

# 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](mailto:IRBreliance@hhrinstitute.org)

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

**IMPORTANT:** Notifying Hennepin Healthcare HRPO is separate from and in addition to the submission to the external IRB. Hennepin Healthcare researchers are responsible reporting information to the external IRB as required, in accordance with their policies and process.

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 <a href="#">HHRI Conflict of Interest (COI) Policy</a>
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 <b>“Administrative check-in”</b> as the applicable type of submission on the Submission intro smart page in Cayuse
Suspension of enrollment for safety (if Hennepin Healthcare site has enrolled participants)	Within three (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 three (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?”  Death is considered <i>expected</i> only if it is identified as caused by a possible risk of the study procedure as described in the protocol and/or consent form, and/or related documents such the Investigator’s Brochure or if death is due to the natural progression of a subject’s underlying disease or condition.  Report the unexpected death of a locally enrolled participant whether considered related to the research or not.

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<p>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</p>	<p>Promptly upon receipt of sIRB determination</p>	<p>Cayuse HE Incident</p>	<p>Select “Yes” to “Is this a ceded study?”</p> <p>When a report to a federal agency is required, Hennepin Healthcare will provide information and input as outlined in the sIRB reliance agreement.</p>
<p>Study modification for the Hennepin Healthcare site of prospective waiver of consent or exception from informed consent (EFIC – 21 CFR 50.24)</p>	<p>Prior to implementation at the Hennepin Healthcare site</p>	<p>Cayuse HE Modification</p>	<p>Provide a thorough description for the justification for the modification submission and edit the applicable section(s) in Cayuse HE</p> <p>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.</p>
<p>Study modification for the Hennepin Healthcare site if it may affect any of the following:</p> <ul style="list-style-type: none"> <li>▪ Ancillary reviews or other required administrative reviews (e.g., changes to plans for radiation exposure, use of Hennepin Healthcare resources)</li> <li>▪ Previous information submitted regarding inclusion of vulnerable populations (e.g., inclusion of children, inclusion of adults lacking capacity to consent)</li> <li>▪ Compliance with institutional policy/state law requirement(s)</li> </ul>	<p>Promptly upon notification of modification to approved protocol</p>	<p>Cayuse HE Modification</p>	<p>Provide a thorough description for the justification for the modification submission and edit the applicable section(s) in Cayuse HE</p> <p>Work with HHRI/HHS ancillary review committees and/or departmental administrators, as applicable (e.g., radiation safety committee, Grants Administration)</p>
<p>FDA, other federal agency, or other external for-cause audit, inspection, or inquiry of the Hennepin Healthcare site:</p> <ul style="list-style-type: none"> <li>▪ Notice of FDA Audit</li> <li>▪ Notice of other federal agency audit</li> <li>▪ Notice of any external for-cause audit, inspection, or inquiry</li> </ul>	<p>Immediately upon the investigator learning of an audit, inspection, or inquiry, by the FDA, other federal agency, or other external for-cause audit</p>	<p>Cayuse HE Incident</p>	<p>Select “Yes” to “Is this a ceded study?”</p>
<p>Report or follow-up from FDA, other federal agency, or other external for-cause audit, inspection or inquiry of the Hennepin Healthcare site</p>	<p>Within seven (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)</p>	<p>Cayuse HE Incident</p>	<p>Select “Yes” to “Is this a ceded study?”</p>
<p>sIRB closure of study/Hennepin Healthcare site</p>	<p>Upon sIRB notification of study/site closure</p>	<p>Cayuse HE Closure</p>	<p>Select “No” to the question “Is Hennepin Healthcare the IRB of record for this study?”</p>