NAVIGATING IRB MENTOR: IRB REVIEWERS

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Email Notifying Reviewer of Protocol Assignment

Emails are sent to the email address that you indicated is your preferred email address in PeopleSoft.

- Note the submission type in the email so that you are generally aware of what you will be reviewing – whether it is an initial submission or revisions to an initial submission; a modification request; an incident report; or a deviation.

- Note the due date – typically 15 days from the date of assignment. You will get a reminder 2 days before your review is due and then an email every day after the due date has passed unless the IRB analyst has changed these default settings for a specific protocol.

- Note any IRB Analyst Internal Comments. If you need to respond, you can do so using the Internal Reviewer Comments field on the Reviewer Checklist and Decision Form that you will fill out as part of your review.

SJSU IRB: Submission for Your Review - 23-001

To:	Gandalf Gray
From:	SJSU IRB Office
Subject:	SJSU Protocol #23-001
Date:	01/30/2023
Submission Type:	Initial Application or Revisions to Initial Application

Dear IRB Reviewer,

You have been assigned to review protocol #23-001.

Study Title: The Long Term Effects of Warp Drive on Behavior

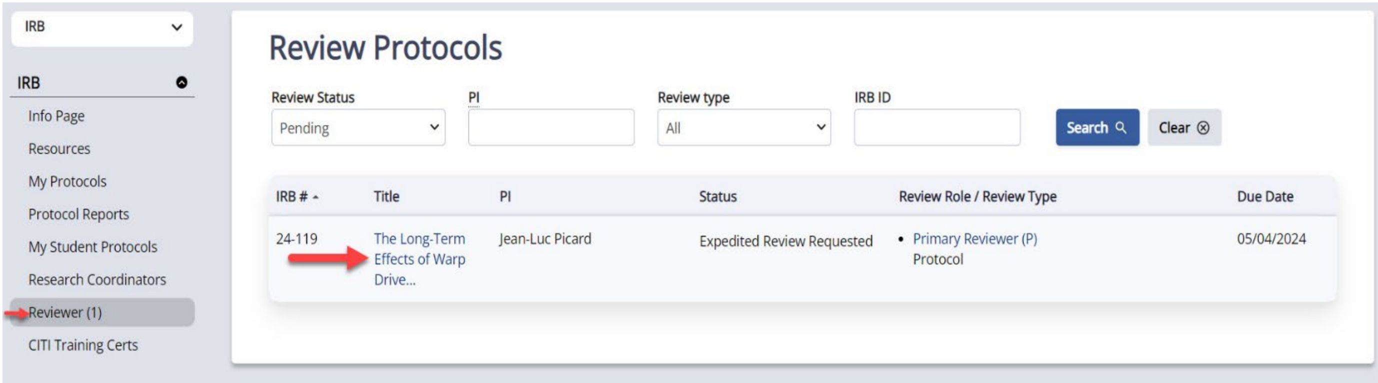
You will find this protocol listed on the Reviewer page under the IRB tab in Mentor. Alternatively, you can click on this link to access the protocol directly:

https://www.axiommentor.com/login/authkey.cfm?i=sjsu&key=mS9xz6QI3XK4yFyEqm1WWNYd07CW%2FijMWjFd6zTQbHZ7nbh9Fm538E81%2BG2bNEH8

Your review is due on 02/14/2023.

Internal IRB Analyst Comments:
Internal analyst comment appears here.

- The URL in the email will lead you directly to the protocol information page for the protocol that you need to review. This is a "free view" version of the protocol, which allows you to focus solely on reviewing the protocol assigned to you. Other pages and features in IRB Mentor cannot be accessed with this free view link. You can access the entirety of the Mentor system as well as all protocols assigned to you by logging into your Mentor account via SJSU single-sign on (the link is appended to bottom of all correspondence generated within the system), navigating to the IRB tab, and selecting the Reviewer page where your assigned protocols and past reviews will be listed.



If you do not see a protocol listed on the Reviewer page, set the Review Status filter to Do Not Filter.

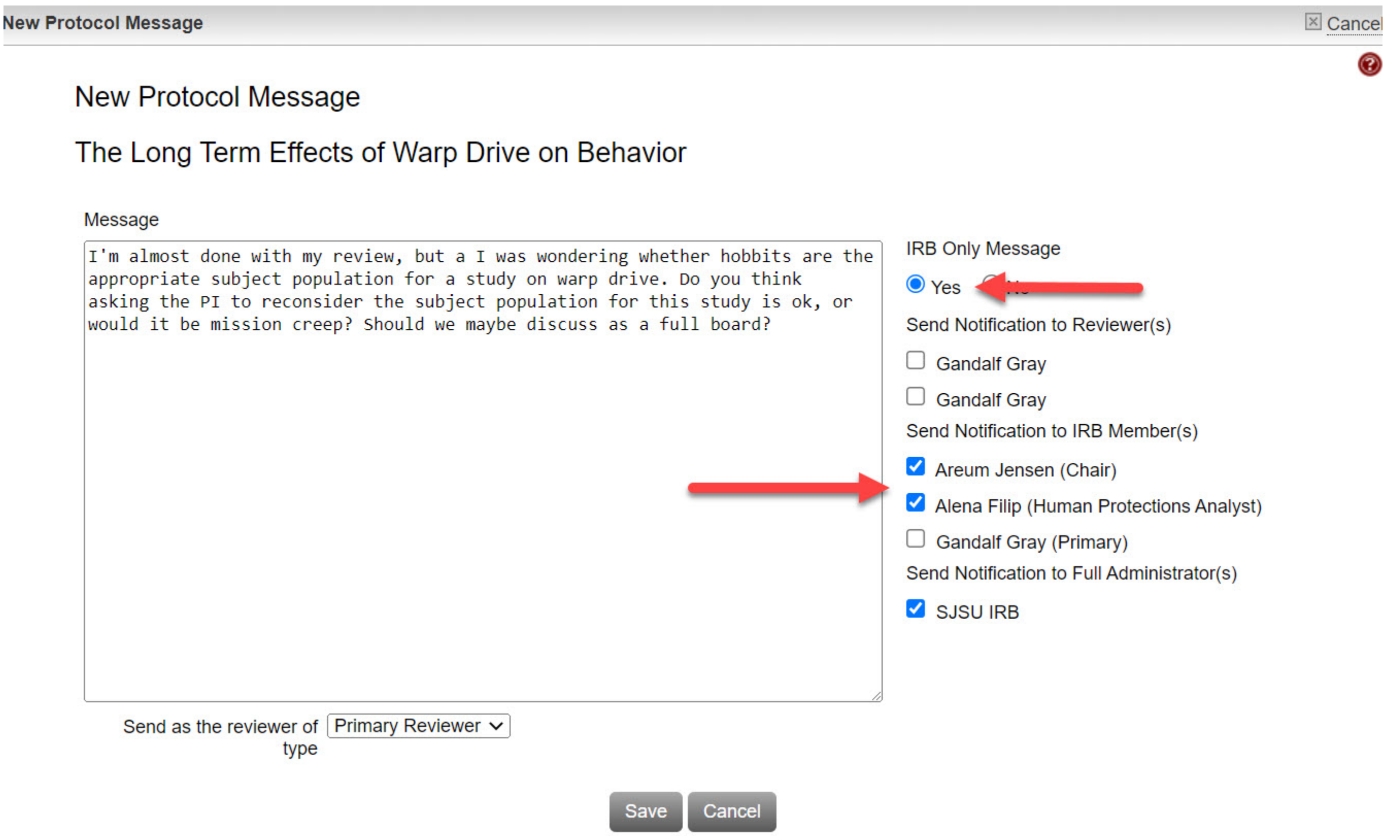
Protocol Messaging in Mentor

If you have a question or concern about a protocol that you want to discuss before completing your review, protocol messaging in Mentor allows you to quickly compose a message and select which IRB members you want to send it to, including the IRB chair and IRB analyst. While you can send a message outside of the system, using protocol messaging has the benefit of automatically appending the study information to the message, and the message history is archived within the system. You can also respond to protocol messages directly in your email as you would reply to any email – the thread continues to be archived within the system.

The messaging feature is not available in the free-view mode of a protocol (i.e., when you click the link in the email notifying you that you have been assigned to a protocol). Protocol messaging should also not be confused with automated notification messages, such as reviewer assignment messages.

In order to use protocol messaging, log into your Mentor account via SJSU single sign-on. Navigate to the specific protocol under the Reviewer page (as shown in the above screen capture). On the protocol information page, go to the messages icon link at the top. Then click on the New Message button.

In the pop-up window for your message, "IRB Only Message" is selected by default so your message is not visible to the study team. If you change the default selection, the study team will be able to see your message as well as your name. Select who you want to send your message to, type up your message (no need to include any protocol identifiers – they will get appended to the email), and click the Save button to send the message.

