HUMAN RESEARCH PROTECTION

Primary Reviewer – Modification Submission Review

Resource type IRB Member Job Aid Version Date 04 JUNE 2021

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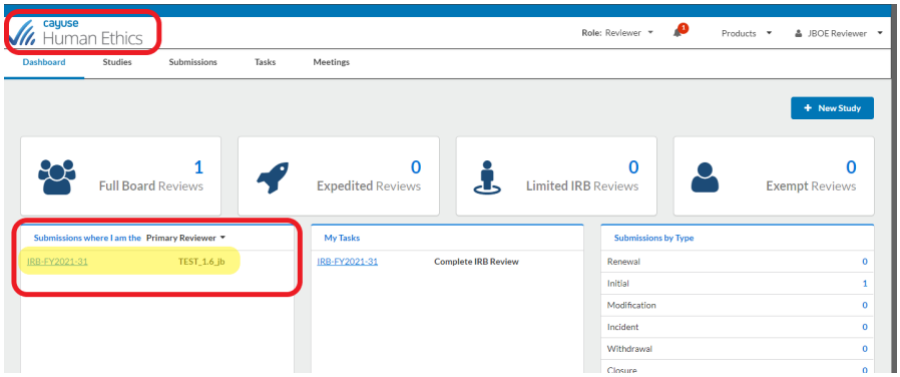
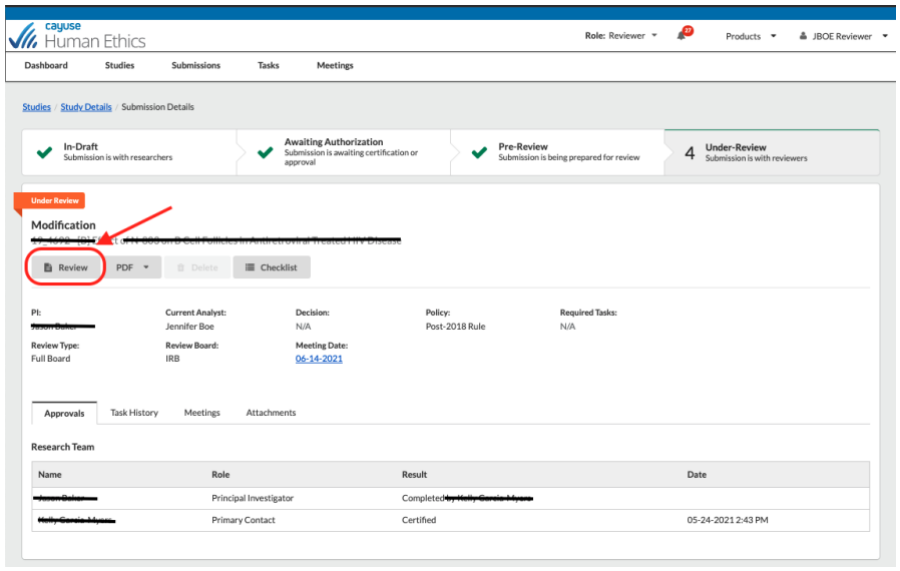
1. Finding the Submission

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.

