



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

March 2022

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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.

Important Information & Reminders

- Please take a moment to review the SOPs and guidance documents that are located on the [RSPP website](#)
- The Advocate IRB website has been retired – Please refer to the AAH [RSPP website](#)
- RSPP/IRB forms can only be found in the Forms and Templates section in IRBNet. Required documents that must accompany any project/submission to the AAH RSPP will be outlined on each form 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 RSPP 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 Outdated versions of the forms will not be accepted.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 Research.preauthorization@aah.org with questions on their submission process. Please note that RAPR authorization is not IRB approval. You may not begin your research study on RAPR authorization alone. Submission and approval by the IRB are necessary to begin research activities at AAH.

- **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. This action cannot be done by the RSPP Office.
 - Go to Project Overview in IRBNet
 - Select Edit and make your updates before submitting the Change form
 - You may reference the IRBNet FAQs in the IRBNet Library for more information.
- **All projects must be electronically signed in IRBNet before submission.**
 - The principal investigator must electronically sign/submit all NEW research submissions in IRBNet including ceded research submissions.
 - Study contact personnel (regulatory specialists, study coordinators, etc.) can sign/submit post-approval research actions as attestations of PI awareness are captured on the RSPP/IRB forms. It is the study team's responsibility to make sure the PI is informed of these actions.
 - 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.
- Study expiration reminders are only sent from IRBNet. We have recently revised the reminder dates 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 IRBNet when submission 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) prior to the expiration of study approval. Please be aware of study expiration and IRB meeting dates.
 - In order 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 (RSPP website). REMEMBER that no research activities may be conducted if IRB approval/oversight has lapsed.
- Any **Legacy Aurora research** study that is now overseen by the AAH IRB and still enrolling subjects MUST revise their research informed consent document to include the new name and email address of the IRB of Record (AAH IRB). This revised consent document must be submitted within the IRBNet platform with the appropriate change form and submitted as a new package within the project; AAH IRB approval must be obtained before use.
 - Legacy Advocate studies that are transitioned to the AAH IRB will be instructed to revise their consent document to include the name of the new IRB of record at the time of the transition. Please note it's not necessary to revise the entire consent to the AAH consent template, just the IRB name and contact information.
 - NOTE there is no need to inform or re-consent currently enrolled subjects of the IRB name change as the contact information for the RSPP/IRB included in the old consent language remains viable.
- IRB Approved Stamped documents. In the past, the Advocate/IL IRB Office provided research teams with PDF/'IRB approved' stamped version of the research consent documents. The Aurora/WI IRB Office did not do this. Conversely, when possible, the Aurora/WI IRB Office provided research teams with IRB approved version of recruitment materials. The Advocate/IL IRB Office did not do this. In order to ensure consistency when returning materials to study teams, the AAH RSPP will be initiating the following steps in all future submissions to the AAH IRB:
 - When at all possible, an 'IRB approved' stamped/PDF version of recruitment materials will be published in the AAH IRBNet system following approval of the submitted package/Change. These stamped versions of recruitment materials should be used for subject recruitment if provided. **NOTE** there are times when the RSPP office is not able to create a stamped/PDF version of recruitment materials – for example, the margins on the submitted material may not be large enough to accept the IRBNet stamp OR the materials are web based and the formatting of these materials does not allow for placement of the 'IRB approved' stamp. Should you NOT receive an 'IRB approved' stamped/PDF version of the recruitment materials, you are still able to use these documents once they have been granted IRB approval. Remember you are

NOT able to alter the IRB approved version of the recruitment material without first submitting it to the IRB for approval.

- There will no longer be an 'IRB approved' stamped version of the research consent documents created and published in IRBNet. We are aware that research teams may need to add subject MRN numbers or other typed information in the research consent documents and may not be able to do so in PDF versions. Therefore, we are discontinuing this process. If you currently have a PDF/'IRB approved' stamped version of the consent document, you do not need to use it to enroll subjects. You should however use the version of the consent document that matches this stamped version as it was approved by the IRB.
- - **REMEMBER** – when you submit a revised consent document using the Change process, you are to revise the version date to reflect the new version (a consent tracking method). Once this new version is approved by the IRB, the version date of this document will be reflected in the upper right-hand portion of the Change form. This Change form with the corroborating consent version date is your documentation of IRB approval.
 - You may **NOT** alter the verbiage of the IRB approved consent document without IRB approval. Failure to obtain IRB approval of the revised consent document will be an incidence of noncompliance.
- HSR Determination requests must be submitted **PRIOR** to starting a project. The project may not begin until a determination has been made by the RSPP office. For more information, please refer to the AAH RSPP Guidance on HSR Determination on the [RSPP website](#).
- Please be aware that it is the responsibility of the study team to secure the authorization/agreement of each clinical/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 agreement with the submission. However, documentation of such agreement should be retained by the study team in case of future audit. Failure to obtain such agreement from the clinical/hospital department or facility for participation in human subject research would be an incidence of noncompliance.
- The Advocate Health Care Network IRBNet workspace will go into maintenance mode on May 27th. All Advocate studies (those overseen by the Advocate IRB or ceded to an external IRB) currently housed in the Advocate IRBNet workspace will be transitioned/transferred to the AAH IRBNet workspace prior to this date. Study teams will be notified when their studies have been transferred to the AAH IRB workspace so that you may proceed with the use of the correct (AAH IRBNet) workspace.

