

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.

Page for Heather Cline

Create ▾

Recently Viewed

Recent Pinned

- STUDY2023-0039: Student Success
- STUDY2023-0040: Print

My Inbox

Filter by ID Enter text to search + Add Filter

Clear All

ID	Name	Date Created	Date Modified	State	Coordinator
STUDY2023-0039	Student Success	6/14/2023 9:06 AM	6/16/2023 1:08 PM	Pre-Submission	
DP00011202	Disclosure Profile for Heather Cline	12/15/2022 12:08 PM	4/7/2023 2:17 AM	Action Required	Heather Cline

2 items

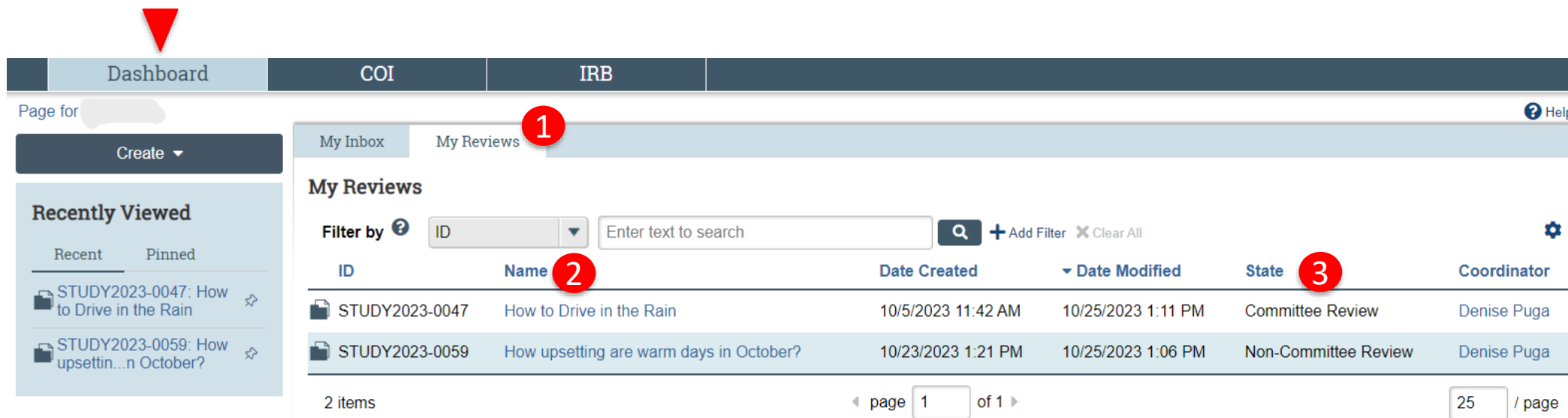
page 1 of 1

25 / page

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.



The screenshot shows the UCI Research Administration dashboard. At the top, there are tabs for 'Dashboard', 'COI', and 'IRB'. Below these, there's a 'Page for' section and a 'Create' button. On the left, there's a 'Recently Viewed' section with two items: 'STUDY2023-0047: How to Drive in the Rain' and 'STUDY2023-0059: How upsetting...n October?'. The main content area is titled 'My Reviews' and has a sub-tab 'My Reviews' (highlighted with a red circle 1). Below this, there's a 'Filter by' section with a dropdown menu set to 'ID' and a search bar. The main table has columns: 'ID', 'Name' (highlighted with a red circle 2), 'Date Created', 'Date Modified', 'State' (highlighted with a red circle 3), and 'Coordinator'. The table contains two rows of data. At the bottom, there's a pagination bar showing '2 items', 'page 1 of 1', and '25 / page'.

ID	Name	Date Created	Date Modified	State	Coordinator
STUDY2023-0047	How to Drive in the Rain	10/5/2023 11:42 AM	10/25/2023 1:11 PM	Committee Review	Denise Puga
STUDY2023-0059	How upsetting are warm days in October?	10/23/2023 1:21 PM	10/25/2023 1:06 PM	Non-Committee Review	Denise Puga

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.

Non-Committee Review

Entered IRB: 10/23/2023 1:30 PM
Last updated: 10/25/2023 1:06 PM

Next Steps

- Review Study
- Printer Version
- ☒ Submit Designated Review
- ☐ Request Clarification by Designated Reviewer
- ☐ Assign to Committee Review
- Add Comment
- Add Private Comment

STUDY2023-0059: How upsetting are warm days in October?

Principal investigator: Denise Puga
Submission type: Initial Study
Primary contact: Denise Puga
PI proxies:

IRB office: IRB 1
IRB coordinator: Denise Puga
Regulatory authority: 2018 Requirements

PI Department: Research Compliance & Biosafety

Pre-Submission → Pre-Review → **IRB Review** → Post-Review → Review Complete

Clarification Requested → Clarification Requested → Modifications Required

History Funding Contacts COI Documents IRB Assignment Details Reviews Snapshots Training

