User Guide: *How to respond to a submission correction or submission response request from IRB in PRIS3M*

Last Update: April 2025

Carilion Clinic **PRIS3M**: Partnership in Research Integrity and Subject Safety Submission Module

For the best experience, use one of the following **recommended browsers**:

Platform	Browser
Microsoft Windows (in recommended order)	Chrome, Firefox, or Edge
Apple Mac	Chrome, or Firefox

Allow pop-ups for this site: Certain actions within the PRIS3M application will not function if the pop-up blocker is enabled.

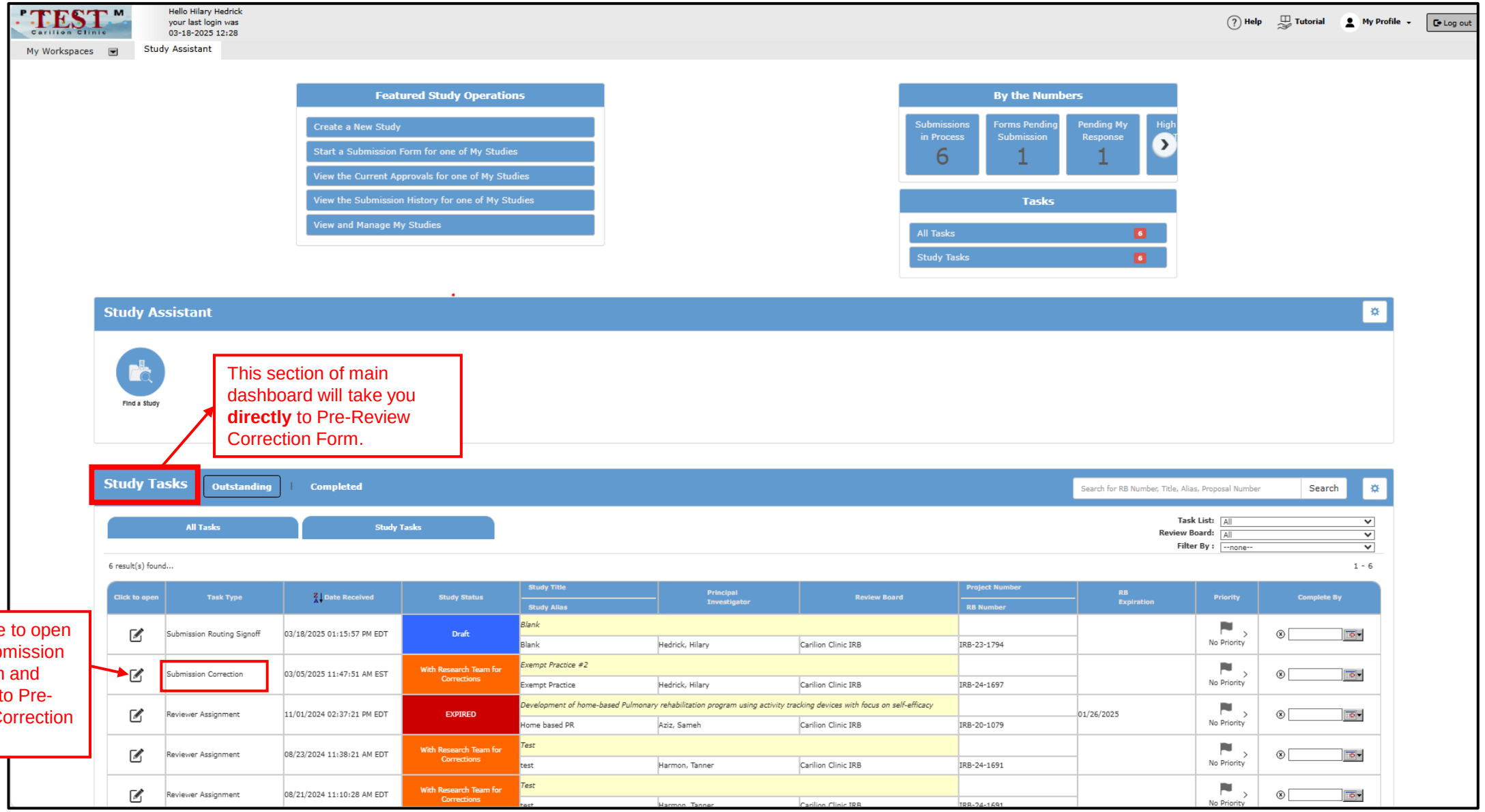
Important terms and notes:

