Research Subject
Protection Program
1020 N 12th St
Suite 3120
Milwaukee, WI 53233

T 414.219.7744
F 414.219.7477
IRBoffice@aah.org

www.aurora.org/IRB

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

January 2022

Contents

AAHRPP Update

The Advocate Aurora Health (AAH) Human Research Protection Program (HRPP) held our re-accreditation AAHRPP (Association for the Accreditation of Human Research Protection Programs, Inc) site visit on November 30 and December 1, 2021. The AAHRPP site visitors interviewed approximately 40 individuals with differing roles in the AAH HRPP: IRB members/Chairs; RSPP staff/leadership; researchers/members of the research teams; AARI leadership, research billing, grants, quality and education team members; members of Research Legal and Research Compliance. If you were part of the site visit, we want to express our sincere thanks for your participation.

Overall, the site visit went very well. The site visitors were complimentary on the education provided to researchers and IRB members and the excellent research quality program within AARI. However, the site visitors mentioned three relatively minor issues that need to be addressed/responded to by January 24, 2022. We are working on that response now.

Next steps…
Following submission of the AAH response to the site visitors' findings, AAHRPP will review the response. Once found to be satisfactory, the AAH HRPP reaccreditation application will be presented to the AAHRPP council (tentatively scheduled for March 2022). After AAHRPP Council reviews of our application, AAH will be notified of the council's findings and determination on accreditation status. We will certainly let everyone know of the council's decision!

Again, thank you to everyone who helped with the accreditation application/site visit. It has been a long journey (almost 3 years from the initial work by the RSPP until now) but it is almost complete - at least for this round! We'll have to do it all over again in a few years….

If you have any questions about the AAHRPP re-accreditation process, please reach out to the RSPP office.

Michelle Maternowski, Director, AAH RSPP

AAH IRB Transition

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: https://www.aurorahealthcare.org/rspp-irb/

- The Advocate IRB website has been retired – Please refer to the AAH RSPP website: https://www.aurorahealthcare.org/rspp-irb/

- The Chair of the AAH IRB per the OHRP Roster is Ngu Phan, PharmD. Other individuals also serve as alternates for Dr. Phan in the AAH IRB.
    - Name of Institution or Organization Operating the IRB: Aurora Health Care, Inc.
    - Mailing Address: PO Box 342, OHC #3120, Milwaukee, WI 53201-0342
    - Street Address: 1020 N 12th Street, #3120, Milwaukee, WI 53233

- 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. Please download a new copy of each form with each submission. 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 the RAPR group https://advocateaurora.ideawake.com/ 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 is necessary to begin research activities at AAH.

- Study expiration reminders are now only sent from IRBNet. These reminders are sent 60, 30 and 15 days prior to expiration and the day of expiration. It is the study team's responsibility to download the 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. No research activities may be conducted if IRB approval/oversight has lapsed. Please be aware of study expiration and IRB meeting dates.

- Users of CyberIRB must download any documents they wish to retain, that are currently housed in this platform, **by February 28, 2022.** CyberIRB will be deactivated in March 2022.

- AAH IRB name change letters for legacy Aurora studies have been uploaded into IRBNet. It is the study team's responsibility to share the letter with their sponsor.

- 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.

    - The original deadline for this change (communicated in an email blast on 12/8/21) was January 10, 2022. We are ***extending this deadline to February 10, 2022,*** to give study teams some extra time to make the necessary changes. After the February 10, 2022, deadline, noncompliance with this requirement will need to be reported as an incident of noncompliance with IRB policy (per RSPP SOP #5).

- 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 and contact information.

- NOTE there is no need to inform or reconsent currently enrolled subjects of the IRB name change as the contact information for the RSPP/IRB included in the old consent language remains viable.

AAH IRBNET

Questions on IRBNet Use

If you have questions on how to use IRBNet, please review the FAQs located in the Forms and Templates section of IRBNet. If this document does not answer your question, feel free to contact the RSPP Office. One of our super-users will be glad to assist you.

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 to the RSPP Office

Keeping the PI informed of the 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 status as a 'full' user for the life of the study at AAH so that they are aware of IRB communications about the project.

Personnel Delegation Logs

- Personnel delegation logs have transitioned to an electronic smart form (Personnel Delegation Log). If you are adding or removing personnel as part of the study delegation, you will need to submit a Change form to the IRB/RSPP and, at the same time, complete a new electronic smart form (Personnel Log) in IRBNet. Paper DOA logs will no longer be accepted with Changes in personnel.
- Regarding Legacy Aurora studies, study teams may NOT use the old, stand-alone delegation of authority logs in the new IRBNet workspace. Study teams do not need to create a new personnel log within IRBNet without any corresponding action item. When study teams have a post-approval action that is not related to a personnel change, the study team may decide, if they wish, to create a personnel log within IRBNet at that time. If the post-approval action includes a change to study personnel, the study team MUST create a personnel log using the smart form in IRBNet.

IRBNet Workspace

Please submit post-approval applications 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.

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

Electronic Signatures in IRBNet

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.) are able to 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 that the PI is informed of these actions.
- For HSR Determinations, the individual submitting the request to the RSPP may sign/submit the form in IRBNet.

Exempt Research – change in reporting requirements

In order to address AAHRPP's area of concern/finding regarding required additional protections for participants in exempt research, the RSPP recently made several changes to the requirements for conducting exempt research at AAH.

