



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

September 2019

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## RSPP Merger Updates

As the legacy Advocate and legacy Aurora Research Subject Protection programs work on the process of merging offices under the direction of Michelle Maternowski, there are some questions that have been answered and some that still remain. See below for a question answer session with director Michelle Maternowski to review the merger progress:

**Q: What will the name of the integrated RSPP/IRB be?**

A: Advocate Aurora Health RSPP/IRB

**Q: Where will the RSPP office reside?**

A: The RSPP office will have a presence in both Illinois (Downer's Grove office) and Wisconsin (Aurora Sinai Medical Center, Occupational Health Building).

**Q: How will researchers/submitters know which rules to follow for submission?**

A: The legacy Aurora RSPP SOPs (with slight modification) will be used in the AAH RSPP/IRB.

**Q: Will the process for submission be changed?**

A: AAH IRB will be using IRB Net from WIRB/Copernicus Group. The legacy Advocate sites have been using IRB Net for one year. Cyber IRB will then be phased out.

**Q: What is the timeline for the merger**

A: The merger of the WI and IL IRB/RSPP office staff is complete. The Advocate Aurora Health RSPP Office is under the direction of Michelle Maternowski. The roster and timing of meetings for the integrated IRB will be finalized this month. The system policy entitled: *Research Involving Humans or their Identifiable Data* has been finalized and is available to review through Policy Tech (WI – Caregiver Connect) and Advocate Document System - ADS (IL). This means that the Human Subject Research policy is now an organizational policy. Please make yourself aware of this important system policy. The policy on Research Misconduct has also been reformed to an organizational policy.

**Q: What can submitters expect in terms of turn around times for submissions during this merger process?**

A: The turn around time expectations will remain the same for the AAH RSPP office. The ease of ceding research to external IRBs will increase at Advocate with merger – the rules/criteria for ceding is expected to be more in line with what is currently being done at legacy Aurora. Watch for more to come on potential changes with the ceding process.

### **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 the WI Office (414) 219-7744 or the IL Office at (630) 929-6151. You can email us at [IRB.Office@aurora.org](mailto:IRB.Office@aurora.org) or [irbmail@advocatehealth.com](mailto:irbmail@advocatehealth.com). 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 central box will also typically get you a much quicker response! If there is a topic that you would like addressed in a future newsletter, please send a detailed description of the topic to [IRB.Office@aurora.org](mailto:IRB.Office@aurora.org). Past editions of the RSPP newsletter can be found on the [RSPP website](#).

### **Advocate HUD Requirements (legacy Advocate submissions only!)**

The processes for submission have not yet been merged for the legacy Advocate and legacy Aurora sites. Please bear with us while we maintain two application processes for the time being. Keep in mind that eventually the submissions will be uniform. When completing a HUD submission application for **legacy Advocate** please refer to section 5 of the IRB Submission Guidelines – 504 located in IRBNet.

All HUD submissions must include the following documents:

- Initial IRB Application
- Delegation Log
- Protocol Review Committee (PRC) Approval
- Local Protocol Implementation Form – HRP-503
- Patient Brochure/Patient Guide
- Any other supporting documents (i.e. FDA letter, IFU, etc.)
- Sign offs from PI, Department Head, and PRC. **No CITI or completion of COI is required.**

If you have questions concerning a submission, please call the IL RSPP Office at: (630) 929-6151

### **Advocate Aurora HUD Update**

NOTE that the contract with the commercial IRB, WIRB, has been updated for both legacy Advocate and legacy Aurora to now allow oversight of HUDs for Advocate Aurora Health. There will be a review fee charged by WRIB for the oversight (no fees are charged by AAH RSPP for ceding of HUDs to external IRBs). Remember if you wish to cede IRB oversight for the HUD to WIRB you must **first** submit a *Request to Rely on an External IRB* to the RSPP Office. Contact the Advocate Aurora Health Research Institute (AAHRI) or the RSPP office for information.

### **Research ceded to an external IRB**

Although researchers/research teams are obligated to follow the SOPs/policies of the external IRB that oversees their research study, **responsibilities to Advocate Aurora Health RSPP remain** (per RSPP SOPs).

