HRPO NEWSLETTER

Hennepin Healthcare Research Institute

News from the Human Research Protection Office

Issue 04 • February 2023

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In this Issue:

Updates to the HRPO Resource Gallery

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

Announcements of newly created or updated materials will be communicated via our quarterly newsletter. Read more about these updates in the table below and access these updated resources on the HRPO website.

TIP: When accessing posted materials, clear your browser history and refresh your screen to make sure you are accessing the most recent versions.

Material ID:	Material Type	Material Title	Revision Description
501	MANUAL	Conducting Human Research	**1.6** What training and education is required to conduct human research? Update to add OEQCR ancillary review/training check process and clarify education/training requirements **2.2** What other types of Hennepin Healthcare approvals does human research require?

			Update to add OEQCR ancillary review/training check requirement New – **7.14** What if I will be working with a community partner or conducting community-based participatory research (CBPR)? New – **7. 15** What if I'm doing international research? **14.2** Do I need IRB approval for HUD use? Update to clarify personnel to be listed in an HUD submission New – **18.4** COI reporting guidance New – **18.8** Data collection, management, and sharing **18.17** What is the process for closing out a study? Update to describe additional PI responsibilities for sponsor-investigator research **19.** HRPP Emergency preparedness and response Content moved to Appendix A New – **19.** Research and mandated reporting New – **20.** Planned emergency/exception from informed consent (EFIC) research New –**Appendix A.** HRPP Emergency preparedness and response (formerly section 19) New –**Appendix B.** Additional data management and sharing requirements for NIH supported research New –**Appendix C.** Additional requirements for Department of Defense (DoD) research New –**Appendix D.** Additional requirements for Department of Justice (DoJ) research **GLOSSARY** Update to add definitions (*Minimal risk*; *Research integrity (NIH)*; *Scientific integrity (CDC, USDA)*)
108	GUIDANCE	Regulatory and external guidance references	Added references to: ▪ Expanded Access guidance ▪ Add additional FDA guidance specific to software as medical device and MMA ▪ NIH section with new DMS policy
109	GUIDANCE	Informed consent	Retired – researchers may refer to the IRB reviewer 720 WORKSHEET Informed consent
113	GUIDANCE	Notifications to HRPO for ceded studies	Revised to clarify *Suspension or Premature Termination of Study* is required within 7 days for ceded studies to align with non-ceded studies
133	GUIDANCE	New information/Incident reporting	Revised **Unexpected death** to specify that death must be described in the protocol **and** consent form to be considered *expected* Added additional description of *serious* for **Serious adverse event (SAE)** Added example for **External new information**: *Disqualification of study team member*
160	GUIDANCE	Criteria for exemption from IRB oversight	Revised section A **Basic eligibility criteria** to remove DoD restriction for research involving children (no longer applicable)

	Cayuse HE	Initial submission	*Getting started* page: Updated to reference EQ training check and where to find additional information on non-CITI requirements; clarifying language regarding how to content addressed in the study protocol vs. information included in smart form response *Study personnel* page: Added question for EQ training check and attachment location for uploading EQ training check cover sheet; Updated language under *Hennepin Healthcare other personnel* to indicate what to include in description of role on the study *Site info page*: Updated language from GWAS to GDS Various pages: Revised wording to reference the protocol section at beginning of instructional text, where applicable (e.g., *Provide the applicable protocol section(s) that describe the study's potential risk(s) to human subjects; OR if there is no protocol, describe below)*
	Cayuse HE	Renewal submission	*Submission intro* page: Added question for EQ training check and attachment location for uploading EQ training check cover sheet *Continuing review* page: Added checkbox option for *Permanently closed to enrollment;* removed reporting dates
	Cayuse HE	Incident submission	*Reporting criteria* page: Added clarifying language to describe incident
HRPO SOPs			
2xx	SOPs	200 series SOP	203 Using worksheets in Cayuse HE Added new worksheets to table (711-A, 757, 788) NEW - 209 OHRP registrations 210 IRB jurisdiction Revised title of SOP from *Determination of IRB jurisdiction* to *IRB jurisdiction* Added specific detail to address AAHRPP Element I.1.C(1)(b) Incorporated content moved from 220 IRB SOP Added reference to A2 APPENDIX *HRPP Components* 212 Criteria for IRB approval Added reference to relevant federal regulations and guidelines, *The Belmont Report, and* 197 GUIDANCE Criteria for IRB approval 214 Use of expert consultants Minor wording change 220 HRPO structure and composition Changed title of SOP from *Jurisdiction, structure, and composition* to *HRPO structure and composition* Moved content related to jurisdiction of HRPO/IRB to 210; add specific detail to address AAHRPP element I.1.C and I.9. 222 IRB member responsibilities for non-exempt human research Updated *Designated reviewer* section to align with 243 IRB SOP

