HUMAN RESEARCH PROTECTION

Primary Reviewer – Initial Submission Review

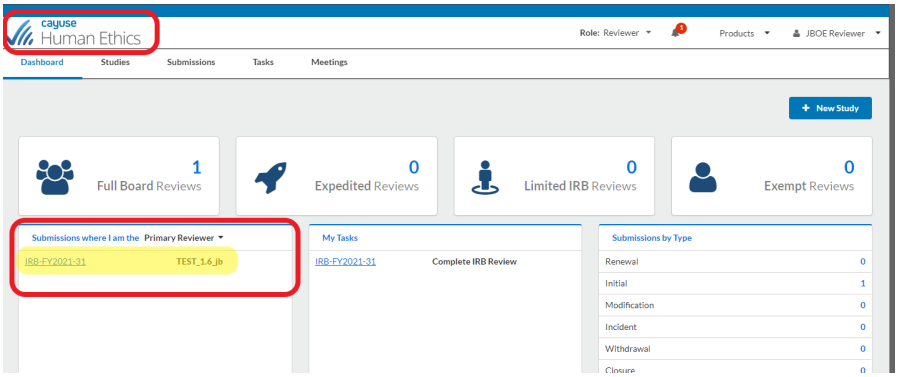
Resource type IRB Member Job Aid

Version Date 08 APR 2021

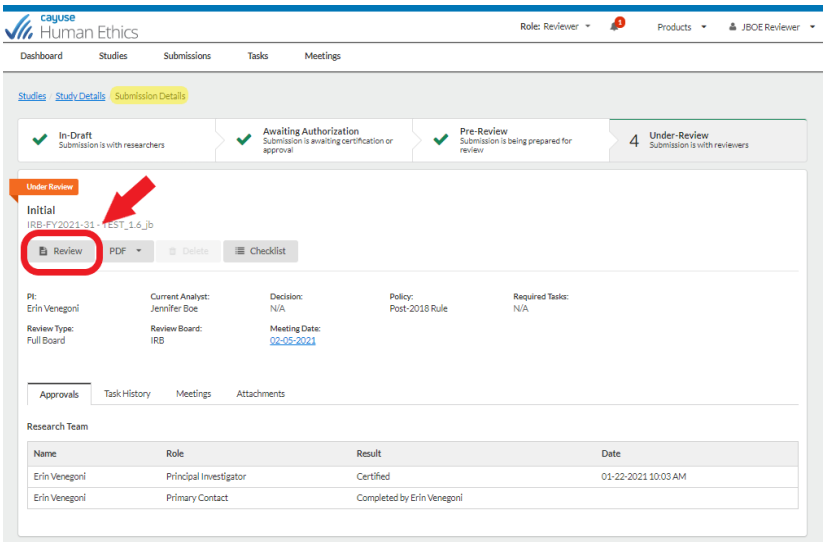
Contents

1. Finding the Submission

When a submission is assigned you as a ***primary reviewer***, you will see it appear under the Tasks square (or Tasks tab) in Cayuse HE. You will also receive an email notification from Cayuse.