Filter by ? Activity ▼ Enter text to search 🔍 + Add Filter ✕ Clear All

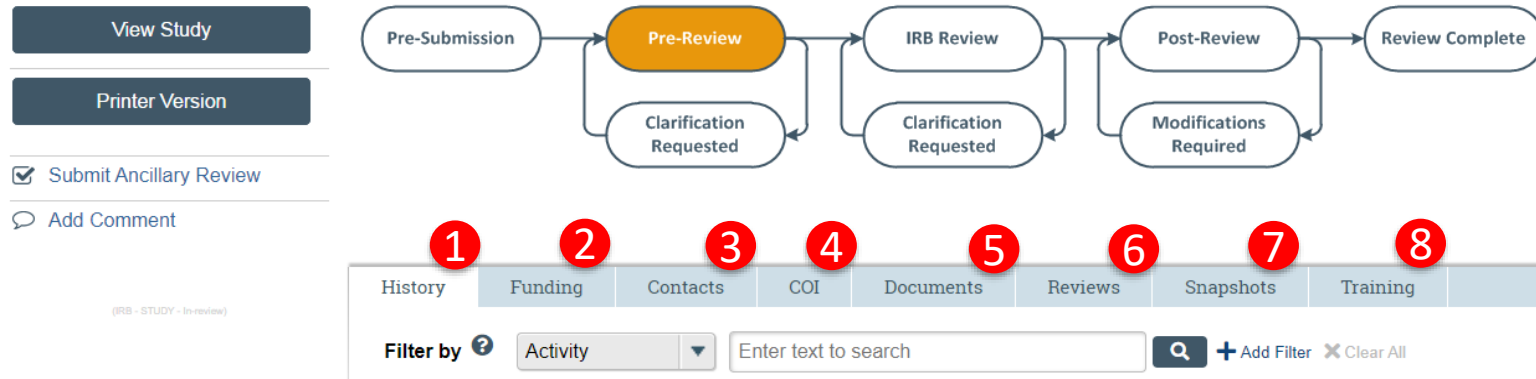
Non-Committee Review

Entered IRB: 11/13/2023 8:58 AM
Last updated: 11/13/2023 9:01 AM

Next Steps

- Review Modification/CR
- Printer Version

Study Workspace



- History:** This tab lists the activity taken on a submission including any comments, attachments, correspondence.
- Funding:** Provides all funding sources associated with the submission along with related grant information, if applicable.
- Contacts:** This tab lists all UCI individuals with study involvement (i.e., PI, Study Team, Other Study Members, Guests).
- COI:** This tab identifies the status of any conflict of interest and how it is managed.
- Documents:** This tab includes all study related and site related documents including documents on drugs, devices, and international research, if applicable.
- 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.
- Snapshots:** Provides a snapshot of the entire study including attachments submitted at different states of the submission (e.g, approved stated, pre-submission state).
- 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.

History	Contacts	COI	Documents	IRB Assignment Details	Reviews	Related RNIs
---------	----------	-----	-----------	------------------------	---------	--------------

Filter by ?



Activity ▼

Enter text to search

Q

+ Add Filter

✕ Clear All

Activity	Author
 Assigned to Designated Reviewer	Puga, Denise A
Assigned Designated Reviewer	
Dr. Jane Doe - the PI has requested a waiver of documentation of consent. Please see the attached worksheet.	
 HRP-411 - CHECKLIST - Waiver of Written Documentation of Consent.docx	

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.

The screenshot displays the IRB review interface. On the left, the **Left Navigator** is visible, with the **Basic Study Information** section highlighted in orange. A red box and a red arrow point to this section, with a red circle containing the number '2' next to it. The main content area shows the **Basic Study Information** section for study **STUDY2023-0047**. The section includes the following fields:

- 1. **Title of study:** Driving in the Rain
- 2. **Short title:** How to Drive in the Rain
- 3. **Brief description:** test test test
- 4. **What kind of study is this?** Single-site study
- 5. **Will an external IRB act as the IRB of record for this study?** Yes No
- 6. **Local principal investigator:** Jane Seawright
- 7. **Attach the protocol:** Driving in the Rain Protocol(0.01)

At the bottom right, there is a table with the following data:

Document	Category	Date Modified	Document History
View Driving in the Rain Protocol(0.01)	IRB Protocol	10/5/2023	History

Committee Review

Entered IRB: 10/5/2023 11:46 AM
Last updated: 10/25/2023 1:11 PM

Next Steps

1

Review Study

Printer Version

Request Clarification by
Committee Member

Add Review Comments

Add Comment

Add Private Comment

Above section has been reviewed: ☐

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

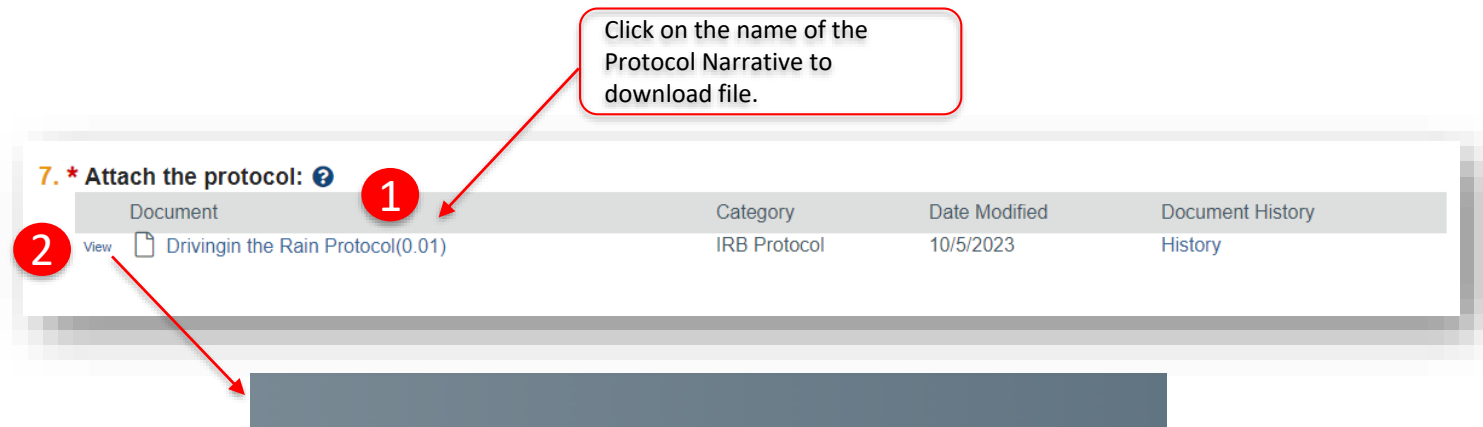
How to download the Protocol Narrative

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.



View Attachment

1. * File to attach:

[Driving in the Rain Protocol\(0.01\)](#) ...

