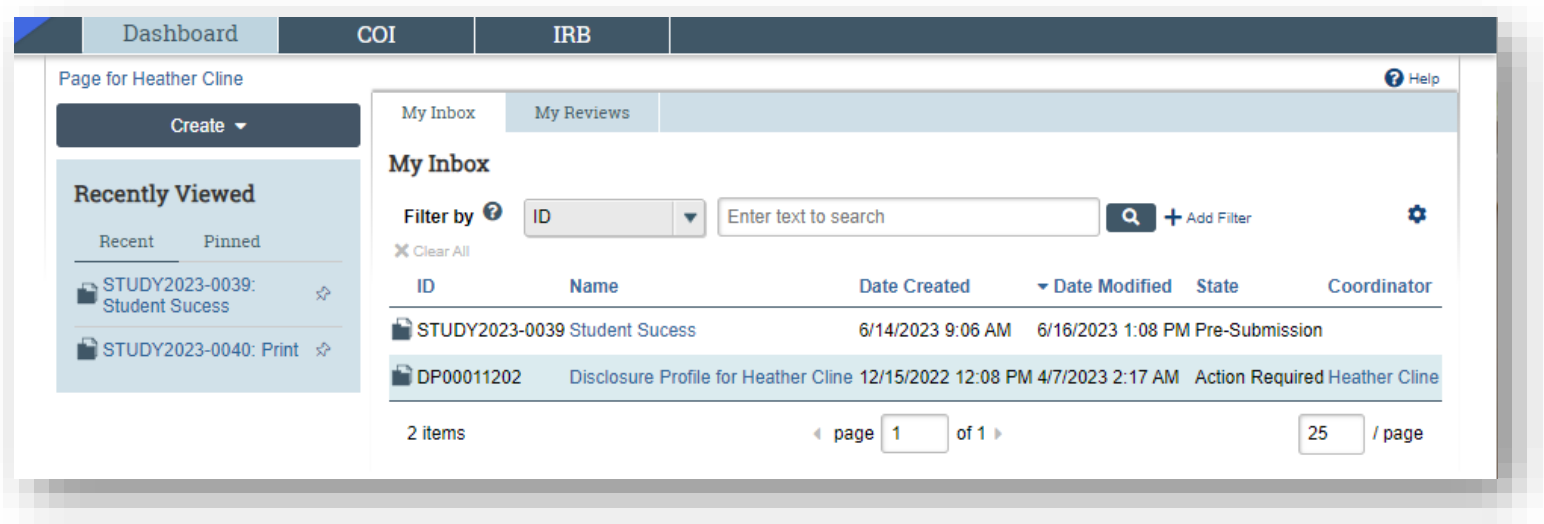
Reviewer's Guide

Human Research Protections

This PowerPoint will guide IRB reviewers on how to complete a submission review.

Dashboard

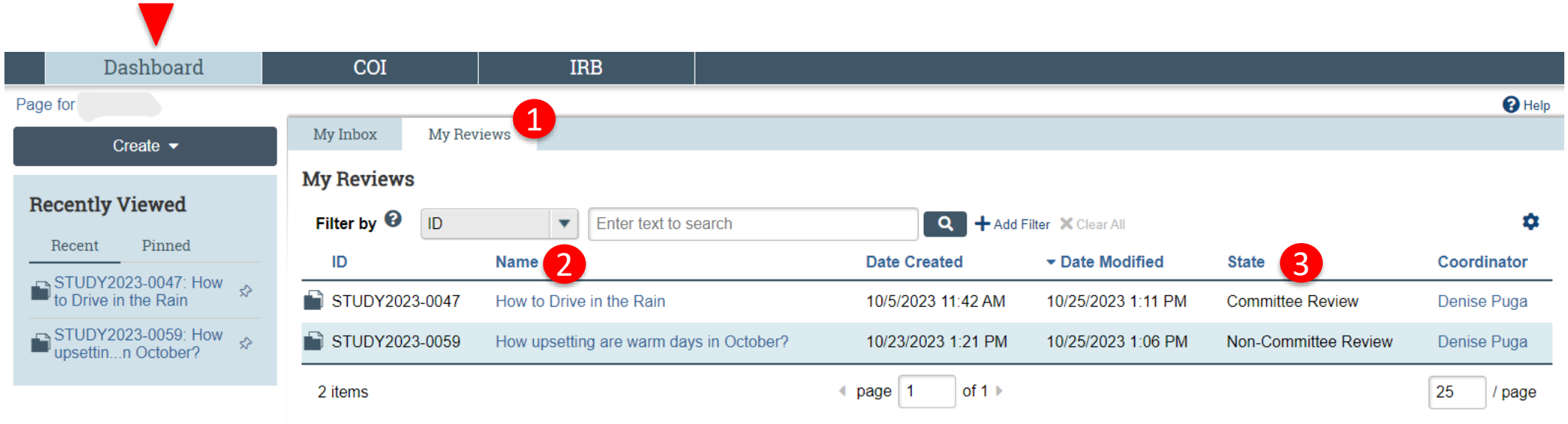
When you log into Zot IRB, your landing page will be your **Dashboard**. Your Dashboard is the starting point for finding items that need your attention.



Locating submissions assigned for your review

From your **Dashboard**:

1. Select **My Reviews** to identify items assigned for your review
2. Click the **Name** of the submission to open it
3. The **State** identifies if the submission is assigned for expedited (***Non-Committee Review***) or full board (***Committee Review***) review.

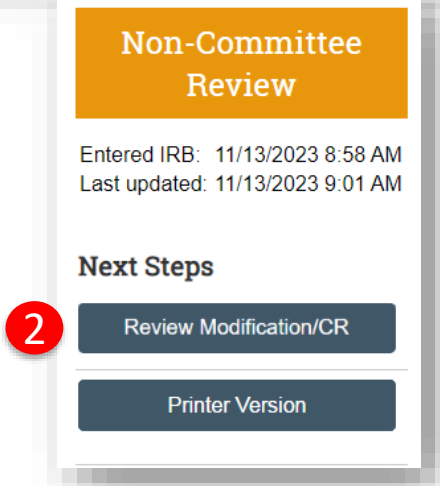


Study Workspace

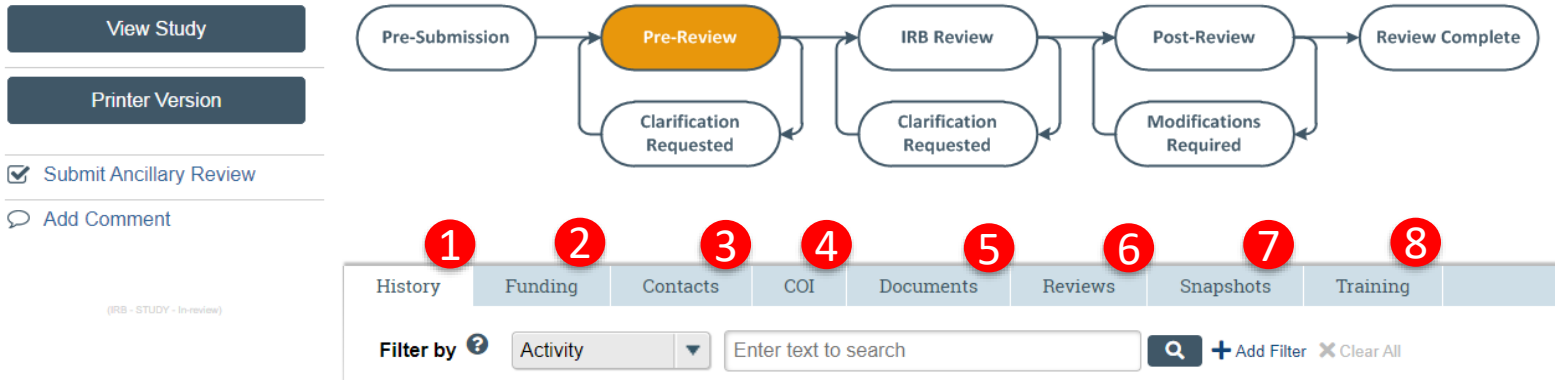
Once you click on the name of the submission in your Dashboard, you will be directed to the **Study Workspace**.

From the Study Workspace, click on the *review* tab to view the submission. The review tab will give a clue as to what type of submission is being reviewed. For example:

1. **Review Study**: You are being asked to review a new study
2. **Review Modification/CR:** You are being asked to review a modification and/or continuing review to an active study.



Study Workspace

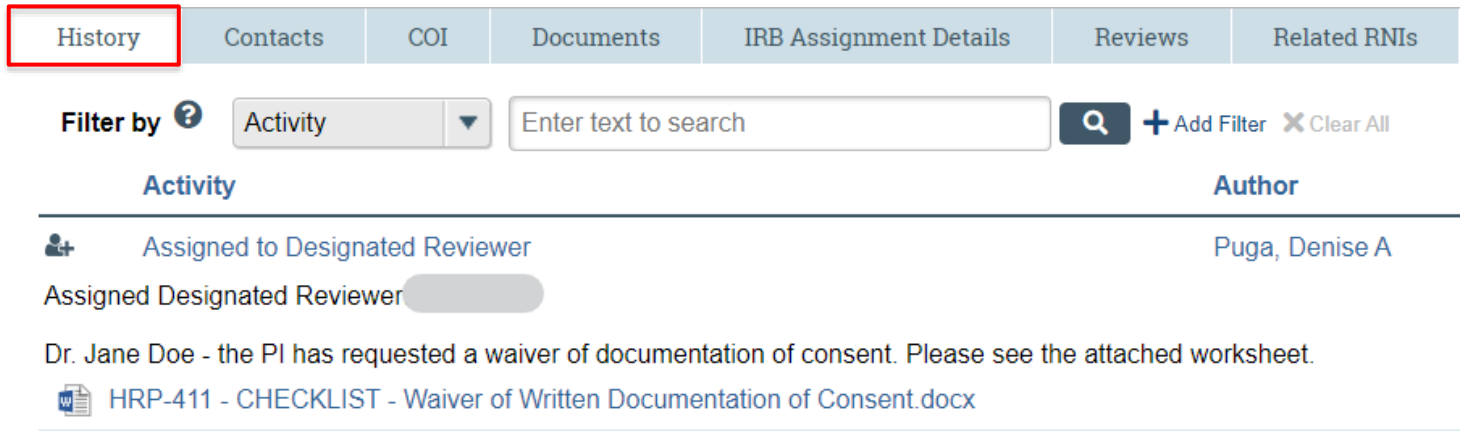


1. **History**: This tab lists the activity taken on a submission including any comments, attachments, correspondence.
2. **Funding**: Provides all funding sources associated with the submission along with related grant information, if applicable.
3. **Contacts**: This tab lists all UCI individuals with study involvement (i.e., PI, Study Team, Other Study Members, Guests).
4. **COI:** This tab identifies the status of any conflict of interest and how it is managed.
5. **Documents**: This tab includes all study related and site related documents including documents on drugs, devices, and international research, if applicable.
6. **Reviews**: This tab will list all ancillary reviews including the reviewers' comments, and Reviews containing the latest pre-review, committee and/or non-committee reviews, determinations (e.g., approval date), review/risk level, notes, missing materials, and checklists completed by the reviewers.
7. **Snapshots**: Provides a snapshot of the entire study including attachments submitted at different states of the submission (e.g, approved stated, pre-submission state).
8. **Training:** This tab includes all CITI training of the individuals/key personnel listed on the study, with the exception of non-UCI researchers.

History Tab

When completing your review, visit the **History** tab. The History tab may contain additional information pertinent to your review.

In addition, when required, IRB staff will provide you with additional regulatory documents (i.e., completed checklists) for your reference during your review.