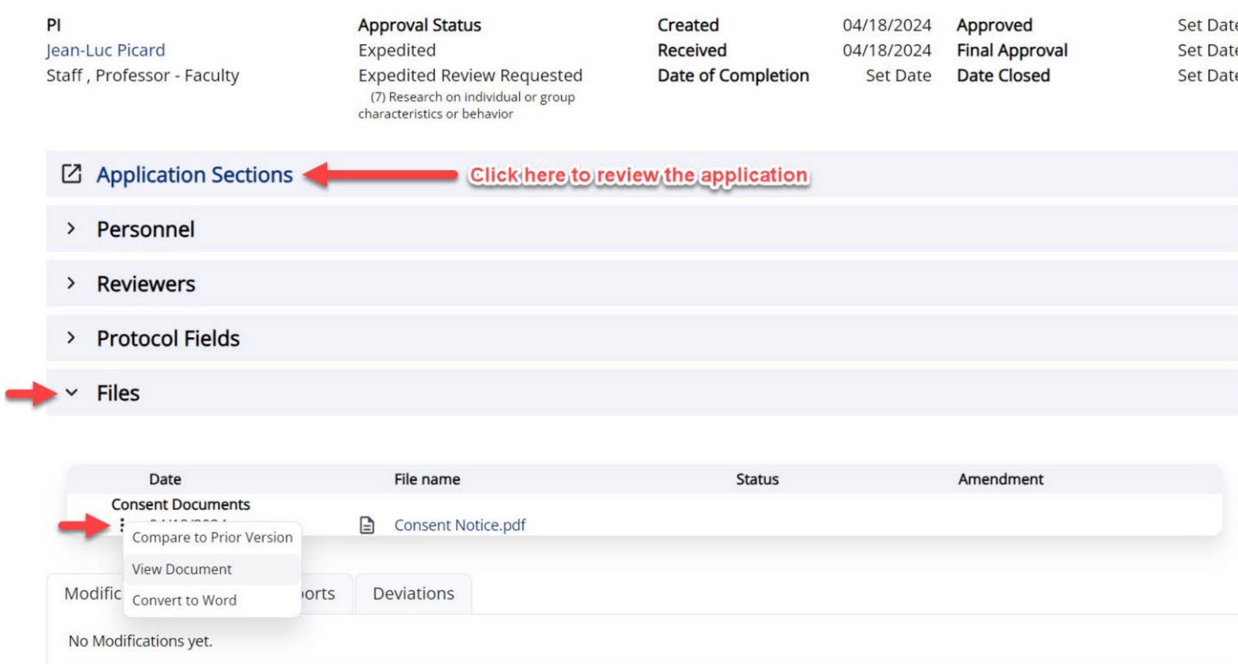


Reviewing an Initial Submission

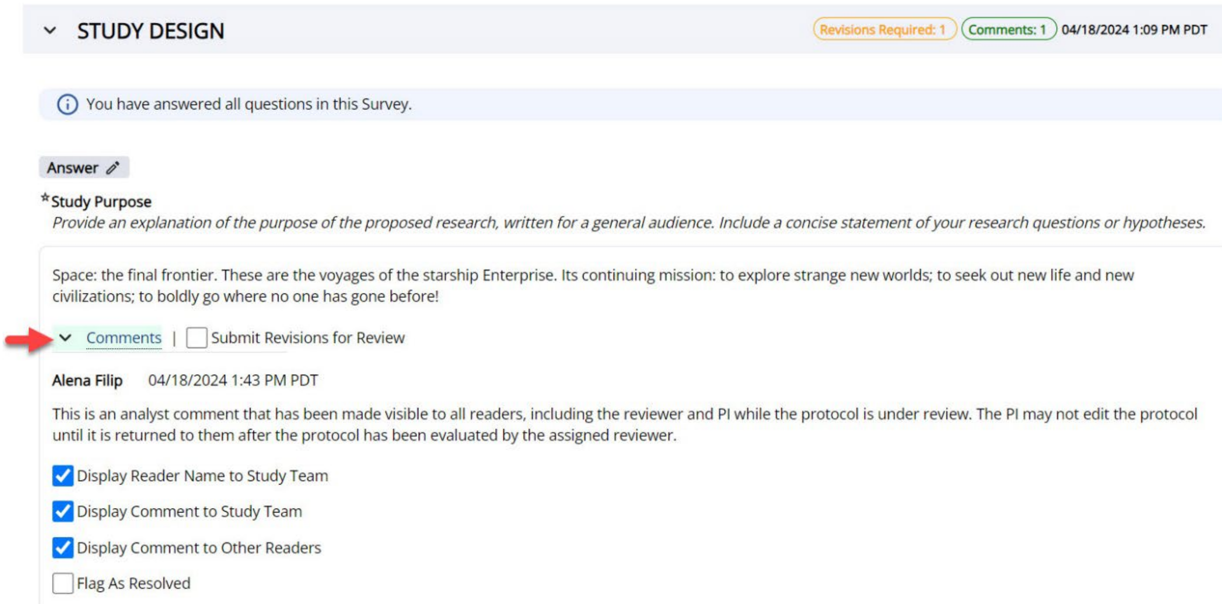
IRB reviewers are blocked from being able to do the following: change the review type, change the protocol tracking status, render comments visible to the study team, or send notifications to the study team. These items are handled by the IRB administrator/analyst so that you can focus solely on reviewing the protocol.

- Note the review type on the protocol information page, as you will be asked if you want the analyst to change it when completing your review. The review type is assigned by the IRB analyst, but on occasion there may be no review type because it cannot be determined until revisions are submitted.

- To review the application sections, click the Application Sections link on the protocol information page. You can review attached documents (e.g., consent forms, data instruments) either from the protocol information page, where all attachments are listed, or directly within the application sections where they are listed under the relevant file upload question. To view a document, click on the context menu for the file (three vertical dots) and select View Document. The context menu also allows you to compare versions of documents when there are iterations of revisions. Notifications to the PI will also be listed on the protocol information page, with a link to a PDF file of the email notifications.

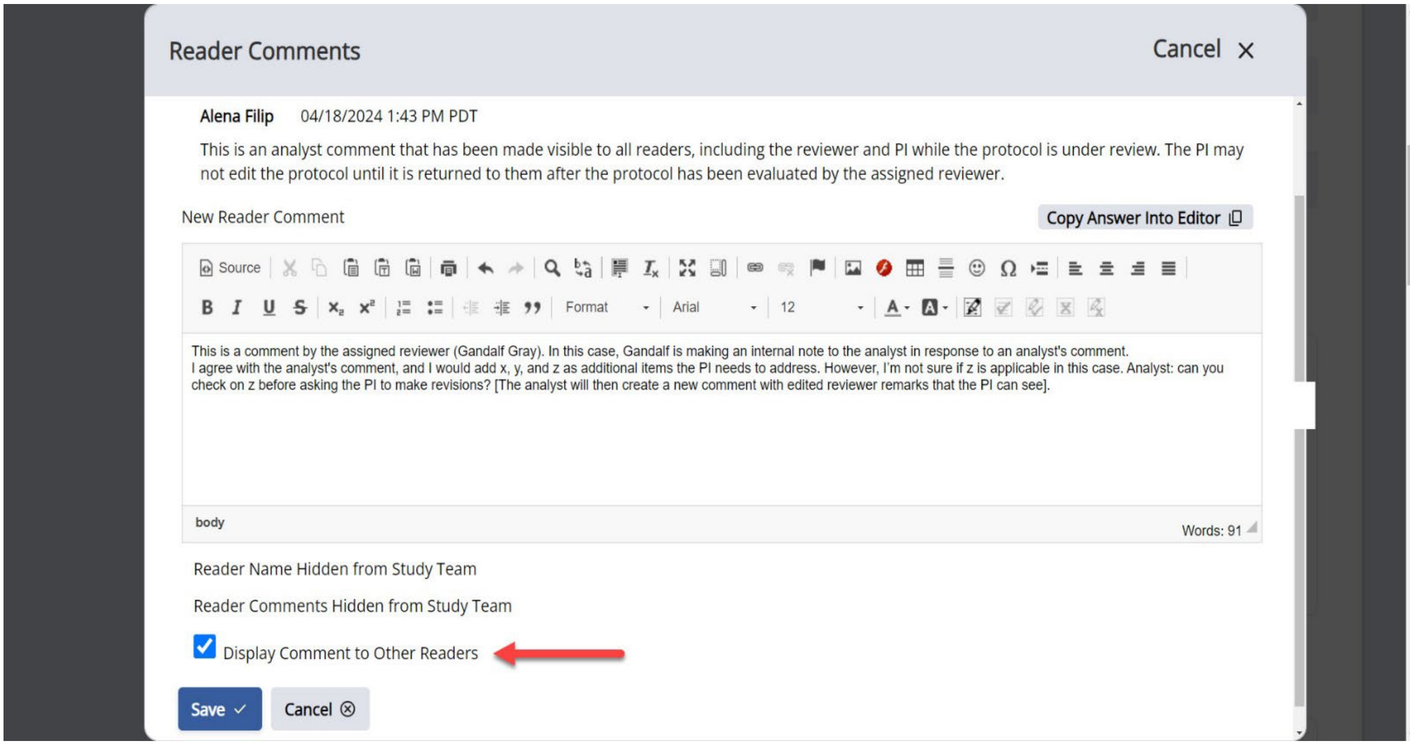


- The application sections where the analyst has already made comments will be flagged with green text. You may be receiving a protocol where there has already been an iterative process between the IRB analyst and PI, and you may notice different flags/alerts on the application sections and questions, depending on what the IRB analyst has enabled during the screening of the submission. You can see analyst comments by hovering over or clicking on the highlighted Comments link for a specific question.