New Master Investigator Obligations Agreement (IOA) template

A new Master Investigator Obligation Agreement (IOA) template has been created by AAH Legal. The Master IOA must be signed by aligned physicians/non-employed researchers participating in human subject research at AAH **PRIOR** to these individuals participating in any new HSR studies. This agreement will be valid for three years, after which time, a new agreement may be necessary.

- The RSPP Office will withhold review of a newly submitted research study or modification to an existing research study until a Master IOA is signed by any aligned physicians/non-AAH employed researchers listed as key personnel. If a Master IOA has not yet been executed for a particular individual, and the study team wishes for the study to move forward in the review process, it will be the study team's option to remove this person from the study application. This researcher may be added back to the study after authorization/approval is issued by the RSPP/IRB.
- The Master IOA requires that aligned physicians/non-employed researchers have or will have reviewed AAH system policies and RSPP SOPs related to the conduct of HSR, as well as federal research regulations and the Belmont Report, prior to his/her participation in HSR at AAH. Because some individuals may not have access to AAH system policies these will be provided to the researcher along with a copy of the final executed agreement.
- There are two Master IOA templates - a WI template and an IL template. Aligned physicians/non-employed personnel conducting research in WI will sign the WI template; the IL template should be used for IL researchers. The template file name reflects the version to be used.
- A Master IOA is not needed for HSR Determination requests.

- Those individuals who have signed a Master IOA will receive an annual reminder of their obligations from the AAH RSPP Office. Therefore, when sending the signed IOA, please make sure that a valid email address, used by the researcher, accompanies the IOA.
- The WI and IL Master IOA templates, and the Master IOA Guidance document are available in the IRBNet Library Manager. **Please review the Guidance document for instruction on how to submit the research-signed document.**

Changes to the Request to Rely on an External IRB form

- The current version (3/10/22) of the Request to Rely on an External IRB form can be found in the document library in IRBNet.
- The “Substantial Modification” box has been removed from the Request to Rely document, and a separate Changes in Ceded Research form created in its place (see below). The only time the Request to Rely form will now be used is when making initial Requests to Rely on an external IRB.
- An additional attestation item has been added to the Request to Rely form. Attestations are collected in lieu of PI signature. Please confirm that all items are secured before checking the attestation box.
 - The additional item that must be attested to is that all necessary department approvals are in place to conduct the research.
 - All necessary resources and department approvals (including space, time, equipment, and personnel) are in place to conduct research.

New Changes in Ceded Research Form and Process

The RSPP has revised the process in which we collect changes in ceded research:

- The Substantial Modification section has been removed from the Request to Rely form. From this point forward, if you wish to revise any information for a ceded research study, you will do so using the Changes in Ceded Research – All Ceded Changes form. This would include changes in study personnel/PI as well as allowing you to make changes in study title, subject population, research location, technology use (including e-consent), recruitment, LAR use, etc. It also allows the research oncology group to provide us with updated versions of their Master Staff Protocol.
- The Changes in Personnel in Ceded Research form has been retired.
- The new Changes in Ceded Research – All Ceded Changes form can be found in the document library in IRBNet.

Changes to HIPAA forms: Preparatory to Research Representation, Decedent Representation; Waiver of Authorization

The definition of who constitutes a ‘workforce’ member at AAH has been updated on these forms to match the system policy definition. Also, instructions on when to use the Decedent Representation (vs. the Preparatory to Research Representation) have been updated. The new versions of these forms can be found in the document library in IRBNet.

WCG, Advarra, Other External IRBs and Sponsors

The RSPP Office does not deal directly with external IRBs or sponsors, or address requests sent to us from these parties. It is the responsibility of the study team to ask the RSPP office to act on issues found by external IRBs or sponsors.

Example 1: In the past, Advocate/IL study teams have received emails from external IRBs (WCG IRB or Advarra IRB) about changes in ceded research consent documents that are requested by a sponsor. The Advocate IRB office was often cc'd on these emails and took direct action. This will no longer occur.

- Now, when the study team receives a request for a change in ceded research from the sponsor or external IRB, the reg spec/study coordinator must intercede and direct the RSPP on the action being requested. The study team’s request may make such a request to the RSPP using the RSPP Office email. This process is to occur even if the RSPP Office was cc'd on the email to the study team.
- The RSPP office will not take any action without direction from the study team.

Example 2: The RSPP is often sent documents directly from the sponsor – for example notifications of unanticipated problems that have occurred in the research study. The RSPP will not take action on these notifications directly from the sponsor. The study team, who should also have received the information from the sponsor, is expected to review the information against the RSPP SOPs and take necessary and appropriate action – including submission to the RSPP/IRB if warranted.

