HUMAN RESEARCH PROTECTION

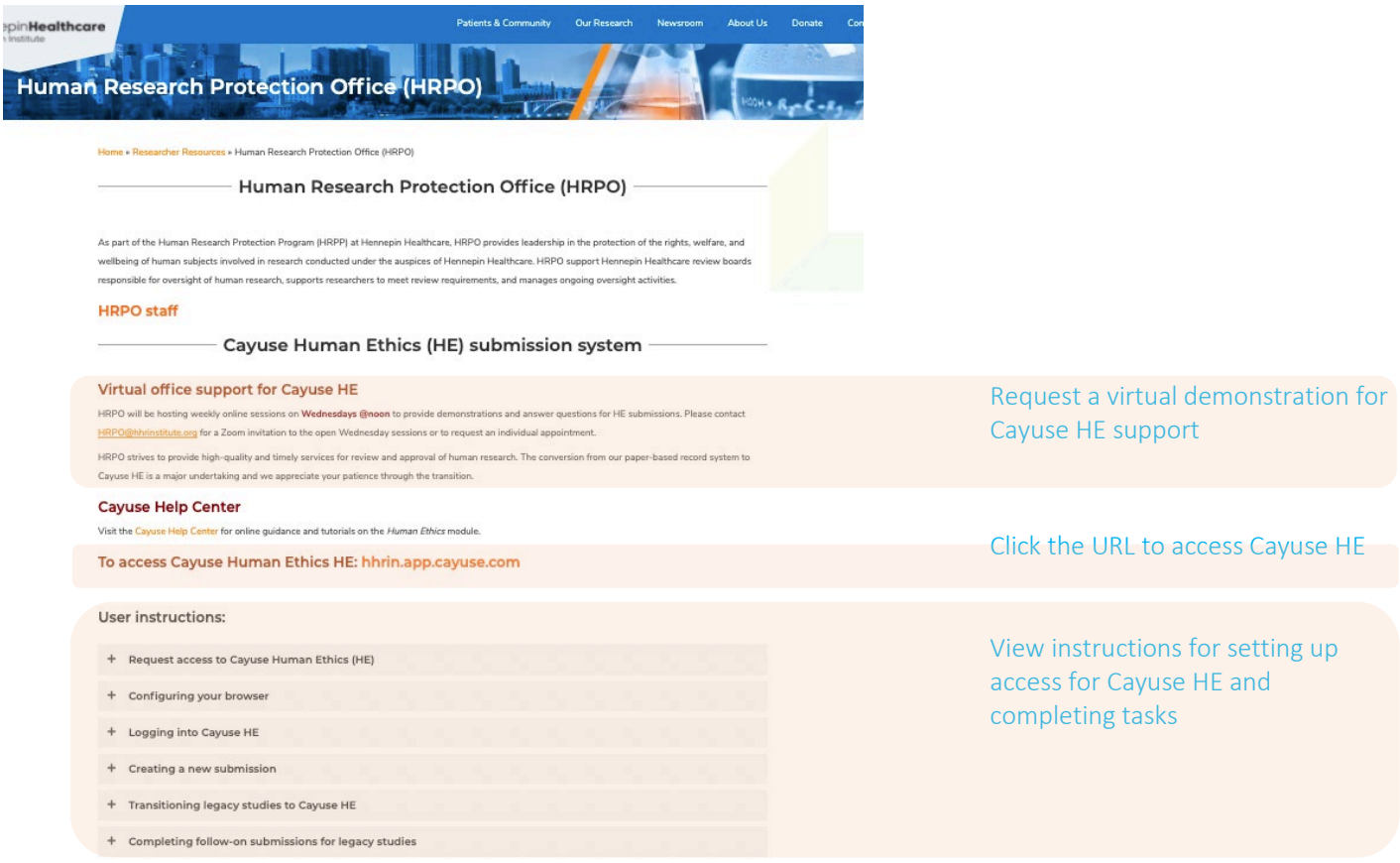
Using Cayuse Human Ethics (HE)