- To make a comment on a PI's response to a question, click on the Comments link. A pop-up window will open, where you can type your comment, which will be identified as "anonymous" when viewed by the study team (though you will see your name in the fields). The comment will get added below any existing comments made by the IRB analyst and yourself in previous iterations of reviewing the protocol.

- Select whether you want other assigned reviewers/readers to see your comments (Display Comment to Other Readers). It's recommended that you enable this in case the protocol needs to be reassigned or assigned to a secondary reviewer. The analyst will typically make these comments visible to other reviewers for training purposes.



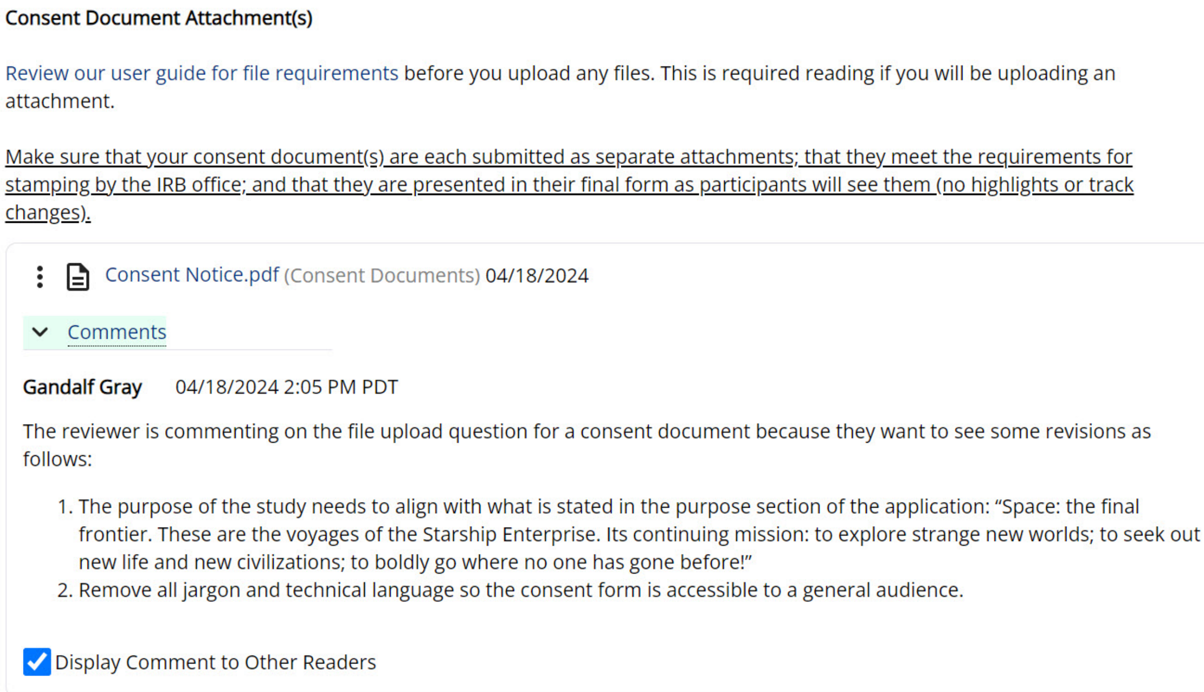
- Click the Save button to save your comment. You can go back and edit or delete comments by clicking on the Comments link again.

Notes on Using Reader Comments

- The IRB administrator(s) and analyst(s) can always see your comments (i.e., you cannot hide comments from the administrator/analyst). The IRB analyst will determine whether to render your comment/request visible to the PI or whether to create a new comment to provide an edited version of your comment to the PI. If you wish to make internal comments visible only to the IRB analyst/administrators, do so on the IRB Reviewer Checklist and Decision Form or make sure to note this directly in the comment.

- For revisions where you do not have any need to have an internal dialogue with the IRB analyst, make sure your comments are directed to the PI and contain clear and actionable requests. If you wish to make an observation or point out an issue to the PI but do not need the PI to make any revisions, make sure to frame your comment so that it is clear to the IRB analyst that they do not need to flag the comment as a required revision. The PI will then see your comment but will not be forced to respond with a revision (unless they want to make a revision).

- To make a comment on an attached document (e.g., you want some revisions to a consent form), compile your request under the Comments link for the specific file upload question within the application, even if you viewed the attachment from the protocol information page.



Consent Document Attachment(s)

Review our user guide for file requirements before you upload any files. This is required reading if you will be uploading an attachment.

Make sure that your consent document(s) are each submitted as separate attachments; that they meet the requirements for stamping by the IRB office; and that they are presented in their final form as participants will see them (no highlights or track changes).

Consent Notice.pdf (Consent Documents) 04/18/2024

Comments

Gandalf Gray 04/18/2024 2:05 PM PDT

The reviewer is commenting on the file upload question for a consent document because they want to see some revisions as follows:

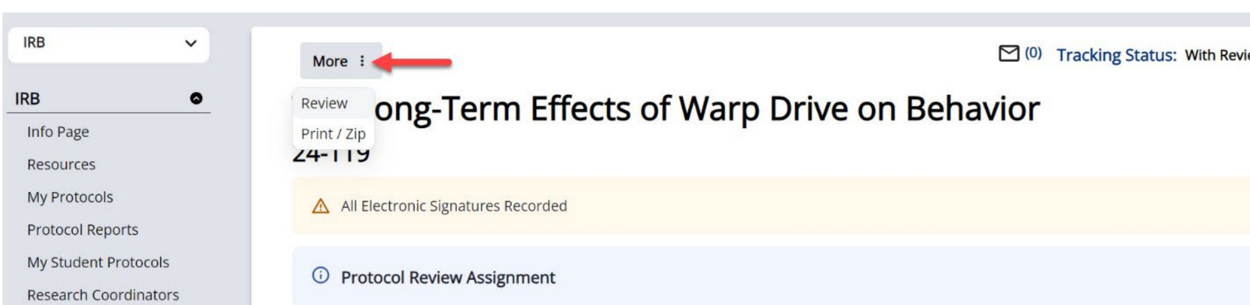
1. The purpose of the study needs to align with what is stated in the purpose section of the application: "Space: the final frontier. These are the voyages of the Starship Enterprise. Its continuing mission: to explore strange new worlds; to seek out new life and new civilizations; to boldly go where no one has gone before!"
2. Remove all jargon and technical language so the consent form is accessible to a general audience.

Display Comment to Other Readers

Filling Out the Reviewer Checklist and Decision Form

After evaluating the application sections, associated forms, and inputting your comments/requests under the comments fields within the application:

1. **Navigate back to the protocol information page by clicking the View Protocol Page at the top the application sections page.**
2. **On the protocol information page, click the More button at the top of the page and select Review.**

