



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

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IRB INTEGRATION

With the merger of the AAH and Wake Forest School of Medicine IRBs to be completed in just a few short months we will increase the publication of the RSPP newsletter to monthly in order to provide you with updated information, and keep you informed on the merger timeline. Look for more information next month!

AAH IRB merger with Atrium/Wake Forest School of Medicine IRB

Advocate Health leadership has charged the Advocate Aurora Health (AAH) RSPP/IRB and the Atrium/Wake Forest School of Medicine (WFSOM) HRPP/IRB with the task of creating a single enterprise-wide IRB **by end of 2023**.

Once finalized:

- the integrated IRB (name TBD) will oversee over 6000 research studies being conducted at Advocate Health
- there will be 8 individual committees under the umbrella of the integrated IRB
- all component institutions of Advocate Health will be AAHRPP accredited.

Action to Date

- The policies of the AAH IRB and WFSOM IRB have been reviewed. Many similarities were found to exist between the two IRBs.
 - There will be some policy and procedure differences for AAH researchers under the integrated system. These will be discussed in future editions of this newsletter and in researcher education.
- Overall, there will be two types of policies for the integrated IRB:
 - The first type are “Enterprise-wide IRB policies”. These policies will be in effect no matter where research is conducted within Advocate Health.
 - The second type are “Regional Policies”. These policies are dictated by regional system policies or laws in the states where the research will be conducted. These Regional Policies will be called-out in the P/P manual.

Examples of Regional policies:

- Research Preauthorization – The Midwest Region (WI and IL) will continue to use the AARI RAPR preauthorization and PI vetting processes as noted in AAH system policy. RAPR documentation will be uploaded within the integrated eIRB application. In the Southeast region (NC and GA), individual research authorizations will be gathered within the integrated eIRB application.
 - Potential research subjects who lack decision making capacity, and Surrogate Decision-Makers (LAR) in research – While none of the state laws (WI, IL, NC, GA) speak specifically about the use of Surrogate Decision Makers (SDM)/LAR in research, each state has their own laws/regulations about the use of a surrogate decision maker in clinical decision making. The clinical policies of the respective organizations are used to dictate the research policies surrounding the use of SDM/LAR in research. Each state has laws that are also a bit different from one another, and these differences will be called out in the P/P manual.
- The first draft of the integrated adult consent/authorization template has been completed. Work continues on the drafting of integrated assent and parental permission documents.
 - Work has begun to address regional differences within the integrated eIRB research application.

eIRB submission platform

One of the biggest changes for AAH researchers will be the use of a new IRB submission platform – eIRB. eIRB (a Huron product) is currently used in the Southeast region and will be used Enterprise-wide for submission to the integrated IRB.

- eIRB uses ‘branching logic’ – questions that researchers see in the application are dictated by their responses to earlier questions.
 - As an example, if the researcher indicates that the study will be conducted in IL, eIRB will auto-populate questions that are specific to policies in the Midwest region. Conversely, if the researcher is conducting the study in North Carolina, eIRB will populate questions related to policies specific to the Southeast region. An example would be the provision of different instructions on Research Preauthorization.
- There will be no need for the AAH researcher to determine which form is needed – eIRB will ask the ‘right’ questions once the submission type/research location is identified by the researcher.
- Currently individuals with AAH credentials are **not** able to access the eIRB system (it resides behind a Wake Forest School of Medicine firewall). An IT team is working on the access issue.
- It is hoped that most data stored within IRBNet will migrate to eIRB. One known caveat...only active data will transition from IRBNet to eIRB. That means, **only data of research actions that have been finalized/approved by the AAH IRB will migrate to eIRB**. If an action has not been finalized/approved, the Midwest researcher will need to resubmit the action in eIRB.
 - If data does not migrate to eIRB or the migrated eIRB submission is missing important information, Midwest researchers will be asked to provide the IRB Office with missing material. In most cases, immediate submission of missing materials will not be necessary – more likely, missing materials will be submitted at the study’s continuing review/annual check-in or when a Change is submitted.

NOTE If you currently use AAH IRBNet to submit documents directly to **WCG IRB**, that ability will cease with the deactivation of the AAH IRBNet platform.

There is no direct link between eIRB and **WCG IRB**. Upon deactivation of AAH IRBNet, AAH research teams will use Connexus, the platform provided by WCG, to submit documents to WCG IRB. WCG IRB has been contacted for instruction on the Connexus system. We will share information as it becomes available.

Tentative Dates for transition to eIRB

Per the IT team, the dates provided below are fairly certain, but if problems present, some revisions to the timeline may occur. **Stay tuned** for more information...

- **AAH IRBNet will be de-activated at end of business on November 30, 2023.**
- Export of active study data from IRBNet will begin on December 1st.
 - Only approved actions will be transitioned – any ‘pending’ actions will be lost and will require resubmission in eIRB.
 - Submissions of actions for AAH IRB studies cannot occur in eIRB until the Go-Live date.
- **Integrated eIRB will Go-Live December 6th.**

No submissions can be made to the AAH IRB between 12/1 and 12/5. PLEASE PLAN ACCORDINGLY.