Number 903 Version date 28 JUN 2021

Resource FAQ

1. Where can I find information about setting up my account or submitting in Cayuse HE?

Instructions for using Cayuse HE are available on our website: https://www.hhrinstitute.org/researcher-resources/ohsr/



2. My study was IRB-approved before Cayuse HE was implemented - what do I need to do?

A study approved by the IRB before the implementation of Cayuse HE is referred to as a ***Legacy Study***. A shell record for *non-exempt* legacy studies has been imported into Cayuse HE, which serves as a placeholder for the ongoing study in Cayuse HE. An initial ***Modification*** *submission* must be completed by the study team to fully transition the study into Cayuse HE. This must be submitted and approved before any actual study modifications are requested and at least 60 days before a study is due for renewal. For studies relying on an external IRB, a limited amount of information is needed for the modification submission, e.g., entering all the current study personnel.

See our website (https://www.hhrinstitute.org/researcher-resources/ohsr/) for **User instructions** on *Transitioning legacy studies to Cayuse HE* and *Completing follow-on submissions for legacy studies*:

3. What information and documents will I need for an *Initial* submission in Cayuse HE?

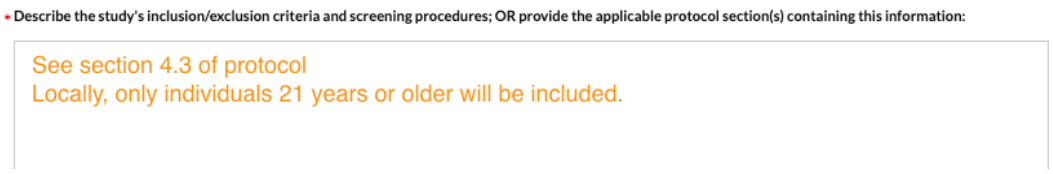
The information and study materials required will vary depending on the review level/type of study submitted. General guidance is provided below.

NOTE: Because questions in the smartform are logic-based, inaccurate responses may cause subsequent logic errors, such as applicable questions and/or sections to be missing or non-applicable questions and/or sections to be generated. You can test the smartform logic by changing selected responses. (If changing a response causes questions/sections to disappear, any previously entered information will be retained and can be accessed by reverting back to the originally selected response.)

If you have questions, please contact the HRPO (HRPO@hhrinstitute.org) to request consultation with an IRB analyst.

- ✓ **Submission type:** Select the appropriate submission type (such as exemption, expedited review, convened IRB review, or IRB reliance). If you're unsure of the submission type, the following guidance documents may be helpful:
  - 160 GUIDANCE Criteria for exemption from IRB oversight
  - 161 GUIDANCE Criteria for expedited IRB review
  - 112 GUIDANCE Relying on an external IRB
- ✓ **Protocol:** A protocol is required for all non-exempt studies. Protocol templates for retrospective data/specimen and intervention studies are available on the HRPO website.

  Sections of the Cayuse HE smartform will ask for information typically included in a protocol. When using a sponsor protocol that cannot be revised, reference the specific section(s) of the protocol; avoid copying and pasting entire protocol sections and add additional text into the smartform, when necessary, to provide information specific to Hennepin Healthcare that isn't captured in the sponsor protocol (see example below). When using an investigator-initiated protocol that can be revised, please try to capture all information directly in the protocol and reference the specific section(s); avoid copying and pasting entire protocol sections into the smartform.



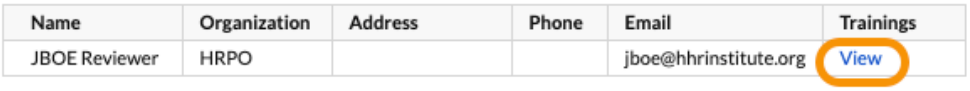
- ✓ **Subject-facing materials:** Provide all subject-facing materials, such as (but not limited to) consent document(s), a stand-alone HIPAA authorization form (when applicable), recruitment materials, and scripts for verbal interactions.

