



Reviewer's Guide

Human Research Protection Program



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

- Instructions for how to complete an **ancillary review** may be found [here](#).



Dashboard

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

IRB Stage

TEXAS A&M UNIVERSITY

Hello, Heather Cline [Switch User](#)

Dashboard COI IRB

Page for Heather Cline [Help](#)

Create

Recently Viewed

Recent Pinned

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

My Inbox My Reviews

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.

Dashboard

COI IRB

Page for [Help](#)

My Inbox **My Reviews**

My Reviews

Filter by ID Enter text to search

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

2 items page 1 of 1 / page

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

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

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

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

Next Steps

Review Study

Printer Version

- Submit Designated Review
- [Request Clarification by Designated Reviewer](#)
- [Assign to Committee Review](#)
- [Add Comment](#)
- [Add Private Comment](#)

History | Funding | Contacts | COI | Documents | IRB Assignment Details | **Reviews** | Snapshots | Training

Filter by Activity + Add Filter ✕ Clear All

1

2

Non-Committee Review

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

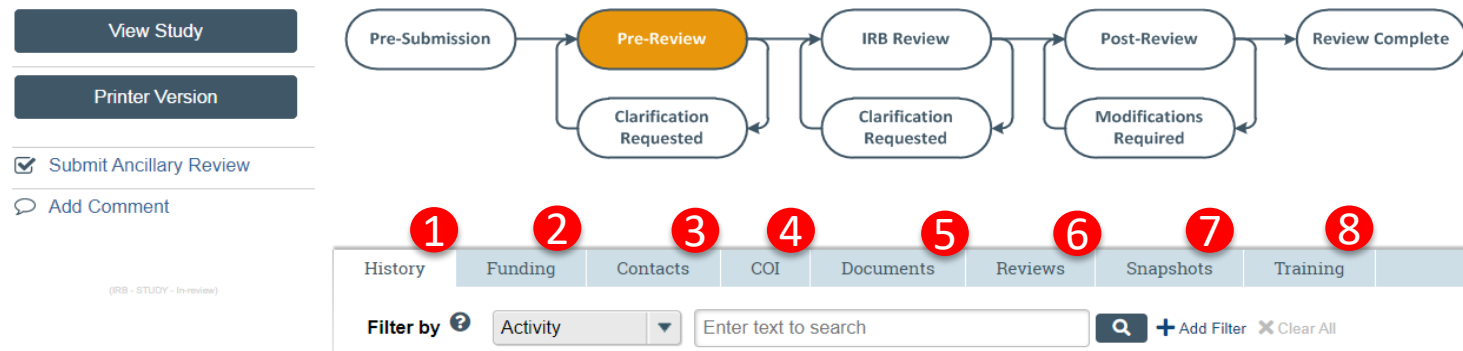
Next Steps

Review Modification/CR

Printer Version

Study Workspace

You may also use the Study Workspace to quickly access basic study information, such as study personnel and sponsor information.



1. **History:** This tab lists the activity taken on a submission including any comments, attachments, or correspondence added.
2. **Funding:** Provides all funding sources associated with the submission along with related grant information, if applicable.
3. **Contacts:** This tab lists all TAMU 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 (note: does not include TTI and TEEEX personnel).
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-TAMU 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 <input type="text" value="Enter text to search"/> <input type="button" value="Search"/> <input type="button" value="+ Add Filter"/> <input type="button" value="X 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						



Type of reviews

New Study: click [here](#) for instructions on how to review a new study

Modification and/or Continuing Review: click [here](#) for instructions on how to review a modification and/or continuing 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.

1 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

You Are Here: How to Drive in the Rain
Reviewing: STUDY2023-0047

Basic Study Information

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:

Document	Category	Date Modified	Document History
View <input type="checkbox"/> Drivin in the Rain Protocol(0.01)	IRB Protocol	10/5/2023	History

Above section has been reviewed:



Reviewing a new study

- ▶ **IMPORTANT!** As part of your review, you will need to download and review the study protocol and supporting study documents.
 - The next four slides will walk you through how to (1) download the study protocol and supporting study documents to your computer and (2) how to use Track Changes and Comments to aid in your review.

How to download the study protocol

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

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

Click on the name of the protocol to download file.

7. * Attach the protocol: ?