2. Name: (if not supplied, the file name will be shown) ?

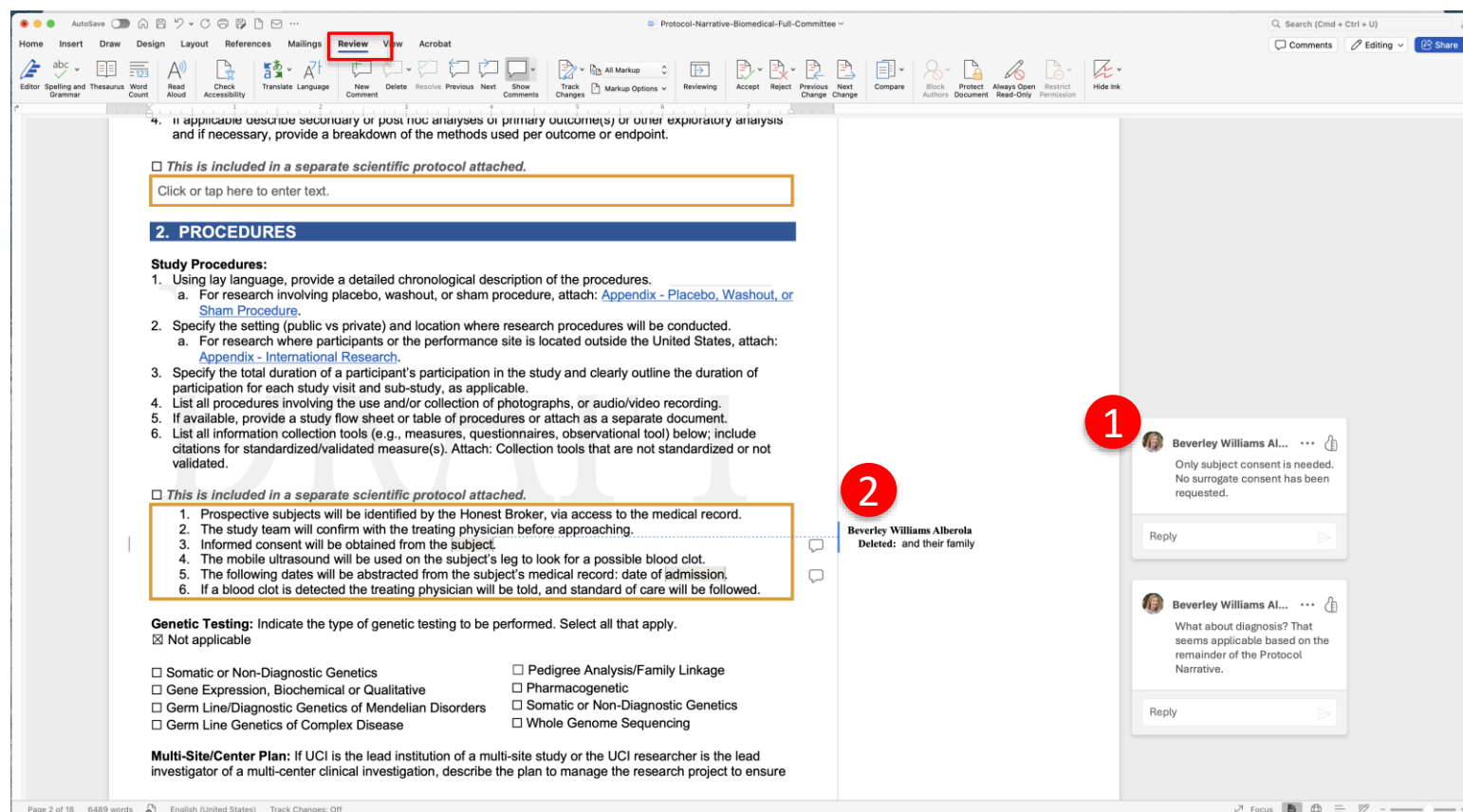
[Driving in the Rain Protocol](#)

3. Version number:

Protocol Narrative Review

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

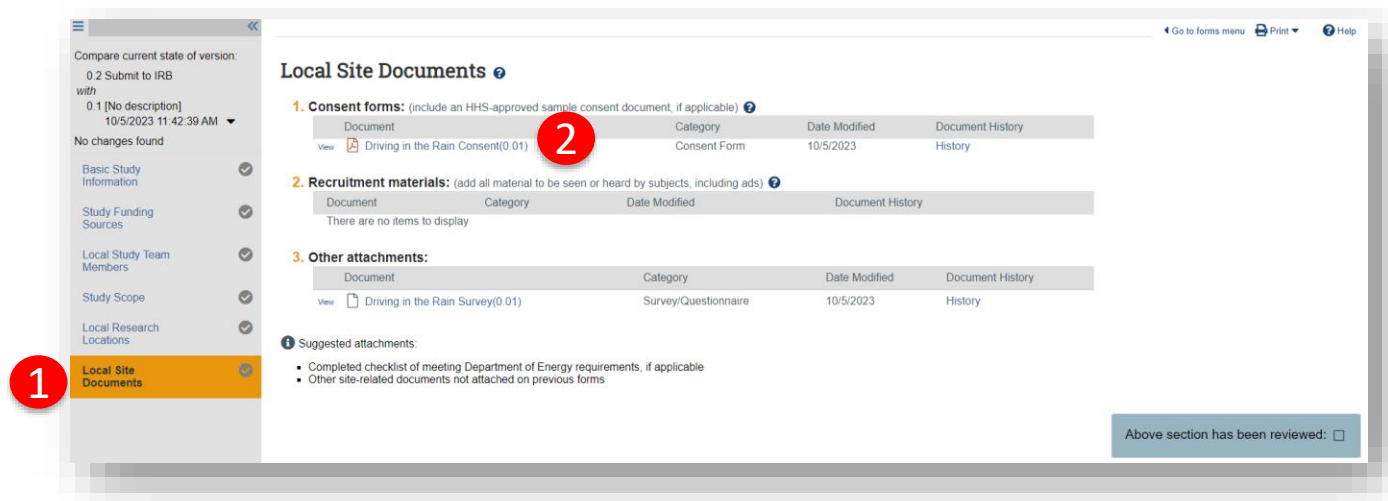
1. **New Comment.** As you review the study protocol, you may add comments directly to the Word document to request additional information or clarifications.
2. **Tracked Changes.** Reviewers may suggest edits to the protocol to secure approval using Track Changes.
3. **Save all comments and tracked changes.** Once you have completed your review of the Protocol Narrative, save a copy of the revised document.