  NOTE: For exempt research that involves interaction with subjects, an information sheet and/or script must be included in the submission.

Visit the HRPO website for **informed consent guidance and templates**

- ✓ Study Materials: Submit all data collection instruments, such as (but not limited to) Case Report Forms (CRFs), data collection aids, and evaluation scales.
- ✓ Personnel Training: All study personnel listed in an IRB submission must comply with the HHRI human research education and training requirements to receive approval.

  IMPORTANT: The Principal Investigator (PI) or Primary Contact (PC) is responsible for verifying that the CITI required modules can be viewed in the Cayuse HE submission and haven't expired for each individual listed (see below). If an individual is affiliated in CITI with HHRI and CITI records do not appear in HE, there's an email mismatch between Cayuse HE and the institutional email in CITI. To update their CITI email, users must follow instructions on the HRPO website: How to update your email in CITI; to update the Cayuse email instead, please contact HRPO@hhrinstitute.org. HRPO requires personnel to match their CITI and Cayuse HE accounts by September 1, 2021.



Name	Organization	Address	Phone	Email	Trainings
JBOE Reviewer	HRPO			jboe@hhrinstitute.org	View

  Visit the HRPO website for more information - ***Education & training for research involving human subjects***

- ✓ Data and Safety Monitoring Plan (DSMP): All studies should have an appropriate DSMP, depending on the risk, size, and scope of the research. Refer to the 150 GUIDANCE Data and Safety Monitoring in Research for more information.
- ✓ Drug/Device documentation: Drug and/or device studies will require specific documentation from the sponsor and/or FDA. Refer to the 108 GUIDANCE Regulatory and external guidance references for more information (e.g., FDA guidance for IND, IDE, and HUD submissions).

  The specific documentation required will depend on the drug/device determination and may include:
  - Confirmation of an IND exempt or IDE exempt category addressing all criteria and required labeling as described in the applicable CFR
  - Investigator's Brochure
  - Validation of IND or IDE # (such as communication from the sponsor documenting the #)

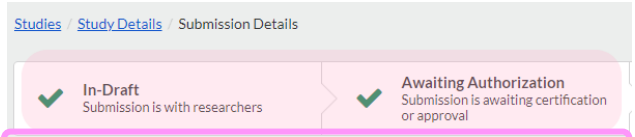
  NOTE: When a Hennepin Healthcare investigator holds the IND/IDE, written communication from the FDA documenting the # is required.

- ✓ Ancillary Approvals: Documentation of approval from certain ancillary review groups is required before final IRB review. The following approvals may apply:
  - Hennepin Healthcare Radiation Safety Committee for studies involving any exposure to ionizing radiation
  - Institutional Biosafety Committee for studies involving biosafety issues
  - HHRI COI committee approval for studies where a potential conflict of interest exists
  - HHRI Office of Education and Quality in Clinical Research study start up program for investigator-initiated studies requiring convened IRB review

  NOTE: All *Initial* submissions require a completed 322 FORM *Physician Chief acknowledgement*

4. What is the submission workflow in Cayuse HE?

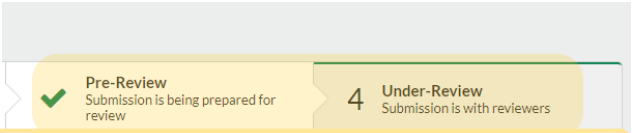
Cayuse HE displays the workflow for each submission on the *Submission Details* page: *In-Draft*, *Awaiting Authorization*, *Pre-Review*, and *Under Review*:



WITH THE STUDY TEAM

In-Draft: submission is available to the PI and PC for editing/completion; approved key personnel also have read/write access

Awaiting Authorization: submission is complete and requires certification. See section: 5. *How do I certify a submission?*