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

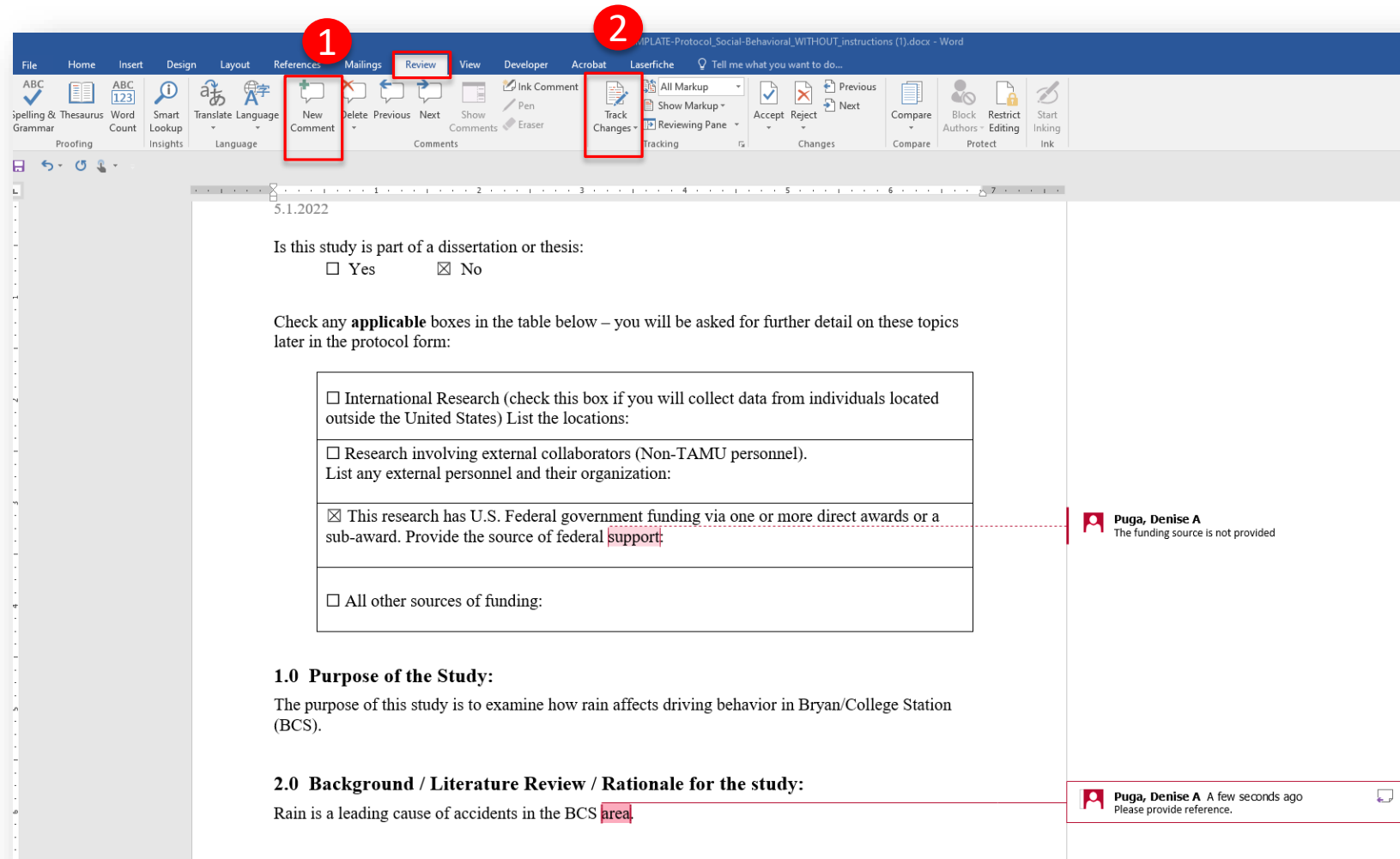
View Attachment

1. * File to attach:
 Drivingin the Rain Protocol(0.01) ...
2. Name: (if not supplied, the file name will be shown) ?
Drivingin the Rain Protocol
3. Version number:

Study Protocol Review

Once you have downloaded the research protocol 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. Instructions on how to add and delete a comment in Word can be found [here](#).
- 2. Tracked Changes.** Reviewers may suggest edits to the protocol to secure approval using Track Changes. Instructions on how to use Track Changes in Word can be found [here](#).
- 3. Save all comments and tracked changes.** Once you have completed your review of the study protocol, 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.

