HRPO NEWSLETTER

Hennepin Healthcare Research Institute

News from the Human Research Protection Office

Issue 03 • November 2022

You are receiving this email because you have a Cayuse HE user account at Hennepin Healthcare. 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

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 clarify CITI Program and OEQCR training requirements and descriptions 2.2 What other types of Hennepin Healthcare approvals does human research require? ✓ Update to clarify Investigational pharmacy requirements 1.8 What if I applied for federal funding and received a Just-in-Time (JIT) notification? ✓ Additional description of submission options 3.4 How do I request IRB approval of new human research? ✓ Update to describe HRPO administrative withdrawals New – 3.5 What information and documents will I need for an Initial submission in Cayuse HE? New – 3.6 What is the submission workflow in Cayuse HE? New – 3.7 How do I certify a submission? New – 3.8 What happens during the Pre-Review and Under Review workflow New – 3.9 Can I make changes when a submission is in the Pre-Review or Under Review workflow? New – 3.10 When can I expect a response about a submission? New – 3.11 My Initial submission has been assigned for convened IRB review; what can I expect next? 3.12 How do I renew IRB approval? ✓ Update to describe IRB decisions: Return to PI, Deferred, and Minor stipulations New – 3.15 How do I submit a protocol exception request? New – 3.17 My follow-on submission has been assigned for convened IRB review; what can I expect next? New – 5.11 Can other providers assist with recruitment? New – 10.8 If I am doing international research, does HIPAA apply to research conducted at international sites? New – 18.5 What should I do if I receive a complaint or concern from a participant? New chapter– 19. HRPP Emergency preparedness and response GLOSSARY Update to add definitions
110	Guidance	Criteria for external IRB reliance	Minor update to allow exception for reliance for exempt research, in limited situations.
113	Guidance	Notification to HRPO for ceded studies	Addition of specific call out for EQ post approval audit closeout Revision to add premature termination to *suspension of enrollment or premature termination*
133	Guidance	New information-Incident reporting	Addition of specific call out for EQ post approval audit closeout Addition of specific call out for suspension or premature termination of a study by the sponsor, investigator, institution or other IRB

315	Form	Planned protocol exception request	NEW – Form for use when submitting a planned protocol exception request via a Modification.
	Cayuse HE	Initial submission	*Getting started* page: Revise link re: investigator responsibilities to link to the 501 Manual *Site info* page: Revised to reference updated IDS email address and description of IDS process *HIPAA* page: Added N/A option for international research under the question *Is the Hennepin Healthcare IRB serving as the Privacy Board to approve a waiver or alteration of HIPAA authorization?*
HRPO SOP revisions:			
200s	SOP	200 series SOP	Origination of SOP compilation format 201 Resource gallery management ✓ Update to reflect SOP compilation format and streamlined process to manage Resource Gallery documents 203 Using worksheets with Cayuse HE ✓ Added reference to 724-A, 720-A, and updates to clarify when 727 is required for expedited research; ✓ Added language to clarify use of worksheets during convened IRB review 211 Reliance on external IRBs ✓ Minor updates to reflect process for IRB reliance and actions taken in Cayuse HE and reference to related resources 212 (formerly 245) Criteria for IRB approval ✓ Content moved into separate SOPs on specific topics; Revised to provide general criteria for approval and reference to worksheets system NEW - 219 HRPO emergency preparedness and response plan NEW – 222 IRB member responsibilities for non-exempt human research NEW – 223 IRB member addition & removal 230 Convened meetings ✓ Added description of Full expedited review type NEW – 232 IRB meeting minutes NEW – 239 Administrative withdrawals and closures

			244 Exempt research ✓ Added reference to 160 GUIDANCE Criteria for exemption from IRB oversight NEW –247 Recruitment and screening of potential participants NEW –248 Recruitment materials NEW –249 Compensation for study participation 250 Continuing review/administrative check-in ✓ Update to the frequency for Admin Check In ✓ Added section: renewal submission with minor stipulations 252 Modifications to previously approved research ✓ Update to incorporate review of protocol exception requests; update to incorporate review via modification for relying site for research under sIRB review; update to remove detail addressed in applicable reviewer worksheet NEW –255 Participant complaints and concerns 260 SOP Compliance activities ✓ Added reference to specific OEQCR SOP 281 Department of Defense-sponsored research ✓ Update to reflect revisions to DOD INSTRUCTION 3216.02 (April 15, 2020) NOTE: 253, 254, 261 revised to remove definitions and reference Glossary for defined terms.
Worksheet revisions: *WORKSHEETS are used/completed by IRB reviewers*			
720	Worksheet	Informed consent	Incorporate DoD specific consent requirements (moved from 781 and updated per revisions to DoD instructions)
781	Worksheet	DoD criteria for approval	Updated to reflect changes to DOD INSTRUCTION 3216.02 (April 15, 2020) and revisions to 281 SOP; moved consent requirements to 720 WORKSHEET

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

Reminders and helpful information

CITI Program requirements

All individuals involved in human research must complete the HHRI **CITI Annual HIPAA and Safety Training for Researchers** course. The HHS (HCMC) employee training is no longer accepted as equivalent.

Principal Investigators/co-Principal Investigators or Advisors/Mentors for **non-exempt** biomedical research must complete the HHRI **CITI Biomedical Principal Investigator** course.

All individuals involved in conducting exempt category 4 research ONLY must complete the HHRI **CITI Secondary/Observational Research** course.

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

Recently released guidance and proposed regulatory changes

Have comments you'd like submitted on any of these FDA documents? Let HRPO know at HRPO@hhrinstitute.org.

- FDA **Draft** Guidance - *Ethical Considerations for Clinical Investigations for Medical Products Involving Children*. On September 25, the FDA released draft guidance intended to help industry, sponsors, and IRBs when considering enrolling children in clinical investigations of drugs, biological products, and medical devices. Public comments are being accepted until December 27, 2022. When finalized, the guidance "will provide the agency's perspective on the ethical considerations for including and protecting children in clinical trials.

- On September 28, FDA released two Notices of Proposed Rulemaking (NPRMs) to harmonize the FDA regulations on the protection of human subjects and institutional review boards with the 2018 Common Rule. Comments to the Proposed Rules are due to FDA by November 28, 2022.The proposed rules, together, harmonize the single IRB requirement for cooperative research, informed consent requirements, continuing review provisions, associated recordkeeping provisions, and some definitions, as well as make some additional formatting and editorial changes for clarity.

  21 CFR 50/21 CFR 56 proposed rule (87 FR 58733) – proposes changes to the regulations to harmonize with the revised Common Rule on topics related to informed consent requirements, three new elements of informed consent, updated/new definitions, continuing review changes, etc.

  21 CFR 56.114 (87 FR 58752) – This proposed rule proposes to "require any institution located in the United States participating in FDA-regulated cooperative research to reply on review and approval by a single [IRB] for that portion of the research conducted in the United States, with some exceptions." The list of exceptions does differ from the list in the Common Rule.

HRPO will share information via this newsletter when these guidance/proposed rules are finalized.

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

December Collaborative Research Forum: Be on the lookout for an invite for the December Collaborative Research Forum:

- Topic: Incident reporting: promptly reportable information and submitting incidents in Cayuse HE, presented by HRPO
- When: Wednesday December 6th @ 12pm

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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