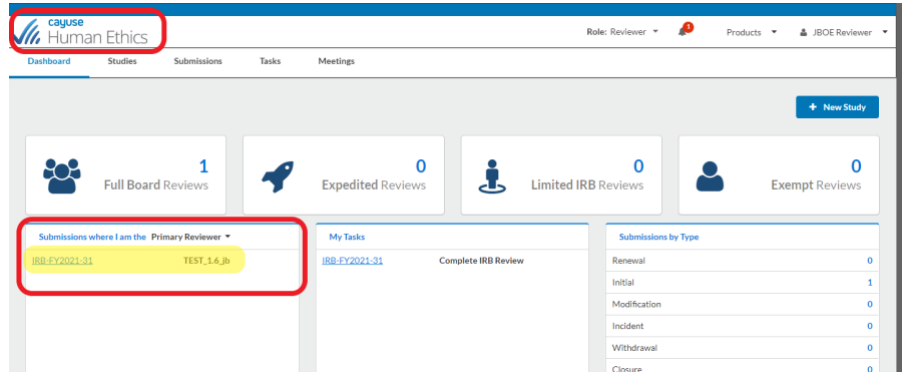


## Contents

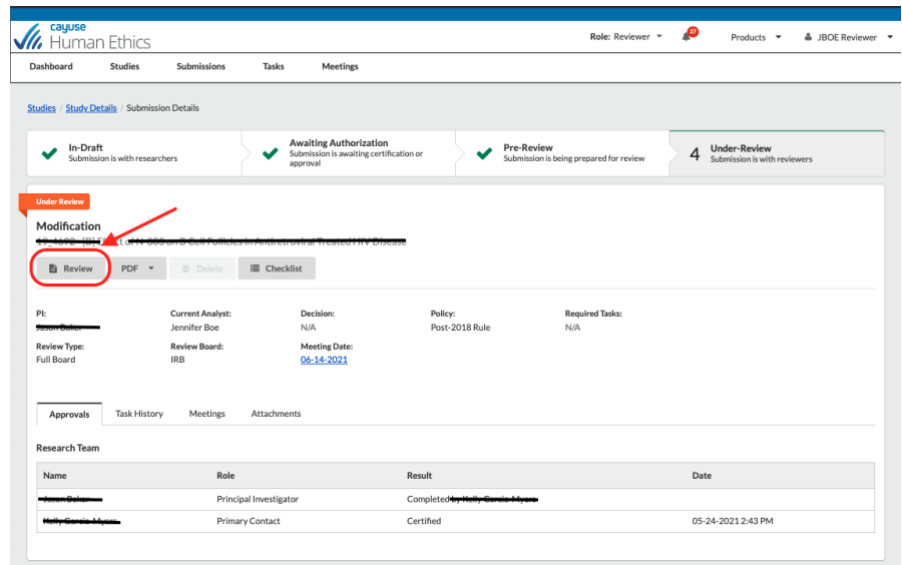
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# 1. Finding the Submission

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.

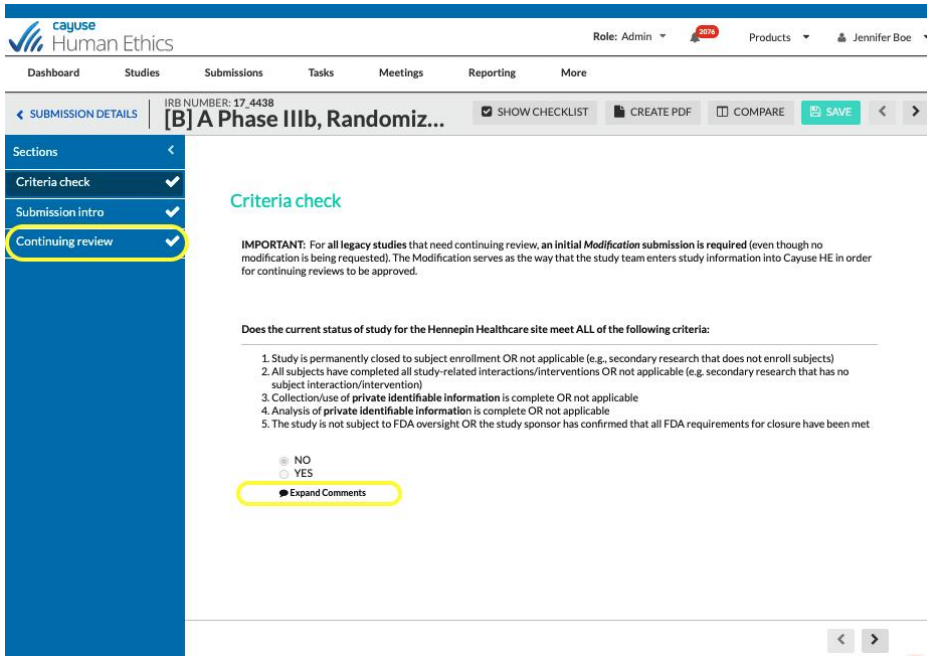


Click on the IRB# and you will go to the Submission Details page. Once in the Submission Details page, click **REVIEW** to open the submission smartform.



