RSPP/IRB Reduction in Mandatory Human Subjects Research Education for COVID-19-related Research

Revised June 3, 2020

While restrictions on the conduct of human subjects research at Advocate Aurora Health have been lifted (as of June 2, 2020), the reduction in mandatory human subject research education for COVID-19 related research will remain in effect until September 30, 2020, at which time the usual education requirements for any human subjects research will resume.

During the COVID-19 pandemic, and while Advocate Aurora Health restrictions are in place for the conduct of human subjects research (HSR), the Advocate Aurora Health Research Subject Protection Program (RSPP)/Institutional Review Board (IRB) will allow a reduction in the amount of mandatory HSR education required for COVID-19-related HSR conducted at Advocate Aurora.

This reduction in HSR education is acceptable ONLY for COVID-19-related research and is applicable whether overseen by Advocate Aurora’s IRB or ceded to an external IRB.

All other HSR submitted to the RSPP continues to require that key research personnel named on the project have completed the standard Advocate Aurora HSR education requirements. Once Advocate Aurora HSR restrictions are lifted, normal education requirements will again be in effect for all HSR conducted at Advocate Aurora.

The abbreviated COVID-19 HSR education course consists of two CITI (Collaborative Institutional Training Initiative) Program training modules:

1. Basic IRB Regulations and Review Process, and
2. Informed Consent

Both modules can be found in a new CITI Program course titled, “Biomedical – COVID-19,” within Aurora Health Care-affiliated course selections. Although the abbreviated course is part of Aurora’s CITI Program affiliation, it is available to Illinois and Wisconsin investigators and team members.

Access to the Biomedical – COVID-19 course is as follows:

- **Wisconsin researchers**
  - Sign in to CITI Program (RSPP/IRB provides instructions for accessing CITI Program training)
  - Select “Biomedical – COVID-19” from the course options within Aurora’s affiliation

- **Illinois researchers**
  - Using Aurora-affiliated CITI Program
    - Sign in to CITI Program (RSPP/IRB provides online instructions for accessing CITI Program training)
    - “Affiliate” with Aurora
    - Select “Biomedical – COVID-19” from the course options presented
  - Using Advocate Health Care-affiliated CITI Program (Note: Biomedical – COVID-19 course is not a choice within Advocate-affiliated courses, so researchers must select both training modules instead)
    - Sign in to CITI Program
    - Select “Group 5: Remedial” from the course options within Advocate’s affiliation
      - Select “Basic IRB Regulations and Review Process” training module
      - Select “Informed Consent” training module
RSPP/IRB will monitor completion of the Biomedical – COVID-19 education course and will only allow COVID-19-related research to move forward when both modules have been completed by all key research personnel on submitted COVID-19-related HSR.

**NOTE:** Both CITI Program training modules within the Biomedical – COVID-19 course are already part of the CITI Program basic course required of all Advocate Aurora key research personnel. Therefore, individuals who are current in their HSR education requirements at Advocate Aurora do not need further education and may be included as part of COVID-19-related research.

Individuals with questions or problems accessing CITI Program course or modules are encouraged to contact the RSPP/IRB office:

- Wisconsin at [irb.office@aaah.org](mailto:irb.office@aaah.org)
- Illinois at [jasmine.taylor2@advocatehealth.com](mailto:jasmine.taylor2@advocatehealth.com)