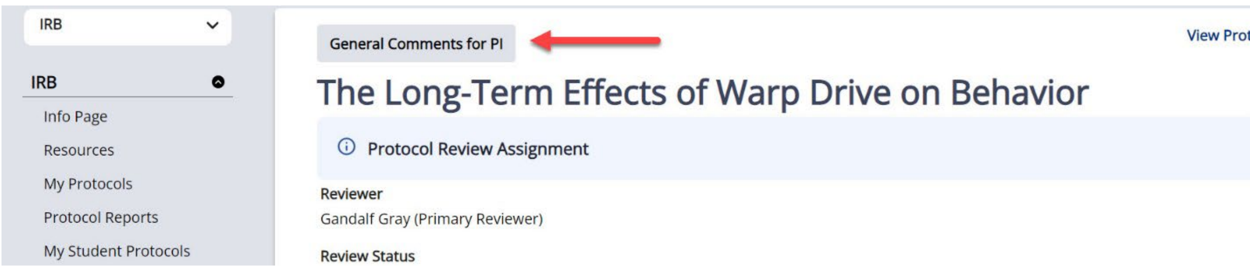


3. **The resulting window opens the Reviewer Checklist and Decision Form.**

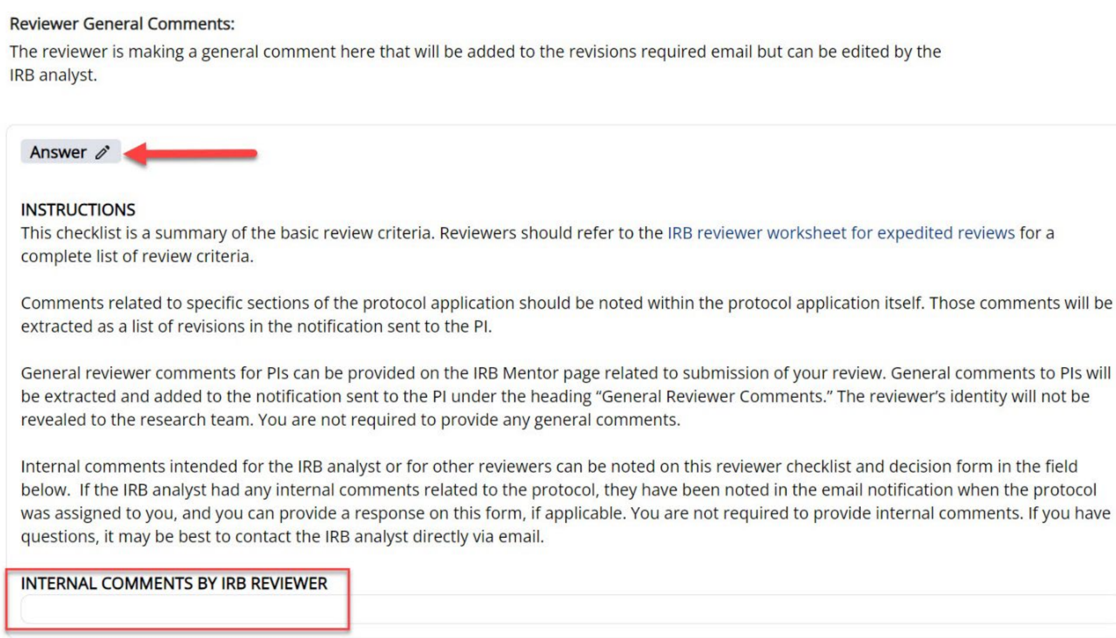
PIs and other study personnel do not have access to this form; however, information can be exported from this form. The IRB administrator/analyst <u>cannot</u> edit this form, so it is important that you fill it out completely and correctly.

The form contains the following elements:

a) A button to input general comments for the PI at the top of the form.

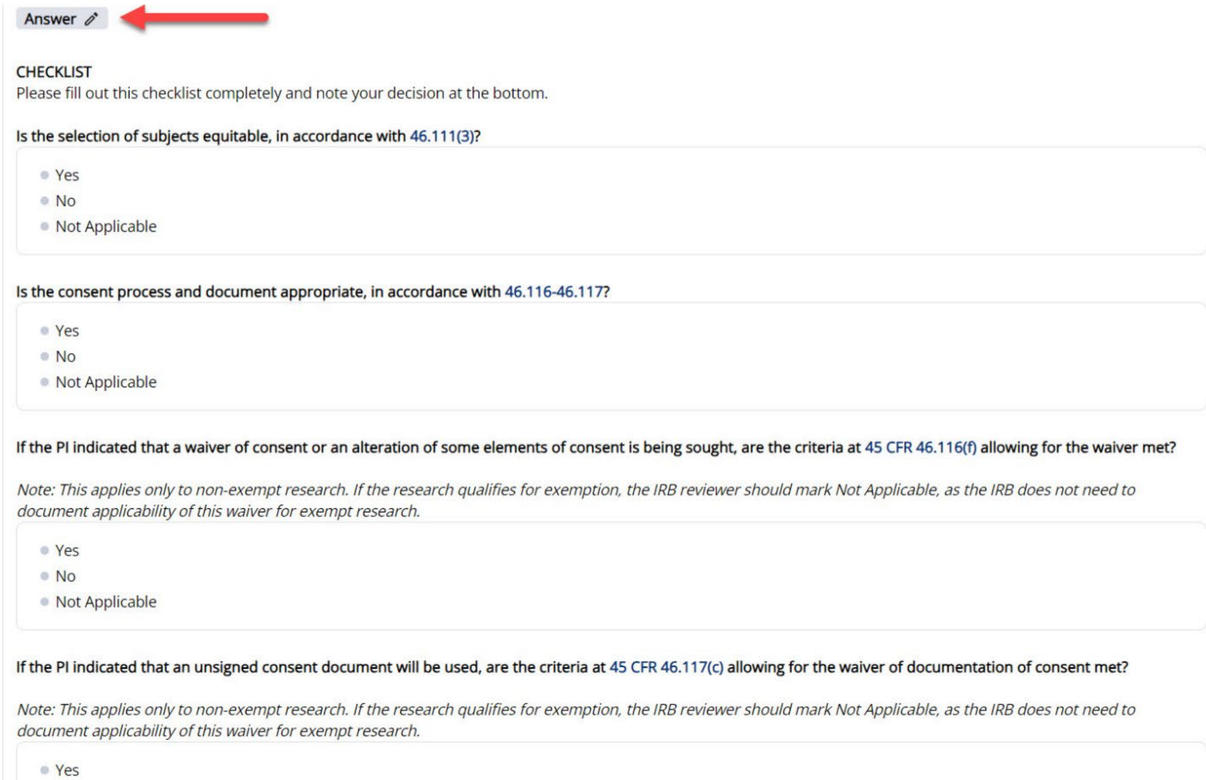


General comments are for the PI and get populated into a revisions required email that the IRB analyst can edit before it is sent out. If you approve the protocol with no requested revisions, the PI will get an approval notification that will not include your general comments, so make sure you do not spend time on this unless you are requesting revisions somewhere in the protocol. <u>Do not use the general comments button for internal comments – use the Internal Comments field on the form for this, as shown in the screen capture below.</u>



b) The reviewer checklist.

Get into the habit of filling out this form in its entirety, which includes a basic review Checklist section as well as a Reviewer Decision Determination section, where you will need to input your decision regarding what you want to happen via the multiple choice menu.



Answer

CHECKLIST
Please fill out this checklist completely and note your decision at the bottom.

Is the selection of subjects equitable, in accordance with 46.111(3)?

- Yes
- No
- Not Applicable

Is the consent process and document appropriate, in accordance with 46.116-46.117?

- Yes
- No
- Not Applicable

If the PI indicated that a waiver of consent or an alteration of some elements of consent is being sought, are the criteria at 45 CFR 46.116(f) allowing for the waiver met?

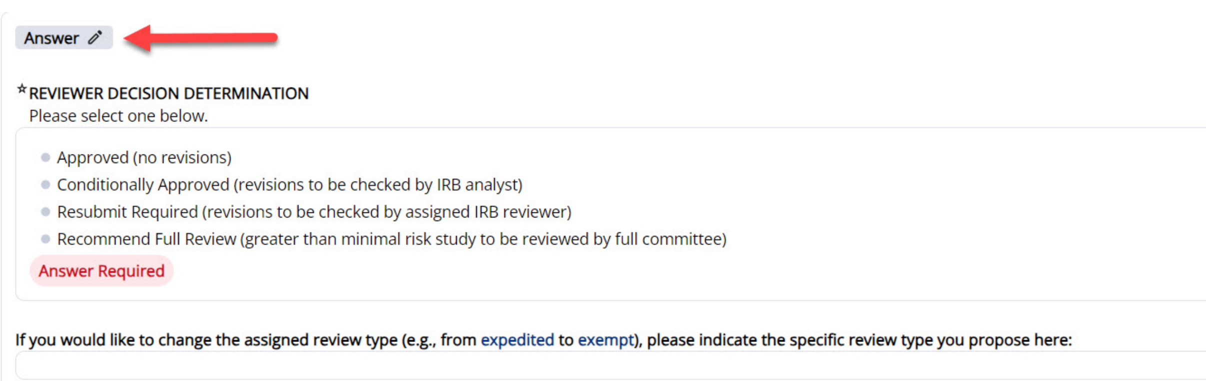
Note: This applies only to non-exempt research. If the research qualifies for exemption, the IRB reviewer should mark Not Applicable, as the IRB does not need to document applicability of this waiver for exempt research.

- Yes
- No
- Not Applicable

If the PI indicated that an unsigned consent document will be used, are the criteria at 45 CFR 46.117(c) allowing for the waiver of documentation of consent met?

Note: This applies only to non-exempt research. If the research qualifies for exemption, the IRB reviewer should mark Not Applicable, as the IRB does not need to document applicability of this waiver for exempt research.

- Yes



Answer

*REVIEWER DECISION DETERMINATION
Please select one below.