1. Once the research study is approved by the external IRB, you must submit a copy of the approval letter/memo to the RSPP office.
2. Reporting to the RSPP of some post-approval activities (see the appropriate SOPs for the reporting process/timeframes):
  - a) Reporting of instances of Noncompliance that occur at AAH
  - b) Reporting of unanticipated problems that rise to the level of possible UPIRSOs and occur at AAH
  - c) Submission of annual (or more frequent at the discretion of the IRB of Record) re-approval/Continuing Review notifications from the IRB of Record
  - d) Submission of Changes in key personnel **BEFORE** they are activated with the IRB of record
  - e) Submission of a Final Report/Study Closure form when the study is closed with the external IRB

**Note that reporting of these actions to the RSPP may still require reporting to the IRB of Record.**

## AAHRPP Reaccreditation

### What is AAHRPP accreditation?

The primary purpose of [AAHRPP accreditation](#) is to strengthen protections for human research participants. Each accreditation advances that objective and helps build public trust and confidence in research. The benefits of AAHRPP's comprehensive approach extend beyond participants to the research enterprise. Organizations that have achieved accreditation must be re-evaluated three years following their initial accreditation, and every five years after that, in order to remain accredited

Legacy Aurora is an AAHRPP accredited institution whose accreditation is valid until September of 2021. With the merger of Advocate Health and Aurora Health Care in 2018, reaccreditation will include the entire Human Research Protection Program (HRPP) of Advocate Aurora Health. Our re-accreditation application is due in September 2020 with an expected site visit in Spring of 2021.

During the next year, the RSPP Office will be undertaking the challenging process of evaluating the HRPP of the merged system against the accreditation standards. The HRPP includes not only the IRB and RSPP office but any department involved in the human subject research endeavor (e.g. Advocate Aurora Health Research Institute leadership, researchers and research staff, Compliance, Legal, Research Business Services, research audit, etc.). While challenging, the application process is a great exercise in ensuring the institution is working under common policies and procedures to best protect research participants.

Stay tuned for future updates on the application process leading up to the 2021 accreditation.

## WHAT'S NEW?

### System Policy Updates

The Advocate Aurora Health Policy Committee has approved two important system policies that affect the conduct of human subject research: **Research Involving Humans or their Identifiable Data or Biospecimens** (Policy #2467) and **Research Misconduct** (Policy #2490). Please take time to familiarize yourself with the content of these policies as they are currently active (effective 7/18/19).

### New RSPP Office (Milwaukee) Location

We have moved!!! We are now located at the Aurora Sinai Medical Center, Occupational Health Building, 1020 North 12th St, Suite 3120, Milwaukee, WI 53233

Current office hours are 7:30 a.m. to 4:00 p.m. Monday through Friday (exclusive of holidays). You may reach the Advocate Aurora RSPP at phone number (414) 219-7744 or via email ([irb.office@aurora.org](mailto:irb.office@aurora.org)) should you have any questions.

### Website Updates

Make sure to bookmark the new searchable RSPP website: <https://www.aurorahealthcare.org/rspp-irb/>! Presently, we are working on resolving a few technical issues. If you encounter difficulties while navigating through this website, please contact Angela Carpenter at: [angela.carpenter@aurora.org](mailto:angela.carpenter@aurora.org)

## RESEARCH NEWS AND HOT TOPICS

### Article: The Rise of Citizen Science in Health and Biomedical Research

*Andrea Wiggins, University of Nebraska at Omaha and John Wilbanks, Sage Bionetworks*

<https://digitalcommons.unomaha.edu/isqafacpub/84/>

**Abstract:** Citizen science models of public participation in scientific research represent a growing area of opportunity for health and biomedical research, as well as new impetus for more collaborative forms of engagement in large-scale research. However, this also surfaces a variety of ethical issues that both fall outside of and build upon the standard human subjects concerns in bioethics. This article provides background on citizen science, examples of current projects in the field, and discussion of established and emerging ethical issues for citizen science in health and biomedical research.

## REMINDERS

### Significant Interest Disclosures

Interest Disclosures: Per legacy Aurora System Policy 269, [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.