HUMAN RESEARCH PROTECTION

Notifications to HRPO for ceded studies

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Resource type GUIDANCE

Visit the Hennepin Healthcare HRPO website for additional information:

https://www.hhrinstitute.org/researcher-resources/ohsr/

If you have additional questions, please contact IRBreliance@hhrinstitute.org

Hennepin Healthcare Human Research Protection Office (HRPO) reporting requirements for studies with an external IRB of record

Where oversight of a study has been ceded to another IRB, Hennepin Healthcare researchers must understand and satisfy the reporting requirements of both the external IRB and Hennepin Healthcare.

- Review this 133 Guidance to understand what needs to be reported to the Hennepin Healthcare.
- Hennepin Healthcare researchers are responsible for understanding and following the reporting requirements of the external IRB overseeing the study, in accordance with their policies and process.

IMPORTANT: Notifying Hennepin Healthcare HRPO is separate from and in addition to the submission to the external IRB.

The table below describes the following information that must be reported to HRPO:

Notification type	When to notify HRPO	How to notify HRPO	Notes
Hennepin Healthcare study personnel changes (Includes change in PI, adding/removing personnel, change of status/role/responsibilities)	For adding new personnel or changing roles/responsibilities, notify HRPO, prior to the personnel assuming study responsibilities	Cayuse HE Modification	
New or changes to conflict of interest (COI) status for any Hennepin Healthcare study personnel engaged in this study that are in a position to influence the design of the research, its conduct, and/or reporting	Changes in a financial or business interest must be reported within 30 days of occurrence	Cayuse HE Modification	If potential conflict of interest exists, contact the HHRI COI committee; See HHRI Conflict of Interest (COI) Policy
Continuing review OR **Annual status check-in**	Upon receipt of continuing review approval from the sIRB If the sIRB does not require continuing review, notify HRPO annually (based on initial sIRB approval date for Hennepin Healthcare site)	Cayuse HE Renewal	Select "**Administrative check-in**" as the applicable type of submission on the Submission intro smart page in Cayuse
Suspension of enrollment or premature termination (if Hennepin Healthcare site has enrolled participants)	Within **3** working days of the investigator learning of enrollment of suspension for safety reasons	Cayuse HE Incident	Select "Yes" to "Is this a ceded study?"

Unexpected death of a Hennepin Healthcare enrolled subject	Within **3** working days of the investigator learning of death of Hennepin Healthcare enrolled participant	Cayuse HE Incident	Select "Yes" to "Is this a ceded study?" Report the **unexpected death** of a locally enrolled subject whether considered related to the research or not. Death is considered *expected* only if it is: ▪ Due to the natural progression of a subject's underlying disease or condition, OR ▪ Identified as a possible risk of the study procedure as described in the protocol and/or consent form, an Investigator's Brochure or device Instructions for Use, package insert, or other related study document(s)
sIRB determination of **serious or continuing noncompliance, suspension, termination, or an unanticipated problem involving risk to subject or others (UPIRTSO)** for the Hennepin Healthcare site	Promptly upon receipt of sIRB determination.	Cayuse HE Incident	Select "Yes" to "Is this a ceded study?" Include the external IRB's determination letter and any additional applicable documentation or information. When a report to a federal agency is required, Hennepin Healthcare will provide information and input as outlined in the sIRB reliance agreement. **NOTE:** HRPO should be contacted prior to any determination being sent to a regulatory agency.
Report a **participant complaint** if either of the following are true: ▪ Complaint of participant(s) that indicates participant or others might be at increased risk of harm or at risk of a new harm OR ▪ Participant complaint that cannot be resolved by the research team	Within 7 working days of awareness	Cayuse HE Incident	Select "Yes" to "Is this a ceded study?" Include the external IRB's determination letter and any additional applicable documentation or information.
Study modification for the Hennepin Healthcare site of **prospective waiver of consent or exception from informed consent** (EFIC – 21 CFR 50.24)	Prior to implementation at the Hennepin Healthcare site	Cayuse HE Modification	Provide a thorough description for the justification for the modification submission and edit the applicable section(s) in Cayuse HE Research that was not originally approved with prospective waiver of consent **MUST be submitted to HRPO prior to implementation of that modification** for the Hennepin Healthcare site to obtain required HHS/HHRI administrative approvals for waiver of consent research.
Study modification for the Hennepin Healthcare site IF it may affect any of the following: ▪ Ancillary reviews or other required administrative reviews (e.g., changes to plans for radiation exposure, use of Hennepin Healthcare resources) ▪ Previous information submitted regarding inclusion of vulnerable populations (e.g., inclusion of children, inclusion of adults lacking capacity to consent) ▪ Compliance with institutional policy/state law requirement(s)	Promptly upon notification of modification to approved protocol	Cayuse HE Modification	Provide a thorough description for the justification for the modification submission and edit the applicable section(s) in Cayuse HE Work with HHRI/HHS ancillary review committees and/or departmental administrators, as applicable (e.g., radiation safety committee, Grants Administration)

External for-cause audits - notifications FDA, other federal agency, or other external for-cause audit, inspection, or inquiry of the Hennepin Healthcare site: ▪ Notice of FDA Audit ▪ Notice of other federal agency audit ▪ Notice of any external for-cause audit, inspection, or inquiry	Within 3 working days upon the investigator learning of an audit, inspection, or inquiry, by the FDA, other federal agency, or other external for-cause audit	Cayuse HE Incident	Select "Yes" to "Is this a ceded study?"
External for-cause audits – follow-up/reports Report or follow-up from FDA, other federal agency, or other external for-cause audit, inspection or inquiry of the Hennepin Healthcare site	Within 7 working days of receipt of any written reports from the FDA, other federal agency, or other external for- cause audit (e.g., FDA Form 483)	Cayuse HE Incident	Select "Yes" to "Is this a ceded study?"
Office for Education and Quality in Clinical Research (OEQCR) post-approval audit - closeout Submit a copy of audit closeout materials from OEQCR (e.g., audit report, CAPA, closeout letter) Applies to both *for-cause* or *not-for-cause* audits	Within 7 working days of receipt of OEQCR closeout materials for post approval audit	Cayuse HE Incident	Select "Yes" to "Is this a ceded study?" Under "Notification type - for ceded studies" select ***OEQCR* post-approval audit - closeout**
Closure sIRB closure of study/Hennepin Healthcare site	Upon sIRB notification of study/site closure	Cayuse HE Closure	Select "No" to the question "Is Hennepin Healthcare the IRB of record for this study?