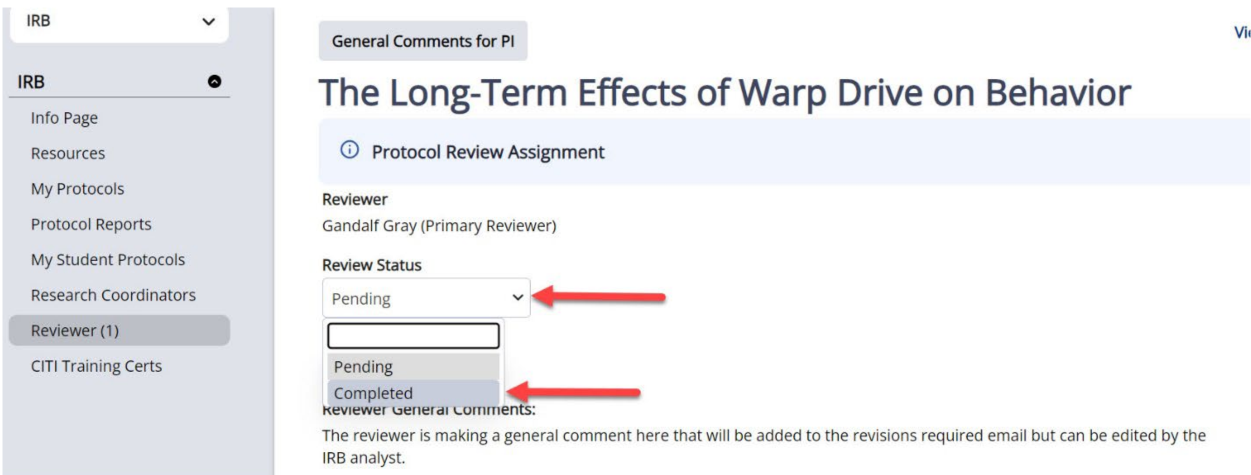
- Approved (no revisions)
- Conditionally Approved (revisions to be checked by IRB analyst)
- Resubmit Required (revisions to be checked by assigned IRB reviewer)
- Recommend Full Review (greater than minimal risk study to be reviewed by full committee)

Answer Required

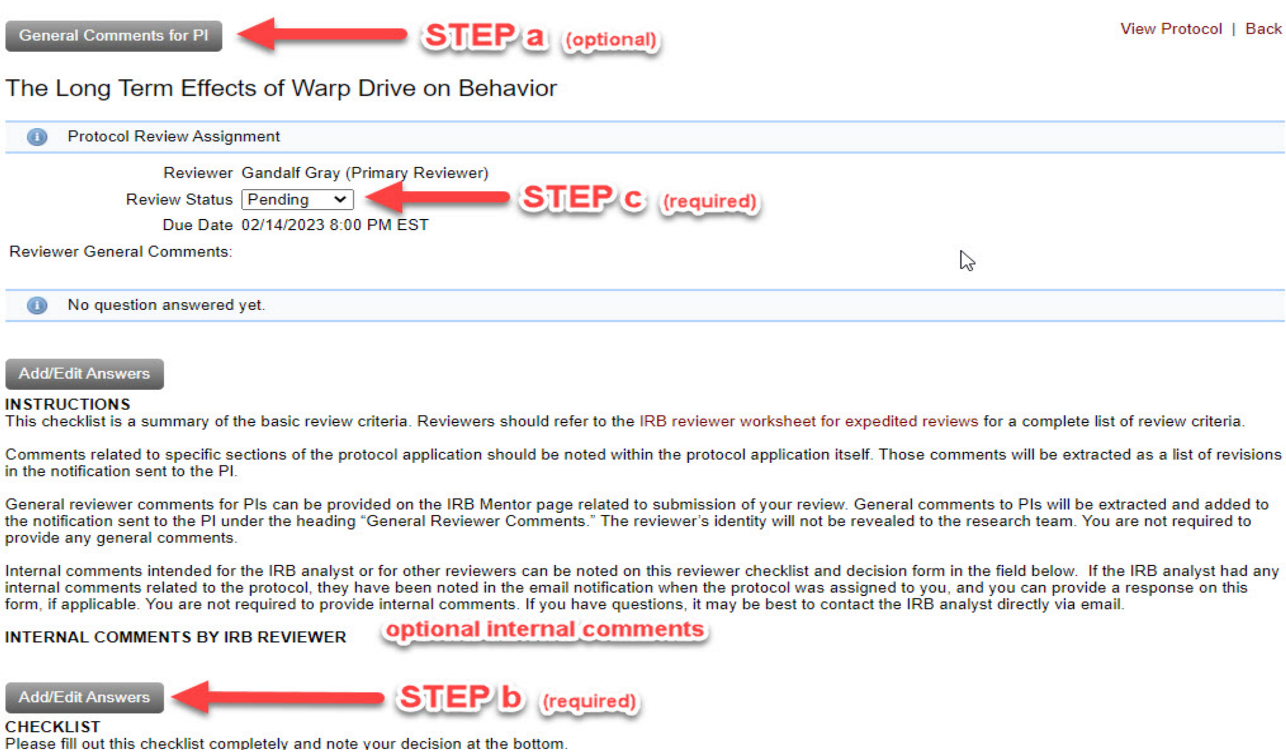
If you would like to change the assigned review type (e.g., from expedited to exempt), please indicate the specific review type you propose here:

c) A status drop-down menu, from which you need to select "Completed."

<u>Do this last after completing items a and b above. Selecting this will alert the IRB administrator that you are done with your review, and the form will be locked.</u>



The workflow for filling out the Reviewer Checklist and Decision Form is summarized in the following screen capture:



Don’t forget to change the review status from the drop-down menu at the top of the Reviewer Checklist and Decision Form from “Pending” to “Completed” (Step c) after you have filled out the form. If you do not complete this step, the IRB administrator will not be notified that you completed the review and you will continue to receive reminder notifications after your due date. Make sure not to forget this step!!!

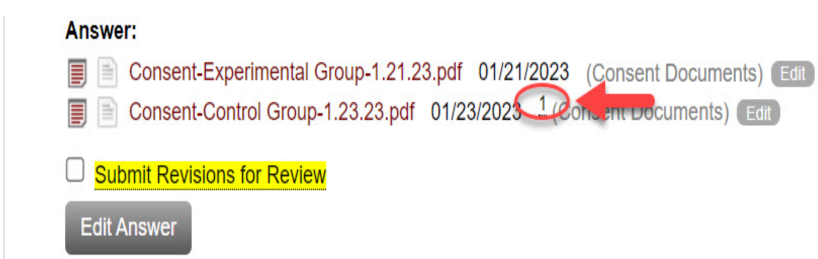
Additional Notes for Reviewing Different Submission Types

Resubmit to an Initial Submission

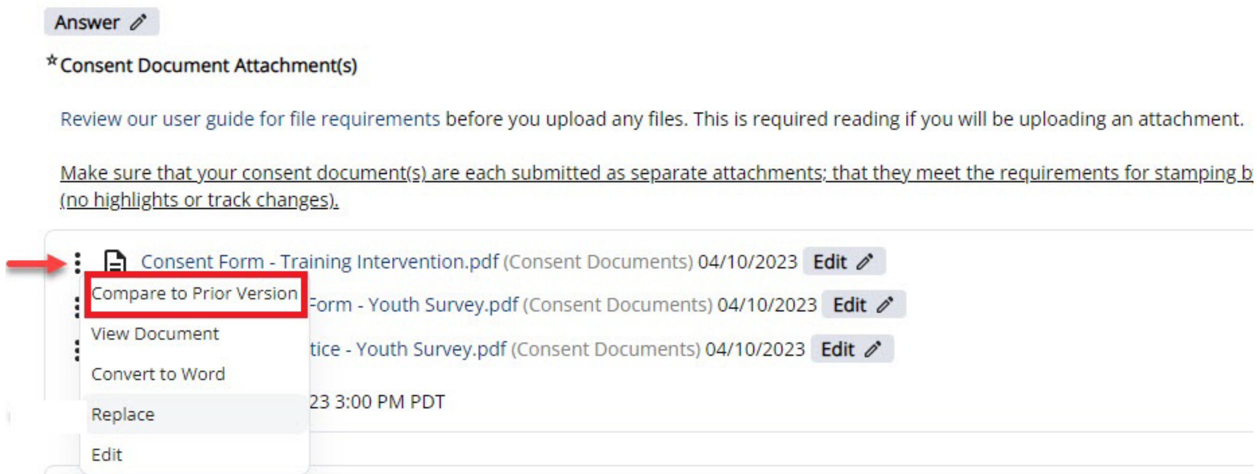
- Track changes are enabled in the application sections, with revised text to answers highlighted in green and a versions button appearing next to multiple choice answers that have been revised. The IRB analyst may accept some or all track changes before reassigning a reviewer to another iteration of a protocol depending on whether it would help to de-clutter and facilitate reading of the PI’s responses. You will always know which sections have comments because they are flagged at the section heading.

The PI may also make revisions where none were requested. These revisions should be highlighted with green track changes, but the section may not be flagged. The IRB analyst will alert you in the email notification whether there is something that you should check that the PI revised where no revisions were requested.