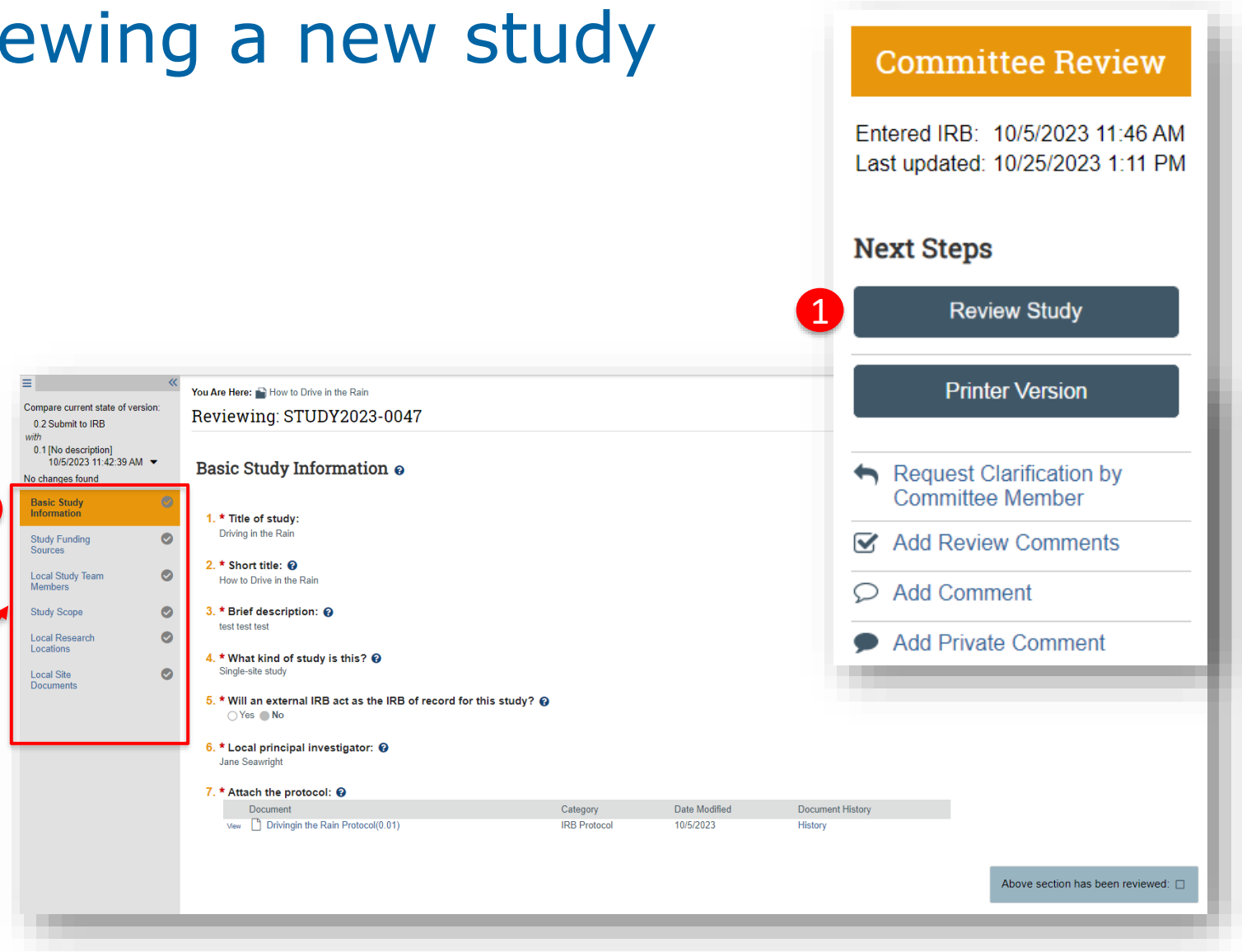
Instructions for reviewing a new study

1. Click **Review Study** in the Study Workspace to view the submission.

2. **Review each section of the study**. You can scroll through the submission or use the Left Navigator to jump to specific sections of the application. The Huron IRB submission provides a quick overview of the study, which includes:

   - Basic study information
   - Funding source
   - Study team personnel
   - Study location
   - Device and drug information (if applicable)
   - External institution information (if applicable).

The **Left Navigator** is located on the left side of the screen, and it allows the user to switch between the main pages of the IRB application. The page currently being viewed will be shown highlighted in orange.



Reviewing a new study

IMPORTANT! As part of your review, you will need to download and review the Protocol Narrative and supporting study documents (e.g., master protocol, consent form, recruitment documents).

- The next four slides will walk you through how to
  (1) download the Protocol Narrative and supporting study documents to your computer
  (2) use Track Changes and Comments to aid in your review

How to download the Protocol Narrative

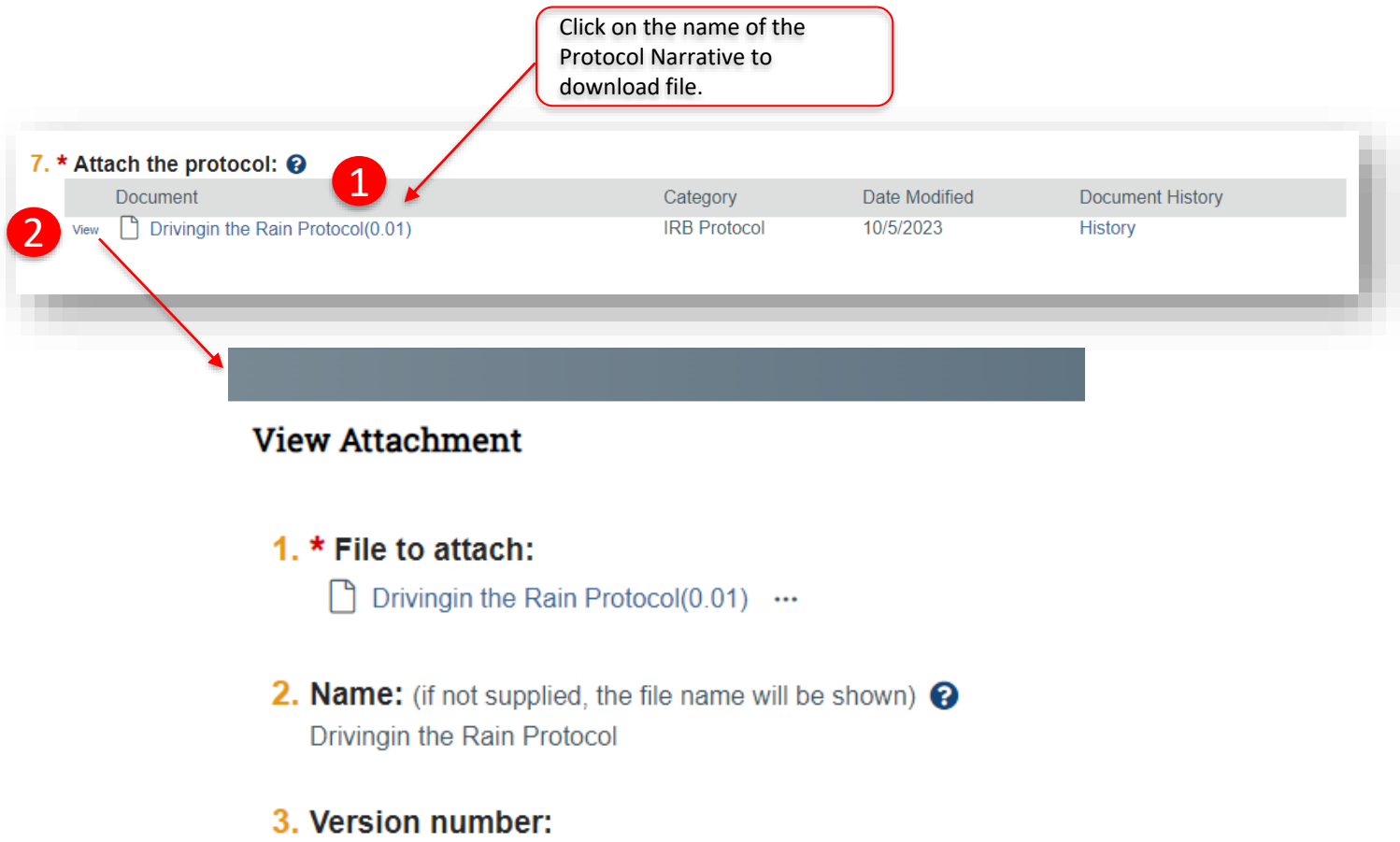
The Protocol Narrative outlines the rationale for the study, its objective, the methodology used and how data will be managed. You will need to download the Protocol Narrative to your computer to complete your review.

NOTE: ***Documents must be downloaded to your computer to be viewed***.

There are two ways to download the Protocol Narrative to your computer:

1. Click on the **Name** of the Protocol Narrative. A copy of the Protocol Narrative will automatically download to your computer.

2. Select **View** (found next to Protocol Narrative name) and a pop-up form will appear. On the pop-up form, click on the name of the Protocol Narrative and a copy of the Protocol Narrative will automatically download to your computer.



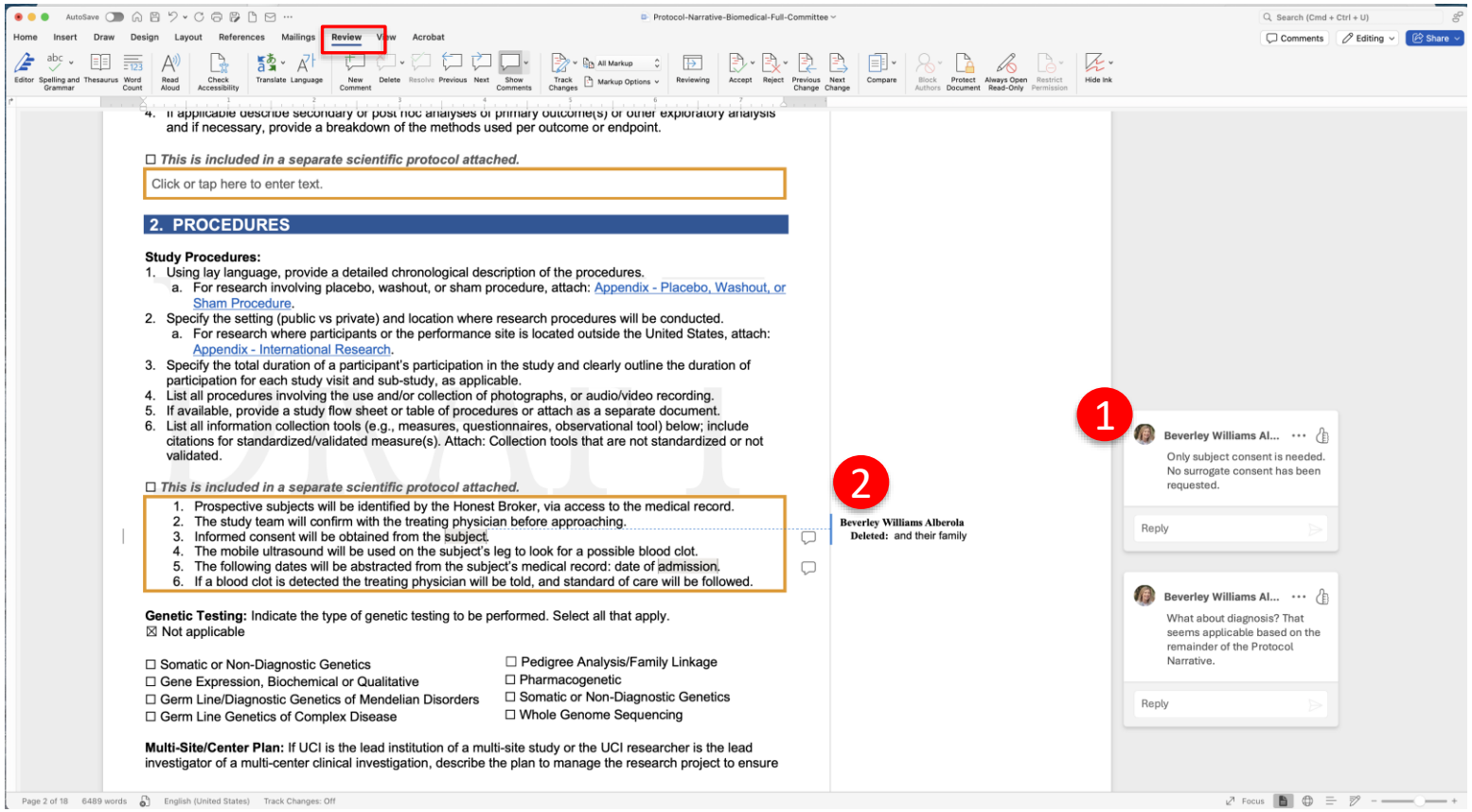
Protocol Narrative Review

Once you have downloaded the Protocol Narrative to your computer, review the study protocol using the following steps:

1. **New Comment**. As you review the study protocol, you may add comments directly to the Word document to request additional information or clarifications.

2. **Tracked Changes.** Reviewers may suggest edits to the protocol to secure approval using Track Changes.

