



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

Special Edition: AAH IRB/IRBNet

October 2021

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Create your IRBNet Account

Visit IRBNet.org to create an IRBNet account. Use your aah.org email address when creating the account. Researchers may search for and register with "Advocate Health Care Network, Downers Grove, IL". On November 3, this name will change to "Advocate Aurora Health, Downers Grove, IL".

You will be sent an email to verify your account. The account has not been created until the account is verified. Please make sure you click on the link sent to your email from IRBNet to complete your registration.

IRB Merger – What do you need to do?

With the merger of the IRBs, you will need to make some active changes to your studies while some of the changes will happen behind the scenes.

Actions needed by the study teams:

- Update consent documents to reflect the AAH IRB as the IRB of record for the study – this will be submitted as a modification after the study has been transferred to the AAH IRB or with a continuing review if it is a Greater than Minimal Risk IL study that is being transferred to the AAH IRB and undergoing a re-review by the AAH IRB.
- For Advocate Studies: Minor modifications can be submitted to the Advocate IRB until the study is transferred to the AAH IRB.
- For Advocate Studies: If there is a major change or other reportable event before the study has been transferred, the modification should be reported to the AAH IRB and the AAH IRB will conduct a re-review of the study with the submission package.
- For Advocate Studies that are Greater than Minimal Risk: Transfer request will need to be submitted to the AAH IRB in IRBNet. This submission should include
 - A completed Continuing Review Reporting Form

- All study consents (if still enrolling) with revisions to the documents reflect the new IRB (AAH IRB) and contact info.
- A current protocol
- For Aurora Studies: Request access to the IRBNet Shell by contacting the RSPP office (see below).

Actions that will happen automatically for study teams:

- For Aurora studies: A 'shell' will automatically be created in IRBNet. This shell includes:
 - Basic study information (Study Title, Sponsor, PI)
 - Date of next Continuing Review if applicable

Important Dates – Mark your Calendars

Invitations have been sent for the Training Webinars. If you did not receive an invitation but would like to attend, email the AAH RSPP at JRBOffice@aah.org.

| | |
|------------|--|
| 11/3/2021 | GO LIVE DATE. All AAH Submitters should be using the integrated forms/SOPs on this date and only IRBNet submissions will be accepted from this point forward |
| 11/9/2021 | Presented by WCG: Open forum Q&A regarding submitting to WCG IRB and converting studies from Conexus to IRBNet. Join Zoom Meeting https://us06web.zoom.us/j/81847206636?pwd=NIV0eG42WkdpN2lsNXhyY01TbW9Kdz09 Meeting ID: 818 4720 6636 Passcode: 398652 |
| 03/31/2022 | Cyber IRB will be taken down. Make sure that if you need study files that are housed in Cyber IRB that you download them to your computer before this date. |
| 05/27/2022 | Advocate IRBNet 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. |

Recorded Training Sessions

The RSPP offered a Webinar on the Integrated Forms and SOPs. A recording of this training session can be found here: [PowerPointPresentation](#).

The RSPP offered a Webinar on IRBNet Basics. This training session can be found here: [IRBNetPowerPoint](#). Additionally, this training session mentioned a Tools for Investigators for IRBNet. That resource can be found here:

- [IRBNet Sign Off Instructions](#)
- [IRBNet Registration](#)
- [IRBNet Sign Off Instructions - Word](#).

IRBNet Resources

There are several ways to get tips and training for the IRBNet system.

IRBNet can be accessed using this link: <https://www.irbnet.org> It is recommended that all researchers set up their account in IRBNet (and confirm with the link sent in email) as soon as possible.

A tip sheet with IRBNet Frequently Asked Questions (FAQs) has been created and is available [here](#).

IRBNet Energizers: IRBNet has created “IRBNet Energizers” – short videos that contain useful information on the IRBNet system. To Access the Energizers, log into the following website:

<http://www.irbnetresources.org/tresources/training.html>

User Name: advocate

Password: training1

IRBNet overview for studies currently overseen by the legacy Aurora IRB:

All studies overseen by legacy Aurora IRB will be entered into IRBNet prior to ‘go live’ so that study teams can access and submit post-approval actions. This will be called the “study shell”. However, in order to access the study, it must first be transferred to a member of the study team. To do this:

- 1) Create an IRBNet account.
- 2) Contact the RSPP office by e-mail (IRBoffice@aah.org) and include the names/IRB numbers of the studies you would like shared, and the name of the individual to whom we should provide access.
NOTE we can transfer each study to only one individual (PI or study contact). This individual will then be able to ‘share’ the study with others on the team. Information on sharing of access with study team members/PI will be provided in the AAH IRBNet training, or you can view the IRBNet energizer on this topic or see the IRBNet FAQs.
- 3) Once the AAH IRBNet system is live, the RSPP office will share the studies with the identified study team member – as long as an IRBNet account has been created. Once shared, the study team will have access to the study so that post-approval actions may be submitted.

