HUMAN RESEARCH PROTECTION

Worksheet Overview & Navigating Cayuse HE for an Initial Review

Resource type IRB Member Job Aid Version Date 18 FEB 2021

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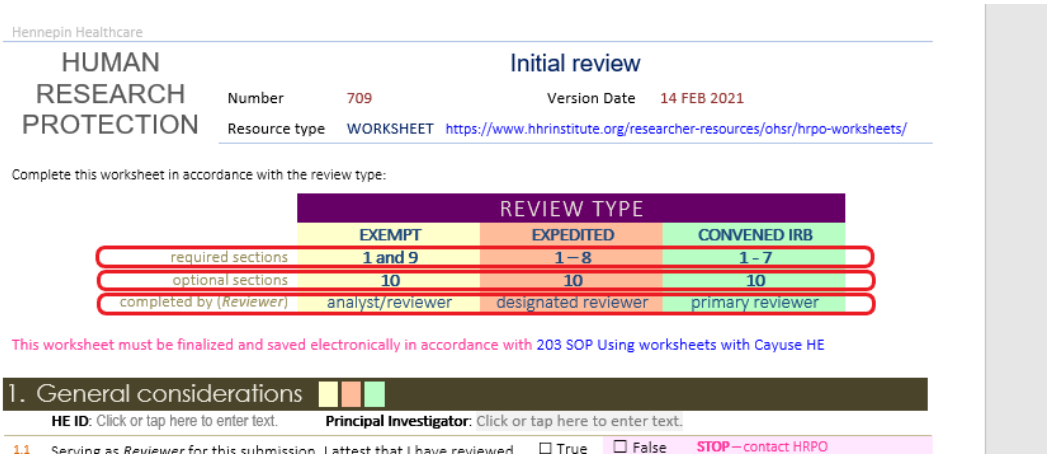
1. Reviewer Worksheets

HRPO worksheets are used to document consideration of and adherence to local and federal policies and regulations. There are worksheets to be completed as part of the general submission review (such as the Initial, Modification, and Renewal worksheets) and there are worksheets to address specific regulatory determinations (such as a waiver of HIPAA/Consent, or inclusion of subparts B, C, or D).

LOCATION: The most recent versions of all worksheets are available on the HRPO website: https://www.hhrinstitute.org/researcher-resources/ohsr/hrpo-worksheets/. The direct link can be found on the *IRB & CRC member resources* page.

The general submission worksheets are used at all review levels (Exempt, Expedited, and Full Committee). Instructions are provided at the top of each worksheet describing which sections must be completed for each review level.



Hennepin Healthcare

HUMAN RESEARCH PROTECTION

Initial review

Number 709 Version Date 14 FEB 2021

Resource type WORKSHEET https://www.hhrinstitute.org/researcher-resources/ohsr/hrpo-worksheets/

Complete this worksheet in accordance with the review type:

	REVIEW TYPE		
	EXEMPT	EXPEDITED	CONVENED IRB
required sections	1 and 9	1 – 8	1 - 7
optional sections	10	10	10
completed by (*Reviewer*)	analyst/reviewer	designated reviewer	primary reviewer

This worksheet must be finalized and saved electronically in accordance with 203 SOP Using worksheets with Cayuse HE

1. General considerations

HE ID: Click or tap here to enter text. **Principal Investigator**: Click or tap here to enter text.

1.1 Serving as *Reviewer* for this submission, I attest that I have reviewed ☐ True ☐ False STOP – contact HRPO

708 WORKSHEET – REVIEWER WORKSHEET LIST: The 708 Worksheet is completed by the IRB analyst before assigning a submission to a Primary Reviewer. The 708 captures general regulatory oversight but also indicates what worksheets must be completed in the review. If a box is checked under the "Required reviewer WORKSHEET" column, the worksheet must be completed as part of the submission review. A submission type review document will also be indicated on the 708 (Initial, Modification, or Renewal).