WITH THE IRB

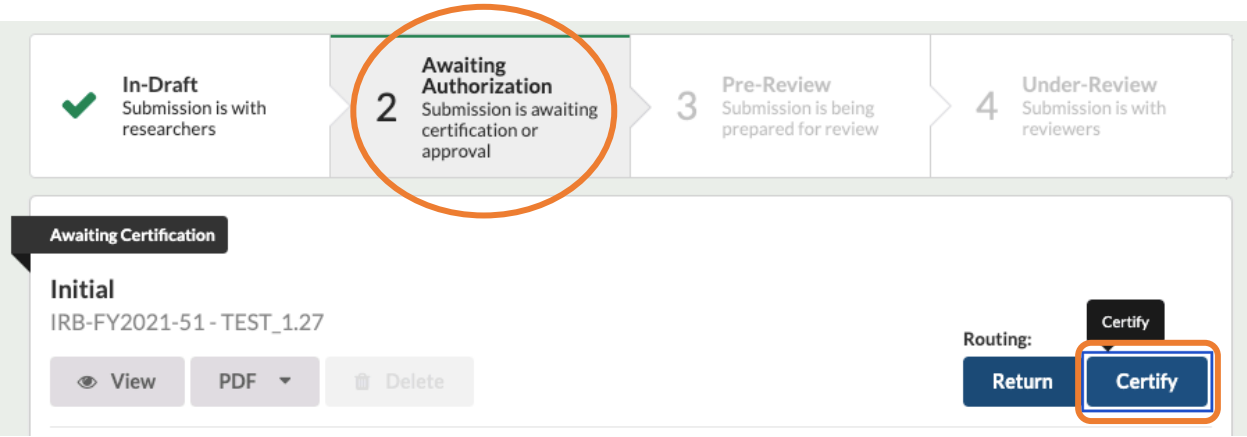
Pre-Review: submission is being assessed by an IRB analyst

Under Review: submission has been assigned to a designated reviewer, and if applicable, to a convened IRB meeting

5. How do I certify a submission?

When all sections of the smartform are complete (indicated by a checkmark in the left-hand navigation of the submission) and the user clicks COMPLETE SUBMISSION, the **Certify** button will appear on the *Submission Details* page and the workflow will indicate **Awaiting Authorization**.

The PI must certify a submission if it's the first time that the submission is being routed for review. If a submission is returned for changes, Cayuse HE allows the PI or PC to re-certify it; PIs should communicate with their study teams whether a PC is authorized to re-certify submissions.



6. What happens during the *Pre-Review* and *Under Review* workflow?

Under **Pre-Review**, an IRB analyst assesses whether a submission is complete and provides sufficient information related to criteria for IRB approval. For example, an analyst will review the protocol for a description of the data and safety monitoring plan. Refer to the 197 GUIDANCE Criteria for IRB Approval for more information.

The following outlines the assessment under Pre-Review:

- ✓ Smartform is accurately completed
- ✓ All study materials (as applicable) are attached in the submission; for example:
  - protocol
  - consent document(s)
  - subject-facing materials
  - data collection instrument(s)
  - As applicable, documentation of approval from ancillary review groups; for example:
    - Physician Chief acknowledgement (322 FORM)

  - Hennepin Healthcare Radiation Safety Committee for studies involving any exposure to ionizing radiation
  - Institutional Biosafety Committee for studies involving biosafety issues
- If a potential conflict of interest exists, HHRI COI committee approval
- For investigator-initiated studies requiring convened IRB review, completion of the HHRI Office of Education and Quality in Clinical Research study start up program
- For FDA regulated studies, sponsor/FDA documentation regarding drug and device determinations
- For EFIC studies, HHS administration approval, if required

✓ Human research training and education requirements are met for all study personnel

If errors are found, key information missing, or there are other issues to be addressed, the submission will be returned to the PI for changes. The PI and/or PC must respond to comments when a submission has been returned and then resubmit it for the IRB review process to continue.