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 ✓

Local Site Documents

1. **Consent forms:** (include an HHS-approved signed consent document, if applicable)

Document	Category	Date Modified	Document History
Driving in the Rain Consent(0.01)	Consent Form	10/5/2023	History

2. **Recruitment materials:** (add all material to be seen or heard by subjects, including ads)

Document	Category	Date Modified	Document History
There are no items to display			

3. **Other attachments:**

Document	Category	Date Modified	Document History
Driving in the Rain Survey(0.01)	Survey/Questionnaire	10/5/2023	History

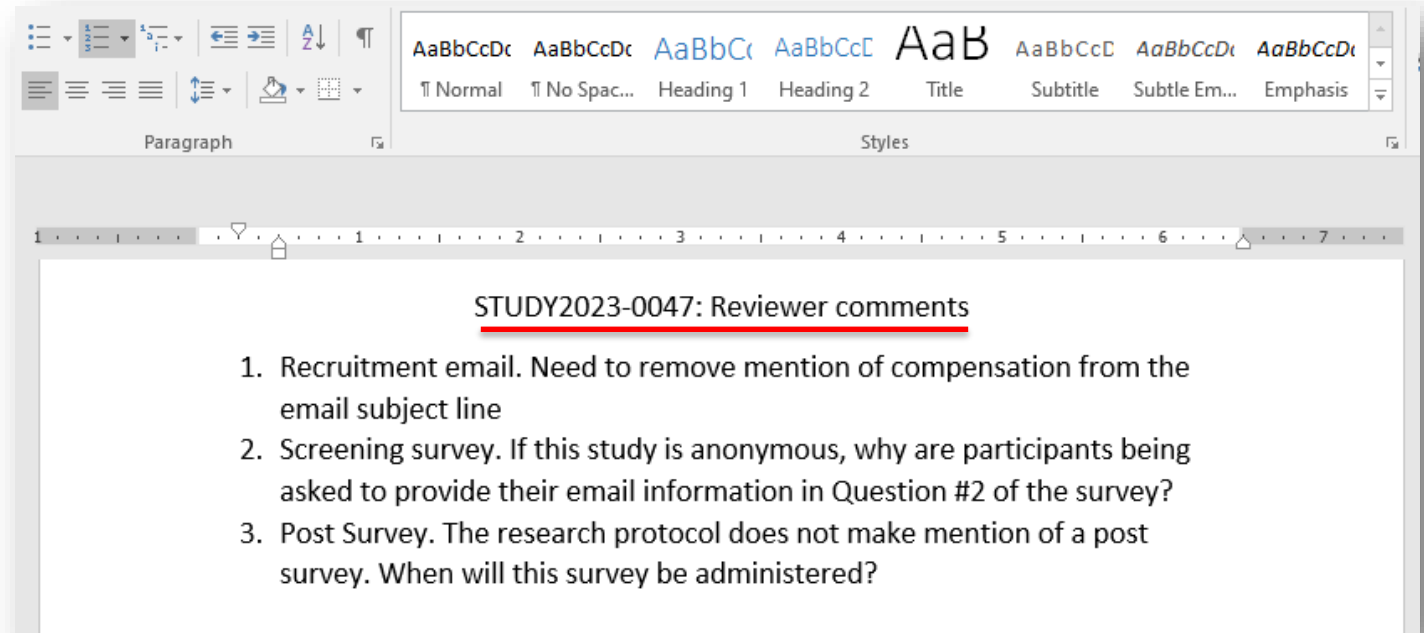
Suggested attachments:

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

Above section has been reviewed:

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 ✓

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

1 Submit Designated Review

2 Request Clarification by Designated Reviewer

3 Assign to Committee Review

4 Add Comment

5 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**.

1

2

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](#)

Administrative Use Only

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:

[Empty text box for 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

- 1 Request Clarification by Committee Member
- 2 Add Review Comments
- 3 Add Comment
- 4 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](#)

1

[Add Review Comments](#)

[Add Comment](#)

[Add Private Comment](#)

2

Add Review Comments

?

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

i 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.

[Add Comment](#)
[Add Private Comment](#)

(IRB - STUDY - In-review)

[History](#) | [Funding](#) | [Contacts](#) | [COI](#) | [Documents](#) | **Reviews** | [Snapshots](#) | [Training](#)

Latest Pre-Review

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:

There is no Non-Committee Review to display at this time.
There is no Committee Review to display at this time.

Ancillary Reviews

Review Type	Organization	Person	Reqd
Other			yes

Committee Member Review Comments

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

Instructions for reviewing a modification and/or continuing review

Huron 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?** ?

- Continuing Review
- Modification / Update
- Modification and Continuing Review**

i To change the PI, choose 'Other parts of the study/site' scope

Modification scope:

- Study team member information
- Other parts of the study

Instructions for reviewing a modification and/or continuing review

- 1. 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

- * Specify enrollment totals at this investigator's sites:** 100
- * Specify enrollment totals at this investigator's sites since last approval:** 100
- * Specify enrollment totals study-wide:** 100
- 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

i Important! If the first four research milestones above are complete, the study will be closed to discontinue IRB oversight.
- 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

1. **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
2. **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
3. *** 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

▼ Differences

[redacted] • modified 16 minutes ago • version 0.2 (MODCR00000001: Modification submitted to IRB)

▶ Added: HRP-503-TEMPLATE-BIOMEDICAL-PROTOCOL_Intructions (2).docx



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.