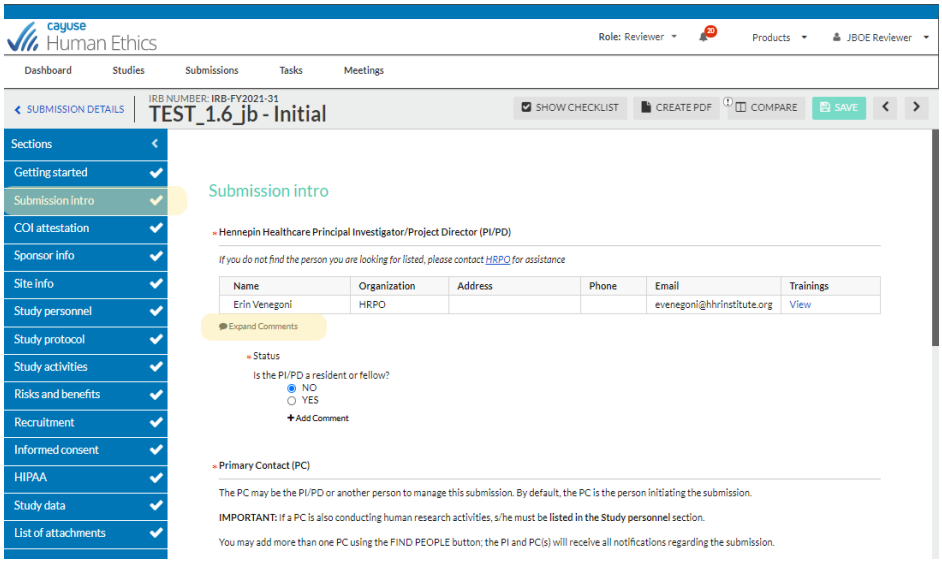
Click on the IRB# and you will go to the Submission Details page. Once in the Submission Details page, click REVIEW to open the submission smartform.



2. Finding reviewer worksheets for an INITIAL submission

The analyst will compile the reviewer worksheets to be completed and attach them as a RESTRICTED comment in the submission. However, if the primary reviewer notices a required worksheet that was not provided, the reviewer can download the worksheet from the IRB member resources page of the HRPO website.

To find the reviewer worksheets for an INITIAL submission:
- Go to the SUBMISSION INTRO page
- Click Expand Comments under the PI name

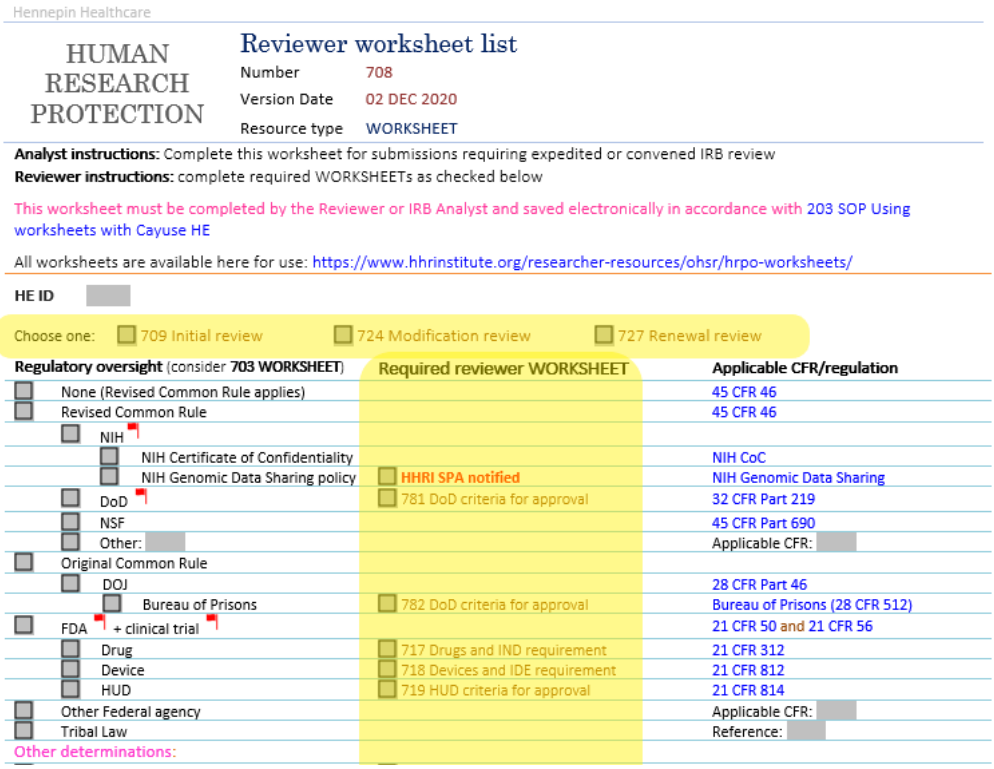


IMPORTANT: Read the comment BEFORE beginning your review. In addition to sharing the reviewer worksheets, the analyst will provide any helpful or relevant notes in this comment. Always review the comment before starting your own review. The analyst may also add notes or stipulations into the attached worksheets. Reviewing the attached documents before starting your review will be helpful.

