HRPO NEWSLETTER

Hennepin Healthcare Research Institute

News from the Human Research Protection Office

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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

133	Guidance	New information-Incident reporting	Updates to formatting/organization: ✓ Specific call outs for protocol deviation, breach of confidentiality, participant complaint, and enrollment of prisoner in study not approved to enroll prisoner ✓ Clean-up/addition of examples meeting criteria for reportable event ✓ Addition that a reportable event may meet more than one category or that an event reported as one category may be determined by IRB to meet criteria for a different reportable event ✓ Addition of information on how to submit an Incident outside of Cayuse (e.g., report of noncompliance if submitter does not have access to Cayuse HE) **IMPORTANT:** The *Incident* submission template in Cayuse HE will be updated to mirror the promptly reportable categories listed in this 133 Guidance.
113	Guidance	Notifications to HRPO for ceded studies	Minor revisions to update description to correspond with parallel edits to 133
117	Guidance	External IRB reliance: Hennepin Healthcare localized language for external consent templates	Edits to incorporate MN state law on child maltreatment and past (preceding three years) abuse or neglect
251	SOP	Incident-new information review	Minor restructuring and clarifying language Addition of reference to externally reviewed research
253	SOP	Noncompliance	Revisions to wording and organization Revisions to noncompliance and continuing noncompliance definitions Addition of specific DoD definitions for noncompliance and serious noncompliance Addition of reference to IRB reliance
254	SOP	UPIRTSOs	Revisions to update the formatting of UPIRTSO definition to mirror the 133 GUIDANCE Addition of reference to DoD Addition of HRPO Director or designee as party that may suspend research consistent with 261 SOP Addition of reference to research relying on an external IRB.
260	SOP	Compliance activities	Revisions to terminology to refer to post approval audits – for cause and not for cause Addition of post approval auditing for studies relying on an external IRB
261	SOP	Suspensions and terminations	Revision of definitions for *suspension* and *termination* Addition of HRPO director or designee as party with authority to suspend
262	SOP	Institutional reporting of non-compliance, UPIRTSOs, suspensions and termination	Addition of AAHRPP reporting requirements Addition of optional parties to receive notification of report
401	CHECKLIST	Required education for IRB approval	CITI categories section added

501	Manual	Conducting Human Research	Section 1.6: Clarifications/updates to CITI and OEQCR education/training requirements Section 2.2: Updates to ancillary review requirements to match existing IRB process; add column *Impact on IRB Review or Approval* Section 3.5: Clarifications to describe continuing review requirements pre-2018 vs. post-2018 common rule **New section** - 5.7: *Can I use Care Everywhere for Research?* **New section** - 5.10: *How should I document screening of subjects?* (EQ Guidance) Section 7.10: Addition of reference to requirement for study staff to obtain fluency certification to bulleted list of researcher responsibilities; updates to instructions for how to obtain language certification and mirrors guidance recently shared by EQ Section 7.11: Clarifications to bulleted list and additional of table *Short form consent – Who signs what?* Add reference to impact on HIPAA authorization when using short form **New section** - 7.12: *How do researchers obtain HIPAA Authorization for non-English speakers?* **New section** - 9.5: *What are some ways to protect the security and confidentiality of research data?* (EQ Guidance) **New chapter** – 17: OEQCR guidance on clinical research evaluation (EQ guidance) **New chapter** – 18: OEQCR guidance on study conduct and management (EQ guidance)
600	TEMPLATE	Informed-consent-with-embedded-HIPAA-authorization	Addition of note to include number of participants (left out in the last update) Made imbedded HIPAA authorization language its own section (i.e., removed from confidentiality section) Addition of GINA template language for inclusion when applicable Addition of MN state law mandated reporter language for minors re: abuse/neglect that occurred in past three years
605	Template	Signature blocks	Edits to clarify process for non-English speakers
	Cayuse HE submission	Initial	Removal of question "is this a legacy submission transition" Addition of QA/QI submission type Update to Exempt Cat. 2: ✓ Clarifying language for when children may be included to align with 160 GUIDANCE Update to Exempt Cat. 4(i): ✓ Clarifying language re: “publicly available” to align with 160 GUIDANCE Clinical trial section: ✓ Update to instruct study team to provide clinical trial registration # (via modification) if registration has not yet occurred Remove ACT checklist as requirement /attachment