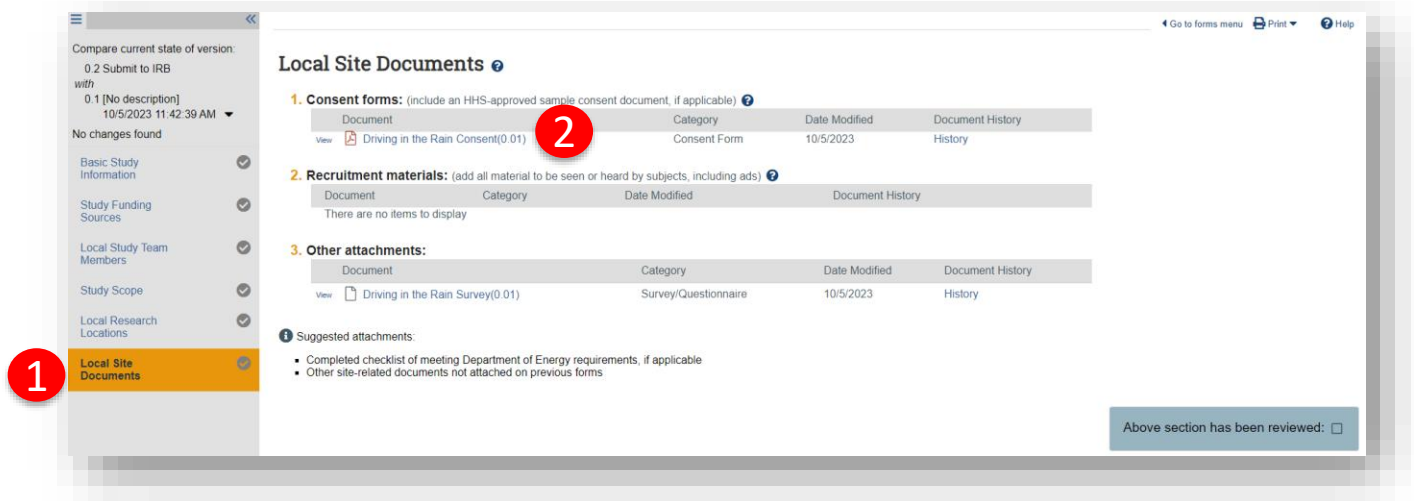
3. **Save all comments and tracked changes.** Once you have completed your review of the Protocol Narrative, save a copy of the revised document.



How to download study documents

Important study documents, such as consent forms, recruitment materials, and data collecting instruments are located in the **Local Site Documents** page. To access these files:

1. Click on the **Local Site Documents** page on the Left Navigator
2. Click on the name of the file of interest to download the document to your computer. *You must download study documents to your computer to view it.*

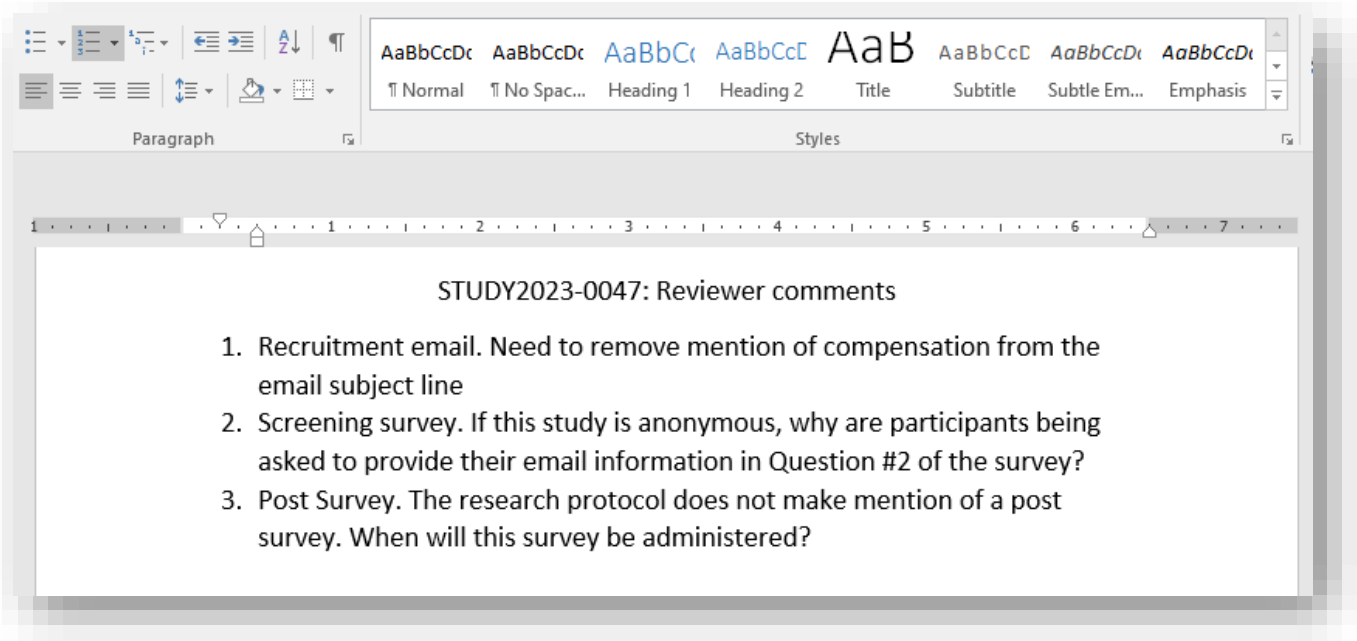


- **NOTE**: As you scroll though the submission, you may also find supporting documents uploaded to specific sections of the application. For example:
- You may find a copy of the grant proposal or contract for a funded study attached under ***Study Funding Sources***.
- Device manuals or drug labels can be found under the ***Devices*** or ***Drugs*** pages, respectively

Study Document Review

- During your review of the study documents, you may use Tracked Changes and comments to request modifications or additional information, if the format of the document allows it (i.e., Word documents).

- Otherwise, you may opt to write down your comments on a separate Word document. You will have the opportunity to upload your saved comments to the reviewer form prior to completing your review.



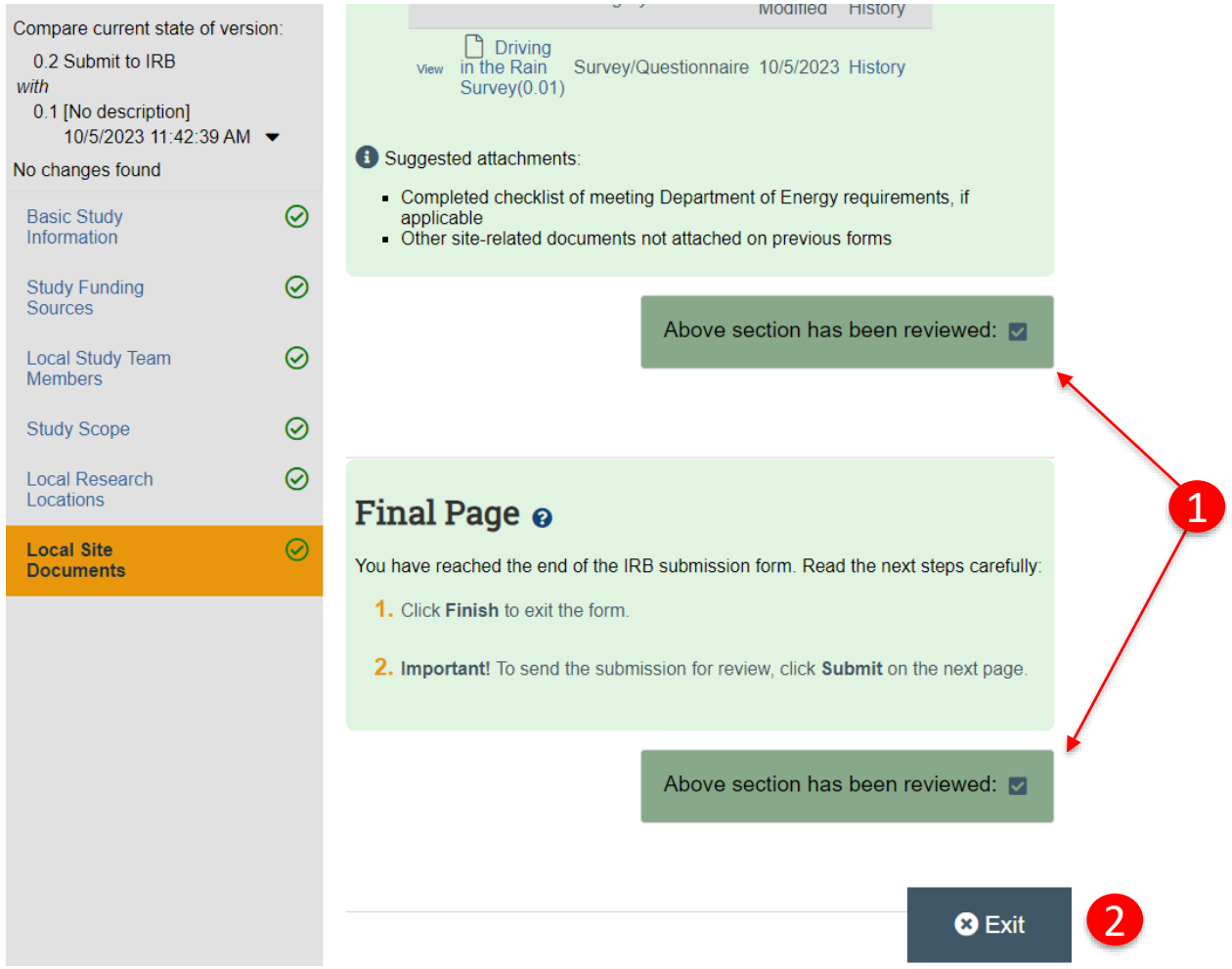
Finalizing your review

After you have completed your review of the application, study protocol and supporting study documents, you are ready to finalize your review.

To finalize your review:

1. Select the **check-box** at the bottom of each section of the application.
   - Once you select the check-box, the section will turn green.
   - Select all the check-boxes.

2. Click **Exit**



Finalizing your review

Non-Committee Review / Expedited Review

From the Study Workspace for a non-committee review, you will have the option to:

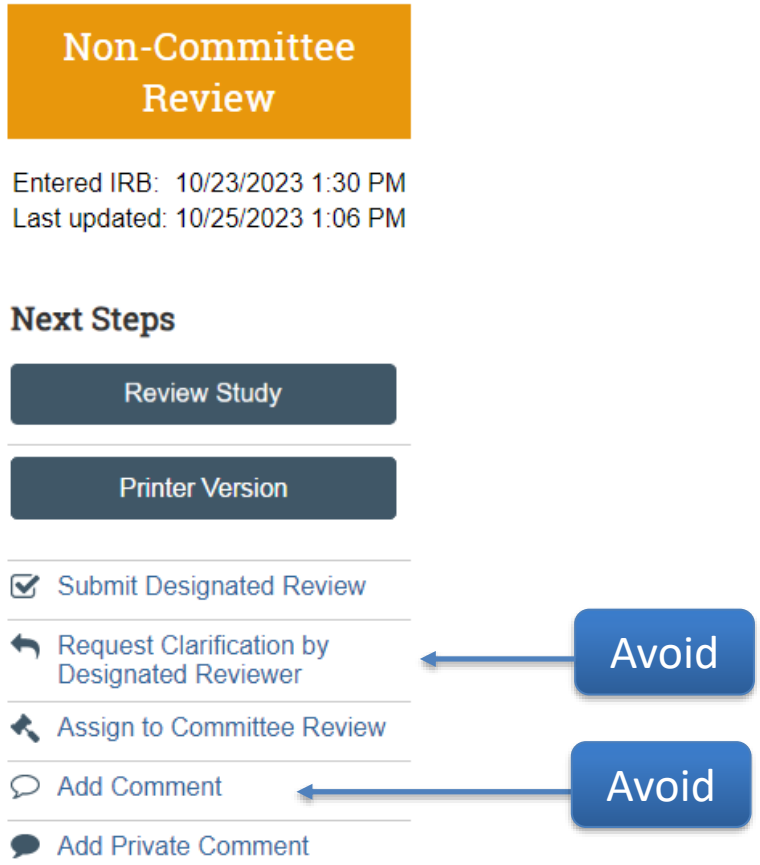
1. **Submit Designated Review**. This option sends your review to the IRB coordinator. This option guarantees your anonymity as the reviewer. The next slide walks you through the steps for submitting your designated review.

2. **Request Clarifications by Designated Reviewer**. This option allows the reviewer to request clarifications from the researcher without routing through the IRB coordinator. This option is ***highly discouraged*** as it will disclose your identify as the reviewer to the research team.

3. **Assign to Committee Review.** Select this option if the study needs to be seen by the convened board.

4. **Add comment**. This option allows you to post a public comment that may be seen by everyone with access to the protocol, including the research team. This option is ***not recommended***, as it will disclose your identify as the reviewer.

5. **Add a private comment.** This option allows you to post a comment that may be seen by the IRB Coordinator, Assigned Reviewers, and/or IRB Director. Use this option to communicate with other assigned reviewers.