3. 708 WORKSHEET (Reviewer worksheet list)

The 708 worksheet is completed by the analyst and serves two functions.

It lets the primary reviewer know what worksheets must be completed for the submission.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HUMAN RESEARCH PROTECTION

Reviewer worksheet list

Number 708
Version Date 02 DEC 2020
Resource type WORKSHEET

Analyst instructions: Complete this worksheet for submissions requiring expedited or convened IRB review
Reviewer instructions: complete required WORKSHEETs as checked below

This worksheet must be completed by the Reviewer or IRB Analyst and saved electronically in accordance with 203 SOP Using worksheets with Cayuse HE

All worksheets are available here for use: https://www.hhrinstitute.org/researcher-resources/ohsr/hrpo-worksheets/

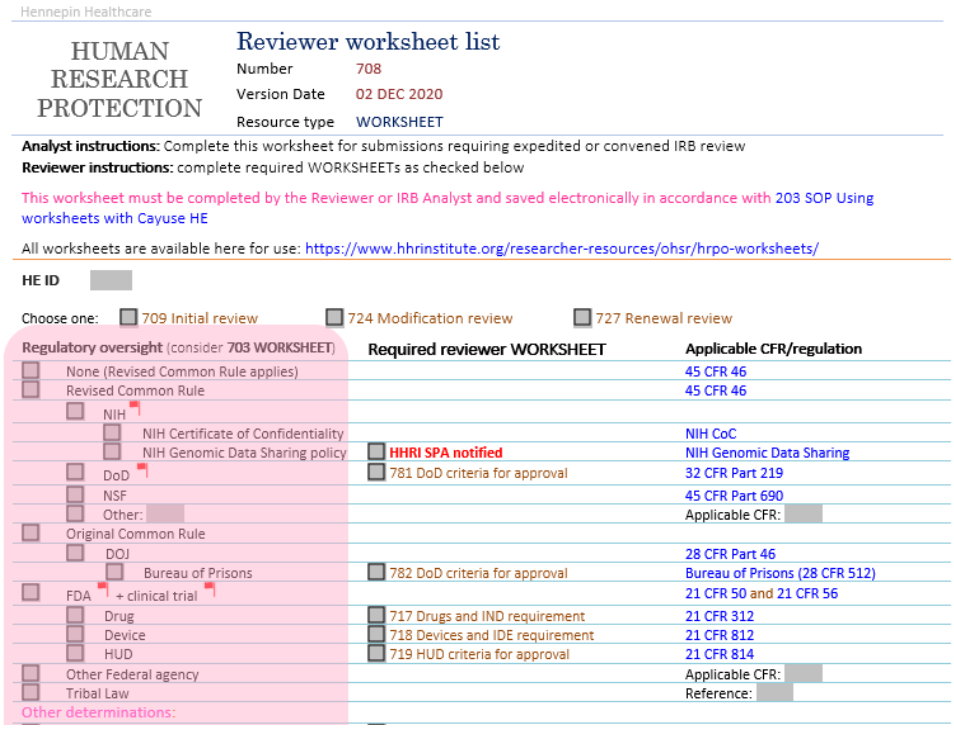
HE ID

Choose one: ☐ 709 Initial review ☐ 724 Modification review ☐ 727 Renewal review

Regulatory oversight (consider 703 WORKSHEET)	Required reviewer WORKSHEET	Applicable CFR/regulation
☐ None (Revised Common Rule applies)		45 CFR 46
☐ Revised Common Rule		45 CFR 46
☐ NIH		
☐ NIH Certificate of Confidentiality		NIH CoC
☐ NIH Genomic Data Sharing policy	☐ HHRI SPA notified	NIH Genomic Data Sharing
☐ DoD	☐ 781 DoD criteria for approval	32 CFR Part 219
☐ NSF		45 CFR Part 690
☐ Other:		Applicable CFR:
☐ Original Common Rule		
☐ DOJ		28 CFR Part 46
☐ Bureau of Prisons	☐ 782 DoD criteria for approval	Bureau of Prisons (28 CFR 512)
☐ FDA + clinical trial		21 CFR 50 and 21 CFR 56
☐ Drug	☐ 717 Drugs and IND requirement	21 CFR 312
☐ Device	☐ 718 Devices and IDE requirement	21 CFR 812
☐ HUD	☐ 719 HUD criteria for approval	21 CFR 814
☐ Other Federal agency		Applicable CFR:
☐ Tribal Law		Reference:
Other determinations:		

It also provides a snapshot of what regulatory oversight applies to the study.

