

HRPO NEWSLETTER



Hennepin**Healthcare**
Research Institute

News from the Human Research Protection Office

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You are receiving this email because you are listed as either a PI or PC in Cayuse HE OR on the HHRI email distribution list, and may receive this email twice. If you did not receive this email directly and would like to be added to our distribution list, please email us at hrpo@hhrinstitute.org

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Updates to the HRPO Resource Gallery

Highlights of recently updated or newly added resources on the HRPO website

In response to research community feedback, we are moving to a quarterly schedule for updates to HRPO resources, unless a timelier update is required. Announcements of newly created or updated materials will be communicated via this newsletter.

You can read more about these updates in the table below and access these resources on the [HRPO website](#). **TIP:** Clear your browser history and refresh your screen to make sure you are able to access the updated materials.

Material ID:	Material Type	Material Title	Revision Description
501	MANUAL	Conducting Human Research	NEW. HRPPO is excited to release this new Manual for feedback and comment. HRPO will present at the May 24th Community Forum session. Please see survey link below for information about how you can submit feedback.
160	GUIDANCE	Criteria for exemption from IRB oversight	1. Added clarifying language to Cat 4(i) re: publicly available. 2. Added clarifying language to Cat 2 (i)(ii) for when children may be included.
117	GUIDANCE	External IRB reliance: Hennepin Healthcare localized language for external consent templates	Update phone # for out-of-study contact; add alternative language for referencing Hennepin Healthcare in the HIPAA section.
401	CHECKLIST	Required education for IRB approval	Updated to reflect new CITI Biomedical PI and CITI HIPAA course requirements; clarify that Biomedical PI course applies to non-exempt biomedical research.
600	TEMPLATE	Informed consent with embedded HIPAA authorization	Corrections to address missing embedded HIPAA authorization language. Study teams should update the HIPAA language used for previously approved research that is still open to new enrollment at the next renewal or when other updates are being made to the consent or HIPAA authorization.
601	TEMPLATE	HIPAA authorization to use and release identifiable health information for research	Revision to add right of access language to stand-alone. Study teams should update the HIPAA language used for previously approved research that is still open to new enrollment at the next renewal or when other updates are being made to the consent or HIPAA authorization.
902	FAQ	Single IRB review for federally-funded research	Correct typos; clarifying language for budget/sIRB plan; added study-start up with EQ.

* Tracked change version of these updates may be available upon request.

Reminders and other helpful information

New CITI Program Requirements (CITI Biomedical PI Course & CITI HIPAA)

Some changes have been made to the required CITI training for research personnel. Principal Investigators/co-Principal Investigators or Advisors/Mentors on an IRB submission for **non-exempt** biomedical research must complete the CITI Biomedical Principal Investigator course (effective April 1, 2022 for new Initial submissions and July 1, 2022 for Renewal submissions). In addition to this new course, all individuals listed as

study personnel on an IRB submission must complete the HHRI CITI Annual HIPAA and Safety Training for Researchers course. The HHS (HCMC) employee training will no longer be accepted as equivalent (effective July 1, 2022).

More information about these changes is available on the [HRPO website](#) under *Education & Training for Research Involving Human Subjects*, including [a summary of the changes](#) and instructions for adding the courses to your CITI profile.

Additional Documentation Required for non-HHRI Affiliated CITI Courses

For individuals who have completed CITI trainings under a non-HHRI affiliated CITI account, documentation of completion must be provided in the study smartform in Cayuse HE. When attaching the files, please compile all certificates for an individual in **one PDF** and include the individual's last name at the beginning of the file name (for example *LastName_CITI_GCP.pdf*).

For initial submissions using the revised smartform, you will see a space on the Study Personnel page requesting these attachments.

For submissions started before the smartform update, the IRB analyst will request that the documents be added on the List of Attachments page.

Please note that the additional documentation is only required for CITI training that does not pull into the individual's training record in Cayuse HE because the course was completed under a non-HHRI affiliation. You can easily see what training has pulled into Cayuse HE by clicking "view" under Trainings in the personnel table.

Trouble opening attachments from the HRPO website in Chrome?

If you've ever clicked on a link to a document on the HRPO website from a Chrome browser and nothing opens, try these workarounds:

- Right click on the file link and select "Open Link in Incognito Window"
- Right click on the file link, select "Copy Link Address", and paste the link into the address bar for the same browser

Upcoming training and education opportunities

Virtual office support for Cayuse HE

HRPO is available to provide demonstrations and answer questions for HE submissions via Zoom. Contact HRPO@hhrinstitute.org to request an appointment for yourself or your group.

May Collaborative Research Forum

HRPO will present at the May (May 24th) Collaborative Research Forum on the new 501 Manual. Look for more information and the meeting link from the EQ office.

Emergency Preparedness and human research survey

Hennepin Healthcare Research Institute (HHRI) is an Association for the Accreditation of Human Research Protection Programs, Inc. (AAHRPP) accredited institution. AAHRPP recently added a new standard - **Element I.1.H: The organization has and follows written policies and procedures specifically designed to protect the rights and welfare of research participants during an emergency.** HHRI will be addressing this newly added standard as part of reaccreditation application (2023). We'd love to hear from you – please complete this survey via the link or QR code below.

<https://www.surveymonkey.com/r/DJXZMXX>



Contact Us

We want to hear from you!

Email us @ hrpo@hhrinstitute.org

Do you have feedback or comments for HRPO/IRB? Complete our survey via the link or QR code below:

<https://www.surveymonkey.com/r/TXG82DL>



Visit our website for guidance, resources and accessing Cayuse HE: <https://www.hhrinstitute.org/researcher-resources/ohsr/>

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