How to download study documents

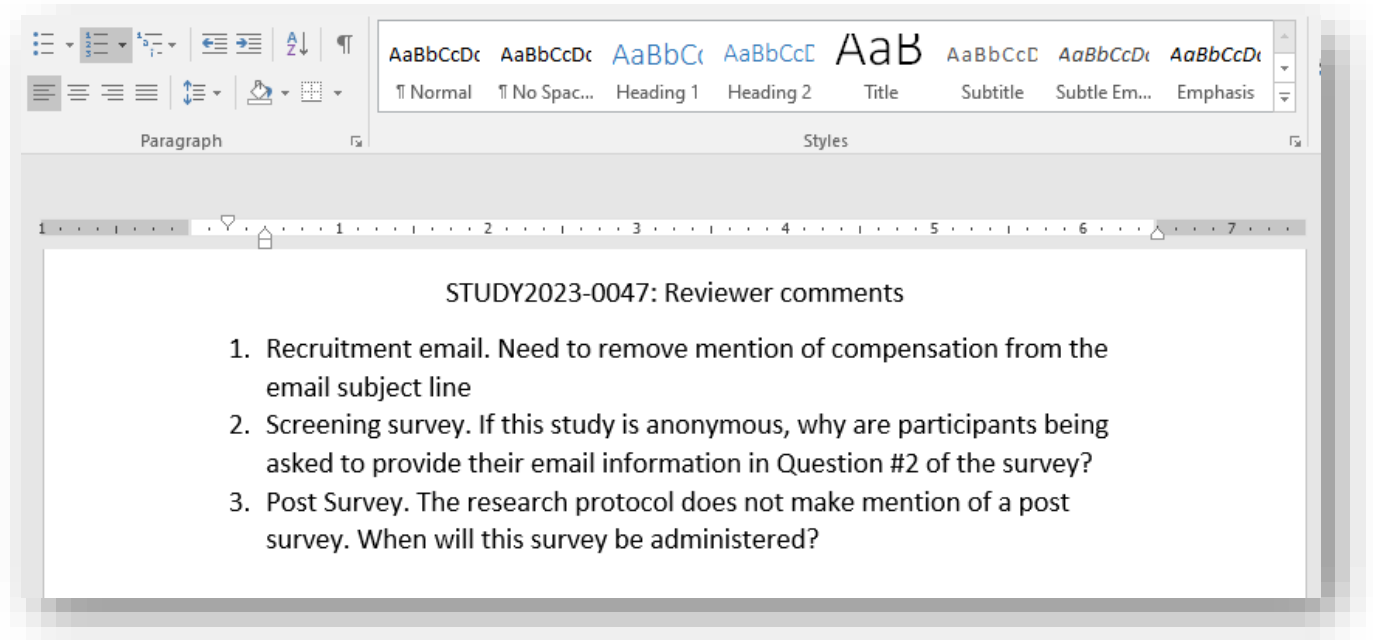
Important study documents, such as consent forms, recruitment materials, and data collecting instruments are located in the **Local Site Documents** page. To access these files:

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 through 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**

Compare current state of version:

0.2 Submit to IRB
with
0.1 [No description]
10/5/2023 11:42:39 AM ▼

No changes found

- Basic Study Information ☒
- Study Funding Sources ☒
- Local Study Team Members ☒
- Study Scope ☒
- Local Research Locations ☒
- Local Site Documents ☒

Modified History

View Driving in the Rain Survey/Questionnaire 10/5/2023 History Survey(0.01)

Suggested attachments:

- Completed checklist of meeting Department of Energy requirements, if applicable
- Other site-related documents not attached on previous forms

Above section has been reviewed: ☒

Final Page ⓘ

You have reached the end of the IRB submission form. Read the next steps carefully:

1. Click **Finish** to exit the form.
2. **Important!** To send the submission for review, click **Submit** on the next page.

Above section has been reviewed: ☒

Exit

1

2

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.

Non-Committee Review

Entered IRB: 10/23/2023 1:30 PM
Last updated: 10/25/2023 1:06 PM

Next Steps

Review Study

Printer Version

☒ Submit Designated Review

 Request Clarification by Designated Reviewer

 Assign to Committee Review

 Add Comment

 Add Private Comment

Avoid

Avoid

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**.

The screenshot shows the 'Submit Designated Review' form. A red box highlights the form area, with a red circle containing the number '2' at the top right. A red circle containing the number '1' is positioned to the left of the 'Next Steps' section.

Dashboard

Submissions | Meetings

IRB > How upsetting are warm days

Non-Committee Review

Entered IRB: 10/23/2023 1:30 PM
Last updated: 11/28/2023 1:41 PM

Next Steps

[Review Study](#)

[Printer Version](#)

☒ [Submit Designated Review](#)

[Request Clarification by Designated Reviewer](#)

[Assign to Committee Review](#)

[Add Comment](#)

[Add Private Comment](#)

Submit Designated Review

1. * Determination:

Name	Related Worksheet
<input type="radio"/> Approved	HRP-314 - Worksheet - Criteria for Approval
<input type="radio"/> Modifications Required to Secure "Approved"	HRP-314 - Worksheet - Criteria for Approval
<input type="radio"/> Not Human Research	HRP-310 - Worksheet - Human Research Determination
<input type="radio"/> Modifications Required to Secure "Not Human Research"	HRP-310 - Worksheet - Human Research Determination
<input type="radio"/> Human Research, Not Engaged	HRP-311 - Worksheet - Engagement Determination
<input type="radio"/> Modifications Required to Secure "Human Research, Not Engaged"	HRP-311 - Worksheet - Engagement Determination

[Clear](#)

2. * Risk level: ?

☐ Greater than minimal risk

☐ No greater than minimal risk

☐ N/A

[Clear](#)

3. * Is continuing review required? ?

☐ Yes ☐ No [Clear](#)

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.

