



## Special Edition Newsletter Advocate Aurora Research Subject Protection Program (RSPP) Institutional Review Board (IRB)

December 2020

This Special Edition Newsletter will provide information on the Advocate Aurora IRB integration. We have also included the plan for using a system-wide submission platform (IRB Net). An electronic survey link is included, and we are asking all research personnel to complete this short survey so we can obtain your feedback on your preferences for the types and methods of education/training in the new IRB Net system. A re-accreditation update is provided for the Association for the Accreditation of Human Research Protection Programs, Inc. (AAHRPP).

**The IRB Net education survey can be found here: <https://www.surveymonkey.com/r/8KDNFP8>. Please consider responding by Friday 1/8/2021 as it will provide us with direction as we design our training/educational plans.**

The RSPP has been promoting IRB integration, organization-wide human subject research policies and procedures and an universal IRB submission platform since early 2020. You are undoubtedly aware that these have not come to fruition – yet. Our plans were sidelined by a multitude of problems/issues, not the least of which is the COVID pandemic – but we are still working toward implementation of these goals in 2021. Below is the latest information on our plans.

### **IRB integration**

Our plans to integrate the legacy Advocate and legacy Aurora IRBs into one organizational IRB – the Advocate Aurora Health IRB – remain. However, before this can happen, the RSPP needs to get the organization-wide version of IRB Net approved and created [see below]. We hope that everything will be in place to transition studies from the two legacy IRBs to the integrated AAH IRB by Q2 of 2021, but factors out of our control could push back this timeline.

When the transition of your study to the AAH IRB occurs, you will be informed of this action. The transition of IRB oversight of your research from legacy Aurora or legacy Advocate IRB to the AAH IRB should have no disruption on your ability to continue with your research. Any necessary action will occur within the RSPP office. We may need some help from your research staff to get the appropriate information to the study sponsor, but this assistance should be minimal.

Once the transition to AAH IRB oversight occurs, you will be expected to follow the new AAH human subject research SOPs that will be implemented with the IRB integration. The new AAH human subject research SOPs will be modeled after those already in place at Aurora.

NOTE: The above Advocate/Aurora IRB integration plans will have no effect on any research study that is ceded to an external IRB (e.g. WRB, CIRB, Advarra, other institutional IRB, etc). If you do have a study that is overseen by an external IRB, you are expected to follow the SOPs of that IRB. In September 2020, you were made aware of a new organization-wide External IRB Reliance process. The new process outlines the obligations to AAH that remain even when research relies on oversight by an external IRB. You are reminded of your obligations in research that relies on an external IRB later in this newsletter. You can also review the RSPP guidance on this topic or contact the RSPP office with questions.

### **System-wide submission platform (IRB Net)**

As was previously reported, the RSPP has made the decision to implement a system-wide version of IRB Net as our electronic IRB submission platform. Those of you in Illinois already have experience using IRB Net – although the new version may include some changes. Its use will be new to those researchers/research teams in Wisconsin.

Part of the delay in IRB integration is related to delays in getting an updated contract with WCG (parent company of IRB Net). A contract, with AAH Legal's recommended revisions, has been sent to WCG. As of mid-December 2020, negotiations on the final points of language are still underway.

Once the contract is finalized, the WCG/IRB Net programmers still need to build the forms that will be used in the new IRB Net system. These forms will be modeled after those already being used in Wisconsin. I have heard estimates from other IRB Net users that it may take anywhere from 12-24 weeks for the IRB Net programmers to create a new IRB Net system. I'm hopeful that because we currently use IRB Net in Illinois that this will decrease these time estimates.

The RSPP will provide education/resources to you/your research team to make you aware/comfortable with the new submission platform/forms prior to implementation. More information will be forthcoming (expect email blasts and special editions of this newsletter) as we have a clearer understanding of when this new system will be ready.

We have prepared a short survey in Survey Monkey that looks to get feedback on your preferences for the types and methods of education/training in the new IRB Net system. **This survey can be found here: <https://www.surveymonkey.com/r/8KDNFP8>**. Please consider responding by **Friday 1/8/2021** as it will provide us with direction as we design our training/educational plans. Thank you in advance!

### **AAHRPP Accreditation**

To remind you, AAHRPP accreditation is not restricted to the institution's IRB(s). AAHRPP accreditation status is granted to the institution's human research protection program (HRPP). The HRPP at AAH includes not only the IRBs and the RSPP office, but also: Advocate Aurora researchers/research teams, the Research Institute (including the areas of research billing, quality review and education), Research

Legal and Compliance, Investigational Pharmacy and Radiation Safety, etc. – basically any program or department who's responsibility it is to ensure that human research participants at Advocate Aurora Health are protected by institutional policy and federal, state and local regulation/law.

The accreditation process requires that AAH provide documentation that the organization follows/meets the baseline level of regulations, institutional policies and federal, state and local laws that pertain to human subject research. AARHPP accreditation then applies a higher standard to these baseline measures. Aurora has been accredited by AARHPP since 2008. This is the first time we will add Advocate to the process.

The AAH AAHRPP re-accreditation submission was deferred in 2020 due to several factors: COVID and non-integration of the IRBs and other parts of the HRPP. Even though organization-wide human subject research SOPs/policies/forms have not been implemented, and the legacy IRBs are not integrated, we recently received direction from AAHRPP on how to submit our accreditation application to account for these plans. Unless there is a future change that puts the proposed timeline in jeopardy, the RSPP is preparing to submit the Step 1 AAHRPP application by mid-March 2021. AAHRPP will review the application and may request further information and revision. After this first level of review, a Step 2 application will be submitted by the RSPP (approximately June 1, 2021). A site visit by an accreditation team will occur most likely in Q3 of 2021. At the site visit, the accreditation team will request to interview members of the AAH HRPP. We will make you aware if an interview is requested. While we won't know the areas of focus for the interviews, prior to the site visit the RSPP will provide you with as much direction as we can based upon our past experiences with accreditation.

We will keep you informed as more information is available on all of these topics. Here's to a healthy and productive 2021.

**Michelle Maternowski, Director, AAH RSPP**