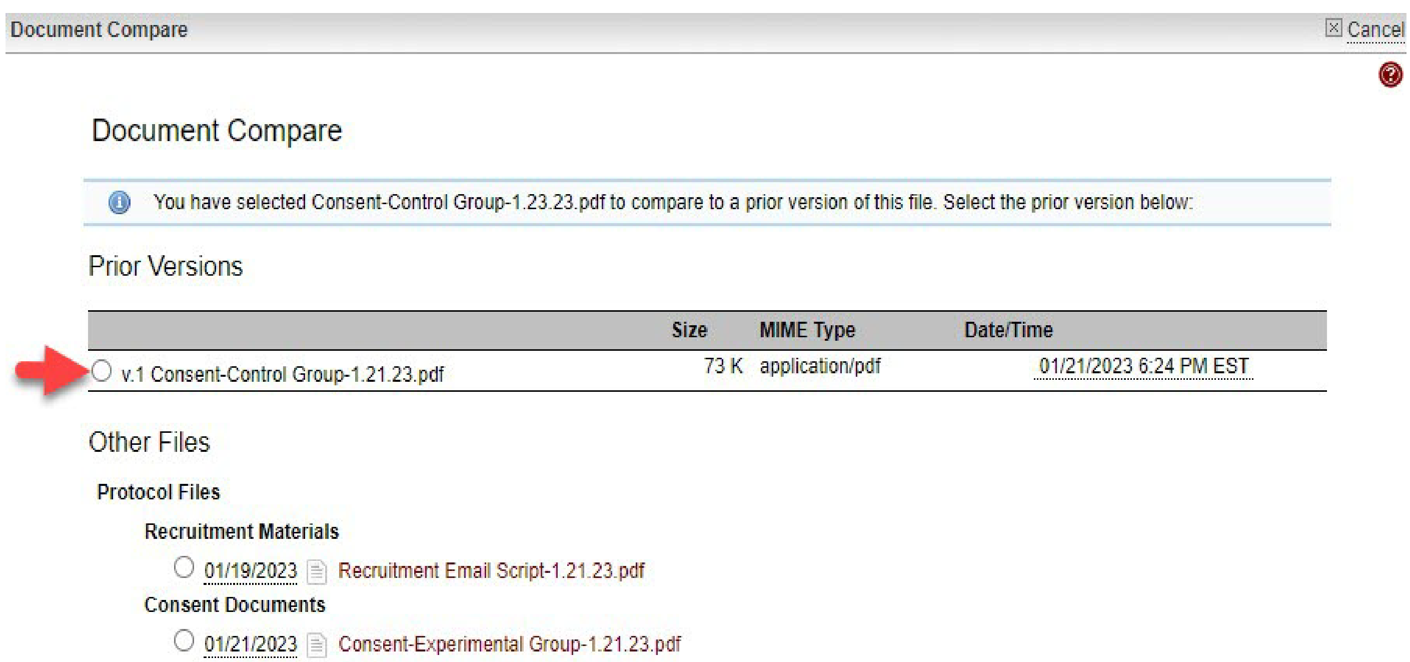
- Attachments that were uploaded and selected to replace a previous version are immediately accessible, while previous versions are hidden behind a superscript (assuming the PI followed instructions and correctly used the replace feature for an attachment).



- You can compare iterations of attachments that are in pdf format by selecting the Compare to Prior Version option from the context menu for an attachment.

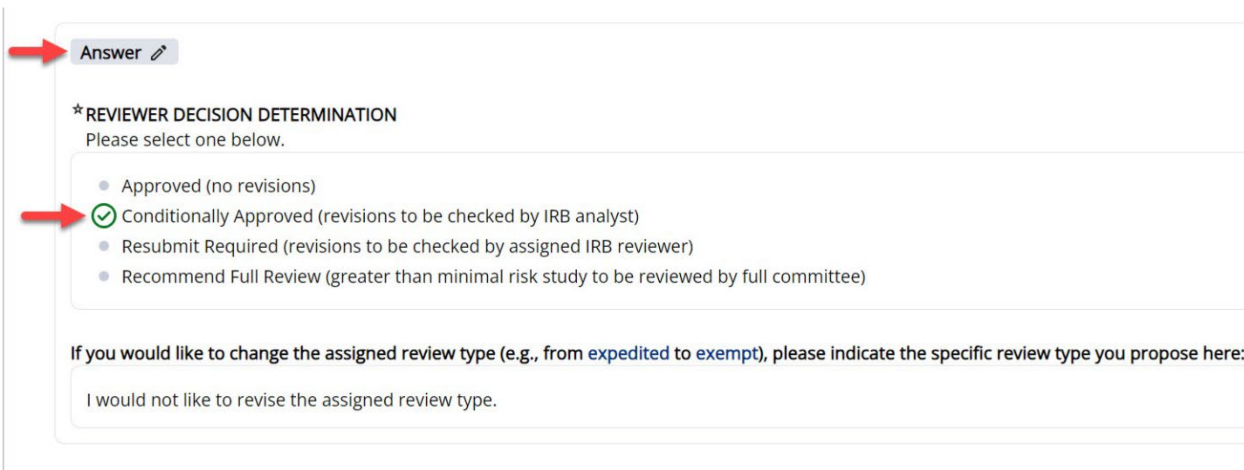


The resulting pop-up window when selecting the Compare to Prior Version option will ask you to select which prior version you want to compare the new document to, with the most recent file matching the same file type listed at the top (v.1 in the below screen capture).



- When you are reassigned as a reviewer on a protocol for which you requested a resubmit, a copy is made of the Reviewer Checklist and Decision Form with all the answers that you previously filled out which you can edit. This appears under the "More" menu at the top of the protocol information page under the Primary Reviewer 2 button (the original version of the reviewer form appears under the first Primary Reviewer button and is locked from editing).

- Follow the same steps as outlined earlier under the Filling Out the Reviewer Checklist and Decision Form of this document. You will continue to receive iterations of the protocol so long as you mark Resubmit Required as your decision on the form. **<u>Make sure to edit your answer in this section of the form if you are satisfied with the changes that the PI made and want to either conditionally approve or fully approve the protocol.</u>**



Modifications

You will receive an email notification just like that for an initial submission alerting you to your assignment as a reviewer on a protocol. However, the submission type will be noted as “Modification.”

SJSU SAN JOSÉ STATE UNIVERSITY

Institutional Review Board

Office of Research

Division of Research and Innovation

SJSU IRB: Submission for Your Review - 23-001

To:	Gandalf Gray
From:	SJSU IRB Office
Subject:	SJSU Protocol #23-001
Date:	02/06/2023
Submission Type:	Modification

Dear IRB Reviewer,

You have been assigned to review protocol #23-001.

Study Title: The Long Term Effects of Warp Drive on Behavior

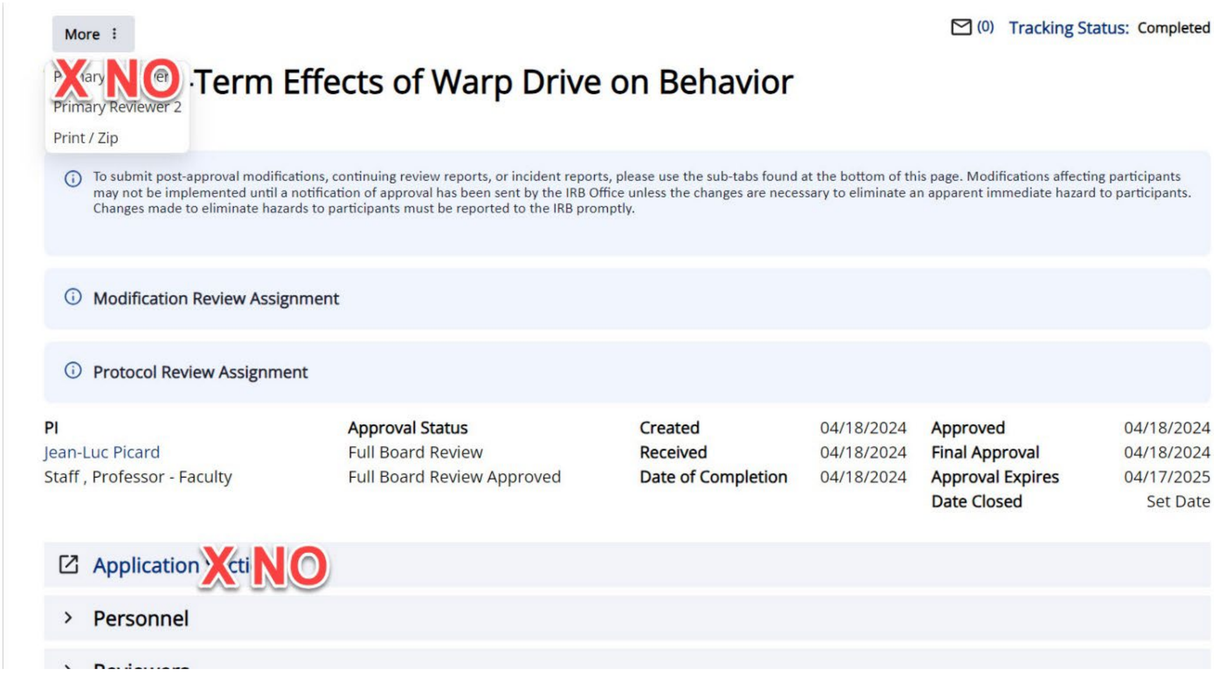
You will find this protocol listed on the Reviewer page under the IRB tab in Mentor. Alternatively, you can click on this link to access the protocol directly:

https://www.axiommentor.com/login/authkey.cfm?i=sjsu&key=mS9xz6QI3XK4yFyEqm1WWNYd07CW%2FijMWjFd6zTQbHZ7nbh9Fm538E81%2BG2bNEH8