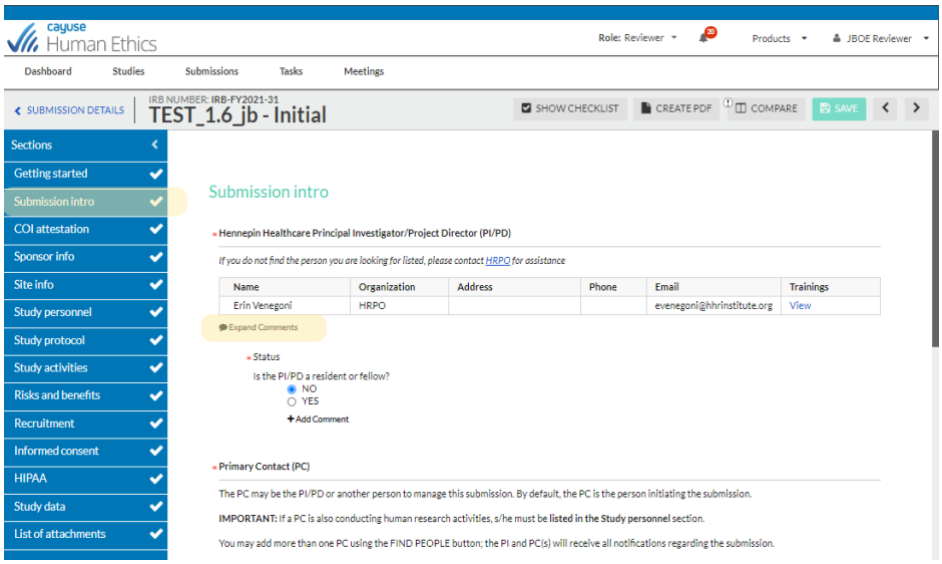


Click on the IRB# and you will go to the Submission Details page. Once in the Submission Details page, click REVIEW to open the submission smartform.



2. Finding reviewer worksheets for an MODIFICATION 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 MODIFICATION submission:
- Go to the SUBMISSION INTRO page
- Click Expand Comments under the PI name

IMPORTANT: Read the comment and open the reviewer worksheets BEFORE beginning your review. In addition to sharing the reviewer worksheets, the analyst will provide relevant notes and/or stipulations noticed during pre-review. Always review the comment and worksheets before starting your own review.

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, as highlighted in yellow →

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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

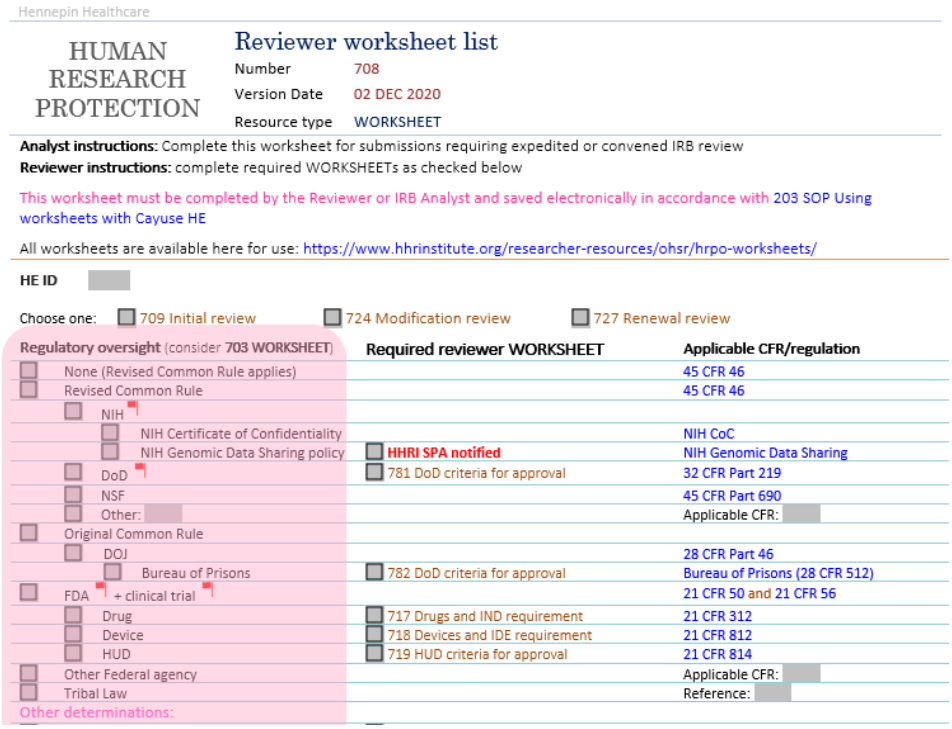
All worksheets are available here for use: https://www.hhrinstitute.org/researcher-resources/ohsr/hrpo-worksheets/