*****IMPORTANT NOTICES – DATES TO KEEP IN MIND*****

- There are only **4 more AAH IRB meetings (10/4/23, 10/17/23, 11/1/23 and 11/21/23)** before integration occurs. Deadlines for submissions are provided below. **PLEASE PLAN ACCORDINGLY.**

The RSPB Office/AAH IRB will work with you, to the best of our ability, to get submitted studies/actions reviewed and approved prior to integration. However, if these deadlines are not followed, there is no guarantee that your submission/action will be finalized/approved before integration.

- **New research submissions or Changes that are Greater Than Minimal Risk and therefore require convened board review must be received in the IRB office no later than October 10, 2023 in order to be considered for inclusion on a convened AAH IRB agenda.**
 - Note incomplete submissions or submissions that require extensive revisions as part of the pre-review process may NOT be reviewed or receive IRB approval prior to integration.
 - Submissions received **after the date provided above** may not receive convened IRB review/approval before integration. Resubmission in the integrated eIRB system would then be required. Contact the IRB office with questions.
- **Submission of new studies that are either **Exempt or Expedited** in design (i.e. Not Greater Than Minimal Risk) or **Changes that are Not Greater Than Minimal Risk** must be received in the IRB Office no later than 11/1/23 in order for IRB review to be conducted before integration.**
 - Note incomplete submissions or submissions that require extensive revisions as part of the pre-review process may NOT be reviewed or receive IRB approval prior to integration.
 - Submissions received **after the date provided above** may not receive expedited/exempt IRB review/approval before integration. Resubmission in the integrated eIRB system would then be required. Contact the IRB office with questions.
- Submission of studies requesting **reliance on an external IRB**, or Changes being requested to studies that have been ceded to an external IRB **must be finalized/authorized before integration. Make sure to allow adequate time for RSPB review of these submissions/actions including execution of necessary reliance agreements.**
 - Note incomplete submissions or submissions that require extensive revisions as part of the pre-review process may NOT be reviewed or receive final authorization prior to integration.
 - Submissions that are not finalized before integration will require re-submission in the integrated eIRB system. Contact the IRB office with questions.
- As noted above, **any Pending actions** in the IRBNet system (i.e. Changes, Continuing Reviews or new submissions that require further IRB review due to conditions of approval or tabling of the study), must be completed

before integration. Please keep in mind the above mentioned AAH IRB meeting dates if your study requires further convened AAH IRB action. Work with the RCA assigned to the project to get the study/action appropriately placed on an AAH IRB meeting agenda if needed.

- Remember that any action that remains **Pending at the time of transition to eIRB** will not be moved to the new system, and **re-submission in the integrated eIRB system will be required**.
- There will be a short period of time when AAH researchers will **NOT** be able to submit any action to the IRB: between the inactivation of IRBNet (12/1/23) and the Go-Live date of the integrated eIRB system (12/6/23). **PLEASE PLAN ACCORDINGLY**.
- **It is the study team's responsibility to track study expiration**. As a courtesy, the integrated eIRB system will provide automatic reminders when study approvals are nearing expiration. However, if your study's expiration falls within one to 6 weeks of transition to eIRB, the system may not send you appropriate/timely reminders. It is important for you to track your study's expiration to ensure that your IRB approval does not lapse.
 - Research teams (PI/study contact) of **AAH IRB studies that are due to expire in early/mid December** are being contacted by the AAH IRB office so that an **early continuing review** may be completed before transition to eIRB.
 - Research teams of **AAH IRB studies due to expire in mid to late December/early January** are also being contacted, and it is **suggested for these studies to complete an early continuing review** application before transition to eIRB.
 - **Do not submit** an early continuing review application unless contacted by the AAH IRB office.
 - It is your choice to submit your continuing review application early. If you choose not to submit your continuing review application as requested/suggested, please be aware that your study approval may lapse, or you will need to submit the continuing review application in eIRB following transition.
 - Please work with the AAH IRB office in submitting your action **on time**. If you are going to submit an early continuing review application, do so **by the deadline provided** by the office. If the application is not submitted by the deadline, there is no guarantee that the study will be re-approved prior to the transition to the integrated eIRB system.
- Excuse the multiple reminders, but please keep in mind that submissions/actions submitted to the AAH IRB must be **approved** in order for the data to be transitioned to the integrated eIRB system. **Pending** actions will not be moved to the integrated eIRB system and will require re-submission.
 - The AAH RSPP/IRB Office will work with study teams to get as many submitted actions as possible approved before IRBNet is de-activated (November 30). If, however, applications are not complete or are submitted too close to the IRBNet deactivation date of November 30, there is no guarantee that the action will be acted upon in time.
 - It is important to work with the RCAs to address study questions and conditions of approval for any studies that have been submitted in IRBNet.
 - Research teams will be contacted in **October** about any submissions that remain **pending in the IRBNet system**. It will be the responsibility of the research team to make the necessary changes to the submission to obtain IRB approval of the action or withdraw the submission from the IRBNet system.