3. * Review level:

Name	Related Worksheet
<input type="radio"/> Exempt	HRP-312 - Worksheet - Exemption Determination
<input checked="" type="radio"/> Expedited	HRP-313 - Worksheet - Expedited Review

[Clear](#)

4. * Indicate the categories: (see HRP-313 for full regulatory criteria, check all that apply)

- ☐ (1)(a) Drug studies
- ☐ (1)(b) Device studies
- ☐ (2)(a) Blood samples from healthy, non-pregnant adults
- ☐ (2)(b) Blood samples from others
- ☐ (3) Noninvasive biological specimens
- ☐ (4) Noninvasive procedures
- ☐ (5) Data, documents, records, or specimens
- ☐ (6) Voice, video, digital, or image recordings
- ☐ (7)(a) Behavioral research
- ☐ (7)(b) Social science methods
- ☐ (8)(a) Long-term follow-up
- ☐ (8)(b) No subjects enrolled
- ☐ (8)(c) Data analysis
- ☐ (9) Convened IRB determined minimal risk
- ☐ Other

5. * Is continuing review required? [?](#)

☐ Yes ☐ No [Clear](#)

6. Dates:

* Approval date: [?](#)

11/28/2023 [📅](#)

Effective date: [?](#)

11/28/2023 [📅](#)

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.

7. * Enter required modifications below: ?

Changes are requested to the protocol (see attached protocol with comments).

Changes are requested to the consent document (see attached consent document with Tracked Changes and Comments).

Additional reviewer comments are attached (see attached reviewer comments).

8. Notes:

9. Supporting documents: (attach any relevant checklists completed as part of the review)

+ Add

Name

Consent document with comments(0.01)

Protocol with reviewer comments(0.01)

Reviewer comments (0.01)

10. * I do NOT have a conflicting interest: ? ☒

11. * Are you ready to submit this review? ?

☒ Yes ☐ No [Clear](#)

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.

Committee Review

Entered IRB: 10/5/2023 11:46 AM

Last updated: 10/25/2023 1:11 PM

Next Steps

Review Study

Printer Version

Request Clarification by
Committee Member

Avoid

✓ Add Review Comments

Add Comment

Avoid

Add Private Comment

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:

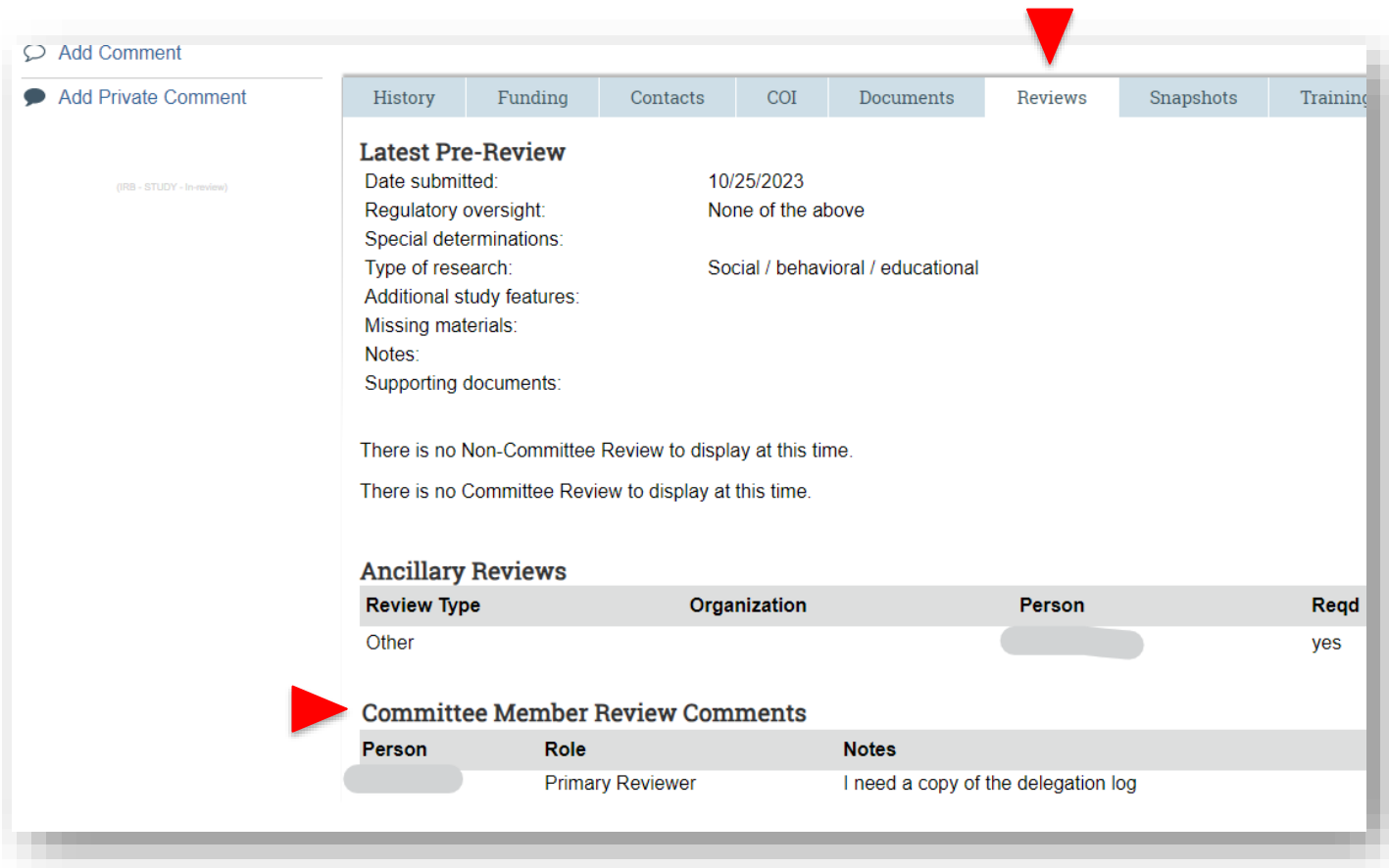
- Attach any documents that require modifications to secure approval, for example: protocol with Tracked Changes and Comments, consent document with Tracked Changes and Comments, Reviewer Comments in Word document.