NOTE: If a box is checked in the first column (Regulatory Oversight) but not the second column (Required reviewer WORKSHEET), it means that the oversight applies but no additional worksheets need to be completed. This is more likely to occur on follow on submissions like Modifications or Renewals and not new Initial submissions.



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☐ Other Federal agency		Applicable CFR:
☐ Tribal Law		Reference:
Other determinations:		

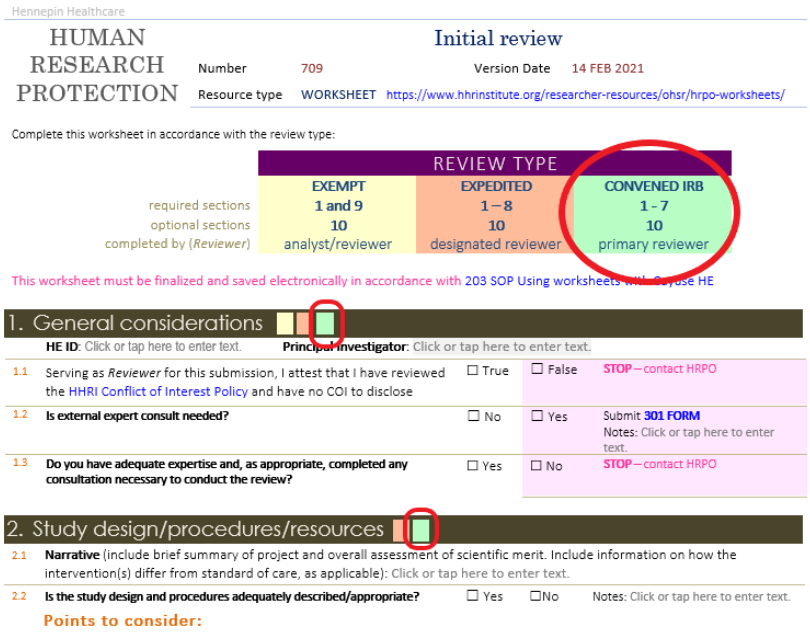
4. 709 WORKSHEET (Initial Review)

The analyst may begin or add notes to the 709 WORKSHEET, if relevant, during the pre-review; however, the ***primary reviewer*** is responsible for completing the worksheets. Several sections of the worksheets have space for notes, but ***primary reviewers*** are not expected to provide notes for every item. ***Primary reviewers*** should add notes to document any special considerations or call out helpful information. The worksheets may be consulted by other IRB members as part of their own review, but the worksheets may also be referred back to in future follow on submissions of the study.

Attachments included on *RESTRICTED* comments are not visible to the study team. Worksheets are not completed with the intention of sharing them with study teams; however, notes and comments should be written as if the study team *could see them*.

NOTE: If the analyst has added stipulations under section #10 of the worksheet, the ***primary reviewer*** made add to the section but should not remove any stipulations previously listed. If the analyst as added notes to any of the other sections, the ***primary reviewer*** may decide whether those notes should be retained or removed before completing the final version of the worksheet.