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, as shown in red →



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Reviewer worksheet list

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

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

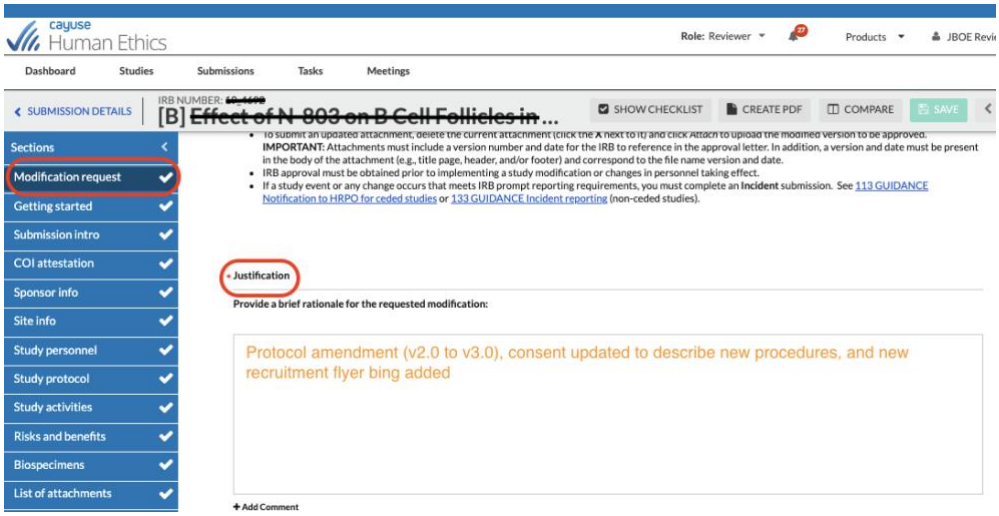
4. Finding the changes in a Modification (How to focus your review)

When reviewing a Modification, start with the assumption that the research, as previously approved, met all applicable criteria for approval. For a Modification submission, evaluate if the research continues to meet criteria for IRB approval by focusing on what has been changed or added in the current submission under review.

To focus your review for a Modification submission always review the **Modification Justification** *first*, review the **Comments section of the 724 Reviewer WORKSHEET** *second*, and use the **Compare feature** in Cayuse HE *third*.

1. Modification Justification

On the Modification Request section of the smartform, study teams are asked to provide a brief description of what is being changed in the submission. This section should provide a quick overview of what changes will require your review.

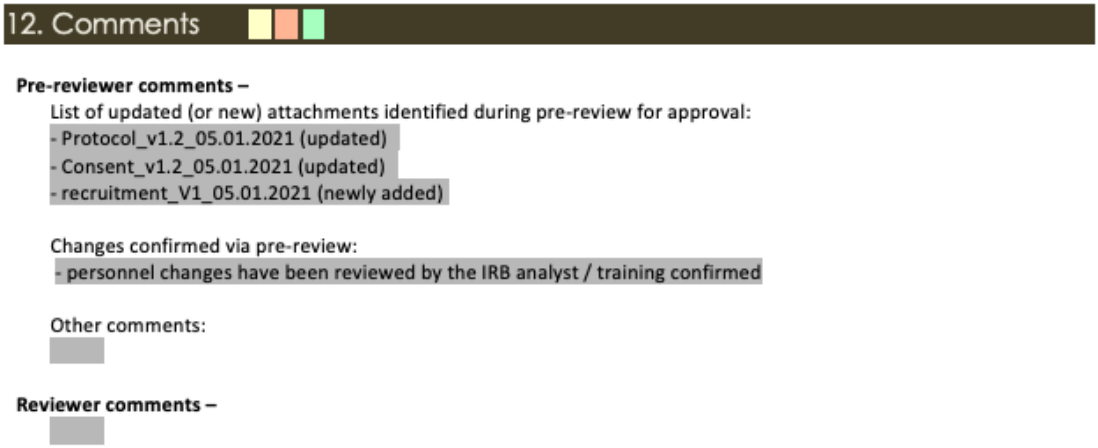


2. Comments section of the 724 Reviewer WORKSHEET

During pre-review, the IRB analyst will complete the Comments section of the 724 WORKSHEET. This section will call out:

- any documents (by file title) that have been updated or added as part of the submission
- any changes made in the submission that have already been reviewed by the IRB analyst
- any additional notes the IRB analyst would like to share with the reviewer

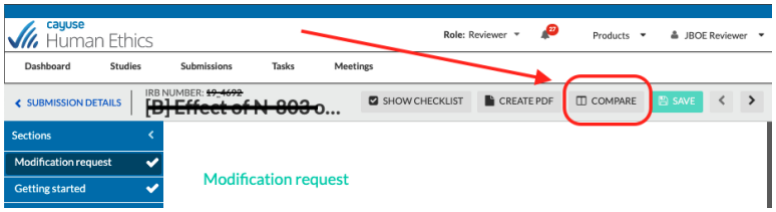
This section also has space for the reviewer to leave comments. Please note that stipulations should be listed in the section titled *Stipulations for approval*.



3. Compare Feature in the smartform

The COMPARE feature in Cayuse HE allows you to see smartform sections that have been changed since the last approval and also to compare attachments.

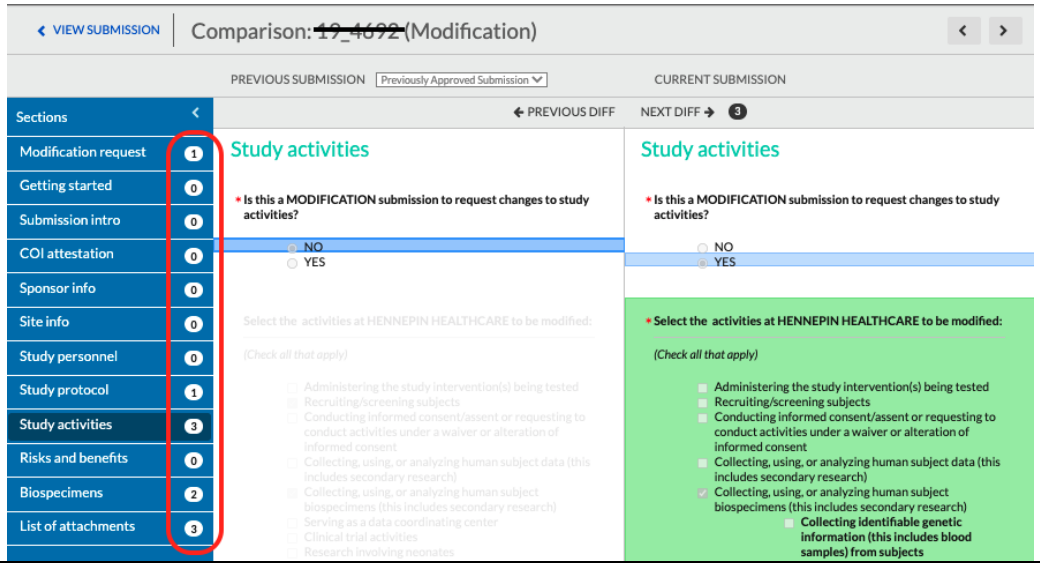
1. Open the smartform (from the submission details view) and click COMPARE.