Finalizing your review

Non-Committee Review / Expedited Review

To submit your designated review:

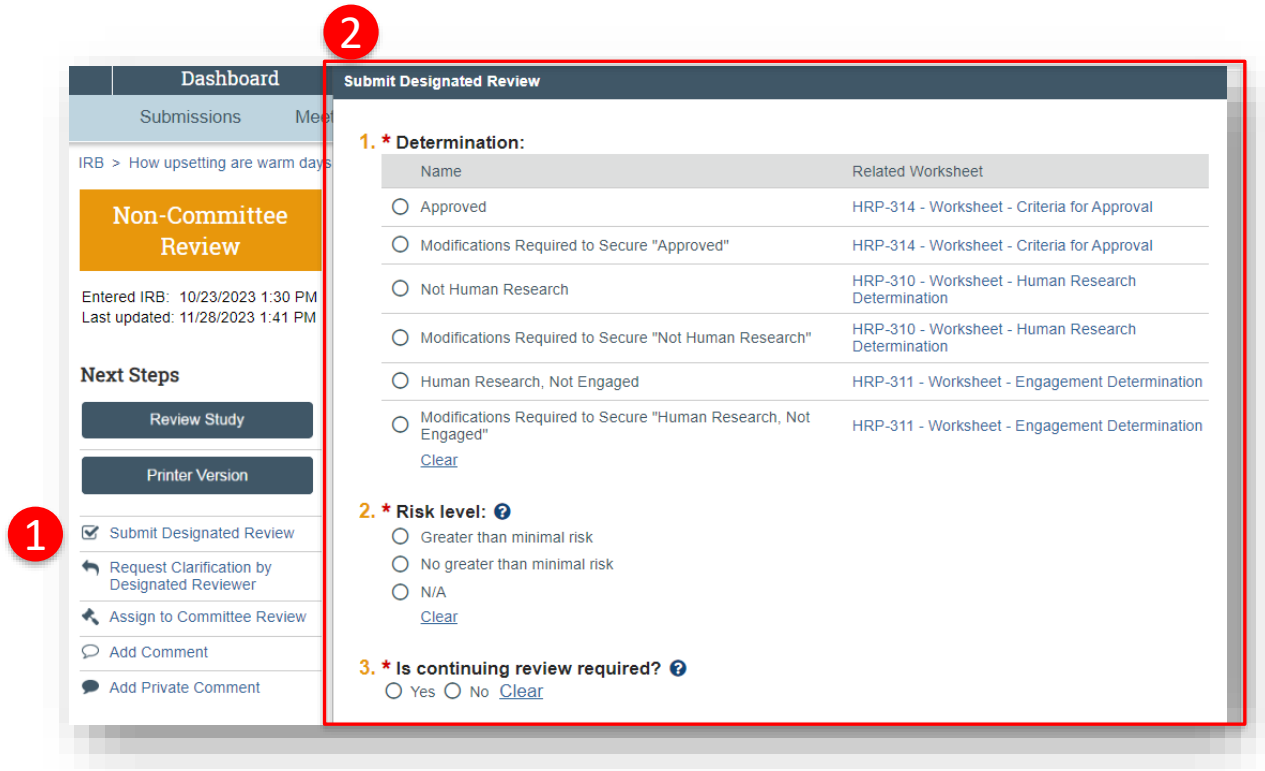
1. Click **Submit Designated Review** and a pop-up form will appear.
2. Complete the pop-up form titled **Submit Designated Review**:

Q1 :

- Select ***Approved*** if the study is ready for approval and no additional changes are required; **OR**
- Select ***Modifications Required to Secure Approved*** if changes are needed to the protocol prior to approval.
- Note: Not Human Subjects determinations are for administrative use only

Q2:

- Select **No greater than minimal risk**
- *Note*: If you believe the study you are reviewing is **Greater than minimal risk**, exit the designated reviewer form by selecting ***Cancel*** at end of the form. This will return you to the Study Workspace. From the Study Workspace, select ***Assign to Committee Review***.



Finalizing your review

Non-Committee Review / Expedited Review

Complete the pop-up form titles **Submit Designated Review**:

Q3:

- Select **Expedited**
- Note: Exempt research is reviewed by IRB staff and is not normally routed to committee members for review.

Q4:

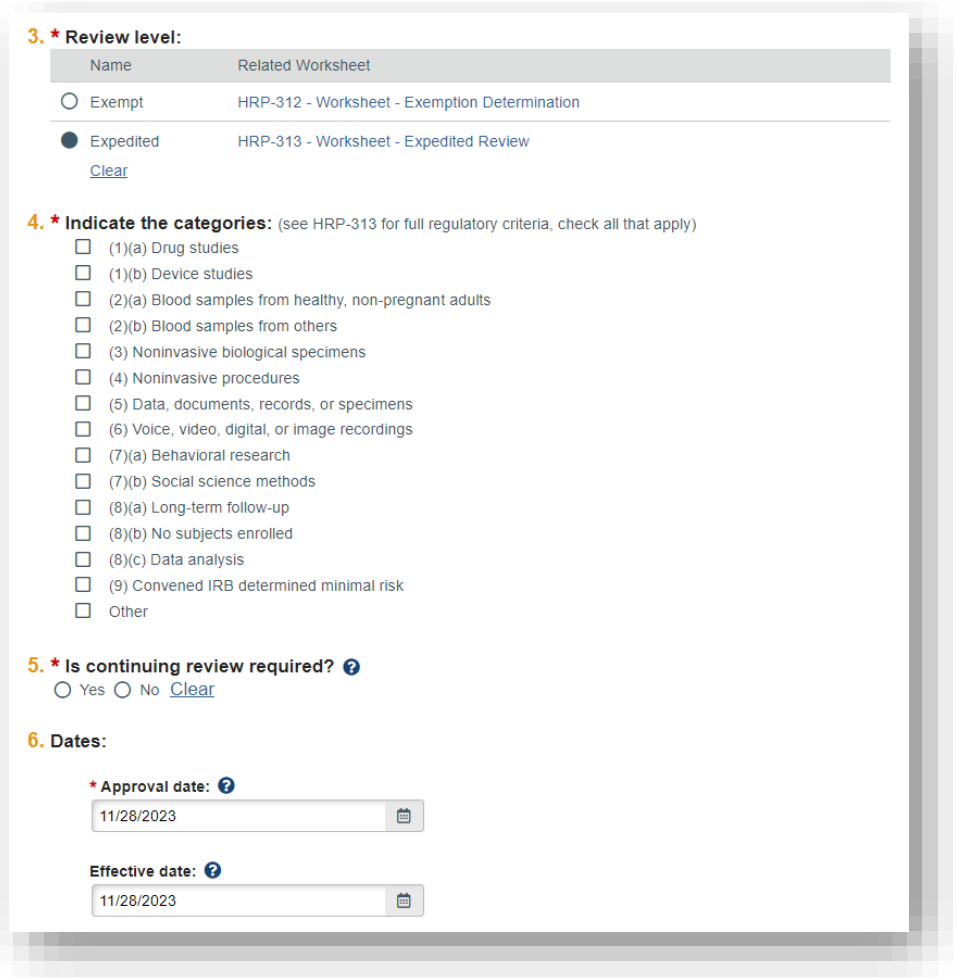
- Select the expedited categories this study is eligible for under HRP-313 (check all that apply).

Q5:

- Due to the Revised Common Rule, continuing review is not required for minimal risk research unless there is a study-specific need for it.
- Note: If *Yes* is selected, an additional questions will branch out asking for the reason a continuing review is being requested.

Q6:

- This date is auto-generated and is based on the date of approval.



Finalizing your review

Non-Committee Review / Expedited Review

- Complete the pop-up form titles **Submit Designated Review**:

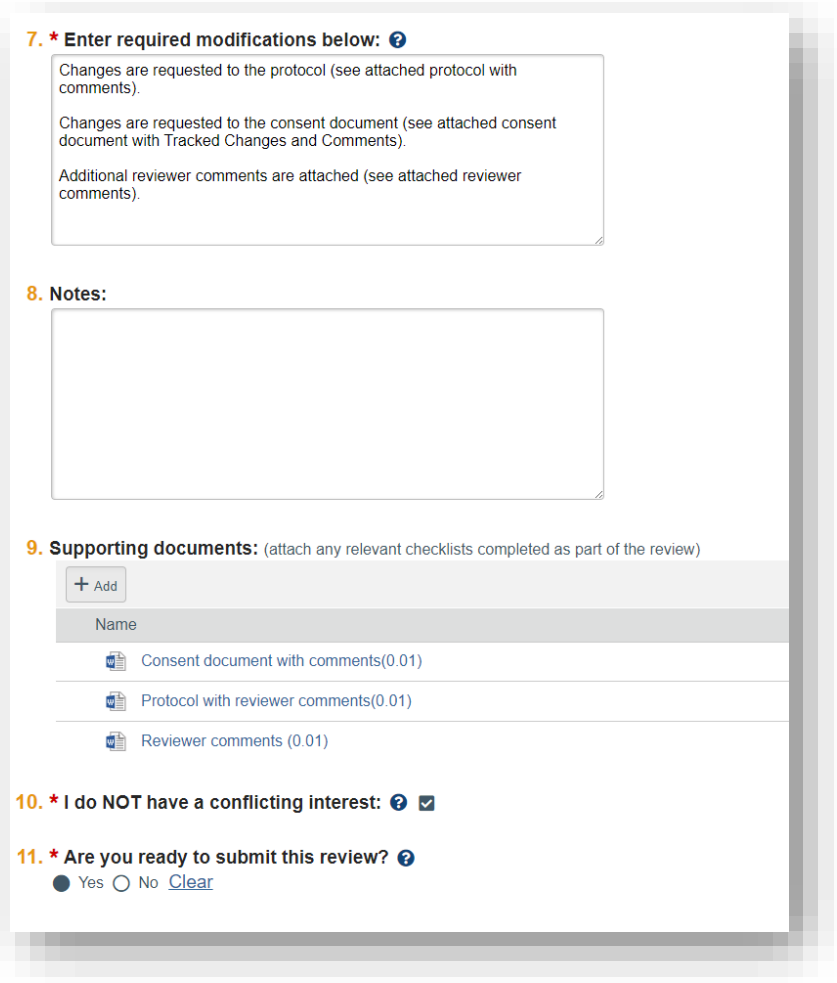
Q7:
- This space is provided to enter any required modifications to secure approval .
- **If you documented your reviewer comments in a Word document**, indicate that you have attached your comments as a separate Word document and attach your reviewer comments in Q9.

Q8:
- Use this space to document any notes to file.

Q9:
- Attach any documents that require modifications to secure approval, for example: protocol with Tracked Changes and Comments, consent document with Tracked Changes and Comments, Reviewer Comments in Word document.

Q10:
- Select the check-box if you do not have a conflict of interest.

Q11:
- Select **Yes** if you are ready to submit your review.



Finalizing your review

Committee Review

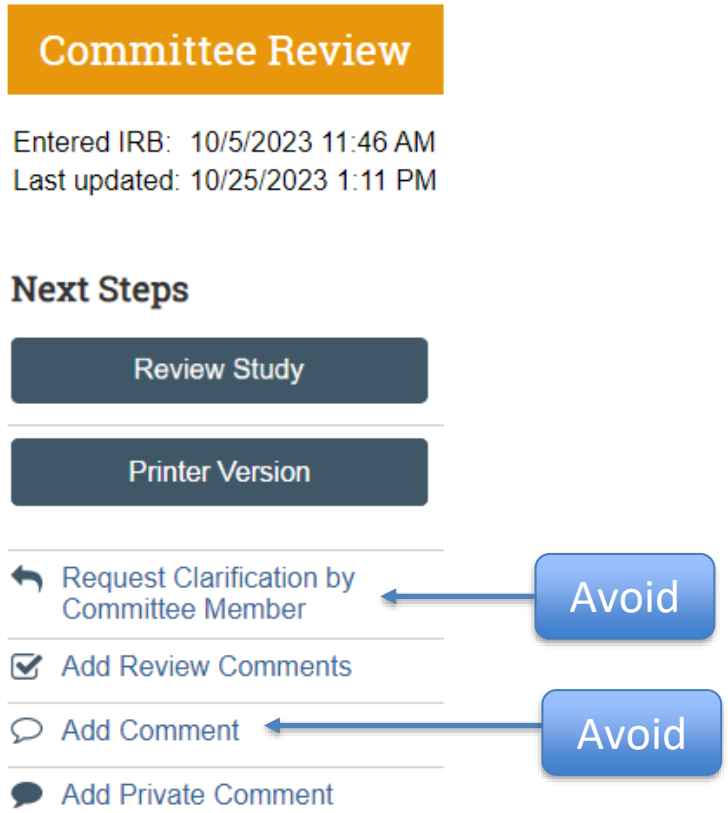
From the Study Workspace for a committee review, you will have the option to:

1. **Request Clarifications by Designated Reviewer**. This option allows the reviewer to request clarifications from the researcher without routing through the IRB coordinator. This option is ***highly discouraged*** as it will disclose your identify as the reviewer to the research team.

2. **Add Reviewer comments:** Use this option to share your reviewer and reviewer comments.

3. **Add comment**. This option allows you to post a public comment that may be seen by everyone with access to the protocol, including the research team. This option is ***not recommended***, as it will disclose your identify as the reviewer.

4. **Add a private comment.** This option allows you to post a comment that may be seen by the IRB Coordinator, Assigned Reviewers, and/or IRB Director. You may use this option to ask a question from the IRB Coordinator during your review.