AAH RSPP SOPs

The RSPP is in the process of conducting our annual review of the AAH RSPP SOPs. You will note below those SOPs that have recently undergone review. As soon as possible after the review, the revised SOPs will be uploaded to the RSPP website. Any significant changes in the SOPs will be called out in the RSPP newsletter.

Recently reviewed RSPP SOPs include:

- AAH RSPP SOP 1: Initial Submission Requirements
- AAH RSPP SOP 2: Review of Initial Submission
- AAH RSPP SOP 3: Post-Approval Responsibilities
- AAH RSPP SOP 4: Review of Post-Approval Submissions

The remainder of the AAH RSPP SOPs will be reviewed over the course of the next two months. Review of the current RSPP Guidance documents will follow thereafter.

REMEMBER it is your responsibility to visit the RSPP website to check that you are following current RSPP SOPs and review RSPP guidance documents.

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 IRBNet. It is expected that the PI retain their IRBNet permission status as a 'full' access user for the life of the study at AAH so they are aware of IRB communications about the project.

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. If this document does not answer your question, feel free to contact the RSPP Office and one of our super-users will be glad to assist you.

IRBNet Workspace

Please make sure that you are submitting your submission paperwork to the correct IRBNet workspace. We realize it is confusing to have two workspaces in IRBNet, but it's necessary until we can transfer all open Advocate IRB studies to the AAH IRB, and transition ceded research currently residing in the Advocate IRBNet workspace to the AAH IRBNet workspace.

- All new submissions should be submitted to the Advocate Aurora Health (AAH) workspace.
- If your study is overseen by the Advocate IRB, please make sure to submit post-approval packages to the Advocate Health Care Network workspace.
- If your research is overseen by AAH IRB, please make sure to submit your post-approval packages to the Advocate Aurora Health (AAH) IRB workspace.

If your package is submitted to the incorrect workspace it will need to be withdrawn and must be resubmitted to the correct workspace. This causes extra work for the RSPP office and a potential delay in the review of your submission.

AREA OF FOCUS – Notifying the RSPP office of a departing PI

The PI is the person who is ultimately responsible for protecting human research participants and/or their collected and stored PHI. AAH System Policy 2467: Research Involving Humans or Their Identifiable Data or Biospecimens (section IV.C.3) requires that, “in order to ensure adequate oversight, the PI must notify the RSPP Office of his or her departure prior to departure but in no case later than seven working days from departure”. If someone cannot be found immediately to replace a departing PI, the study team must provide a plan to the RSPP to “ensure that study leadership is appropriately maintained or the study closed”. Any study not overseen by a PI may have research conduct suspended or terminated by the RSPP/IRB— especially those studies that are still enrolling, have research subjects who are still receiving research intervention, and/or subjects who are in follow-up.

- It is the study team’s responsibility to find someone to replace the PI who is leaving AAH within a reasonable amount of time. This replacement of the PI will be monitored by the RSPP to consider when action should be taken to ensure the protection of our subjects.
- The best option is to immediately replace an out-going PI with a new PI via the appropriate Changes form. A new Personnel Delegation log removing the current PI and adding the new PI from the study must also be submitted. Remember in IRBNet the change in PI must also be completed using the process outlined above or included in the IRBNet FAQs (located in the IRBNet library).
- If no immediate change in PI can be made, the study team or current PI is expected to notify the RSPP of the departure by completing the Significant New Information form. NOTE that the SNI form should include a plan for study oversight in the absence of a PI.
- If the study is still open to enrollment, but is without a PI, the study team should think about placing that study on administrative hold to enrollment until a new PI can be named.
- Another option could be closing the study.

Important Dates – Mark your Calendars

03/31/2022 CyberIRB will be deactivated. Please make sure that if you need study files that are housed in CyberIRB that you download them to your computer before this date.

05/27/2022 The Advocate IRBNet workspace will be placed into data maintenance mode. You will still be able to access Advocate IRB information in IRBNet after this date but will be unable to submit anything to the Advocate IRB workspace.

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 8:00am. Effective 06/14/2022 the Tuesday meetings will begin at 7:00am. If there is no business that warrants convened board consideration, the meeting may be canceled.

- 04/06/2022
- 04/19/2022
- 05/04/2022
- 05/17/2022
- 06/01/2022
- 06/14/2022

The 2022 IRB meeting schedule is located on the [RSPP website](#) – note this is subject to change as necessary.

IRB Help Information

Individuals from either Wisconsin or Illinois that have any questions or comments about IRB processes or for the IRB office 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](#).

Significant Interest Disclosures

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, 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. The disclosure questionnaire is available through Policy Tech, Aurora's on-line system. 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.

Upcoming

Watch for a Special Edition of the RSPP/IRB Newsletter where we'll cover an educational topic: Criteria for IRB Approval.