For an Initial submission being reviewed at the convened IRB meeting, the primary reviewer will complete the sections required for CONVENED IRB (each section is color-coded). Most items provide space for notes; however, you do not need to add notes for every item. Notes can be added as reminders throughout your review or as ways to document special circumstances/considerations that may be helpful historical information about the review.



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 the HHRI Conflict of Interest Policy and have no COI to disclose	☐ True	☐ False	STOP – contact HRPO
1.2	**Is external expert consult needed?**	☐ No	☐ Yes	Submit **301 FORM** Notes: Click or tap here to enter text.
1.3	**Do you have adequate expertise and, as appropriate, completed any consultation necessary to conduct the review?**	☐ Yes	☐ No	STOP – contact HRPO

2. Study design/procedures/resources

2.1	**Narrative** (include brief summary of project and overall assessment of scientific merit. Include information on how the intervention(s) differ from standard of care, as applicable): Click or tap here to enter text.			
2.2	**Is the study design and procedures adequately described/appropriate?**	☐ Yes	☐ No	Notes: Click or tap here to enter text.

Points to consider:

5. 720 WORKSHEET (Informed Consent)

The 720 Worksheet will be completed for any new Initial study that obtains consent. The analyst will complete this worksheet and any sections missing will be noted as required stipulations on the 709 WORKSHEET. The ***primary reviewer***s should refer to this document in their own review of the consent forms but the ***primary reviewer*** should not need to complete the 720 WORKSHEET. If any required items are missing, they will remain unchecked and noted as requested in stipulations.

NOTE: There may be more than the 709 WORKSHEET to be completed by the ***primary reviewer***. If there are any other regulatory determinations that require a worksheet, it will be noted on the 708 WORKSHEET and attached with the other reviewer worksheets (in the comment in Cayuse HE). For example, if there is a drug or device, there is a specific worksheet. The analyst may start or add notes to these worksheets, but the reviewer is responsible for completion.

6. Requesting clarification and stipulations

During the review, evaluate whether all criteria for approval has been meet (see 197 GUIDANCE). Stipulations that must be addressed by the PI in order to meet criteria for approval should be listed in the Reviewer worksheet before the final version is submitted. Minor stipulations do not need to be communicated with the study team during your review. All stipulations agreed upon by the full board will be communicated with the PI via the IRB decision letter (sent through Cayuse HE after the meeting).

If you feel that clarification is necessary in order to confirm whether a submission meets the criteria for approval, please connect with the IRB Analyst as soon as possible in order to determine whether the study may be deferred. The IRB Analyst and Primary Reviewer may contact the PI prior to the meeting to request additional information. The PI should not revise study materials during the review period. Revisions requested (whether to address deferral or resolve minor stipulations) will be communicated with the PI via the IRB decision letter and the PI will submit revised materials that address items stipulated in the letter. If the IRB defers a study, the study will return to the full board for review, once required revisions have been submitted.

When should the IRB defer a study?
The IRB should **defer** a study when the IRB is unable to make determinations required for approval at 45 CFR 46.111 and/or 21 CFR 56.111, and any relevant subparts (B, C, D).

If the IRB requires *clarification* in order to confirm criteria for approval are met, the study should be deferred.

A study should be **deferred** if the IRB:

- requests that the PI provide a justification for something (such as justification for the inclusion of a certain vulnerable population)
- requests that the PI revise the study design
- requests that the PI provide additional information in order to understand study procedures or assess risks
- requests that the PI provide additional information regarding the consent process

When should a study be approved with Minor Stipulations?
When the IRB has confirmed that criteria for approval has been met, but has concrete or descriptive stipulations, the study can be approved with Minor Stipulations. The stipulations are specific and do not require additional review by the convened IRB.