As a result of these changes, **researchers MUST now report incidents of noncompliance and unanticipated problems in exempt research.** The reporting requirements, definitions and timelines for reporting these events for exempt research are no different than any other type of Human Subject Research conducted at AAH – see RSPP SOPs 5-8 for more information. NOTE that the reporting of changes in personnel participating in exempt research is still in effect, as is the requirement to inform the RSPP when changes to study design/conduct are anticipated that may affect the exempt determination (see RSPP SOP 3).

To document the need for these changes, the RSPP has revised several RSPP SOPs, the system policy for human subject research (#2467), the exempt determination letter template and the RSPP guidance on exemptions. The revised RSPP documents can be found on the RSPP website. Please contact the RSPP office if you have questions.

AREA OF FOCUS – Noncompliance

In 2022, the RSPP is going to be highlighting one area of focus for research teams with each newsletter. This time we are looking at reporting of Noncompliance (NC).

You are probably aware that there were some differences in reporting requirements and time frames between legacy Advocate IRB and legacy Aurora IRB when reporting incidents of noncompliance. As of November 3, 2021, with the implementation of universal RSPP SOPs, there is only one set of reporting requirements for incidents of noncompliance. Take some time to become familiar with the NC reporting requirements (noted in RSPP SOPs 5 and 6) so that you remain compliant in this regard.

NOTE that you must also report noncompliance in studies ceded to external IRBs using the same criteria in effect for research overseen by the AAH IRB (see RSPP SOPs 5 & 6; as well as RSPP guidance on Deferral/Ceding of Research to an External IRB – located on the RSPP website).

Highlights of the AAH NC reporting requirements

- Report NC to the RSPP (using IRBNet) within 10 working days from the date of discovery – **no matter the IRB that oversees the research**
- Report using the NC Reporting form found in the Forms and Templates section of IRBNet
- Provide accurate detail of the NC incident so that the reviewer understands what occurred – if the information is unclear, you will be asked to revise the reported information
- Definition of Noncompliance:
    - 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 #9: Changes to Previously Approved Human Subject Research). Noncompliance may be related to studies reviewed by the AAH 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.

- Examples of Noncompliance include but are not limited to: (the most common NC incidents are highlighted in yellow)
  - Failure to obtain IRB approval prior to any protocol change
  - Failure to follow protocol as approved by the IRB (e.g., out of window visits, dosing error, lab processing error, inclusion/exclusion criteria error, etc.) except for those caused by study subjects (e.g., subject refused follow-up appointment, subject failed to take prescribed drug despite instructions, etc.)
  - Failure to obtain document informed consent or failure to use the IRB approved consent form or other material
  - Failure to obtain IRB approval for human subject research
  - Failure to follow AAH system policies on human subject research or RSPP/AAH IRB SOPs
  - Failure to follow study specific IRB directives
  - Failure of the IRB or RSPP caregivers to follow applicable regulatory requirements (e.g., make required determinations)

- The RSPP office will review all reports of NC as they are submitted.
  - If the information is unclear, you will be asked to revise/amend the reported information
  - If the report is submitted outside the SOP mandated reporting time period, this will be noted as an additional incident of noncompliance.
  - All incidents of noncompliance are tracked by the RSPP office for all research conducted at AAH. This is so that we can determine when potential continuing noncompliance has occurred.
  - Make sure to provide a thoughtful and accurate corrective action and preventative action plan (CAPA). If a plan is not provided, or does not seem to be sufficient to address the NC incident, you will be asked to provide/revise this plan.
- For studies which the AAH IRB oversees, the office will make an initial decision whether the NC is potentially serious and/or continuing or 'other' noncompliance. An IRB Member or Chair may be brought into the discussion to make this initial determination.
  - If determined to be potentially serious or continuing NC, an IRB Chair will be asked to determine if suspension or termination of research activities is necessary to protect the rights and welfare of AAH subjects.
  - If the incident appears to rise to the level of serious and/or continuing noncompliance, the convened IRB will review and make the final determination on the status of the noncompliance.
    - The IRB may request information on the implementation of the CAPA. The IRB may add to the CAPA to ensure that AAH subjects (current or future) are protected.
- For studies that are ceded to an external IRB, the RSPP review will consist of:
  1) making a determination whether the incident has occurred previously, and therefore must be reported to the IRB of record as potentially continuing noncompliance. Any determination of continuing or serious noncompliance must be made by the IRB of record.
  2) deciding if immediate action needs to occur to protect AAH subjects.
  - Note that although the AAH IRB does not oversee the research study when ceded to an external IRB, the Institutional Official may halt (temporarily or permanently) research activities in order to protect the rights and welfare of AAH subjects.
- Following AAH IRB or RSPP review, the PI/study team will receive a copy of the NC report with the determination noted.
- In cases where the convened board makes the decision that serious and/or continuing NC has occurred, reporting outside of the institution (e.g., OHRP, FDA, NIH, etc.) will be necessary. The RSPP will follow the process outlined in RSPP SOP 12 to make these reports to the necessary entities.

NOTE that multiple incidences of the same type of noncompliance (e.g. several subjects have missed a blood sample being taken for research purposes) may be reported on the same Noncompliance Reporting form. Make sure to explicitly list the subject ID numbers and dates of occurrence on the form. If you are reporting different types of noncompliance

(e.g. consenting issues as well as eligibility issues) – even if for the same subject, you must submit separate NC reports to the RSPP.

If you have questions on the reporting of any incident of noncompliance please contact the RSPP Office.

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. If there is no business that warrants convened board consideration, the meeting may be canceled.

- 02/02/2022 (W)
- 02/15/2022 (T)
- 03/2/2022 (W)
- 03/15/2022 (T)

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 the IRB process 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 at 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. The RSPP website is also the place to go to find the current RSPP/IRB SOPs.

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.