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

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Contents

AAH RSPP Update - Michelle Maternowski, Director, AAH Research Subject Protection Program (RSPP)

Dear AAH Research Community:

I wanted to take some time to let you know about our on-going plans for merging of the Advocate and Aurora IRBs into one IRB – the AAH IRB. You have heard me speak about our plans for the merger since late 2019/early 2020. Unfortunately, things happened during this time that pushed back our merger plans. However, I am now happy to report that the merger WILL BE happening this year – in November 2021! Of course, that means change, not only for you but for the RSPP and IRB as well. You may have heard some of the following information already, but I think it bears repeating.

New submission platform: AAH IRB Net – In order to have a successful and consistent IRB for the organization, not only do we need to have a single set of forms and SOPs/policies (see more about this later), but also a single submission platform. In June of 2021, we finally executed the necessary contract with WCG/IRB Net that is allowing us to build the AAH IRB Net submission system. For those of you in IL, this new system is much like the one already used at Advocate. But after implementation, the new IRB Net system will become the only submission method available for the organization. Although ambitious, and admittedly a quick turn-around, our anticipated 'go live' date for the new AAH IRB Net system is November 3, 2021. On this date, the AAH IRB Net system will become the only submission platform that you will be able to use to submit new initial reviews of research studies, HSRs, Requests to Rely forms to the RSPP, as well as post approval actions (CRs, NC, UPs, Changes) once your study has been transferred to the AAH IRB.

The RSPP is in the process of building the new IRB Net system and learning how to use it at the same time - we will become your 'trainers'! The office will be announcing training opportunities on the new IRB Net system shortly. There will be a host of training resources available to you: Microsoft Teams webinars led by RSPP team members, videos provided by WCG/IRB Net, FAQs and guidance documents from the RSPP as well as IRB Net. Look for email blasts from the RSPP office announcing these opportunities soon.

Unified forms and SOPs/policies – While we currently do things a little differently between the Advocate and Aurora IRBs, I am convinced that both methods result in the same endpoint – the protection of our human subjects. However, because we have an accredited human subject research program at AAH, the AAH IRB needs to have a single set of SOPs/policies and forms to show our consistency as an organization. To this end, with the start of the AAH IRB Net system, we will be instituting the use of a single set of forms and SOPs/policies for all research conducted at AAH. The forms and SOPs that we will be using are very similar to those already in use at Aurora IRB. [If you want to take a peek at the current Aurora IRB forms/SOPs feel free to look at the AAH RSPP website.] The new forms/SOPs will be available soon, and the office will be announcing training opportunities shortly.

You may be asking 'what is different about these new forms from what is currently used at Aurora'? The new forms have eliminated redundant information that will now be collected as part of the IRB Net submission process. Also, for those of you who are used to submitting to the Advocate IRB, the information collected in these new forms is much more precise than what you may be used to submitting, but we have found this specificity to be beneficial not only to IRB members who review the applications, but for individuals who complete the forms. Submitter responses are triggered by the questions so that important information is not forgotten.

Transfer of IRB oversight to the AAH IRB - All research currently approved by either the Advocate or Aurora IRB will undergo a transfer of IRB oversight to the AAH IRB. While this change in IRB oversight will only minimally impact the AAH researcher/research team or sponsor, it is crucial to our processes and plan to have one IRB at the organization. As we have over 800 studies to transfer this will be a process that will take several weeks/months to complete. Therefore, we ask for your patience. If you have any questions during this time, please contact the RSPP office.

My office will make the research team aware when the IRB transfer of their study is scheduled to occur. After the transfer in IRB oversight is complete, the researcher and the sponsor will receive a letter from the AAH RSPP acknowledging the transfer. While we will be sending letters directly to the sponsor, we ask for your assistance in making sure that your CRO/sponsor is aware of the change in IRB, and to keep an eye out for the letter from the AAH RSPP. We don't want anyone to miss this important information.

Current Aurora IRB studies – these studies will be transferred to the new AAH IRB no later than the go-live date of AAH IRB Net. A shell of information on these studies will be administratively entered into the new AAH IRB Net system, and you will need to use the new IRB Net system to submit post approval actions (effective on the go-live date).

Current Advocate IRB studies - We will transfer current Advocate IRB studies to the AAH IRB in a staggered fashion so as not to overwhelm the office and IRB.

- Those Advocate IRB approved studies that are greater than minimal risk (GTMR) – still require convened board action - may be transferred to the AAH IRB any time between the AAH IRB Net go-live date and the point at which the Advocate IRB Net system is deactivated (May 2022) **OR** when study is due for continuing review. The office will work with you to ensure that the study is transferred to the new IRB efficiently and correctly. We will be issuing instructions on the process for transfer of these GTMR studies over the coming weeks. In a nutshell, these studies will require review by the convened AAH IRB. Study teams will be asked to provide information on the current status of the study via a CR form. This completed CR form as well as the current protocol and a revised consent document (to include the name and contact information for the AAH IRB – only if you are still enrolling subjects) will be uploaded by the research team into IRB Net. The AAH IRB will review this information, and you will receive a new approval letter from the AAH IRB.

- Those Advocate IRB approved studies that are no greater than minimal risk (NGTMR) – did not require convened board action at initial approval - will undergo an expedited transfer to the AAH IRB. No action on the part of the research team will be required prior to the finalizing the transfer of the study to the AAH IRB. You will receive a new approval letter from the AAH IRB when the transfer has been completed. **AFTER** you receive notice of transfer you will need to update your consent document (if using one to enroll new subjects) to include the correct IRB name and contact information. This revision to the consent will require that you submit a Change form to the AAH IRB.