## 2. Finding Primary Reviewer worksheets

Reviewer worksheets for a renewal submission are available on the **Criteria Check page** *under the current study status question*. The IRB analyst will attach the required worksheets, as a restricted comment, in the smarform along with instructions for the Primary Reviewer. Once their review is complete, the primary reviewer's completed worksheets will be available to all IRB members in order to assist in their own review.



The screenshot shows the Cayuse Human Ethics interface. The top navigation bar includes 'Dashboard', 'Studies', 'Submissions', 'Tasks', 'Meetings', 'Reporting', and 'More'. The user is logged in as 'Jennifer Boe' with the role of 'Admin'. The main content area is titled 'SUBMISSION DETAILS' for IRB NUMBER: 17\_4438, specifically for '[B] A Phase IIIb, Randomiz...'. A sidebar on the left lists sections: 'Criteria check', 'Submission intro', and 'Continuing review', with 'Continuing review' highlighted in yellow. The main content area displays the 'Criteria check' section, which includes an important note about legacy studies and a list of five criteria for the Hennepin Healthcare site. Below the criteria are radio buttons for 'NO' and 'YES', and an 'Expand Comments' button.

**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.

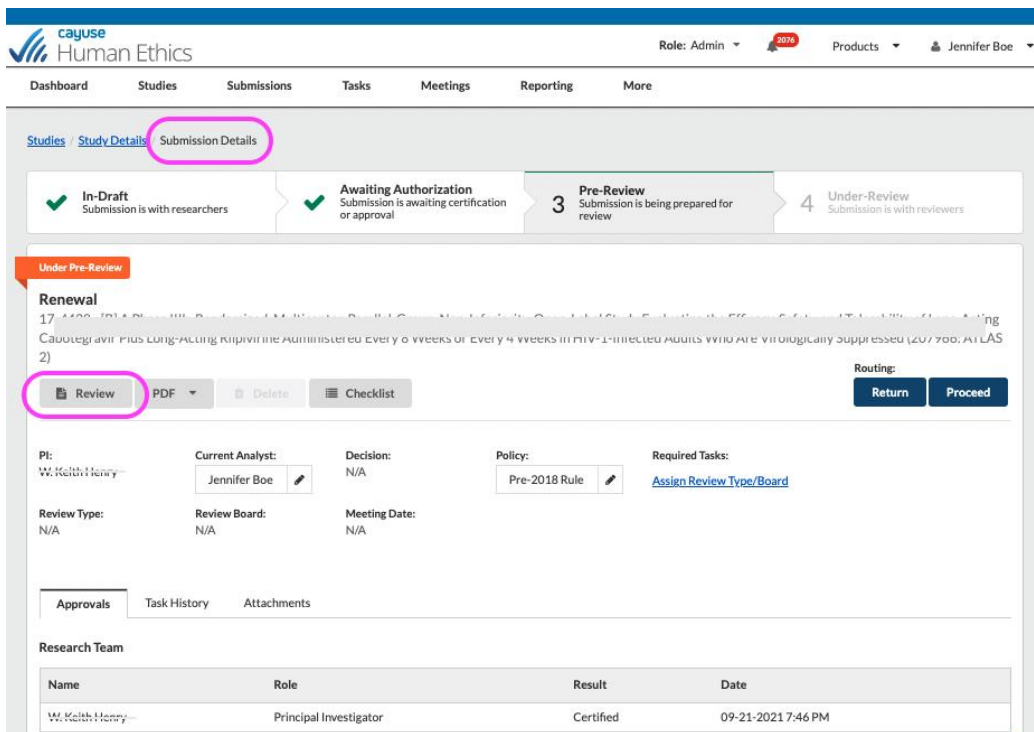


**IMPORTANT:** Read the comment and open the reviewer worksheets BEFORE beginning your review. In addition to sharing the reviewer worksheets, the analyst will provide relevant notes and/or stipulations noticed during pre-review. Always review the comment and worksheets before starting your own review.