Be sure to select "Previously Approved Submission"

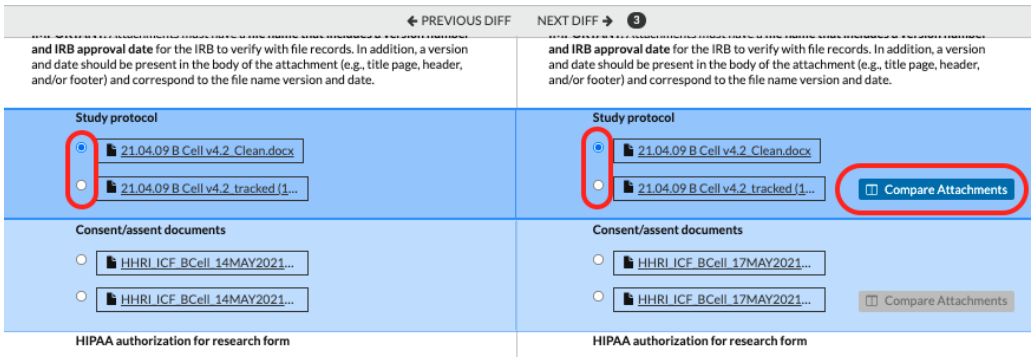
2. Numbers will appear next to each smartform section with a number representing the number of items with changes.

Click into the section to view what has changed.



3. In sections with attachments, click the COMPARE ATTACHMENTS next to the documents to view changes.

If multiple attachments are in one section, you will need to select the radial dial next to each document you wish to compare.



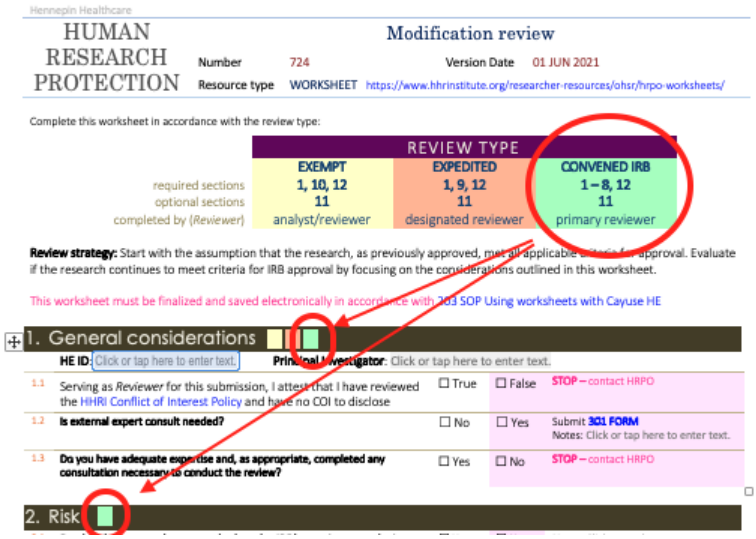
5. 724 WORKSHEET (Modification Review)

The analyst may begin or add notes to the 724 WORKSHEET (and/or other required worksheets), if relevant, during the pre-review; however, the ***primary reviewer*** is responsible for completing the worksheets.

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*.

IMPORTANT: If the analyst has added stipulations under section #11 of the worksheet, the ***primary reviewer*** may add to the section but should not remove any stipulations previously listed. If the analyst has added notes to any of the other sections, the ***primary reviewer*** may decide whether those notes should be retained or removed before saving the final version of the worksheet.

For a Modification 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. 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.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HUMAN RESEARCH PROTECTION

Modification review

Number 724 Version Date 01 JUN 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, 10, 12	1, 9, 12	1 – 8, 12
optional sections	11	11	11
completed by (Reviewer)	analyst/reviewer	designated reviewer	primary reviewer

Review strategy: Start with the assumption that the research, as previously approved, met all applicable criteria for approval. Evaluate if the research continues to meet criteria for IRB approval by focusing on the considerations outlined in this worksheet.

This worksheet must be finalized and saved electronically in accordance with 303 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. Risk

6. Requesting clarification and stipulations

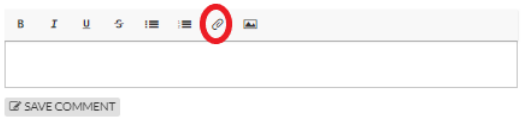
During the review, evaluate whether all criteria for approval has been meet (see 197 GUIDANCE). Stipulations that must be addressed by the PI in order to meet criteria for approval should be listed in the Reviewer worksheet before the final version is submitted. Minor stipulations do not need to be communicated 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).