			223 IRB member addition & removal Updated reference to education requirements to remove 401 Checklist and replace with Section 1.6 of 501 Manual 232 IRB meeting minutes Added language to Recoding minutes section to explicitly call out consideration of participants with diminished capacity to consent [AAHRPP II.5B.1(i)] 250 Continuing review/administrative check-in Minor revision to specifically call out additional factors considered by the IRB [AAHRPP II.2.E(1)(a)(v)] 251 Incident/New Information Added information regarding expedited and convened IRB review processes and IRB actions 255 Participant complaints and concerns Added reference to new online compliant form. NEW - 200-A1 APPENDIX Compliance statement NEW – 200-A2 APPENDIX HRPP Components
TEMPLATES			
600	TEMPLATE	Informed consent with embedded HIPAA authorization	Revised language regarding sensitive information in section 9. **HIPAA Authorization for Research** Added language and link to online feedback/complaint form in section 16. **Contact information for questions** Updated footer
601	TEMPLATE	Authorization to use and release of identifiable health information for research	Revised language regarding sensitive information in section **5. What about sensitive information?** Added language and link to online feedback/complaint form in section **12. Questions?** Updated footer
602	TEMPLATE	Informed consent for emergency use of a test article	Added language and link to online feedback/complaint form under **Who can I talk to?**
604	TEMPLATE	Use of an FDA-designated Humanitarian Use Device (HUD) Information Sheet	Added language and link to online feedback/complaint form under **Hennepin Healthcare contact information**
606	TEMPLATE	Information sheet for EXEMPT research	Added language and link to online feedback/complaint form under **What do I do if I have any questions or concerns?**
Worksheet revisions: *WORKSHEETS are used/completed by IRB reviewers*			
708	WORKSHEET	Reviewer worksheet list	Added row for NIH DMS policy Added row and reference worksheet for Emergency use (New) Added row and reference worksheet for international research (New) Added row and reference worksheets for sIRB
709	WORKSHEET	Initial review	Removed DoD restriction for research involving children (no longer applicable) Added section 10 **Hennepin Healthcare as sIRB** (Hennepin Healthcare does not currently serve as an sIRB)
711	WORKSHEET	Reliance review	Added reference to l*ocal context* and created an appendix for reference to section **D. Hennepin Healthcare activities and populations** Added section **I. EFIC Plan**

			Added section **J. Expanded access** Updated to align with ancillary review process changes (e.g., EQ/pharmacy)
711-A	WORKSHEET	Local context considerations	New
713	WORKSHEET	Incident/new information review	Added reviewer attestation section
720	WORKSHEET	Informed consent	Updated **For research funded by the National Institute of Justice (NIJ)** section Updated **For research funded by the Department of Defense (DoD)** section
724	WORKSHEET	Modification review	Edited sections 8 and 9 to align with 709 WORKSHEET updates related to sIRB
757	WORKSHEET	International research	New
782	WORKSHEET	DoJ criteria for approval	Updated **Additional Criteria for Department of Justice (DoJ)** section
787	WORKSHEET	Planned emergency/exception from informed consent (EFIC) research	Overall revisions to align with FDA/DHHS regulations
788	WORKSHEET	Emergency use of a test article	New

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

Reminders and helpful information

NEW - QEQCR ancillary review/education check

Researchers must contact OEQCR (EQ@hhrinstitute.org) to complete an education check process **prior to** routing *Initial* and *Renewal* submissions to the IRB as well as *Modification* submissions requesting approval of study personnel. OEQCR will review study personnel to verify that training and education requirements are met.