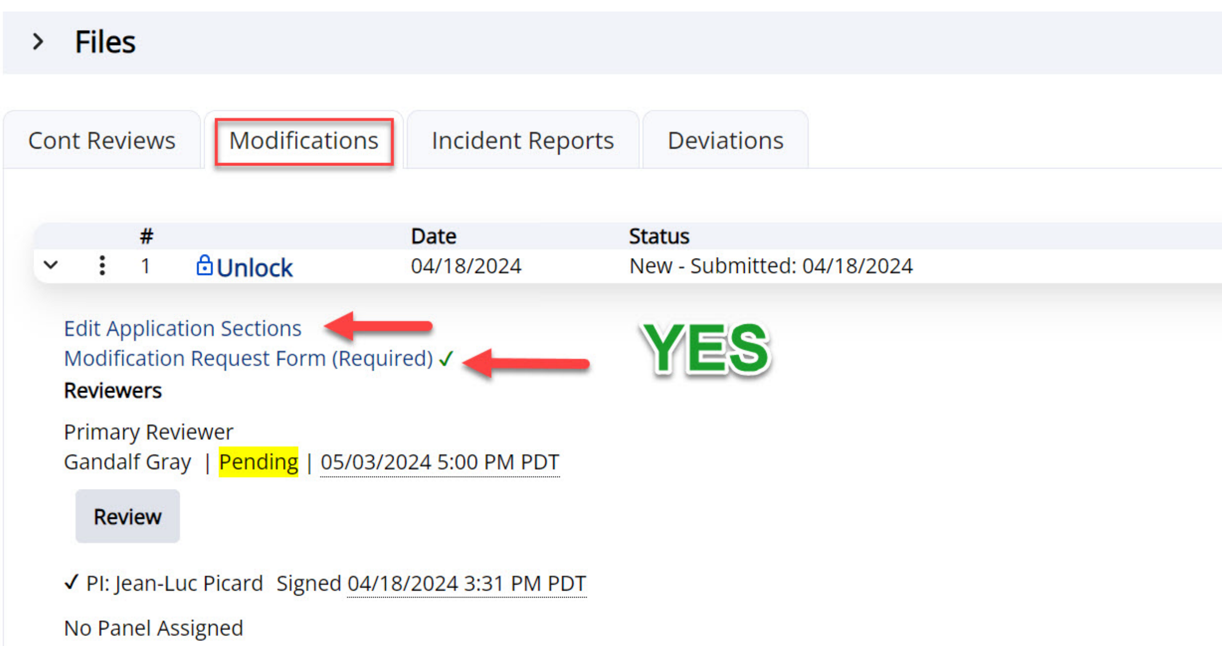
The free-view link in the email will lead you directly to the protocol information page. The modification request will appear under the modification tab at the bottom of the page.

IMORTANT NOTES:

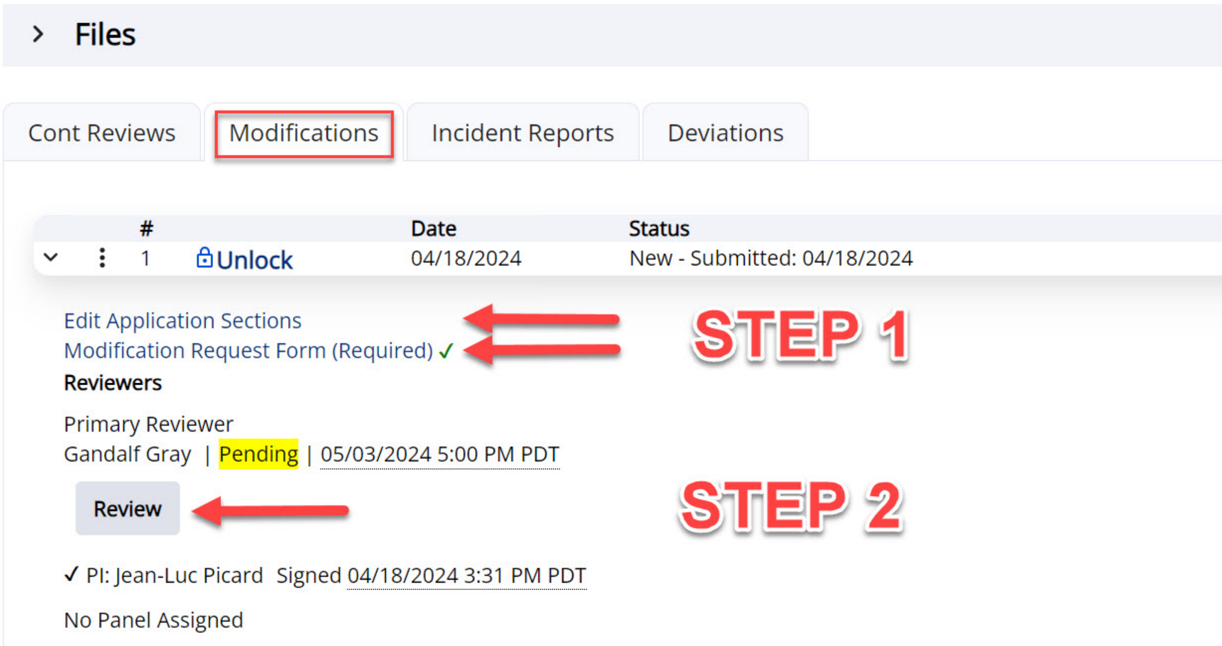
- The Primary Reviewer options under the “More” button at the top of the protocol information page is <u>not</u> applicable to the modification request. The Reviewer Checklist and Decision Form that you or another reviewer filled out for the initial application will appear in read only format. A new button, labeled “Review” and appearing under your name for the modification request (under the Modifications tab at the bottom of the protocol dashboard), will direct you to an editable Reviewer Checklist and Decision Form for the modification request.



- While you can access the application sections of the originally approved protocol by clicking the Application Sections link on the protocol dashboard, this version <u>will not</u> show you the modification edits and you will not be able to make comments here. When the modification is approved, however, the revised application will be copied to this section. To view the edited application sections for a modification request, click the Edit Application Sections link under the specific modification request under the Modifications tab.



The workflow for reviewing a modification is summarized in the screen capture below.



STEP 1:

- Review the Modification Request Form to see a summary of the revisions made to the study protocol. Make any comments, as needed, following the same procedures as commenting on an initial application.
- Review the revised application sections by clicking the Edit Application Sections link. Only application sections that the PI has chosen to edit will be shown (not the entire application). Make any comments, as needed, following the same procedures as commenting on an initial application.
- Review any revised documents/attachments either by accessing them via the modification information section or under the relevant file upload question for the edited application section. Utilize the same tools for viewing attachments as with an initial submission, by clicking on the context menu for a file (three vertical dots). Revision requests for a file should be typed into the Comments for the relevant file upload question.