Saving of AAH IRB Approval Documentation currently housed in IRBNet

Due to the imminent sunsetting of the IRBNet submission platform, if you have not already done so, it is recommended that you begin **downloading IRB approval documentation (letters, forms) currently house in IRBNet at this time**. It is unknown how long research teams will have access to documents housed in IRBNet.

Researchers are required by federal regulations and AAH system policy to retain copies of documents related to the conduct of research – including IRB submissions and approvals - for a minimum period of 3 years after the closure of the study.

The IRB office and the IRBNet submission platform should not be considered the source/holder of IRB documents. Researchers/research teams should develop a plan to download and retain research documents that does not rely on the IRB office or access to the IRBNet system for document retention.

Researcher Education

Researcher education on integrated IRB policies (including differences from current AAH IRB policies) as well as the eIRB submission platform will be coming in October. Stay tuned....

- Information will be provided in future editions of this newsletter, Teams sessions, individual training sessions (as requested), and/or resource documents (tip sheets, FAQs, etc).

What's New with the AAH IRB?

Newest version of forms/documents in the IRBNet Library - to be used immediately (submission of older versions of forms/documents may be returned to you):

- AAH Change forms and HIPAA forms – updated instructions

General Reminders/Tips

IRBNet

- **REMEMBER to review emails sent from the IRBNet system.** Not only does IRBNet remind you when action items are due (for instance, continuing review notifications), but **IRBNet project email** is also used by the RSPP office to inform you when clarification/follow-up is needed, or that your final documents/letters have been uploaded into the system.
 - In general, the RSPP office does NOT communicate with researchers/submitters about IRBNet packages via personal email. All communication is sent within IRBNet project email for audit purposes.
- It is important to make sure that the IRBNet project is **'shared' with the PI** so that s/he is aware of activity surrounding the research study.
- **'Lock'/'relock' your IRBNet submissions** - especially after you submit revisions. The RSPP does not receive notification of returned/revised submissions until the resubmitted package has been 'locked', and we do not take action on submissions that have not been 'locked'.
- **Always check the IRBNet library for the most current form/document.** Current versions of the RSPP/IRB forms must be submitted – if the current version of a form is not submitted there is a good chance it will be returned to you to be redone.
- The following **resource documents** are available in the IRBNet library:
 - **Submission Guidelines**
 - **IRBNet FAQs**
 - **HSR Education_CITI FAQs**

Please take some time to review these helpful resources.

All Research

- A research protocol is required for **every** research submission, including exempt human subject research. A **protocol template** is available in the IRBNet library should you need assistance in creating your protocol.
- If you or someone on the research team (including residents, fellows or other students) is leaving/has left AAH or has completed participation in the research study, **submit a personnel change in IRBNet removing you/the individual from the research team.**

Our personnel lists are used by others within the organization (AARI, Compliance, etc) when they are looking to secure lists of current researchers. Inaccurate personnel logs may cause people to be inadvertently contacted about a research study if not appropriately removed.
- It is policy of the AAH IRB for research teams to **submit monitoring/audit or inspection reports** to the AAH IRB/RSPP when there are **findings of a serious or potentially serious issue in the conduct of the study.** Reports may be from federal agencies, the study monitor or sponsor, or the AAH Council for Quality Assurance and Improvement in Research (CQAIR).

Reports should be submitted in IRBNet within 14 working days of receipt using the Significant New Information form. The IRB will review to determine if the findings require action on the part of the PI or institution, and if they

rise to the level of an unanticipated problem or incident of noncompliance.

General Research Education

- If you are looking for educational materials about human subject research, the RSPP would like to recommend that you review the OHRP [Education & Outreach website](#). There are many types of educational materials on the website including webinars, mini-tutorials, videos, etc. Current presentations on 45 CFR 46 found [here](#) are especially informative and interesting.
 - Also, the FDA issued finalized [Guidance on Informed Consent](#) for IRBs, clinical investigators and sponsors in August 2023. This new guidance replaces FDA guidance from 1998 and finalizes the draft guidance issued in July 2014. The new guidance includes a series of frequently asked questions.
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Significant Interest Disclosure Questionnaires

With the use of a new Significant Interest disclosure system (Disclosure Manager) in AAH Compliance, there is a new process to establish an account for a new researcher.

If you wish to establish an account in Disclosure Manager for a new researcher, send the name of the individual and their email address (if the individual has an AAH email, use it) to IRBOffice@aah.org. We will inform the caretakers of the Significant Interest disclosure system and a link, specific for that person, will be sent to the email address provided.

Remember that no one may be added to a research study until they have completed their Significant Interest disclosure.

IRB Help Information

Individuals from either Wisconsin or Illinois who 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](#).