The ***primary reviewer*** should consult this document to ensure all required worksheets are completed in their review. Other IRB members may find it helpful to review the regulatory oversight indicated on the 708, but do not need to consult this document as part of a general review.

2. Guidance Documents

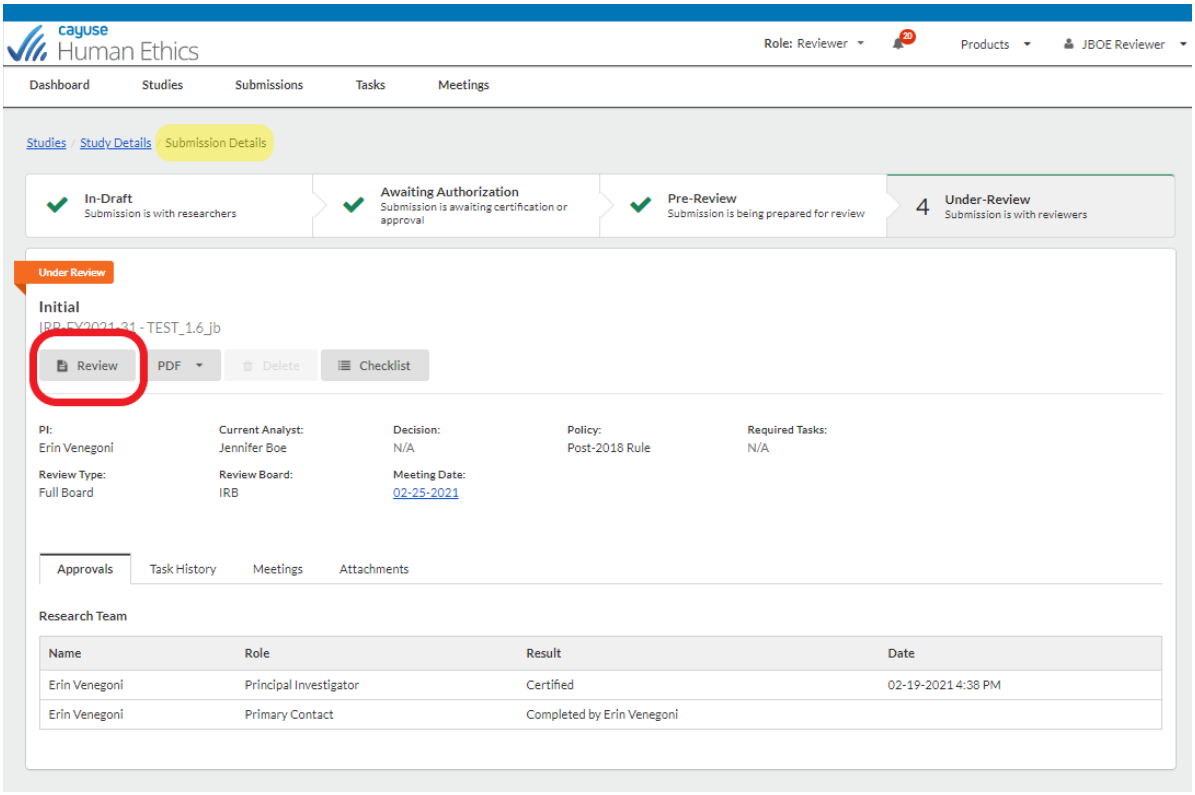
In addition to revised reviewer worksheets, there are several new or revised guidance documents to be referenced by the IRB and research community. Guidance documents are not completed or saved as part of a submission review, but can be referred to, as necessary, for additional support or clarity. You may notice certain reviewer worksheets refer to guidance documents. For example, 197 GUIDANCE- Criteria for IRB Approval may be referred to for additional detail regarding the criteria of approval for a submission.

LOCATION: Guidance documents are available on the HRPO website: https://www.hhrinstitute.org/researcher-resources/ohsr/.