Finalizing your review

Committee Review

Submitting your reviewer comments:

1. Click **Add Reviewer Comments** and a pop-up form will appear.
2. Complete the pop-up form titled **Add Reviewer Comment**:

Q1

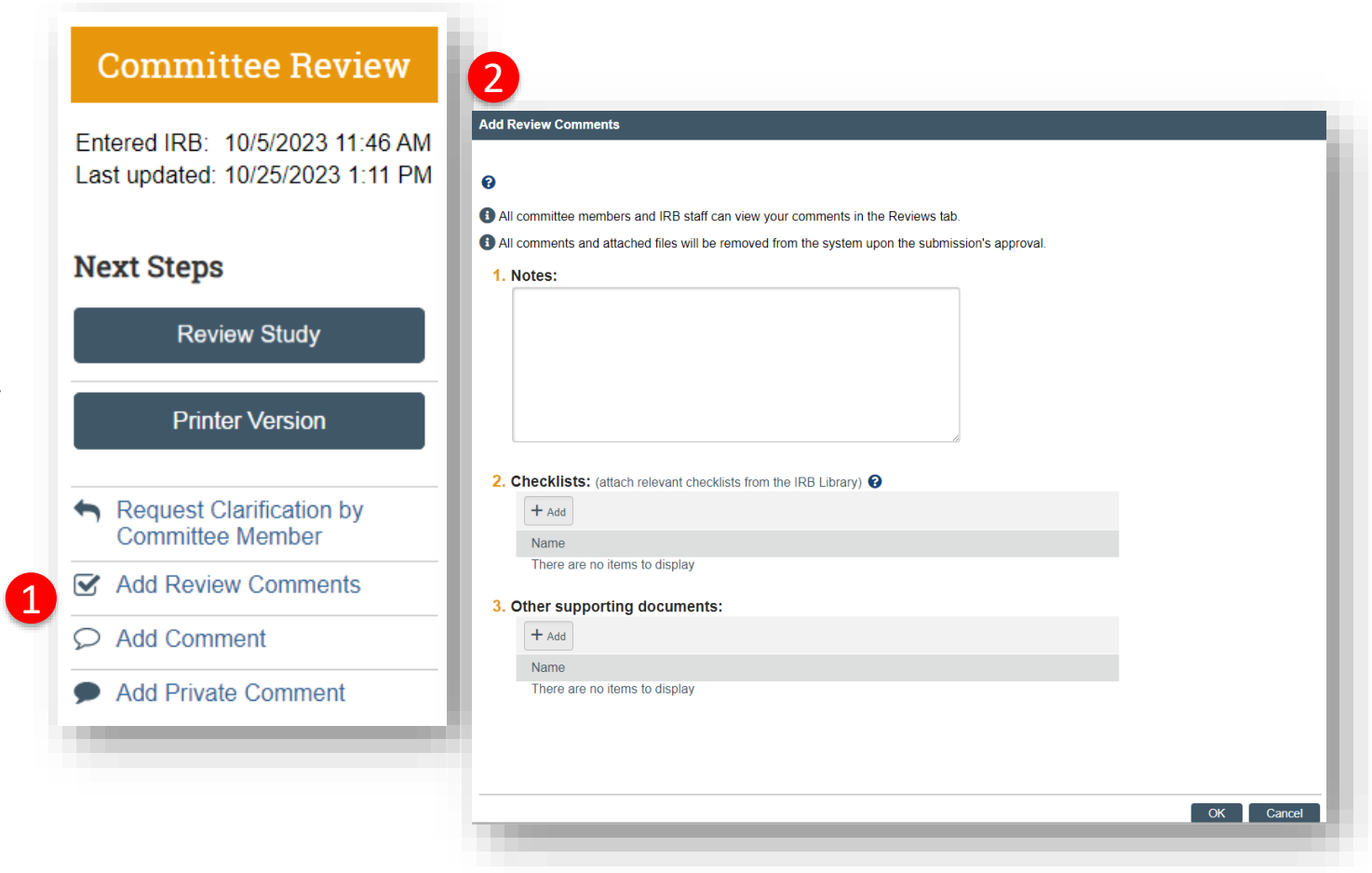
- This space is provided to enter your comments.
- **If you documented your reviewer comments in a Word document**, indicate that you have attached your comments as a separate Word document and attach your reviewer comments in **Q3**.

Q2

- Checklists are normally attached by IRB staff. Unless otherwise instructed by IRB staff, you may skip this question

Q3:

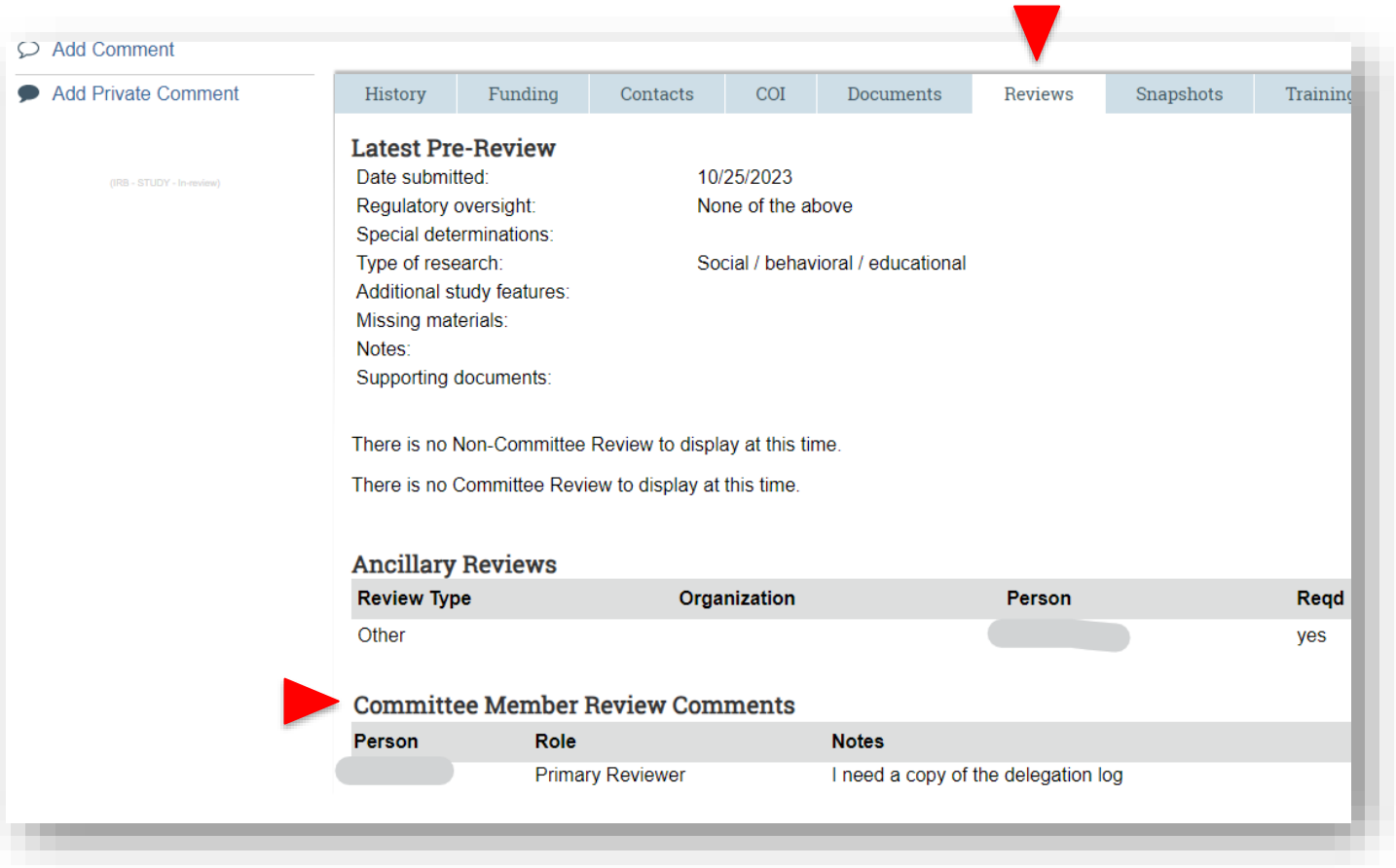
- Attach any documents that require modifications to secure approval, for example: protocol with Tracked Changes and Comments, consent document with Tracked Changes and Comments, Reviewer Comments in Word document.



Finalizing your review

Committee Review

Once you have submitted your reviewer comments, other committee members will have access to your comments under the **Reviewer** tab.

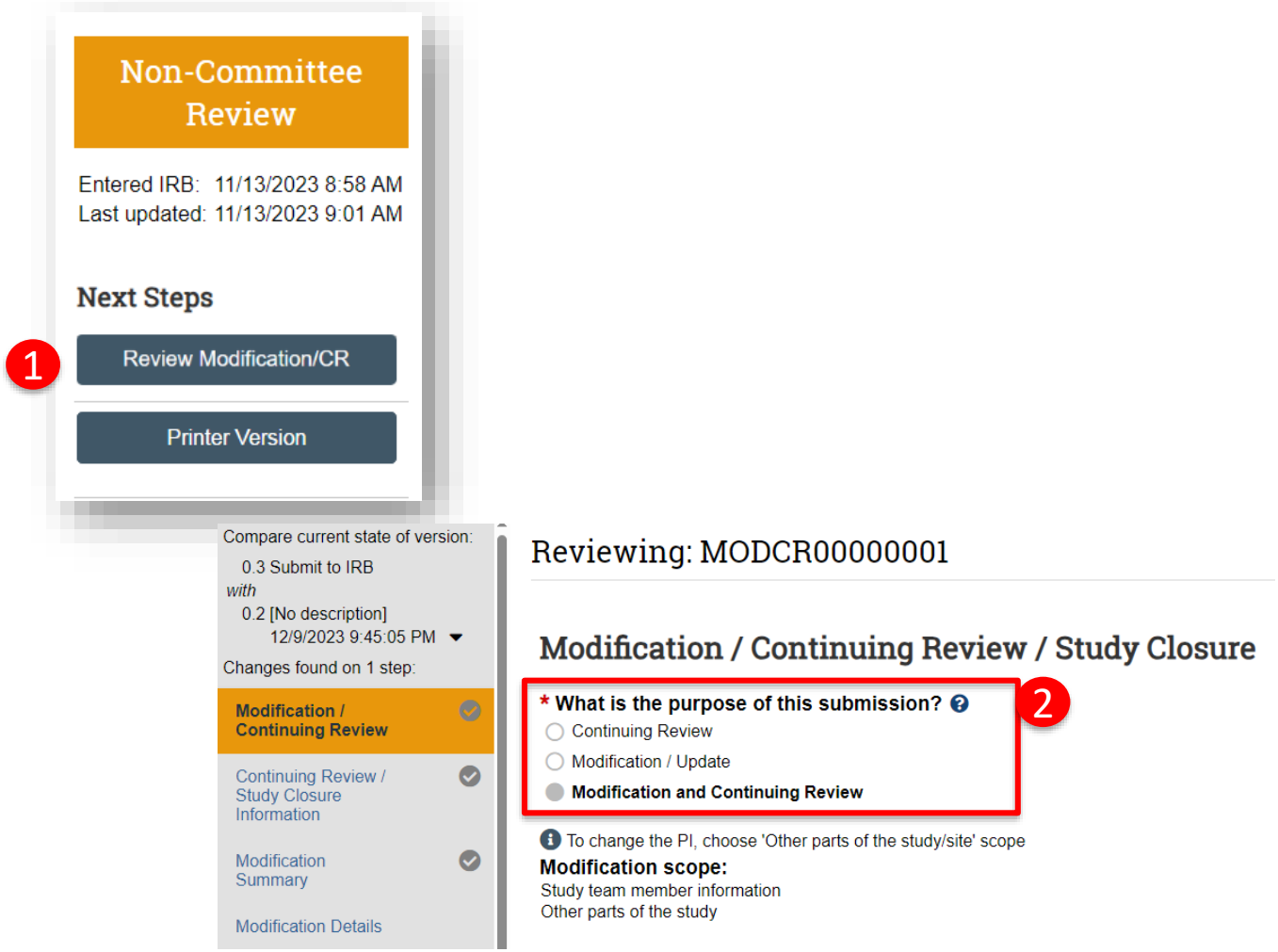


Instructions for reviewing a modification and/or continuing review

- Zot IRB allows investigators to submit a modification during a continuing review. This means that Huron uses the same form for modifications and continuing reviews. To begin your review:

1. Click **Review Modification/CR** in the Study Workspace to view the submission.

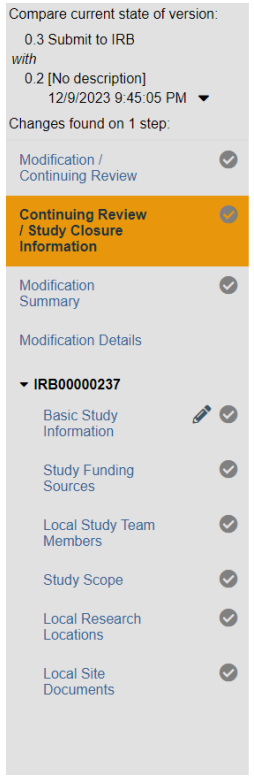
2. Under **What is the purpose of this submission**, you will be able to ascertain if you are reviewing a modification, a continuing review, or both.