The image shows two overlapping screenshots of a web application. The background screenshot, labeled with a red circle '1', is the 'Committee Review' form. It has an orange header with the title 'Committee Review'. Below the header, it shows 'Entered IRB: 10/5/2023 11:46 AM' and 'Last updated: 10/25/2023 1:11 PM'. Under a 'Next Steps' section, there are four buttons: 'Review Study', 'Printer Version', 'Request Clarification by Committee Member' (with a blue arrow icon), and 'Add Review Comments' (with a blue checkmark icon). The 'Add Review Comments' button is highlighted with a red circle '1'. The foreground screenshot, labeled with a red circle '2', is the 'Add Review Comments' pop-up form. It has a dark grey header with the title 'Add Review Comments'. Below the header, there is a help icon and two informational messages. The first message is '1. Notes:' followed by a large text area. The second message is '2. Checklists: (attach relevant checklists from the IRB Library)' followed by a '+ Add' button, a 'Name' field, and the text 'There are no items to display'. The third message is '3. Other supporting documents:' followed by a '+ Add' button, a 'Name' field, and the text 'There are no items to display'. At the bottom right of the pop-up form are 'OK' and 'Cancel' buttons.

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.



UCI Research Administration interface showing the 'Reviews' tab. The interface includes a sidebar with 'Add Comment' and 'Add Private Comment' options. The main content area displays the 'Latest Pre-Review' section with fields for Date submitted, Regulatory oversight, Special determinations, Type of research, Additional study features, Missing materials, Notes, and Supporting documents. Below this, there are messages indicating no Non-Committee or Committee reviews are currently displayed. The 'Ancillary Reviews' section shows a table with columns for Review Type, Organization, Person, and Required. The 'Committee Member Review Comments' section shows a table with columns for Person, Role, and Notes.

Review Type	Organization	Person	Reqd
Other			yes

Person	Role	Notes
	Primary Reviewer	I need a copy of the delegation log

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.

Non-Committee Review

Entered IRB: 11/13/2023 8:58 AM
Last updated: 11/13/2023 9:01 AM

Next Steps

1 Review Modification/CR

Printer Version

Compare current state of version:
0.3 Submit to IRB
with
0.2 [No description]
12/9/2023 9:45:05 PM
Changes found on 1 step:

- Modification / Continuing Review ✓
- Continuing Review / Study Closure Information ✓
- Modification Summary ✓
- Modification Details

Reviewing: MODCR00000001

Modification / Continuing Review / Study Closure

*** What is the purpose of this submission?** **2**

☐ Continuing Review

☐ Modification / Update

☒ Modification and Continuing Review

Modification scope:
Study team member information
Other parts of the study

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.

Compare current state of version:
0.3 Submit to IRB
with
0.2 [No description]
12/9/2023 9:45:05 PM ▼
Changes found on 1 step:

Modification / Continuing Review ✓

Continuing Review / Study Closure Information ✓

Modification Summary ✓

Modification Details

▼ IRB00000237

Basic Study Information ✎ ✓

Study Funding Sources ✓

Local Study Team Members ✓

Study Scope ✓

Local Research Locations ✓

Local Site Documents ✓

Continuing Review / Study Closure Information

1. * Specify enrollment totals at this investigator's sites: ?
100
2. * Specify enrollment totals at this investigator's sites since last approval:
100
3. * Specify enrollment totals study-wide: ?
100
4. Research milestones: (select all that apply) ?
 - ☐ Study is permanently closed to enrollment OR was never open for enrollment
 - ☐ All subjects have completed all study-related interventions OR not applicable (e.g. study did not include interventions, no subjects were enrolled)
 - ☐ Collection of private identifiable information is complete OR not applicable (no subjects were enrolled)
 - ☐ Analysis of private identifiable information is complete OR not applicable (no subjects were enrolled)
 - ☐ Remaining study activities are limited to data analysis
 - ☐ Study remains active only for long-term follow-up of subjects

Important! If the first four research milestones above are complete, the study will be closed to discontinue IRB oversight.
5. Check the items that are true since the last IRB approval for all sites involved in the study: (initial review or last continuing review)
 - ☒ NO subjects experienced unexpected harm
 - ☒ Anticipated adverse events have NOT taken place with greater frequency or severity than expected
 - ☒ NO subjects withdrew from the study
 - ☒ NO unanticipated problems involving risks to subjects or others
 - ☒ NO complaints about the study
 - ☒ NO publications in the literature relevant to risks or potential benefits
 - ☒ NO interim findings
 - ☒ NO multi-center trial reports

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.



Compare current state of version:
0.3 Submit to IRB
with
0.2 [No description]
12/9/2023 9:45:05 PM ▼
Changes found on 1 step:

Modification / Continuing Review ✓

Continuing Review / Study Closure Information ✓

Modification Summary ✓

Modification Details

▼ IRB00000237

Basic Study Information ✎ ✓

Modification Information

- Study enrollment status:**
 - ☒ No subjects have been enrolled to date
 - ☐ Subjects are currently enrolled
 - ☐ Study is permanently closed to enrollment
 - ☐ All subjects have completed all study-related interventions
 - ☐ Collection of private identifiable information is complete
- Notification of subjects:** (check all that apply)
 - ☒ Current subjects will be notified of these changes
 - ☐ Former subjects will be notified of these changes

i Attach files: If notifying subjects, add a description of how they will be notified
- * Summarize the modifications:** **?**
I want to increase participant enrollment to 200.

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.

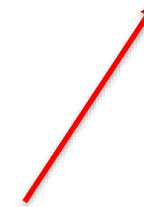
More often than not, these notification boxes will signal that a new version of an existing document has been generated (e.g. research protocol, consent document). The next slide will provide instructions on how access the revised documents.

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.

Continuing Review / Study Closure Information
Modification Summary
Modification Details
IRB00000237
Basic Study Information
Study Funding Sources

7. * Attach the protocol: ?

Document	Category	Date Modified	Document History
View HRP-503-TEMPLATE-BIOMEDICAL-PROTOCOL_Intructions (2).docx(0.01)	IRB Protocol	12/9/2023	History
<div><div>▼ Differences</div><div><div>ME</div><div>modified 16 minutes ago • version 0.2 (MODCR00000001: Modification submitted to IRB)</div><div>▶ Added: HRP-503-TEMPLATE-BIOMEDICAL-PROTOCOL_Intructions (2).docx</div></div></div>			



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**, select 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.