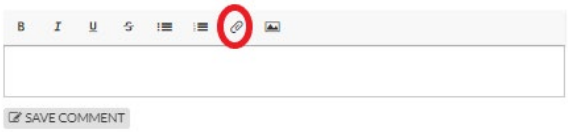
A study should be approved with **Minor Stipulations** if the IRB:

- can stipulate that the PI confirm the IRB's understanding of something by revising the submission or study materials
- can stipulate that the PI make precise changes to the study materials with clearly stated parameters

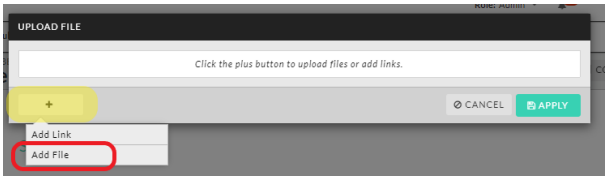
7. Submitting reviewer worksheets

To submit completed reviewer worksheets:

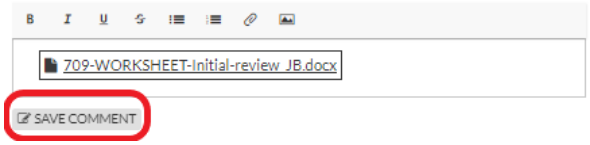
- Click REPLY under the restricted comment from the analyst (on the Submission Intro page, under the PI name)
- Click the paperclip to add attachments



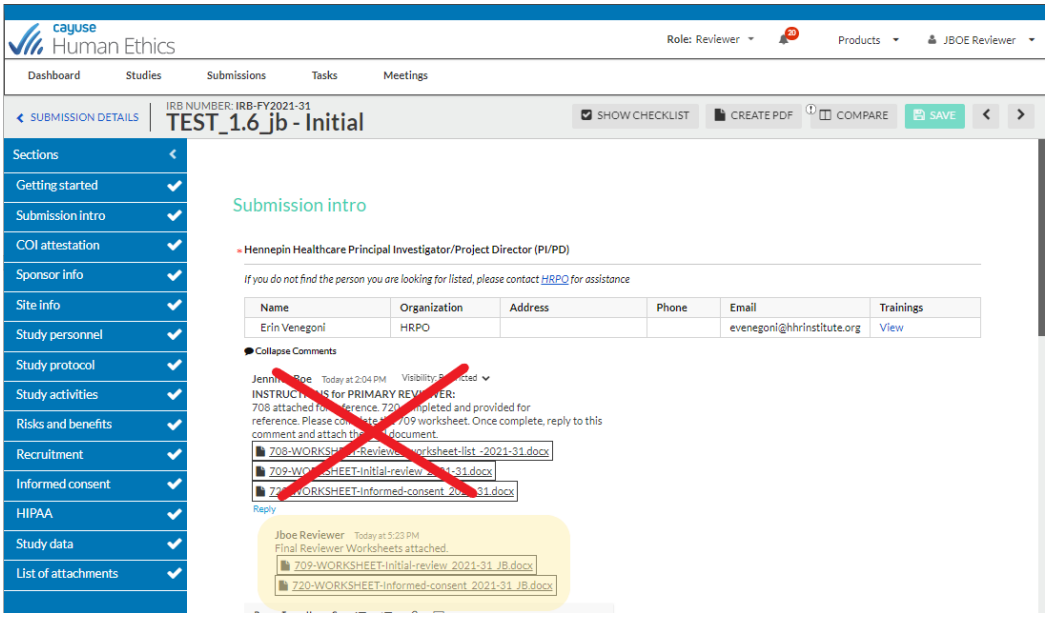
- Click +, Add File
    - NOTE: Save completed worksheets with your initials at the end.



- Select the final worksheets, then click Open
    - NOTE: You can attach multiple comments at once or repeat the process before saving the comment.
- Click Apply and Save Comment



Once saved, the worksheets will be visible internally (analysts and other IRB members) to download and review.



IMPORTANT: Once the final worksheets have been attached, please email the analyst to confirm that the worksheets have been completed and attached in the submission. The analyst will review the worksheets for completeness and follow up with the reviewer if any additional information is needed.