

Updated CITI module requirements for human research

NEW - CITI Biomedical Principal Investigator course

What's new?	To provide focused and supportive information for the Principal Investigator (PI), the Hennepin Healthcare HRPP has added a new course requirement for any PI conducting biomedical research. The course modules will cover the topics: <ul style="list-style-type: none">• Qualifications and Training of Research Staff• Implementing SOPs and Working with the IRB• Complying with the Protocol• Accounting for Investigational Products• Informed Consent• Assessing and Reporting Adverse Events• Required Records and Reports• Understanding the FDA Inspection Process
Who does it affect?	All individuals listed as Principal Investigator/co-Principal Investigator or Advisor/Mentor on an IRB submission for NON-EXEMPT biomedical research must show current completion of the HHRI CITI Biomedical Principal Investigator course.
When does it take effect?	Effective April 1, 2022 for IRB approval of <i>Initial</i> submissions and July 1, 2022 for <i>Renewal</i> submissions
How to add the course to your CITI profile	A job aid will be posted on the HRPO website on how to add the course to your profile. You may also contact HRPO@hhrinstitute.org if you have questions or need assistance.

CHANGE – CITI HIPAA course requirement

What's the change?	The Hennepin Healthcare Human Research Protection Program (HRPP) requires that all researchers complete the HHRI online CITI HIPAA and Safety Training for Researchers course; the HHS(HCMC) employee training and UMN HIPAA training will no longer be accepted as equivalent due to the differences between research regulations/requirements and hospital usual care/standard of care encounters with PHI.
Who does it affect?	All individuals listed as study personnel on an IRB submission must show current (annual) completion of the HHRI CITI Annual HIPAA and Safety Training for Researchers course. <i>This change primarily affects HHS(HCMC) employees who have been substituting Cortex training for HHRI's online CITI Annual HIPAA and Safety Training for Researchers course.</i>
When does it take effect?	Effective July 1, 2022 for IRB approval of personnel on <i>Initial</i> submissions, <i>Modification</i> submissions involving personnel additions, and <i>Renewal</i> submissions (continuing review/admin check-in)
How to add the course to your CITI profile	A job aid will be posted on the HRPO website on how to add the course to your profile. You may also contact HRPO@hhrinstitute.org if you have questions or need assistance.

NOTE:

- The Hennepin Healthcare IRB may modify the education requirements to obtain IRB approval for personnel involved in human research activities as described above when deemed appropriate for approval criteria
- Education requirements do NOT apply for Humanitarian Use Device (HUD) submissions