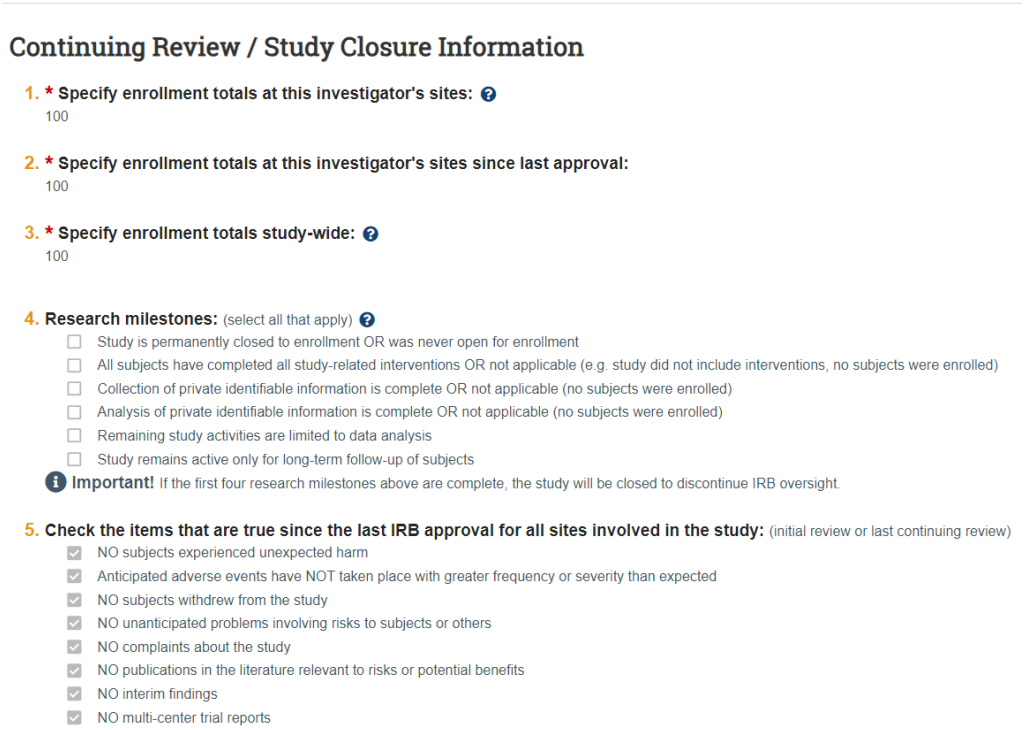


Instructions for reviewing a modification and/or continuing review

Review each section of the submission. You can scroll through the submission or use the Left Navigator to jump to specific sections of the submission.

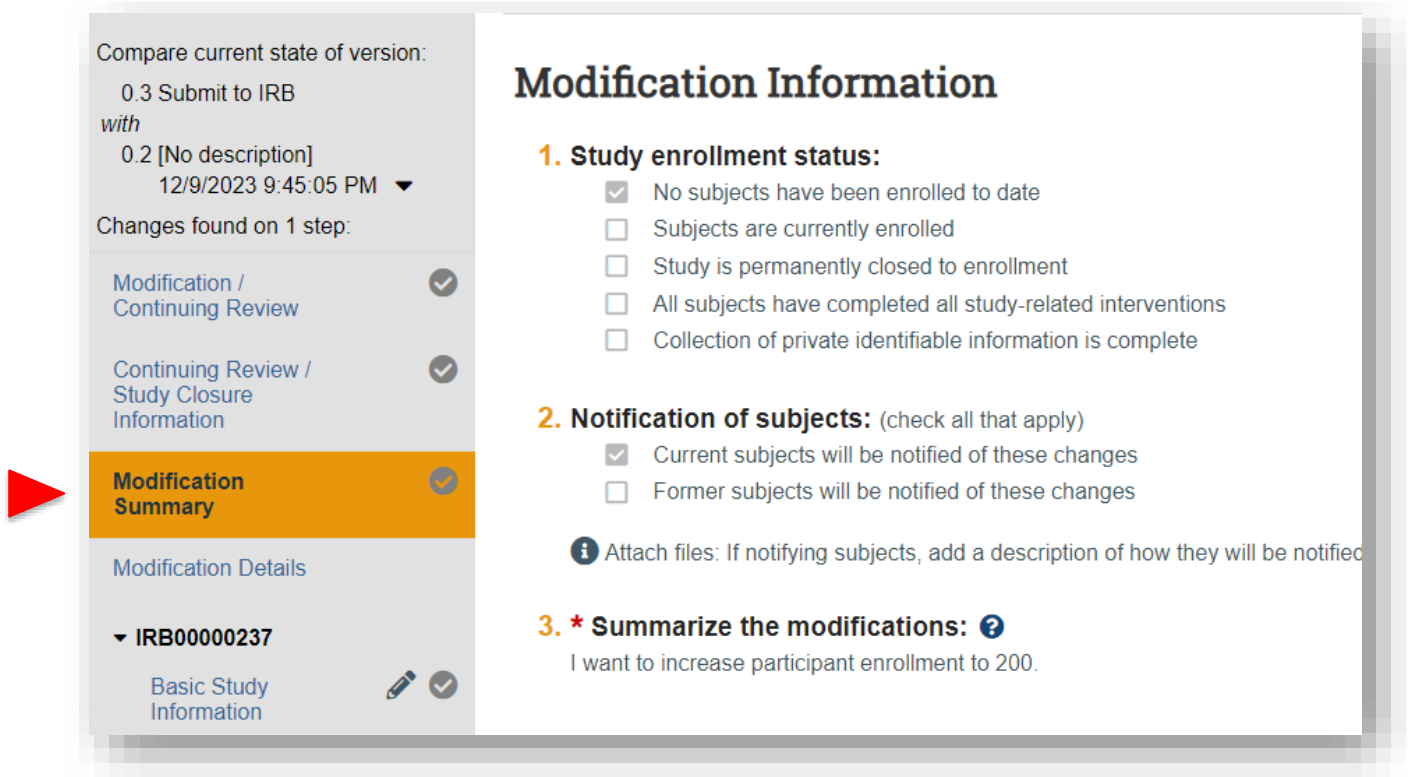
The **Left Navigator** is located on the left side of the screen, and it allows the user to switch between the main pages of the submission. The page currently being viewed will be shown highlighted in orange.





Instructions for reviewing a modification and/or continuing review

If the submission includes a modification to the approved protocol, the **Modification Summary** page provides a summary of the proposed changes to the submission.

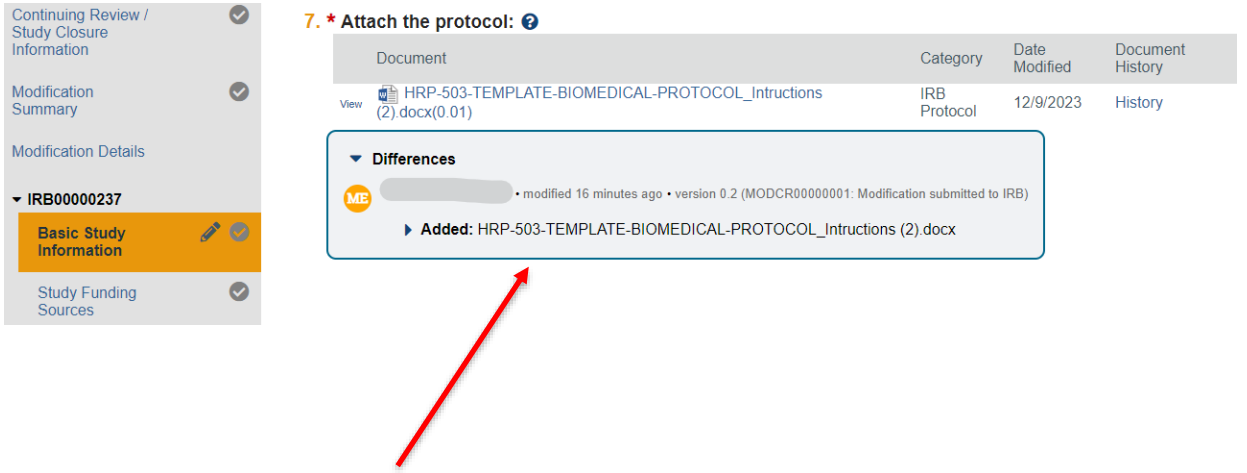


Instructions for reviewing a modification and/or continuing review

As you scroll through the submission, you will find notification boxes that identify any differences detected from the previously approved study.

More often than not, these notification boxes will signal that a new version of an existing document has been generated (e.g. research protocol, consent document). The next slide will provide instructions on how access the revised documents.

IMPORTANT! All modifications must be added to the written protocol. As part of your review, you will need to verify that the revised protocol continues to meet the criteria for approval.

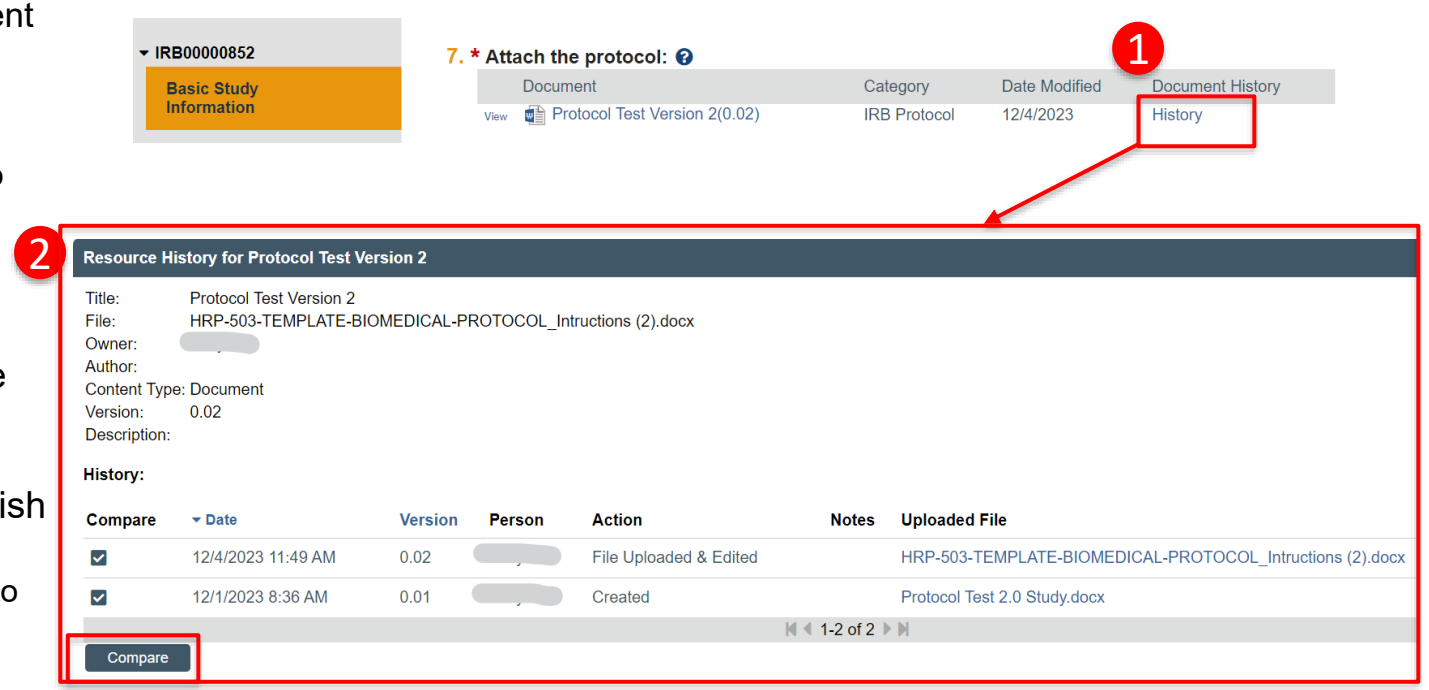


Instructions for reviewing a modification and/or continuing review

If you are reviewing a modification, you may use the document history to access and compare different versions of a document.

