are participating, please send to the RSPP office email.  Please do not include specific monetary values in the email.

NOTE that Compliance is working on a new SI disclosure system/process. The new system should be unveiled within a month or so. Stay tuned for more information from the AAH Compliance department.

## Coming Soon

- ➤ Watch for a Special Edition of the RSPP/IRB Newsletter where we'll cover an educational topic: Criteria for IRB Approval.
- ➤ The RSPP office is putting together an updated guidance document regarding new submissions. Please stay tuned for this helpful document.