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

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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@aah.org or 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. Past editions of the RSPP newsletter can be found on the RSPP website.

Exempt Research and PI Responsibilities

As a reminder, per Aurora RSPP SOP #3 and federal regulations on Exempt research, continuing review and reporting of Noncompliance and Unanticipated Problems are NOT required of exempt research studies. However, you are REQUIRED to submit the following prior to implementation: any changes in investigator/key personnel or PI; and substantial changes in the study design/conduct. You may submit these changes via a *Changes in Exempt Research* form. Lastly, you must inform the Aurora RSPP when this study can be closed by submitting a *Final Report* form. Copies of RSPP SOPs and forms can be found here.

Expedited and Full Committee Research and PI Responsibilities can be found here.

AAHRPP re-accreditation

https://www.aahrpp.org/apply/maintaining-accreditation/applying-for-reaccreditation

The process of conducting and overseeing human subject research at AAH is accomplished through the combined effort of the many parts of the Human Subject Protection Program (HRPP) at the organization. The HRPP not only includes the RSPP office but the IRB, investigators and study team members, AARI, research business services (billing and

contracting), research quality (CQAIR), Legal and Research Compliance. The next accreditation application will be the first submitted for the merged organization.

In preparation for reaccreditation, the integrated RSPP Office (WI and IL) has begun a GAP analysis to identify areas of programmatic weakness. The gap analysis requires us to review each AAHRPP standard against organizational policies, AARI/RSPP SOPs, guidance documents, checklists and forms to see where the HRPP at AAH measures. Documentation/'proof' of how each standard is met is required as part of the application process.

The actual accreditation application will be submitted by the RSPP on behalf of the organization at the end of 2020, with a site visit occurring some time in 2021.

We will soon be contacting other members of the HRPP at AAH to ask their assistance in ensuring that their area meets applicable standards. If you are asked to provide information on how you meet a particular standard, your assistance is appreciated.

New Forms and Updated Guidance documents

We have taken this opportunity to take the best parts of the WI and IL processes for reliance on an external IRB and determination of human subject research to create two new integrated forms (and updated guidance documents). Request to Rely on an External IRB and Human Subject Research Determination forms are now ready to be used all across the organization! You may notice some revised submission requirements and application questions, but the process should be an improvement – especially for those of you in IL.

The new forms indicate what materials must be included along with the completed form. There are some differences from the past processes, so please review the new forms carefully. If you have any questions, please refer to the associated guidance document or contact the RSPP offices in WI or IL.

These new forms can be found on the RSPP website, CYBER IRB forms library and the IRB Net forms library on or before Tuesday, September 1. The legacy versions of these forms will not be accepted after Friday, September 18, 2020.

For the time being, please continue to use the submission platform/method that you currently use for your location (IRB Net in IL or CYBER IRB/email in WI). We will hopefully soon have one submission platform for all of AAH – but we are not quite there yet.

E-mail address update – CYBER, IRB Net and CITI

HIT has completed (or soon will) migrating Advocate and Aurora e-mail addresses to @aah.org. Please remember to change your migrated e-mail address in CITI and IRB Net so you will continue to receive information from these electronic platforms (e.g. timely reminders of when your CITI training is to expire; reminders of the need for continuing review, etc.).

Website Updates

Please make sure to bookmark the searchable RSPP website: https://www.aurorahealthcare.org/rspp-irb. If you encounter difficulties while navigating through this website, please contact Angela Carpenter in the RSPP office at: angela.carpenter@aah.org

Research News and Hot Topics

The use of Investigational COVID-19 Convalescent Plasma (CCP) has become an area of interest for clinicians treating COVID positive patients. Multiple COVID positive patients at AAH have been treated with this investigational agent via the expanded access mechanism. The FDA has issued guidance to provide recommendations to health care providers on the administration and study of investigational convalescent plasma collected from individuals who have recovered from COVID-19 (COVID-19 convalescent plasma) during this public health emergency. If you have interest in using CCP in treating a COVID positive patient contact the Transfusion Services department at AAH.

COVID-19 Research Guidance from OHRP and FDA

For the latest information on research guidance for clinical trials during the COVID-19 emergency, visit the following links:

- https://www.coronavirus.gov/ for the latest Coronavirus Disease (COVID-19) updates

- https://premier-research.com/fda-guidance-clinical-trials-covid-19/
- **FDA guidance**: https://www.fda.gov/regulatory-information/search-fda-guidance-documents/fda-guidance-conduct-clinical-trials-medical-products-during-covid-19-pandemic
- **OHRP guidance**: https://www.hhs.gov/ohrp/regulations-and-policy/guidance/ohrp-guidance-on-covid-19/index.html

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.