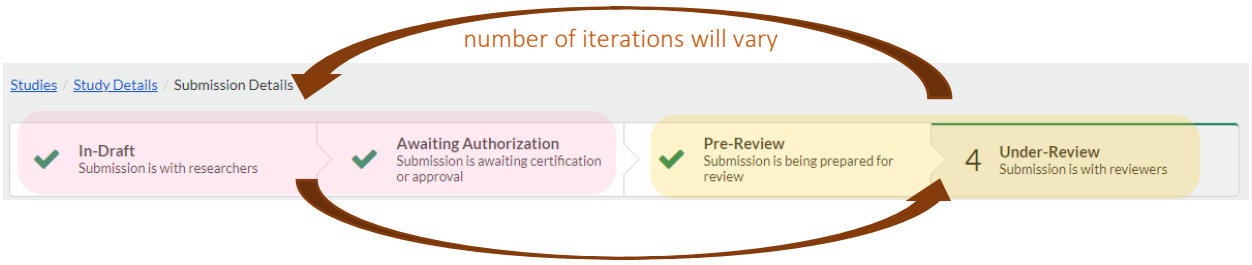
Once pre-review is complete, the IRB analyst will assign the submission to a designated reviewer and, when applicable, the convened IRB; the workflow will indicate **Under Review.**

IMPORTANT:

- For a submission requiring convened IRB review, the process of pre-review must be completed at least 2 weeks prior to a scheduled IRB meeting. See the IRB meeting schedule for dates.
- Completion of *pre-review* does not guarantee IRB approval
- For an initial submission requesting to rely on an external IRB, all issues identified via *pre-review* must be resolved for the Hennepin Healthcare IRB to agree to rely on the external IRB

7. When can I expect a response about a submission?

Submissions are received on a rolling basis and review times will vary depending on a number of factors, such as submission completeness, study personnel verifications, research complexity, overall submission volume/HRPO workload, and reviewer availability. In addition, review activity is paused when a submission is returned for requested changes and/or clarifications, i.e., when the submission is *In-Draft* or *Awaiting Authorization*.



NOTE: When a submission is **Under Review**, it may be returned with stipulations for approval; the PI and/or PC must update the submission accordingly and then resubmit for further IRB review. When the *Under Review* workflow is completed, the IRB determination is sent via an email notification to the PI and PC.

8. My *Initial* submission has been assigned for convened IRB review; what can I expect next?

When an *Initial* submission **Under Review** is assigned for convened IRB review, the Principal Investigator (PI) and Primary Contact (PC) will receive an email notification that the submission has been added to an IRB agenda. HRPO requests confirmation that the PI or a key person named on the study is available to attend the upcoming meeting. Additional study team members may attend upon PI request. A calendar invitation for the meeting with details will be sent out to attendees.

NOTE: For virtual attendees that will be calling in, please respond to the email invite with your call-in number to help HRPO manage the virtual waiting room.

Prior to the IRB meeting, the PI may receive questions via email from the IRB. The PI should reply to these questions; however, Cayuse HE allows no changes to a submission while it is *Under Review*. If any changes are required to the submission, it will be returned for changes after the meeting.

Within 5 working days after the IRB meeting, the IRB determination is sent via an email notification to the PI and PC. Often, there will be stipulations that must be addressed for final approval; the PI and/or PC must update the submission accordingly and then resubmit for further IRB review.

9. My follow-on submission has been assigned for convened IRB review; what can I expect next?

If a follow on (Modification, Renewal, Incident) submission **Under Review** is assigned for convened IRB review, the PI and PC will receive an email notification that the submission has been added to an IRB agenda. HRPO does NOT request PI attendance for convened IRB review of follow-on submissions unless there are qualifying circumstances.

10. Can I make changes when a submission is in the *Pre-Review* or *Under Review* workflow?

If a submission is in *Pre-Review* and you need to make changes, email the assigned IRB analyst or HRPO@hhrinstitute.org to request the submission to be returned.

If you need to make changes when a submission is *Under Review*, email the assigned reviewer or HRPO@hhrinstitute.org to request the submission to be returned. Because the submission is *Under Review*, a *Decision Outcome* of **Return to PI** will be added to the *History* for the submission; if a submission has been assigned for convened IRB review and you request it to be returned, it will be removed from the IRB agenda.