1. To view the history of a document, click **History** and a popup window will appear.

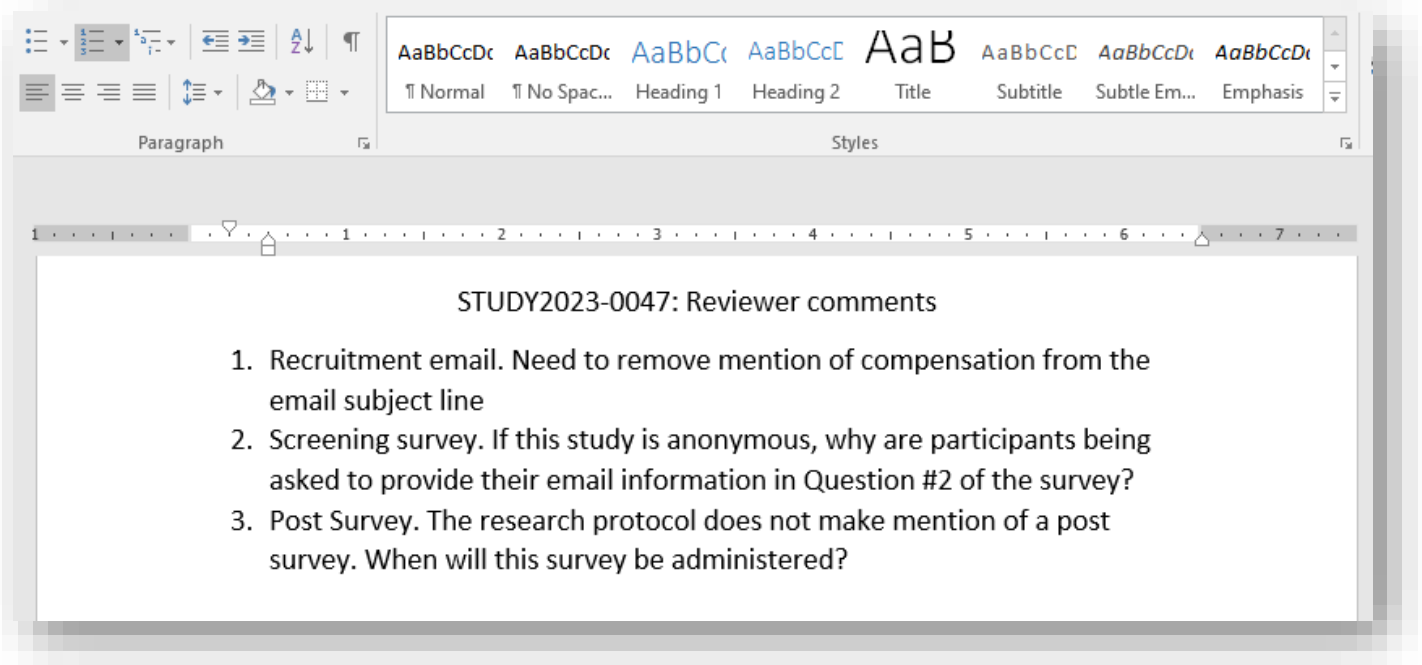
2. From the popup window, you will be able to access and compare different versions of the document:
   - **To view a document**, click on the name of the document. A copy of the document will automatically download to your computer.
   - **To compare, s**elect the two documents you wish to compare and click **Compare**.
     - A Word document will automatically download to your computer. The document will use Tracked Changes to identify any changes detected between the two selected items.
     - ***Note:*** The compare function is only available for Word documents.



Documenting your reviewer comments

- During your review of the study documents, you may use Tracked Changes and comments to request modifications or additional information, if the format of the document allows it (i.e., Word documents). Visit Slide 12 for links that explain how to use these functions in Word.

- Otherwise, you may opt to write down your comments on a separate Word document. You will have the opportunity to upload your saved comments to the reviewer form prior to completing your review.

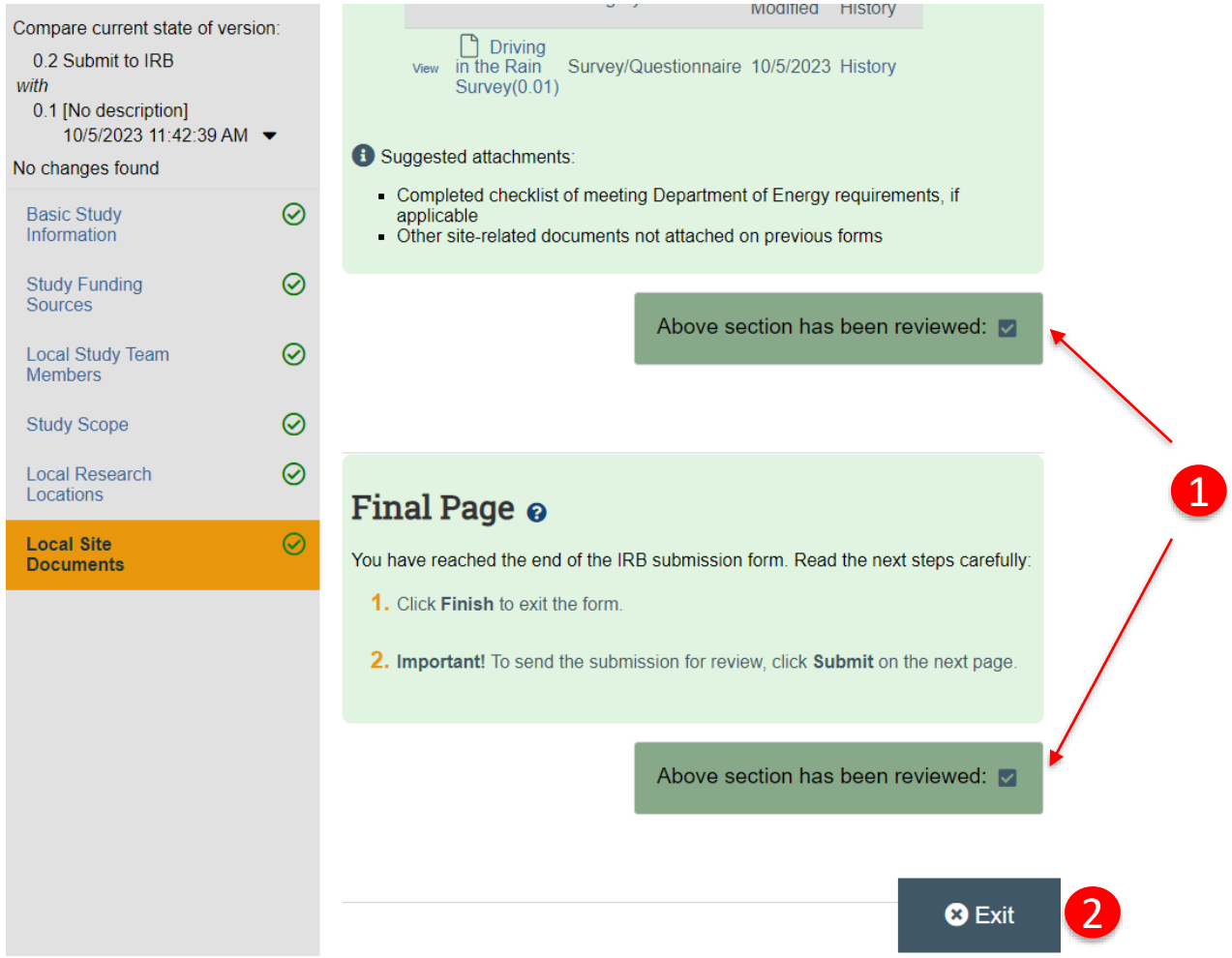


Finalizing your review

After you have completed your review of the submission.

To finalize your review:

1. Select the **check-box** at the bottom of each section of the submission.
   - Once you select the check-box, the section will turn green.
   - Select all the check-boxes.
2. Click **Exit**



Finalizing your review:

Non-Committee Review / Expedited Review

From the Study Workspace for a non-committee review, you will have the option to:

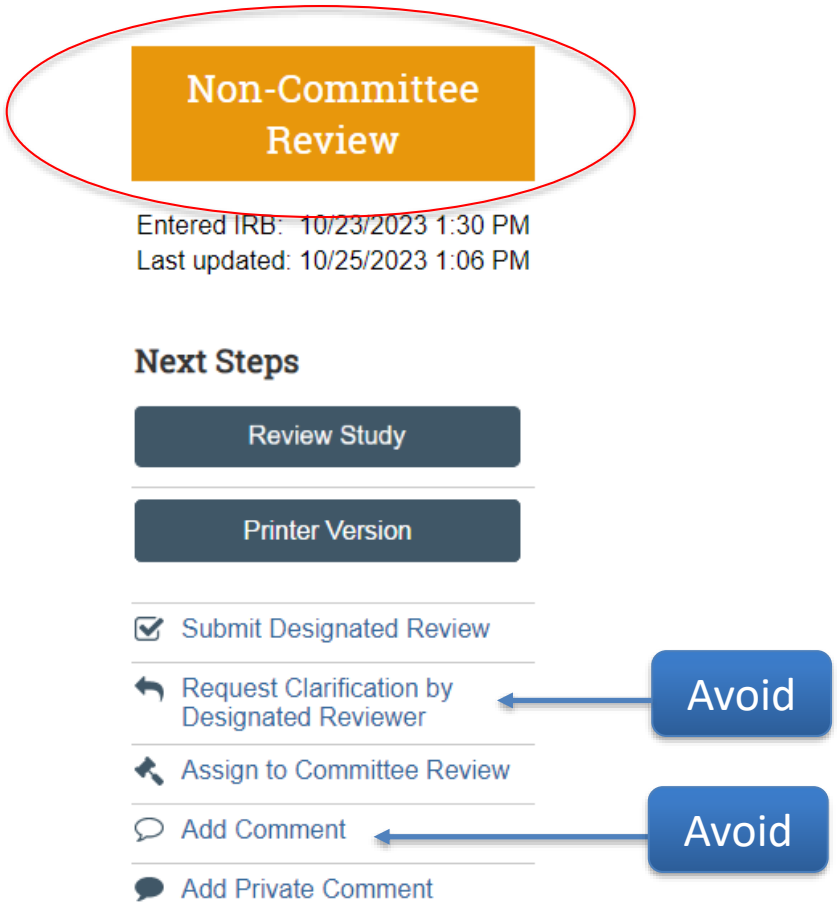
1. **Submit Designated Review**. This option sends your review to the IRB coordinator. This option guarantees your anonymity as the reviewer. The next slide walks you through the steps for submitting your designated review in Huron.

2. **Request Clarifications by Designated Reviewer**. This option allows the reviewer to request clarifications from the researcher without routing through the IRB coordinator. This option is ***highly discouraged*** as it will disclose your identify as the reviewer to the research team.

3. **Assign to Committee Review.** Select this option if the study needs to be seen by the convened board.

4. **Add comment**. This option allows you to post a public comment that may be seen by everyone with access to the protocol, including the research team. This option is ***not recommended***, as it will disclose your identify as the reviewer.

5. **Add a private comment.** This option allows you to post a comment that may be seen by the IRB Coordinator, Assigned Reviewers, and/or IRB Director. Use this option to communicate with other assigned reviewers.



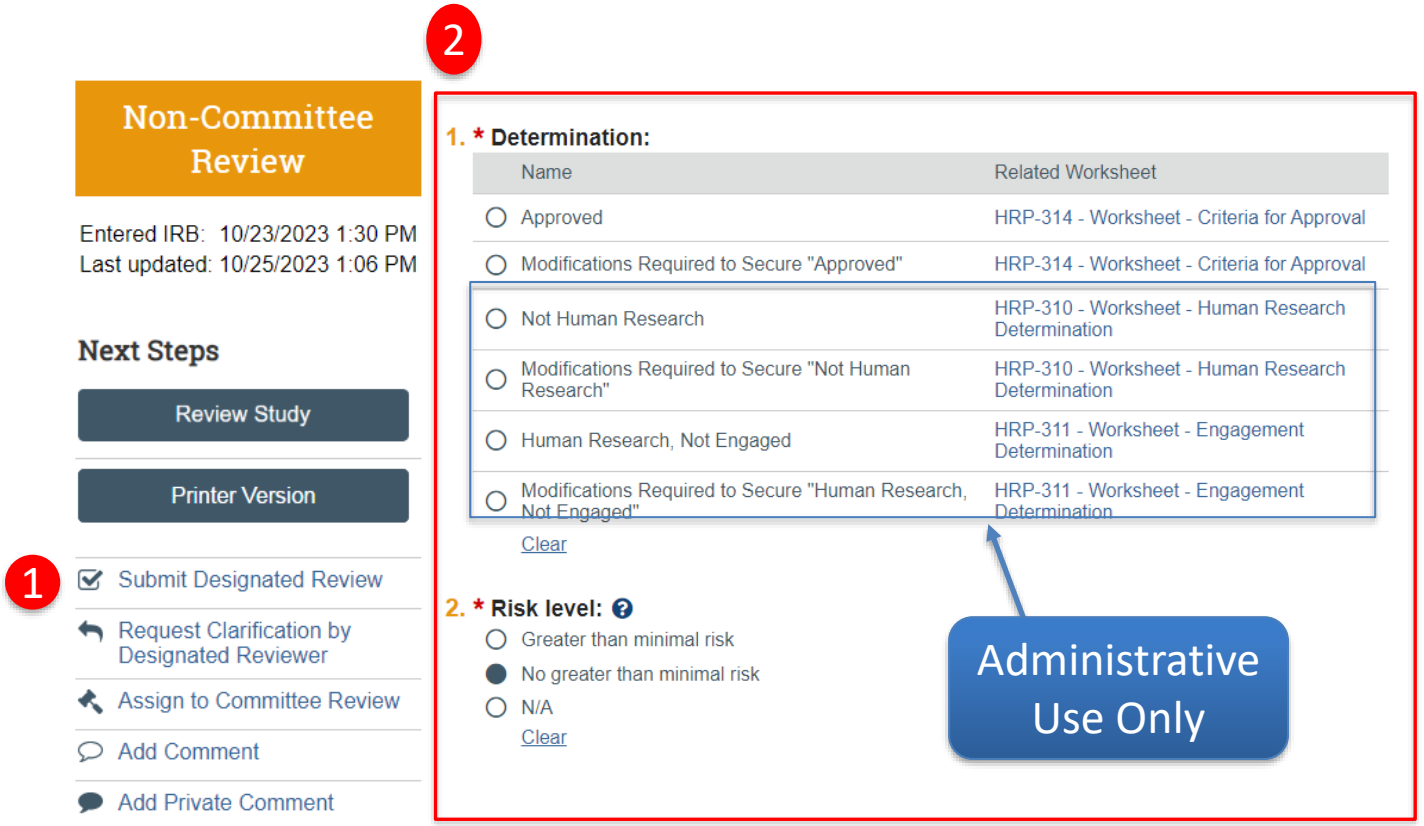
Finalizing your review:
Non-Committee Review