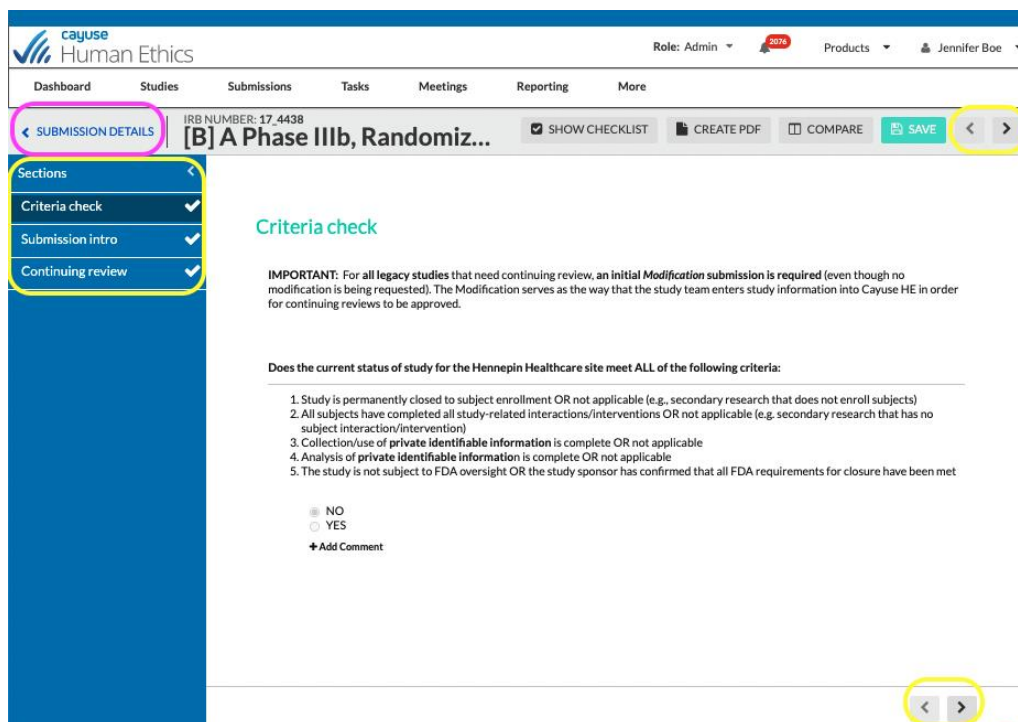
### 3. Navigating Cayuse for review of Renewal submission

The renewal submission collects information regarding *the last reporting period*. Please note that permanent study materials and information (such as the protocol, consent, or study personnel) are not available in the renewal submission.

From the Submission Details page, click Review (under the study title) to view the smartform.



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.



## 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 on intro

Hennepin Healthcare Principal Investigator/Project Director (PI/PPD)

If you do not find the person you are looking for listed, please contact [HRPO](#) for assistance

Name	Organization	Address	Phone	Email
Erin Venegoni	HRPO			evenegoni@hhri

● Collapse Comments

Jennifer Boe Today at 2:04 PM Visibility: Restricted

INSTRUCTIONS FOR PRIMARY REVIEWER:  
708 attached for reference. 720 completed and provided for reference. Please complete the 709 worksheet. Once complete, reply to this comment and attach the final document.

- 708-WORKSHEET-Reviewer-worksheet-list\_2021-31.docx
- 709-WORKSHEET-Initial-review\_2021-31.docx
- 720-WORKSHEET-Informed-consent\_2021-31.docx

Reply

Jboe Reviewer Today at 5:23 PM  
Final Reviewer Worksheets attached.

- 709-WORKSHEET-Initial-review\_2021-31\_JB.docx
- 720-WORKSHEET-Informed-consent\_2021-31\_JB.docx

Image 2 healthcare other personnel

Is there Hennepin Healthcare personnel who may carry out study activities involving human subjects (e.g., clinic providers/s

NO  
 YES

● Collapse Comments

Jennifer Boe Today at 1:47 PM Visibility: Unrestricted

Clarification to the study team (UNrestricted / visible to study team). No actual change necessary - please reply with DONE and return.)

Reply

Resolved Today at 5:19 PM by Jennifer Boe

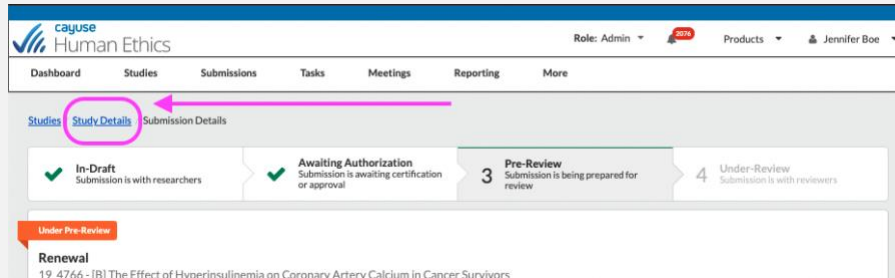
Reply

SAVE COMMENT

## 4. Finding current study information and materials

Information relevant to the last reporting period is collected in the renewal submission. In order to view permanent study materials and information (such as the protocol, consent, or personnel), reviewers will need to navigate in Cayuse HE to the most recently approved modification submission.