Still Stuck? Contact the RSPP office for help. They will get you in touch with one of the IRBNet Super Users to assist you.

Forms Reminders

With the inception of the AAH IRB, the entire research community at AAH will be using one set of RSPP forms and SOPs. All current Advocate forms and SOPs will be retired (removed from IRBNet and no longer accepted) as of 11/3/21.

The RSPP forms will be available in the AAH IRBNet Library after the go-live date. You can currently view the forms on the [RSPP website](#). The forms will eventually be removed from the RSPP website and only reside in the IRBNet Library.

The new RSPP SOPs are also now available on the RSPP website. These SOPs will go into effect on 11/3/21.

Below are some of the new forms and reporting deadlines that are outlined in the new SOPs. Please take time to make yourself familiar with the new RSPP forms and SOPs.

Reportable New Information (RNI) Form:

The Legacy Advocate Reportable New Information (RNI) form will be retired on November 3. After this date reportable events should be reported using the following:

Noncompliance Reporting Form:

- Reported 10 working days from discovery
- What to report:
 - The failure (intentional or unintentional) of an Investigator, his/her designees, IRB members, RSPP staff members, or others involved in the conduct or review of research involving human subjects to adhere to:
 - a) federal, state or local human subject protection laws, regulations, or policies;
 - b) Aurora system policy Research Involving Humans or Their Identifiable Specimens;
 - c) Aurora Research Subject Protection Program (RSPP) standard operating procedures governing the review and conduct of human subject research;
 - d) IRB determination; and/or
 - e) IRB-approved protocols, excluding changes made to eliminate apparent immediate hazard to subjects (see RSPP SOP Changes to Previously Approved Human Subject Research).
Noncompliance may be related to studies reviewed by Aurora’s IRB as well as studies ceded to an external IRB.
 - *Note: Noncompliance does not include failure by the study subject to follow protocol or investigator/study team instructions.*

Unanticipated Problems Reporting Form:

- Reported 5 working days from discovery
- What to report:
 - Local UPs that, in the judgement of the PI or study sponsor, are determined to more likely than not meet the definition of an Unanticipated Problem Involving Risks to Subjects or Others (UPIRSO).
 - External UPs that the sponsor or lead PI of a multi-center trial has determined meets the definition of a UPIRSO.
- See [SOP 7](#) (Unanticipated Problems Submission Requirements) for definitions of Unanticipated Problems (UPs) and UPIRSOs (Unanticipated Problems Involving Risks to Subjects and Others)

Significant New Information Reporting Form:

- Reported 14 working days from receipt of notification
- Submit Significant New Information form to the RSPP Office to report information that could impact the conduct or design of the research study but does not qualify as reportable Noncompliance, Unanticipated Problem or a Change to Previously Approved Human Subject Research.
- Ceded studies annual renewals (CRs) will be submitted on SNI form

Changes

Legacy Advocate IRB had one Change/modification form for all changes needing to be made on any human subject research study conducted in IL. With the new forms, there are several different change forms that are available depending on the type of study that is being conducted. There is:

- a general Changes to Previously Approved Human Subject Research form. This form will be used for any human subject research overseen by Advocate IRB or AAH IRB. There are numerous categories of changes that can be requested using this form – as well as an ‘other’ box should your change not fit into one of the prescribed categories.
- a Changes in Exempt research form to be used only when you are making changes to Exempt research. This includes personnel changes in this type of study.
- a Changes in Key Personnel in Ceded Research. This form is to be used only when making changes in personnel on research ceded to an external IRB.
- NOTE if you have significant changes that need to be made to a study that is ceded to an external IRB (for example, a change in FDA oversight, subject population, method for obtaining consent, etc) you will need to use the Request to Rely form – and check the significant modification form.

Research Preauthorization in IRBNet

Research preauthorization (RAPR) is required for the RSPP Office to accept a new research submission (exempt, expedited/full or ceded research). A letter/email outlining Research preauthorization must be uploaded in IRBNet with the submission. Contact the RAPR office (research.preauthorization@aah.org) for more information.

NOTE that IL research studies have historically required PRC and department head sign-off prior to submission to the IRB. These signoffs were obtained by sharing the IRBNet submission with the PRC and department heads. The new research preauthorization (RAPR) process being developed by AARI will include departmental consideration of the protocol as part of the authorization process. Therefore, no further sharing with these groups will be required.

IRBNet in Ceded Research

STUDIES CONDUCTED AT BOTH AURORA AND ADVOCATE SITES

Effective November 3, 2021, if a new study will be operating on both sides of the border (at both Advocate AND Aurora locations) you will only need to submit the project once to the AAH RSPP/IRB. Be sure to include specific information in your submission paperwork so that the RSPP Office is aware that you are conducting the project at both Advocate and Aurora sites, as a reliance agreement will need to be executed * for the study. *Please Note- the execution of the reliance agreement will be done ‘behind the scenes’ for you by the RSPP Office, so there is no extra work required on your part to complete.