1

▼ IRB00000852

Basic Study Information

7. * Attach the protocol: ?

Document	Category	Date Modified	Document History
View Protocol Test Version 2(0.02)	IRB Protocol	12/4/2023	History

2

Resource History for Protocol Test Version 2

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:

History:

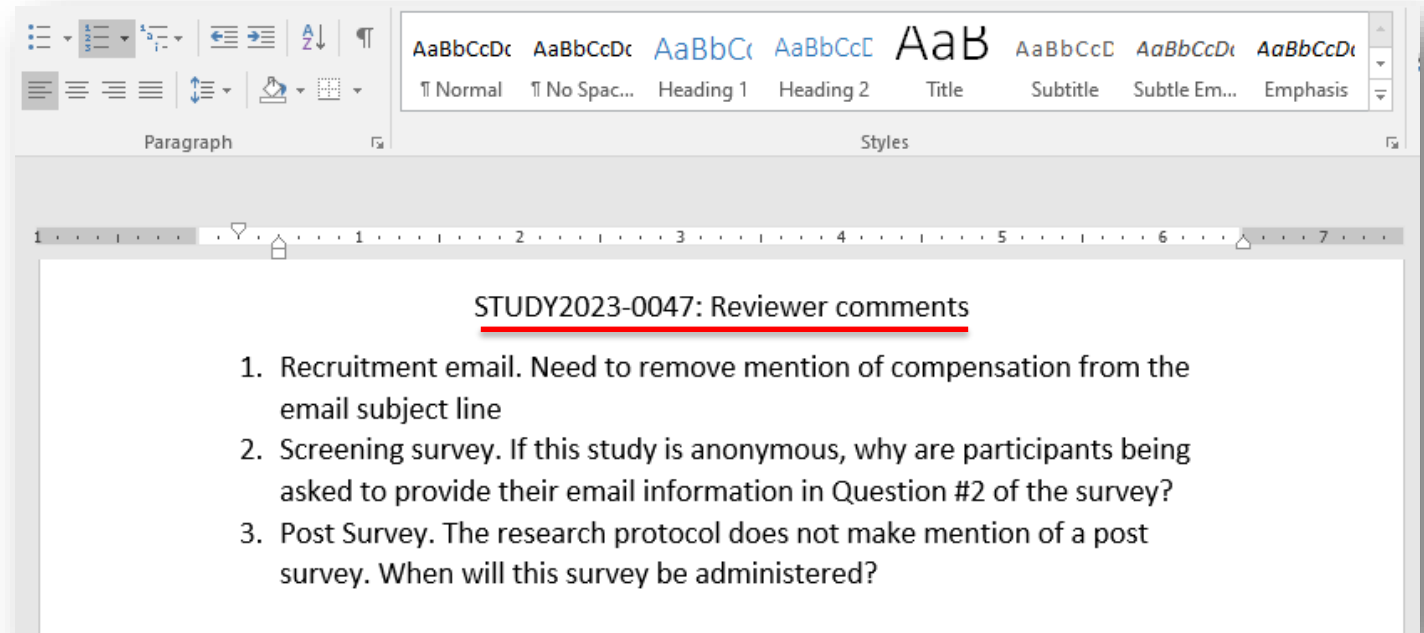
Compare	Date	Version	Person	Action	Notes	Uploaded File
<input checked="" type="checkbox"/>	12/4/2023 11:49 AM	0.02	[Redacted]	File Uploaded & Edited		HRP-503-TEMPLATE-BIOMEDICAL-PROTOCOL_Intructions (2).docx
<input checked="" type="checkbox"/>	12/1/2023 8:36 AM	0.01	[Redacted]	Created		Protocol Test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

◀ 1-2 of 2 ▶

Compare

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

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

i 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 **i**

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 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.

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

2 Request Clarification by Designated Reviewer

3 Assign to Committee Review

4 Add Comment

5 Add Private Comment

Avoid

Avoid

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

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 titled **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

- 1 Request Clarification by Committee Member
- 2 Add Review Comments
- 3 Add Comment
- 4 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

Add Review Comments

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

[Add Comment](#)
[Add Private Comment](#)

(IRB - STUDY - In-review)

[History](#) | [Funding](#) | [Contacts](#) | [COI](#) | [Documents](#) | **Reviews** | [Snapshots](#) | [Training](#)

Latest Pre-Review

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:

There is no Non-Committee Review to display at this time.
There is no Committee Review to display at this time.

Ancillary Reviews

Review Type	Organization	Person	Reqd
Other			yes

Committee Member Review Comments

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