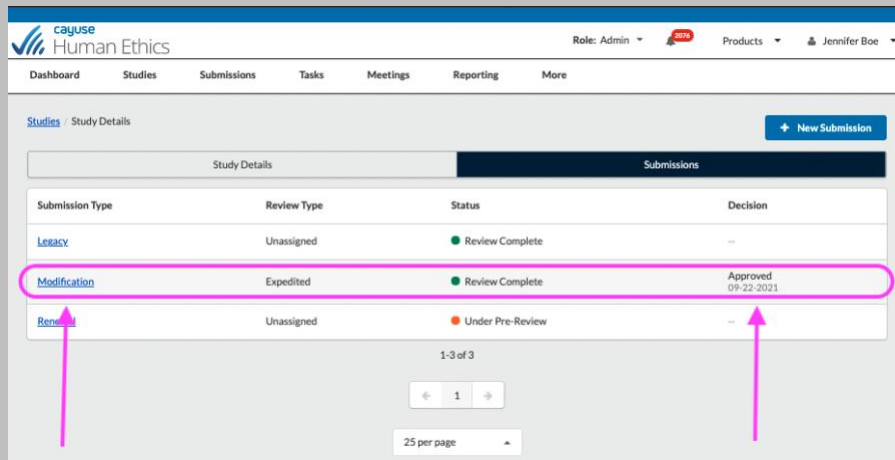
**NOTE:** Confirm the current status of the study (on the *Continuing Review* page of the smartform) before reviewing current study materials.



From the *Submission Details* view, navigate to the **Study Details** view.



Next, click on **Submissions** to view a complete list of all submissions on the study.



To view the most current study materials, click on the **Modification** with the *most recent approval date*.

Reviewers can click into each follow on submission in this list to get an overview of study activity in Cayuse HE. However, please remember that review of the renewal should focus on the past year (or reporting period) of the study.

## 5. Request clarifications 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.

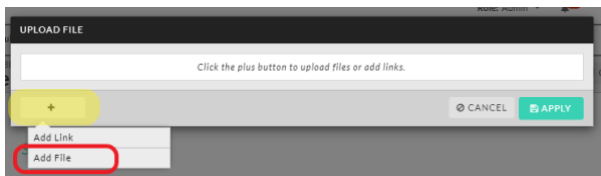
## 6. Submitting reviewer worksheets

To submit completed reviewer worksheets:

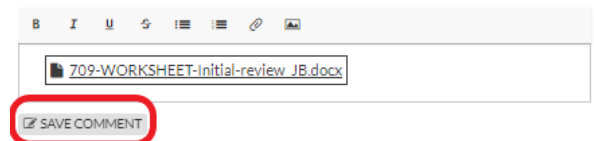
- Click REPLY under the restricted comment from the analyst (on the Submission Intro page, under the PI name)
- Click the paperclip to add attachments



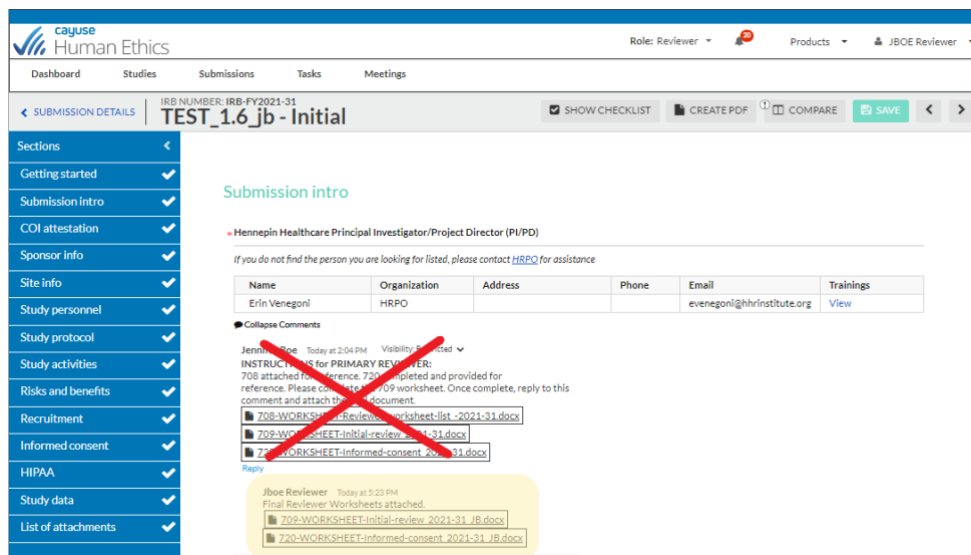
- Click +, Add File
  - o NOTE: Save completed worksheets with your initials at the end.



- Select the final worksheets, then click Open
  - o 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.