- Those studies that are ceded to an external IRB or are classified as Exempt will undergo an administrative transfer to the AAH IRB system so that you may continue to submit actions (Changes in personnel, NC, UPIRSOs) for these studies. You will be notified then this administrative transfer has been completed.

During the transition period to the AAH IRB, there may be a need for you to report post-approval actions (continuing reviews, modifications, new information, Noncompliance, Unanticipated Problems) for Advocate IRB studies not yet transferred to the AAH IRB. **DO NOT WAIT** to report these incidents/actions until your study has been transferred. If you have any questions on how to submit your action in IRB Net, please contact the RSPP office – we have a team of 'super users' ready to help!

My team and I appreciate your understanding and support as we move to this new phase in IRB oversight at AAH. We have over 800 studies to transfer into the AAH IRB Net system, so things be a bit bumpy at first. However, we are doing everything possible to make these changes as smooth as possible for you. Your study will not experience any interruption in IRB oversight during this transfer process. By working together, we can make this happen! As always, call with any questions.

Sincerely,

Michelle Maternowski

Director, Research Subject Protection Program (RSPP)

Important Dates – Mark your Calendars

10/14/2021 1:00 – 2:00	AAH RSPP SOPs/Forms: A TEAMS Webinar to highlight how the use of the SOPs/Forms will change for IL research staff. WATCH FOR EMAIL INVITE.
10/20/2021 12:30 – 1:30	AAH RSPP SOPs/Forms: A TEAMS Webinar to highlight how the use of the SOPs/Forms will change for IL research staff. WATCH FOR EMAIL INVITE.
10/26/2021 10:00 – 11:00	IRBNet Training: A TEAMS Webinar Provided by RSPP Staff to show research teams where to go to get the tools they will need to a successful IRB Net Submission. WATCH FOR EMAIL INVITE.
10/28/2021 1:00 – 2:00	IRBNet Training: A TEAMS Webinar Provided by RSPP Staff to show research teams where to go to get the tools they will need to a successful IRB Net Submission. WATCH FOR EMAIL INVITE.
10/27/2021 10:30 – 11:30	IRBNet submissions to WCG: A Webinar showing how to use IRBNet for WCG IRB Submissions Go to link: https://irbnet-meetings.webex.com/irbnet-meetings/j.php?MTID=m75cd0d8ba067869797ac1f5b39f27d8a Meeting number: 2632 471 7197 Password: 8JkHMsZ2aX6 Then, join by phone: +1-415-655-0001 US Toll Access code: 263 247 17197
11/3/2021:	GO LIVE DATE. All AAH Submitters should be using the integrated forms/SOPs on this date and only IRB Net submissions will be accepted from this point forward

Criteria for IRB ceding: Exceptions

The Request to Rely form includes specific instructions so that submitters can easily identify what studies may be ceded to an IRB other than one at Advocate Aurora Health. At times, however, a study does not meet the criteria and an exception is needed. When this happens a waiver of ceding criteria will be needed.

If your study meets at least one of the following criteria it qualifies for ceding to an external IRB:

- Federally funded;
- No greater than minimal risk;
- There is an institutional conflict of interest;
- The research is a phase III or IV drug study or a device study where there is evidence of safety;
- Expanded access (single patient/intermediate group) or HUD

Do not complete the Request to Rely Form until you know that your study meets the criteria or is granted an exception.

If ceding criteria are not met, contact IRBOffice@aah.org to request a waiver of the ceding criteria. The waiver request should include a statement that the study does not meet the current ceding criteria, the name of the AAH PI, and a copy of the protocol. Detailed instructions can be found in SOP 1 Initial Submission Requirements & Processes found here.

The following RSPP guidance document: IRB Reliance for Multi-center Research Guidance identifies the process on how to submit a request for an exception to cede to the RSPP Office.

AAHRPP Update

The Association for the Accreditation of Human Research Protection Programs (AARHPP) reaccreditation application has been submitted and accepted by AAHRPP. It is currently under review by our site reaccreditation team at AAHRPP. Next steps are 1) study review (IRB documents for a sample of studies being conducted at AAH are sent to the accreditation team for review), and 2) the (virtual) site visit - scheduled for 11/30/21 and 12/1/21. As part of the site visit, the accreditors will request that 1) individuals with a role in the Human Research Protection Program at AAH, 2) IRB members, and 3) researchers/research staff conducting research at AAH be interviewed. These interviews will be conducted as Teams meetings - so no travel is involved. As soon as the AAH RSPP is made aware of who the accreditors wish to interview, we will notify these individuals.

Reporting Funding Sources

Researchers and research staff must include all forms of funding for their research study within their submission application to the RSPP/IRB. Not only does this assist in us determining exceptions to IRB review fees, but it also helps us document when studies are funded by a federal grant.

Research teams must ensure that accurate information is entered on the IRB application regarding the existence of IRB review fees.

If you have questions of who is funding the research, please contact AARI, Research Business Services or the Sponsor.

Health Information Management (HIM)

The Department of Health Information Management (HIM) uploads research documents into EPIC. They have noticed instances of incorrect pagination in research consents. They want to make sure that pages of the research consent are not missing. Please double check that the page numbering is accurate when you submit to the IRB of record.

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 IRBmail@aah.org email help box and Central IRB inboxes are being phased out so please update your contact lists. 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.

Remember to update your address book to include the RSPPs central email box: IRBOFFICE@aah.org .

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.