3. Navigating Cayuse for review of Initial submission

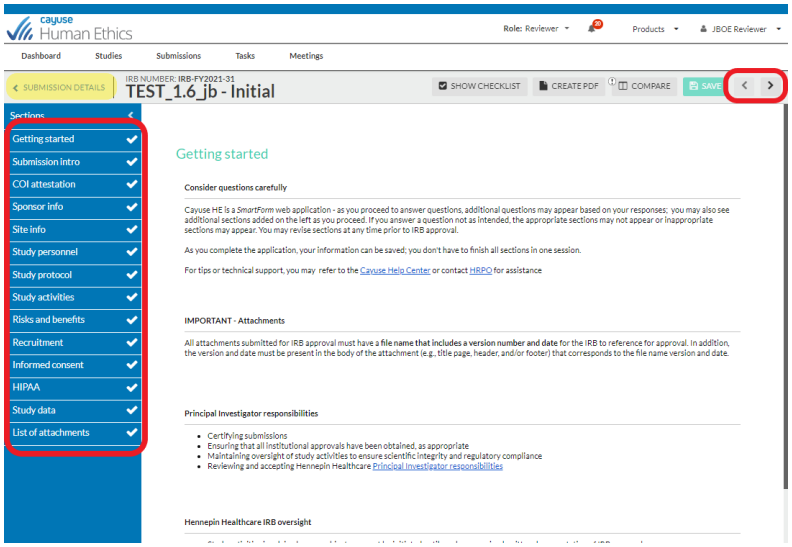
The initial submission is where all of the study information and attachments are collected. From the Submission Details page, click Review (under the study title) to view the smartfom.

NOTE: The Attachments tab does not display submission documents until after the submission is approved. The Attachments tab can be used to view documents on a submission *after* it has been approved, but it will not display documents for pending review items.



Once in the submission, click on SUBMISSION DETAILS to return to the submission details page. You can click on each smartform page to go to the different sections or you can use the arrows to the right of the screen to move through each page.

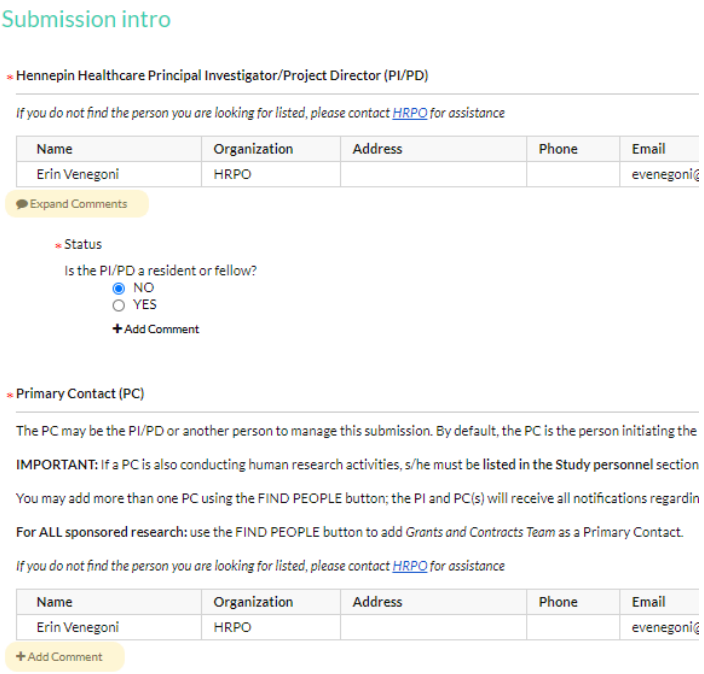
NOTE: The submissions have built in logic. Different questions and pages will appear depending on the response to each question. Depending on the details of the study, you will not always see the exact same submission structure.



Comments in Cayuse HE

The ***analyst*** and ***primary reviewer*** may add *RESTRICTED* or *UNRESTRICTED* comments to almost any item in the smartform. Restricted comments are not visible to the study team. If you are not assigned as the primary reviewer of an item, you will not need to add or respond to any comments in the submission.