	Cayuse HE submission	Incident	**Updates** to categories to align with 133 GUIDANCE

Worksheet revisions: *WORKSHEETS are used/completed by IRB reviewers*

713	WORKSHEET	Incident-new information review	Update of *continuing noncompliance* definition to align with 253 SOP definition Add in information re: what IRB must consider vs. may consider from AAHRPP Element I.5.D
717	WORKSHEET	FDA Drugs and IND requirement	Clarifications/simplification edits from consultant review
718	WORKSHEET	Devices and IDE requirement	Remove "category" numbers under IDE Exempt and clarify when IRB would need to make device risk level determination; minor clarifications from consultant review.
719	WORKSHEET	HUD criteria for approval	Revise to remove/replace reference to 797 Worksheet Incorporate clarifying edits from consultant review.
720	WORKSHEET	Informed consent	Edits to clarify process for non-English speakers

* 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. **As of July 1**, 2022, 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.

Also, as of April 1, 2022 for new Initial submissions and July 1, 2022 for Renewal submissions, 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.

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.

Minor Stipulations – what does it mean?

When you receive an IRB determination letter with Decision: Minor Stipulations, it means that the submission was approved pending the resolution of stipulations outlined in the letter. That is, a minor stipulations decision means that the criteria for approval (45 CFR 46.111 / 21 CFR 56.111) have been met but the IRB identified specific changes to be made. The PI's response to minor stipulations does not typically need to be reviewed by the convened IRB (or assigned to a meeting agenda), unless it was originally reviewed by the convened IRB and the PI's response is considerably different from what has been stipulated. The minor stipulations IRB decision is different from a *deferral decision*, which means that the criteria for approval have not been met. Responses to deferral must always be reviewed by the convened IRB.

All stipulations will be included in the letter. Occasionally comments in the smartform will be used to direct you to certain items, but this may not be

the case for every submission or stipulation. You should review the letter closely for the complete list of stipulations.

If you receive a Minor Stipulations decision for a renewal submission decision, you may need to submit a separate modification submission to address the changes required. Instructions for this are included in the IRB determination letter after “Next Steps”.

When addressing stipulations, submit the response as soon as possible and do not make changes beyond what is requested in the IRB determination letter. If there are other pending changes to be submitted, you must wait until the submission under review has been resolved.

For all IRB determinations, the full letter is provided in the email, but you can always access the letter in the submission details in Cayuse HE. To find a letter, go to the submission details page for the submission under review – you should see it under My Tasks on the main dashboard while it is still under review. On the submission details page, you will see a “Letters” tab at the bottom of the page. Here you will find a link to any IRB determination letter provided.

Reminder to submit renewal on time to avoid a lapse in IRB approval

The IRB must conduct continuing review of research that is reviewed by the convened IRB, subject to the pre-2018 rule, or regulated by the FDA, DOJ, or Consumer Product Safety Commission. When continuing review is required, your approval letter will include a renewal date. Cayuse HE sends auto-generated email courtesy reminders to the PI and PC beginning 90 days prior to the renewal date. To request continuing review, you must complete a Renewal submission in Cayuse HE.

Submit for renewal no later than 45 days prior to the renewal date to prevent approval from expiring. Renewals that must be reviewed by the convened IRB must complete be ready for final review (or have addressed all pre-review clarifications) before it can be assigned to a meeting agenda. Submitting no later than 45 days prior to expiration will help avoid lapses in IRB approval.

See section 3.5 of the 501 MANUAL for more information about how to renew IRB approval.

Reminder - Language Fluency Certification for Study Staff

Any study staff who are hired to connect with, recruit, and continue to communicate with non-English speaking study participants are required to be fluent in the non-English language and English. Such study staff must **complete language fluency certification requirements**. These requirements must be completed before any non-English communication tasks are completed on a study.

See Section 7.10 of the 501 MANUAL for more information on how to obtain the language fluency certification.

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

September Collaborative Research Forum (9/29 @ 12PM) - Investigational Drug Studies

Zoom Link: https://hhrinstitute.zoom.us/j/84352692237?pwd=dFFESlM5L0ZjK241WWRYNmlCY2VYUT09
Meeting ID: 843 5269 2237
Passcode: 261767

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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