To submit your designated review:

1. Click **Submit Designated Review** and a pop-up form will appear.
2. Complete the pop-up form titled **Submit Designated Review**:

Q1 :
- Select ***Approved*** if the submission is ready for approval and no additional changes are required; **OR**
- Select ***Modifications Required to Secure Approved*** if changes are needed to the submission prior to approval.
- Note: Not Human Subjects determinations are for administrative use only

Q2:
- An answer should already be populated. This answer corresponds to the risk level originally assigned to the study.
- **IMPORTANT!** If you are reviewing a study that was originally found to be minimal risk, and you believe the current submission increases the risk of the study to Greater than minimal risk, exit the designated reviewer form by selecting ***Cancel*** at end of the form. This will return you to the Study Workspace. From the Study Workspace, select ***Assign to Committee Review***.



Finalizing your review:
Non-Committee Review

- Complete the pop-up form titles **Submit Designated Review**:

Q3:
- An answer should already be populated. Please do not edit this response prior to consulting with IRB staff.

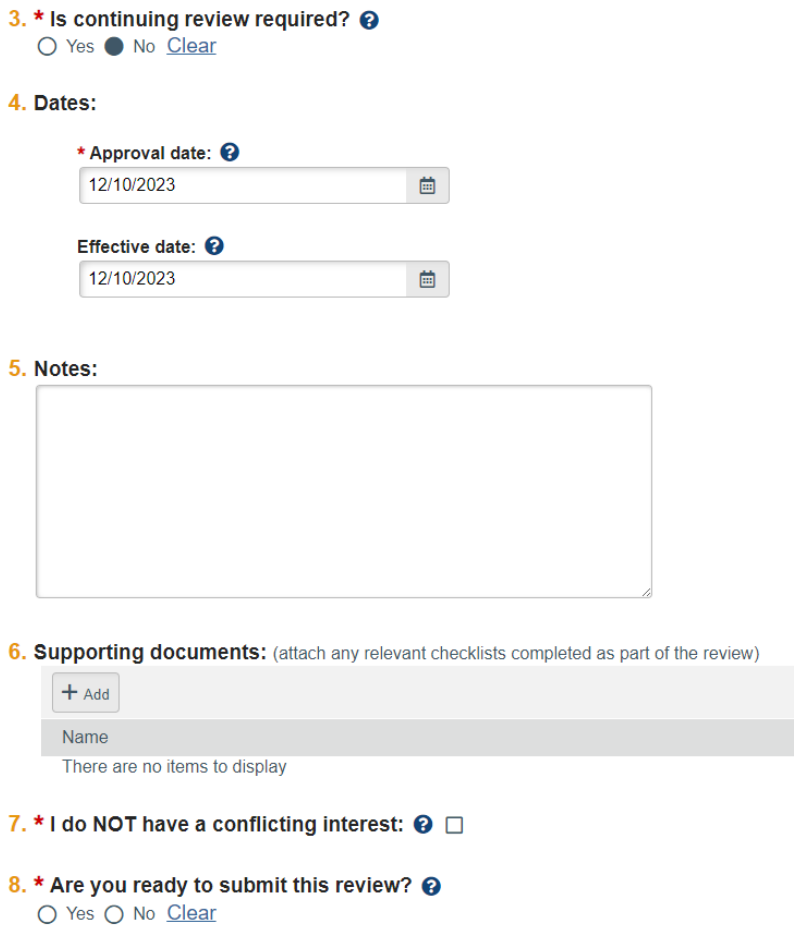
Q4:
- This date is auto-generated and is based on the date of approval.

Q5:
- This space is provided to enter any required modifications to secure approval .
- **If you documented your reviewer comments in a Word document**, indicate that you have attached your comments as a separate Word document and attach your reviewer comments in Q6.

Q6:
- Attach any documents that require modifications to secure approval, for example: protocol with Tracked Changes and Comments, consent document with Tracked Changes and Comments, Reviewer Comments in Word document.

Q7:
- Select the check-box if you do not have a conflict of interest.

Q8:
- Select **Yes** if you are ready to submit your review.



Finalizing your review:
Committee Review

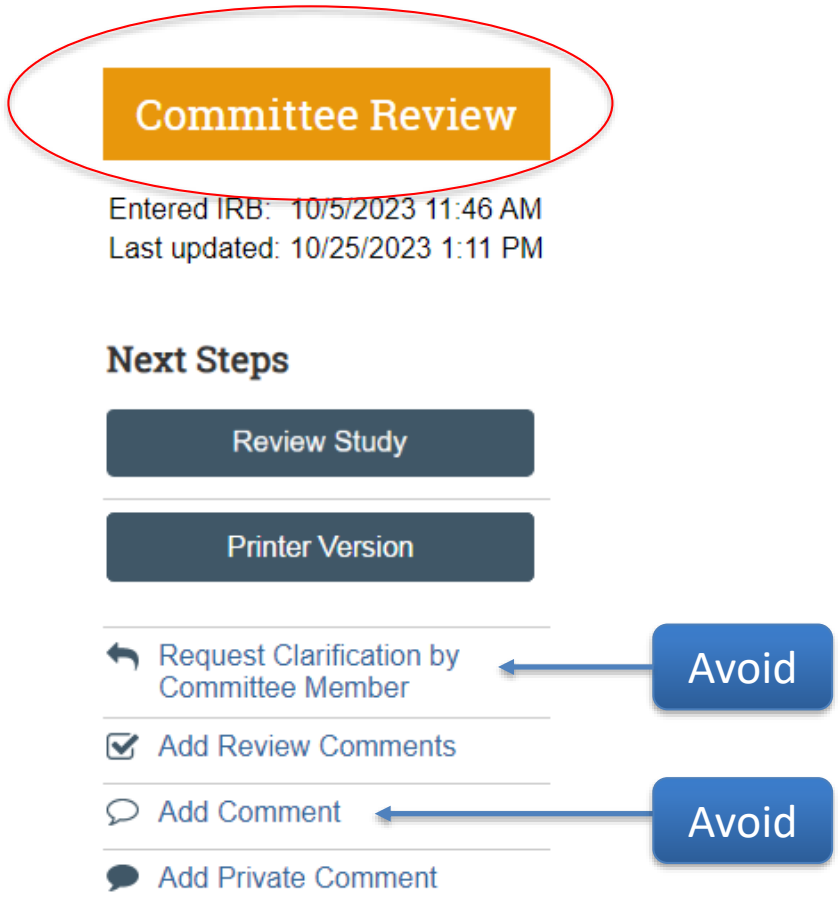
From the Study Workspace for a committee review, you will have the option to:

1. **Request Clarifications by Designated Reviewer**. This option allows the reviewer to request clarifications from the researcher without routing through the IRB coordinator. This option is ***highly discouraged*** as it will disclose your identify as the reviewer to the research team.

2. **Add Reviewer comments:** Use this option to share your reviewer and reviewer comments.

3. **Add comment**. This option allows you to post a public comment that may be seen by everyone with access to the protocol, including the research team. This option is ***not recommended***, as it will disclose your identify as the reviewer.

4. **Add a private comment.** This option allows you to post a comment that may be seen by the IRB Coordinator, Assigned Reviewers, and/or IRB Director. You may use this option to ask a question from the IRB Coordinator during your review.



Finalizing your review:
Committee Review

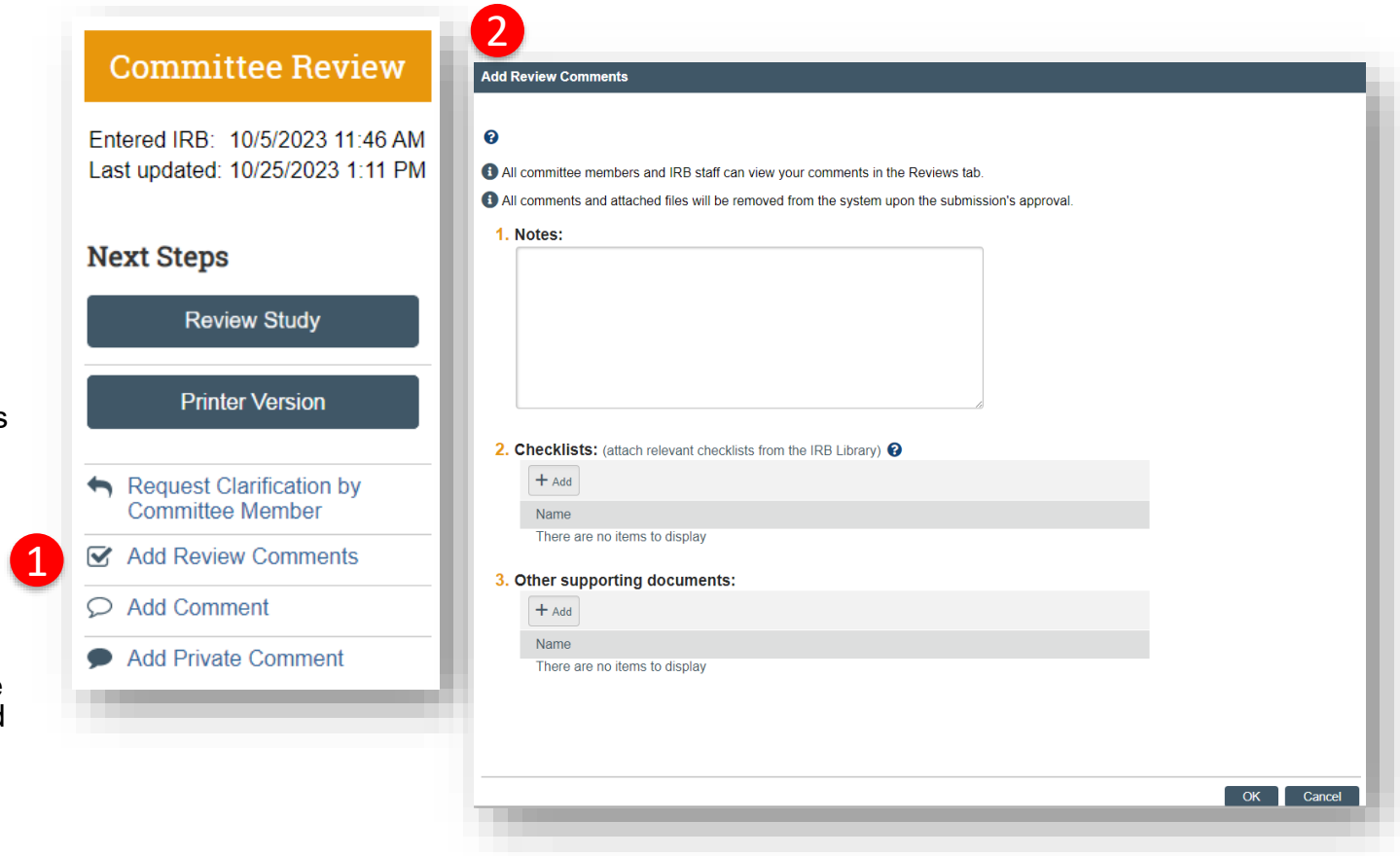
Submitting your reviewer comments:

1. Click Add Reviewer Comments and a pop-up form will appear.
2. Complete the pop-up form titled Add Reviewer Comment:

Q1
- This space is provided to enter your comments.
- If you documented your reviewer comments in a Word document, indicate that you have attached your comments as a separate Word document and attach your reviewer comments in Q3.

Q2
- Checklists are normally attached by IRB staff. Unless otherwise instructed by IRB staff, you may skip this question

Q3:
- Attach any documents that require modifications to secure approval, for example: protocol with Tracked Changes and Comments, consent document with Tracked Changes and Comments, Reviewer Comments in Word document.



Finalizing your review:
Committee Review

Once you have submitted your reviewer comments, other committee members will have access to your comments under the **Reviewer** tab.