STEP 2:

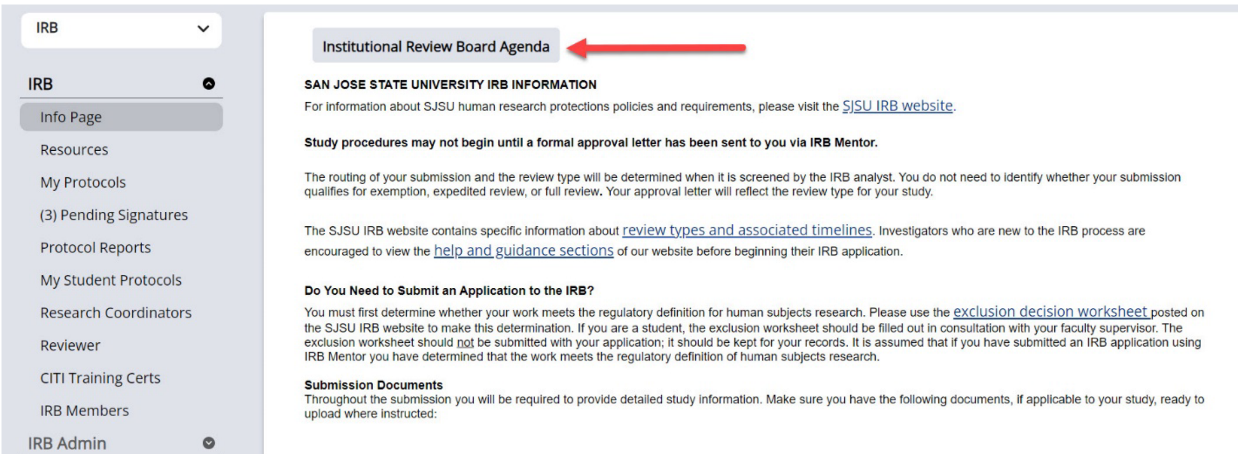
Click the Review button on the modification information page and fill out the Reviewer Checklist and Decision Form following the same workflow as with an initial submission (the form is the same as with an initial submission). <u>Don't forget change the review status from the drop-down menu at the top of the Reviewer Checklist and Decision Form from "Pending" to "Completed" so that your review is delivered to the IRB office.</u>

Full Board Reviews

The assigned primary reviewer will have already made comments within the application sections along with any comments made by the IRB analyst.

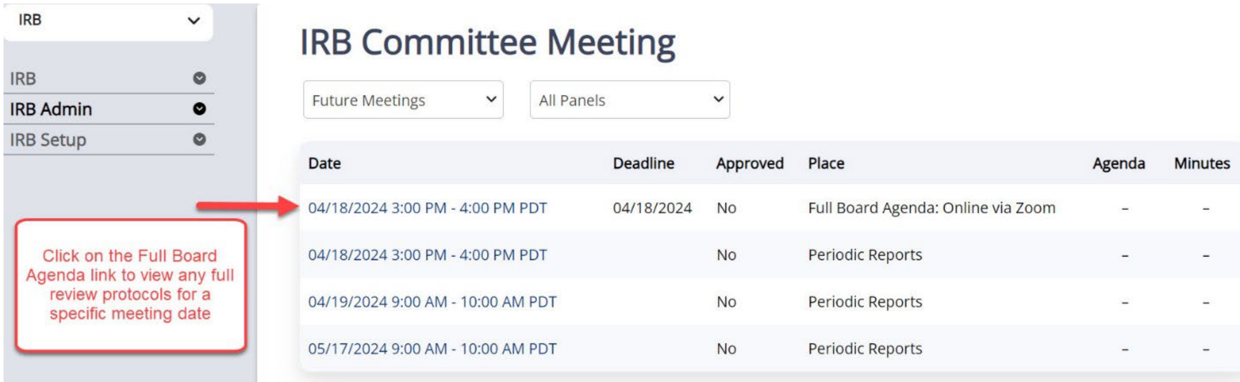
Notifications: you will receive an initial email if there is a full review protocol alerting you to review the protocol by the meeting date. Approximately one week before the meeting, you will receive an attendance poll email. Make sure to respond to the attendance poll so that the IRB chair can ensure a quorum will be present for the meeting.

Viewing a meeting agenda and full review protocol: If a meeting is scheduled, you can access meeting agendas by clicking Institutional Review Board Agenda link on the IRB home page.



You can also access the agenda by clicking the IRB Admin link in the left navigation menu and selecting Agenda. These links are only available if you are identified as a current IRB member within the Mentor system.

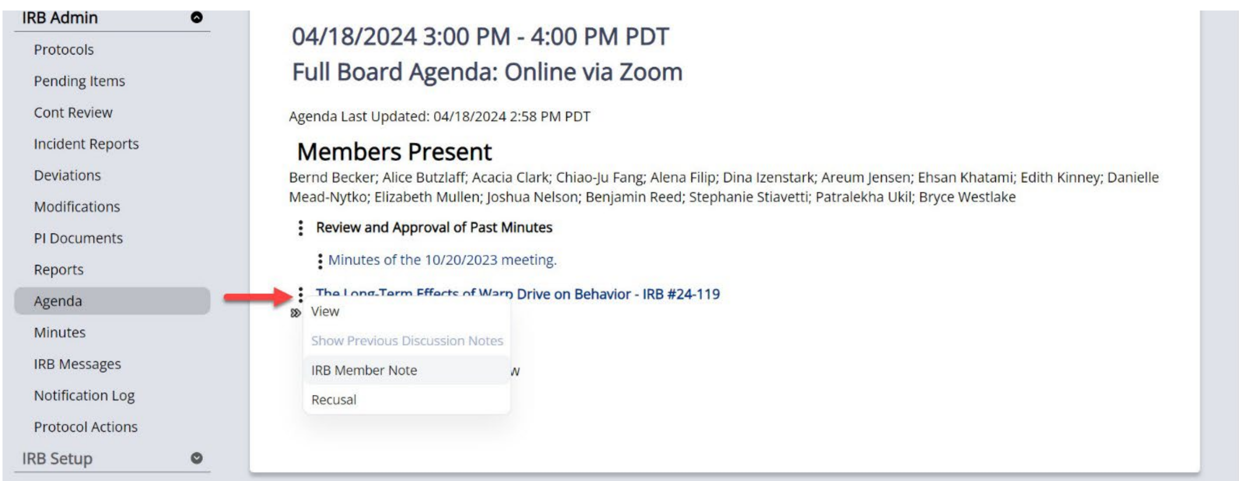
Be aware that if there is a full review there will be two agendas listed for a specific date. One agenda is for the full review(s). It will be labeled as “Full Board Agenda: Online via Zoom” under the place column. Full review protocols will be listed on this agenda. The other agenda will be labeled as “Periodic Reports.” The periodic reports agenda compiles all protocols that went through exempt, expedited, or other administrative review for the period of time between two meetings, and inclusion of this agenda fulfills the regulatory requirement at 45 CFR 46.110(c).



If no full review is scheduled, non-review agenda items will appear on the periodic reports agenda and there will be no full board agenda.

Make sure to check the agenda(s) the day before the meeting, in case there are any updates.

Adding a note to a full review protocol: all members can make notes on any protocol added to the full review agenda. Adding notes is optional – the purpose is to facilitate discussion; if you wish to add notes, do so before the meeting date. Your notes are visible to other members but not to the PI or study team. These notes do not automatically get added to the minutes unless the IRB analyst elects to do so. To add your notes to a full review protocol, navigate to the Full Board Agenda and select IRB Member Note from the context menu (three vertical dots) for the specific protocol.



Meeting minutes: a draft of the minutes will be sent soon after the meeting as a Word document to confirm the accuracy of any discussion items to be sent to the PI of a full review protocol. The finalized minutes will appear under the agenda link in Mentor and will also be listed as a linked item on the subsequent meeting agenda (which will capture the vote on the previous meeting minutes).

Continuing Reviews

A primary reviewer is typically not assigned to evaluate the continuing review form before a meeting because the form captures basic information about the study status. The protocol is automatically added to the meeting date closest to the expiration date for the protocol if the PI submits the continuing review form on time. The continuing review form is included on the full board meeting agenda items for all reviewers to read ahead of time.

Incident Reports

Incidents are any problematic or unanticipated events that may adversely impact the study participants or the conduct of the study.

Incident reports get routed to the IRB Chair and Institutional Official (IO) after the IRB analyst has triaged the report. Other reviewers would only see an incident report on the rare occasion that it gets added to a full board meeting agenda (in the event that the IRB needs to suspend or terminate approval for a study).

The IRB Chair and IO will be notified by email that an incident report is assigned to them for review. The email alert will include any IRB analyst comments regarding the reporting requirements for the incident as well as any suggestions on corrective actions, which the IRB Chair and IO will need to confirm on the Incident Report Triage Form. The steps for completing the form are similar to the steps under "Filling Out the Reviewer Checklist and Decision" described earlier. However, the Incident Report Triage Form contains different fields. Specific Instructions for the IRB Chair and IO are provided on the form as well as in the email notification alerting the IRB Chair and IO that they have been assigned to an Incident Report.

Deviations

A protocol deviation/violation is a departure from the approved protocol procedures made without prior IRB approval. Deviation reports rarely, if ever, get assigned to an individual IRB member for review. The investigator is typically sent an acknowledgement with any applicable corrective actions by the IRB analyst. However, if an investigator engages in serious or continuing non-compliance, the protocol and associated deviation may be put on a full board agenda. The IRB can then determine if approval for the study should be suspended or terminated.

If an individual reviewer is assigned to evaluate a deviation report, the same steps as apply to reviewing modifications would be followed. The deviation report can be accessed via the Deviations tab at the bottom of the protocol information page. The same Reviewer Checklist and Decision Form that is used for the initial submission and for modifications is filled out by the IRB reviewer for a study deviation, but a new form specifically for deviations may be developed in the future.