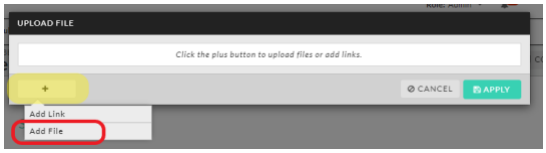
If you feel that clarification is necessary in order to confirm whether a submission meets the criteria for approval, please connect with the IRB Analyst as soon as possible in order to determine whether the submission may be deferred. The IRB Analyst and Primary Reviewer may contact the PI prior to the meeting to request additional information. The PI will 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 submission, the submission will return to the full board for review, once required revisions have been submitted.

7. Submitting reviewer worksheets

To submit final reviewer worksheets:

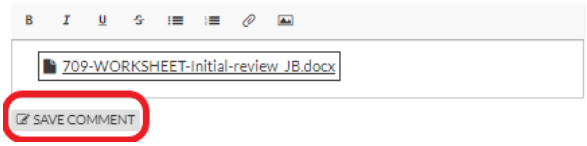
- Click REPLY under the restricted comment from the analyst (on the Submission Intro page, under the PI name)
- Click the paperclip to add attachments and Click +, Add File



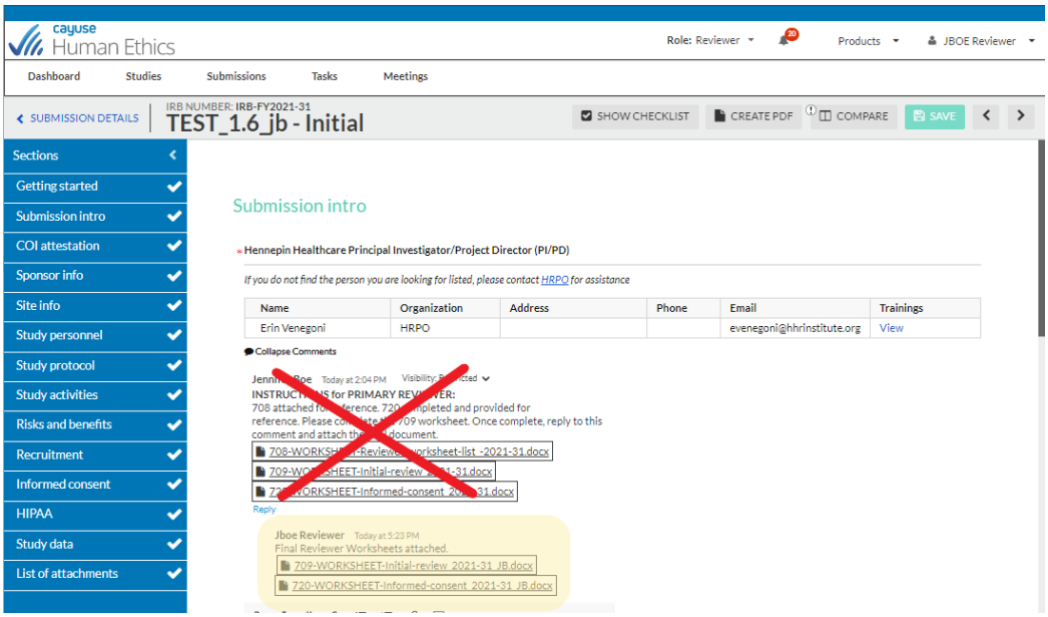


IMPORTANT: Save completed worksheets with your initials at the end.

- Select the final worksheets, then click Open
- Click Apply and Save Comment



Once saved, the worksheets will be visible internally for IRB 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.