



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

April 2020

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## Changes in Human Subject Research during COVID-19

- The RSPP/IRB office staff continues to review all new submissions during the COVID-19 crisis. However, we are prioritizing certain submissions (COVID research, research with a prospect of benefit, expanded access and HUD's). A full statement explaining our process of reviewing and prioritizing studies during this emergency can be found [here](#).
- A change in requirements have been implemented in noncompliance reporting during the COVID-19 crisis. Specific details concerning the reporting of noncompliance can be found [here](#).
- You can find the latest information concerning Human Subject Research restrictions at Advocate Aurora Health by clicking on the following links:

[Research Institute COVID-19 Update Page](#)  
[RSPP & IRB Website](#)

## Registration Instructions for CITI Training - COVID-19 Research Only

All Key Personnel conducting research at AAH are required to complete training modules found on the CITI web site. An abbreviated training course has been implemented for investigators doing COVID-related Human Subject Research. You may find specific details on this course [here](#).

If you have questions about the registration process, you may call the Aurora IRB office at 414.219.7744 or contact the CITI support staff at [support@citiprogram.org](mailto:support@citiprogram.org).

Prior to reviewing the research study, the RSPP office will verify that all key personnel listed on the application have completed the required training.

## Reminder from AAH Research Compliance - Use of non-FDA approved products and research trials/data collection

Please review the [Updated Mandates on Human Subject Research](#), which limits research activities in an effort to protect research participants and team members during the COVID-19 pandemic. Additionally, it is important to remember that the following activities should continue to follow Advocate Aurora Health policies, federal regulations and guidance and good clinical practice:

- emergent and non-emergent clinical use of drugs, biologics and devices not approved by the FDA
- clinical trials
- collection of patient data for research purposes

In almost all cases, this means that you need prior Research Institute and Institutional Review Board approval.

Questions and concerns should be directed as follows:

- Emergent and non-emergent clinical use of drugs, biologics and devices not approved by the FDA. Research Subject Protection Program Office via pager 414-222-4792
- Clinical trials and data collection research. Research Subject Protection Program Office [email](#)
- General questions or concerns Compliance Hotline via [online reporting](#) or via phone at 1-888-847-6331

### Resources

- [FDA Guidance on Conduct of Clinical Trials of Medical Products during COVID-19 Pandemic](#)
- [Investigational COVID-19 Convalescent Plasma –Emergency INDs](#)
- [FDA Guidance on Expanded Access to Investigational Drugs for Treatment Use](#)
- [FDA Regulations on Expanded Access to Investigational Drugs for Treatment Use](#)

### 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@aurora.org](mailto:angela.carpenter@aurora.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 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.