The screenshot displays the UCI Research Administration interface. On the left, a sidebar shows 'IRB00000852' and 'Basic Study Information'. The main area shows a document titled 'Protocol Test Version 2(0.02)' with a category of 'IRB Protocol' and a date modified of '12/4/2023'. A red box labeled '1' highlights the 'Document History' link in the top right corner. Below this, a popup window titled 'Resource History for Protocol Test Version 2' is shown, with a red box labeled '2' highlighting the 'Compare' button at the bottom left. The popup window contains the following information:

Title: Protocol Test Version 2
File: HRP-503-TEMPLATE-BIOMEDICAL-PROTOCOL_Intructions (2).docx
Owner: [Redacted]
Author: [Redacted]
Content Type: Document
Version: 0.02
Description: [Redacted]

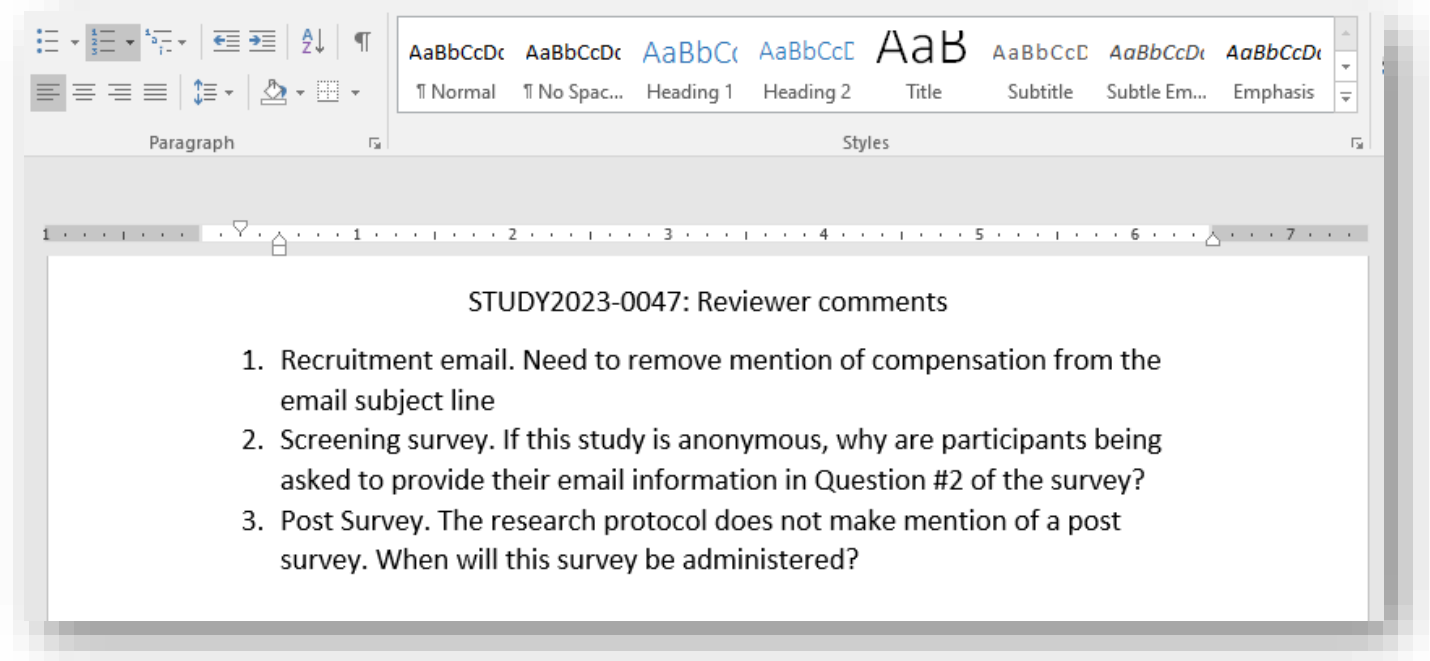
History:

Compare	Date	Version	Person	Action	Notes	Uploaded File
<input checked="" type="checkbox"/>	12/4/2023 11:49 AM	0.02	[Redacted]	File Uploaded & Edited		HRP-503-TEMPLATE-BIOMEDICAL-PROTOCOL_Intructions (2).docx
<input checked="" type="checkbox"/>	12/1/2023 8:36 AM	0.01	[Redacted]	Created		Protocol Test 2.0 Study.docx

At the bottom of the popup window, there is a 'Compare' button and a pagination indicator '1-2 of 2'.

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**

Compare current state of version:
0.2 Submit to IRB
with
0.1 [No description]
10/5/2023 11:42:39 AM ▼
No changes found

Basic Study Information	✓
Study Funding Sources	✓
Local Study Team Members	✓
Study Scope	✓
Local Research Locations	✓
Local Site Documents	✓

Modified History

View Driving in the Rain Survey/Questionnaire 10/5/2023 History Survey(0.01)

Suggested attachments:

- Completed checklist of meeting Department of Energy requirements, if applicable
- Other site-related documents not attached on previous forms

Above section has been reviewed: ☒

Final Page ⓘ

You have reached the end of the IRB submission form. Read the next steps carefully:

1. Click **Finish** to exit the form.
2. **Important!** To send the submission for review, click **Submit** on the next page.