To facilitate efficient OEQCR ancillary review and IRB approval processes, it is important for the PI and/or PC to review and ensure education and training requirements are met and kept up-to-date for all study personnel throughout the study lifecycle. The PI or PC is responsible to attach the OEQCR training check documentation in the Cayuse HE submission (required to obtain final IRB approval).

NOTE: An individual (other than the PI) with incomplete or expired training or education may be removed from a submission to facilitate IRB approval; however, such an individual may not conduct any human research activities until a subsequent *Modification* submission is IRB-approved in which the individual is added once training has been completed.

For more information, refer to the 501 MANUAL Conducting Human Research - section 1.6 *What training and education is required to conduct human research?* or contact EQ@hhrinstitute.org

Researcher experience survey reminder

An invitation to complete the annual Hennepin Healthcare Human Research Protection Program (HRPP) - researcher experience survey was sent out via email last week. This anonymous online survey asks you to rate your experience with the Office for Education and Quality in Clinical Research (EQ) and the Human Research Protection Office (HRPO); the results are used to help improve HRPP performance to better serve the Hennepin Healthcare research community. We appreciate your time to complete the survey and share your feedback.

If you didn't receive an email invitation, you may access the survey here: https://www.surveymonkey.com/r/XG3283M.

What other types of approvals do I need for human research?

In addition to IRB approval, you may need to contact other components of the Hennepin Healthcare HRPP to review and approve their respective aspects of human research oversight. Some reviews will depend on the type of research being done. For example, research that will dispense medicine must complete the Investigational Pharmacy review. And some reviews will apply to all research, such as the Department/Physician Chief Acknowledgement required to ensure departmental approval. These ancillary reviews are confirmed during the IRB review, and have an impact on final approval.

To learn more about the different ancillary reviews and their impact on IRB review, refer to the 501 MANUAL Conducting Human Research - section 2.2 *What other types of Hennepin Healthcare approvals does human research require?*

EQ announcements and reminders

Changes to hazardous materials training

Starting in January 2023, new IATA regulations will change how EQ trains and assesses competency for those shipping hazardous materials. The new process will involve two parts, which will be required to be repeated every 2 years for anyone involved in shipping biospecimens or other hazardous materials:

1. Completion of the CITI course: **Shipping and Transport of Regulated Biological Materials** (must not be expired when taking the in-person competency assessment)
2. In-person box packing competency assessment - still managed and scheduled by EQ, but now to be conducted by Pa Houa Thor, Laboratory Services Supervisor

EQ expects everyone responsible for taking this training to do the in-person competency training in the first quarter of the year it's due. EQ will be offering sessions in January, February, and March. Completion of the CITI portion can occur at any point during the year it's due, as long as the CITI training is current at the point you are scheduled to take the in-person training.

Please remember that if your Hazmat training has expired, there is no grace period. Per federal regulations, you must be current on your training to pack any biospecimens or other hazardous materials for shipping.

Any new employees hired after the March dates will be required to take the CITI training when hired, and will join the first quarter training dates when they are next available. If new hires need to do any independent shipping before attending the in-person competency assessment, they should contact EQ for guidance.

EQ will continue to contact new employees and those due to renew Hazmat training, and will give guidance on how to do so. In the meantime, please contact EQ directly at EQ@hhrinstitute.org with any questions!

Clinicaltrials.gov records – increased enforcement of reporting accurate and timely results

Do you have a ClinicalTrials.gov record? Will your study be completed soon? Based on recent information and communications from both the FDA and NIH, there is increased effort for clinical trial results to be reported timely and accurately. Missing FDA required deadlines could mean consequences for you, your institution, and continued federal funding.

To find out more about the increased compliance efforts there is also a CITI webinar available: “ClinicalTrials.gov Enforcement: An Update”

If you have questions about your ClinicalTrials.gov record, would like to review the CITI webinar, or just connect about ClinicalTrails.gov, contact EQ at: EQ@hhrinstitute.org We’re happy to help.

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

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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.

Collaborative Research Forum

Cayuse Tips and Tricks and EQ Training Requirements (zoom link)

Wednesday, February 22nd @ 12pm

Contact Us

We want to hear from you!

Email us @ hrpo@hhrinstitute.org

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

The Hennepin Healthcare Research Institute (HHRI) is an Affirmative Action/Equal Opportunity Employer: Minorities, Women, Veterans and Individuals with Disabilities