Click Expand Comments to view previous comments left by the analyst, study team, and/or reviewer. These comments could be internal notes/ reminders or comments to request clarification from the study team. Any unrestricted comment requesting clarification would also be noted as "resolved" once the analyst or reviewer marked it as resolved.



Once you click Expand Comments, you will see the name of who left the comment, the date/time, and visibility.

NOTE: Restricted comments cannot be seen by study team members (Image 1). UNrestricted comments were visible to the study team as initial clarification requests and should be marked as resolved (Image 2).

Image 1

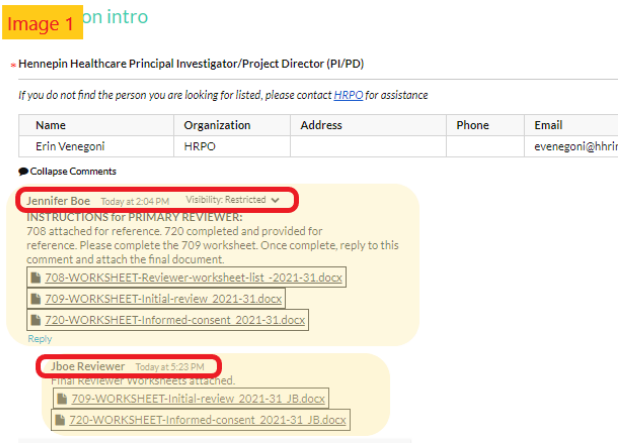
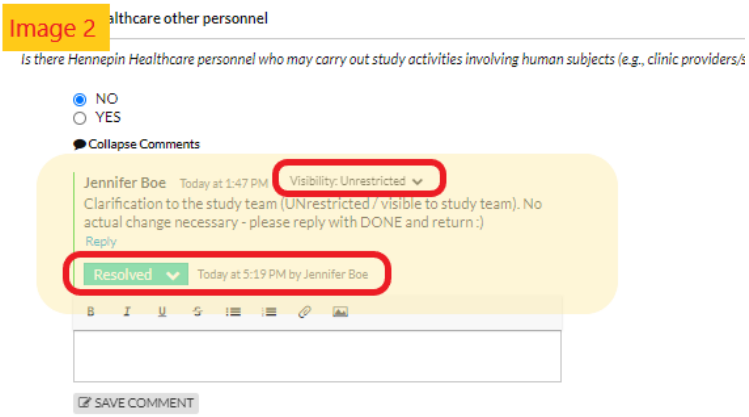
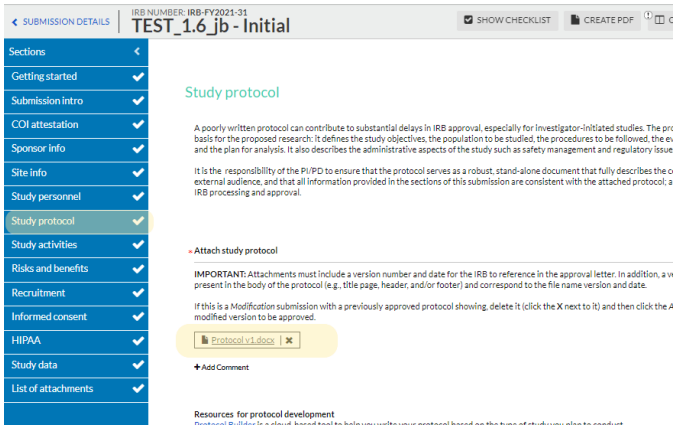