Above section has been reviewed: ☒

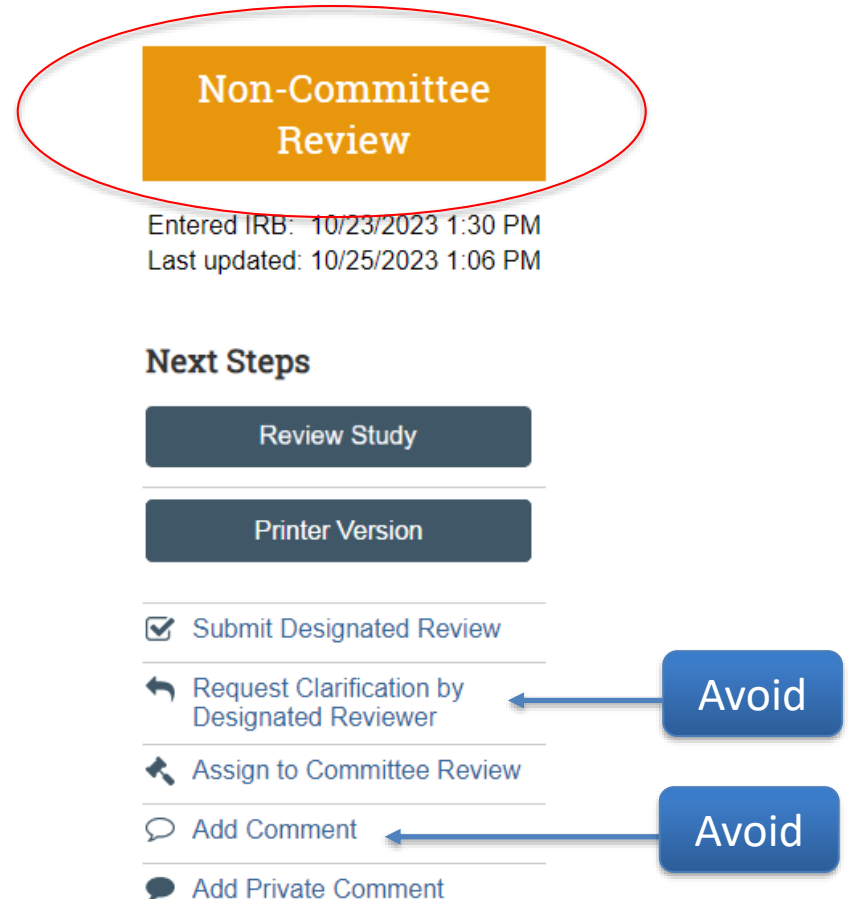
Exit 2

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.



The screenshot displays the IRB review interface. At the top, an orange button labeled "Non-Committee Review" is circled in red. Below it, the text "Entered IRB: 10/23/2023 1:30 PM" and "Last updated: 10/25/2023 1:06 PM" is visible. Under the heading "Next Steps", there are two buttons: "Review Study" and "Printer Version". Below these are five options, each with a blue arrow pointing to it from a blue box labeled "Avoid":

- ☒ Submit Designated Review
- Request Clarification by Designated Reviewer
- Assign to Committee Review
- Add Comment
- Add Private Comment

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**.

Non-Committee Review

Entered IRB: 10/23/2023 1:30 PM
Last updated: 10/25/2023 1:06 PM

Next Steps

Review Study

Printer Version

1

☒ Submit Designated Review

Request Clarification by Designated Reviewer

Assign to Committee Review

Add Comment

Add Private Comment

2

1. * Determination:

Name	Related Worksheet
<input type="radio"/> Approved	HRP-314 - Worksheet - Criteria for Approval
<input type="radio"/> Modifications Required to Secure "Approved"	HRP-314 - Worksheet - Criteria for Approval
<input type="radio"/> Not Human Research	HRP-310 - Worksheet - Human Research Determination
<input type="radio"/> Modifications Required to Secure "Not Human Research"	HRP-310 - Worksheet - Human Research Determination
<input type="radio"/> Human Research, Not Engaged	HRP-311 - Worksheet - Engagement Determination
<input type="radio"/> Modifications Required to Secure "Human Research, Not Engaged"	HRP-311 - Worksheet - Engagement Determination

[Clear](#)

2. * Risk level: ?

- ☐ Greater than minimal risk
- ☒ No greater than minimal risk
- ☐ N/A

[Clear](#)

Administrative
Use Only

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.

3. * Is continuing review required? ?

☐ Yes ☒ No [Clear](#)

4. Dates:

* Approval date: ?

12/10/2023

Effective date: ?

12/10/2023

5. Notes:

6. Supporting documents: (attach any relevant checklists completed as part of the review)

+ Add

Name

There are no items to display

7. * I do NOT have a conflicting interest: ? ☐

8. * Are you ready to submit this review? ?

☐ Yes ☐ No [Clear](#)

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.

Committee Review

Entered IRB: 10/5/2023 11:46 AM

Last updated: 10/25/2023 1:11 PM

Next Steps

Review Study

Printer Version

Request Clarification by
Committee Member

Avoid

☒ Add Review Comments

Add Comment

Avoid

Add Private Comment

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.

Committee Review

Entered IRB: 10/5/2023 11:46 AM
Last updated: 10/25/2023 1:11 PM

Next Steps

[Review Study](#)

[Printer Version](#)

[Request Clarification by Committee Member](#)

☒ [Add Review Comments](#)

[Add Comment](#)

[Add Private Comment](#)

2

Add Review Comments

[?](#)

1 All committee members and IRB staff can view your comments in the Reviews tab.

1 All comments and attached files will be removed from the system upon the submission's approval.

1. Notes:

2. Checklists: (attach relevant checklists from the IRB Library) [?](#)

[+ Add](#)

Name

There are no items to display

3. Other supporting documents:

[+ Add](#)

Name

There are no items to display

[OK](#) [Cancel](#)

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.

The screenshot shows the 'Reviews' tab selected in the top navigation bar. The left sidebar contains 'Add Comment' and 'Add Private Comment' options. The main content area displays the 'Latest Pre-Review' section with the following details:

Date submitted:	10/25/2023
Regulatory oversight:	None of the above
Special determinations:	
Type of research:	Social / behavioral / educational
Additional study features:	
Missing materials:	
Notes:	
Supporting documents:	

Below this, there are two messages: 'There is no Non-Committee Review to display at this time.' and 'There is no Committee Review to display at this time.'

The 'Ancillary Reviews' section contains a table with the following data:

Review Type	Organization	Person	Reqd
Other			yes

The 'Committee Member Review Comments' section contains a table with the following data:

Person	Role	Notes
	Primary Reviewer	I need a copy of the delegation log