For existing studies, if you wish to now conduct the study at both Aurora and Advocate sites, you will need to revise your study (using the Change process). A reliance agreement will need to be executed for this activity.

CEDED RESEARCH

Continued oversight notification to the AAH RSPP – via Significant New Information (SNI) form:

If you have a ceded research study, as of 11/3/21 there will be a change to the way that you notify the AAH RSPP of continued oversight. All notifications of continued IRB oversight must be submitted in IRBNet using the Significant New Information (SNI) form (the Advocate RNI form is being retired.) The AAH IRBNet platform does not specifically account for an SNI form, so select the “Other” option in the pull-down box and attach the completed SNI form and the IRB of Record’s CR Approval document.

Documents to include with new ceded research requests:

Are you planning to OPEN a ceded study at AAH? If so, you will need submit a Request to Rely form, Protocol, Project Summary Form and Personnel Delegation Log form (the Project Summary Form and Personnel Delegation Log forms are SMART forms and are located under the Wizards tab in IRBNet), Pre-Authorization from Research, and any other documents that may be required for your project. (Ex. A completed Representation for Reviews Preparatory to Research form, executed Independent Investigator Authorizations, etc.). The application can be shared with others on the study team and must be signed by the study Principal Investigator in IRBNet prior to submission. If the submission is not signed by the PI it will be unlocked and returned to the study team. No action will be taken on the submission by the RSPP Office until all documents have been uploaded, and the application is signed by the PI.

Integrated Forms

The AAH IRB’s Integrated submission forms will be available in the IRBNet Library on November 3rd. The AAH RSPP website has temporarily been updated to include these forms. These updated forms are to be used in conjunction with an IRBNet submission so should not be submitted prior to the Nov 3 IRBNet Rollout. The forms can be found [here](#).

Submission Timelines

In order to help you prepare your new submissions to the AAH IRB, the following are the dates of the convened AAH IRB meetings for the remainder of 2021 and 2022.

NEW SUBMISSIONS – The AAH RSPP/IRB requires a processing and pre-review period of 4 weeks for studies that require convened board review. This means that your new submissions to the AAH IRB must be submitted no less than 4 weeks prior to the meeting date on which you are requesting IRB review. If your submission is not complete, it will not be accepted by the RSPP, and therefore inclusion on the requested meeting agenda is not guaranteed. We reserve the right to move a submission to a later meeting as necessary. You will be notified if your submission is moved.

CONTINUING REVIEWS – The study contact will be notified by IRBNet when the research study is due to expire. Notifications will be sent by the IRBNet system at 60, 30, and 15 days prior to study expiration, as well as a ‘cease research activity’ notification on the date of expiration. It is the study team’s responsibility to ensure that the RSPP office has sufficient time to conduct a pre-review of the continuing review application prior to the convened board meeting and allow ample time for the study materials to be provided to the IRB members prior to the assigned IRB meeting. Therefore, you should plan on submitting a completed continuing review application (found in the IRBNet library) no less than 4 weeks prior to the last AAH IRB meeting before study expiration. For example, if your study expires on 5/3/22, the study needs to be reviewed by the convened board no later than the 4/19/22 meeting to prevent a lapse in IRB oversight. This means that the latest you can return the completed continuing review form is by March 22, 2022, in order to allow time for the Office to conduct a pre-review and schedule the CR for the 4/19/22 meeting. Ideally you should allow for a two-meeting span between submission and study expiration – just in case the IRB has issues with quorum or problems in the study requiring conditional approval and is moved to the next meeting date. (NOTE all conditions of IRB approval must be met before study expiration). In this example it means that ideally the study would be reviewed by the convened board at the 4/6/22 meeting – which would require that the completed continuing review is submitted for pre-review no later than 3/9/22. It is your choice if you wish to make allowances for this potential study expiration situation.

2021 AAH IRB meeting dates:

11/16/21 (T)

12/1/21 (W)

12/21/21 (T)

The 2022 meeting dates have been established and will be posted on the AAH RSPP website.

Remember to Submit

When working in IRBNet, remember to submit to the AAH IRB. If this action is not completed, the AAH RSPP will not know that this submission is waiting for action.

IRB Help Information

Individuals from either Wisconsin or Illinois that have any questions or comments about the IRB process or for the RSPP office, should not hesitate to contact us at IRBOffice@aah.org. The central box is a great way to ensure that you get in touch with the appropriate individual at the Advocate Aurora Health RSPP offices. 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. The RSPP website is also the place to go to find the current RSPP/IRB SOPs: <https://www.aurorahealthcare.org/rspp-irb/>