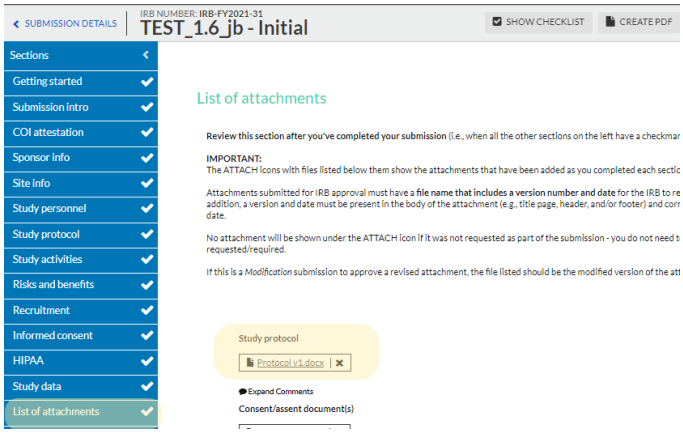
Image 2



Viewing Study Documents

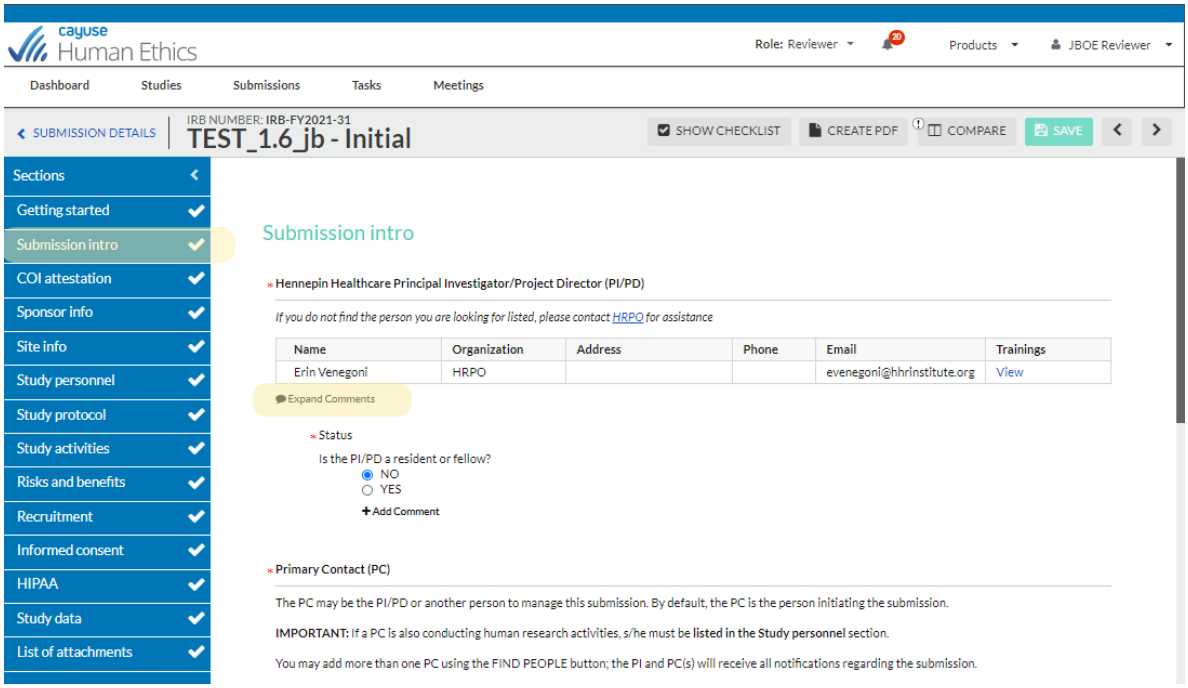
Various pages of the smartfrom will solicit certain documents from the study team. Any document uploaded in the smartform will also be visible on the final LIST OF ATTACHMENTS page. For example, a protocol uploaded on the PROTOCOL page is the same document which appears under the protocol section of the LIST OF ATTACHMENTS page. The LIST OF ATTACHMENTS page will be an easy way to download all study documents from one page; however, it is still important to review the smartform since some information is collected in the responses and not necessarily provided in the documents attached.





4. Finding completed Primary Reviewer worksheets

The primary reviewer's completed worksheets will be available to all IRB members in order to assist in their own review. To find the worksheets for a new INITIAL submission, go to the Submission Intro page and click Expand Comments under the PI name.



NOTE: Be sure to view the most recent copy of the worksheet. Clicking on the attachment from an older comment will not bring up the complete/final version of the worksheet.