- **Submission response**: Used when the study is in the **pre-review state**.
- **Submission correction**: Used when the study **has been reviewed** by analyst and/or IRB Committee and there are additional questions. Also referred to as "**stipulations**."
  - Questions and instructions are relayed and linked to applicable section in the PRIS3M application

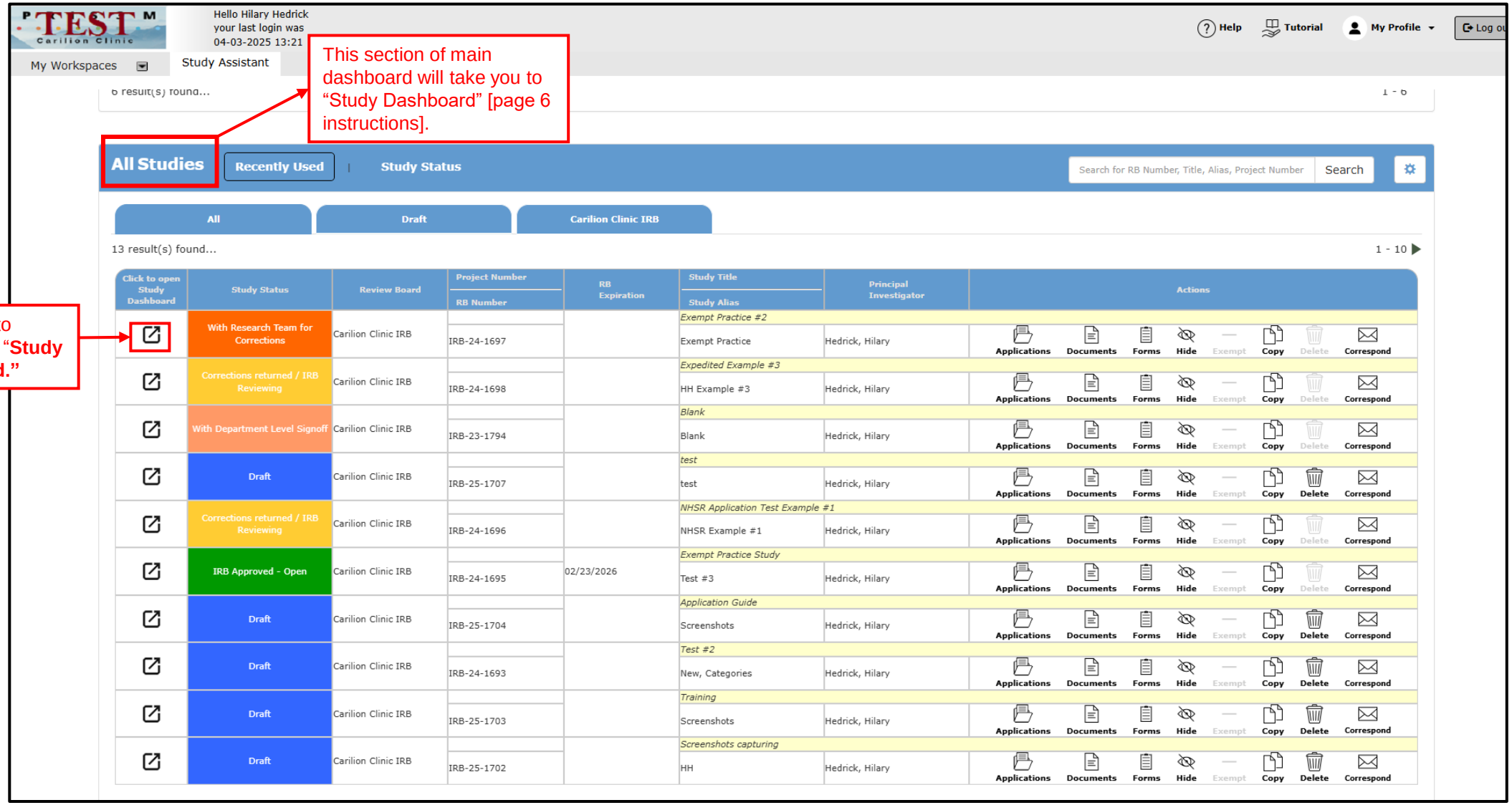
PI and study contact(s) will be notified by email that the IRB has requested additional information.

- Email will be from CarilionPRIS3M@imedris.net and provide link to log on to PRIS3M.
  - Email from PRIS3M may go to "Focused" or "Other" tab in Microsoft Outlook depending on your personal settings.

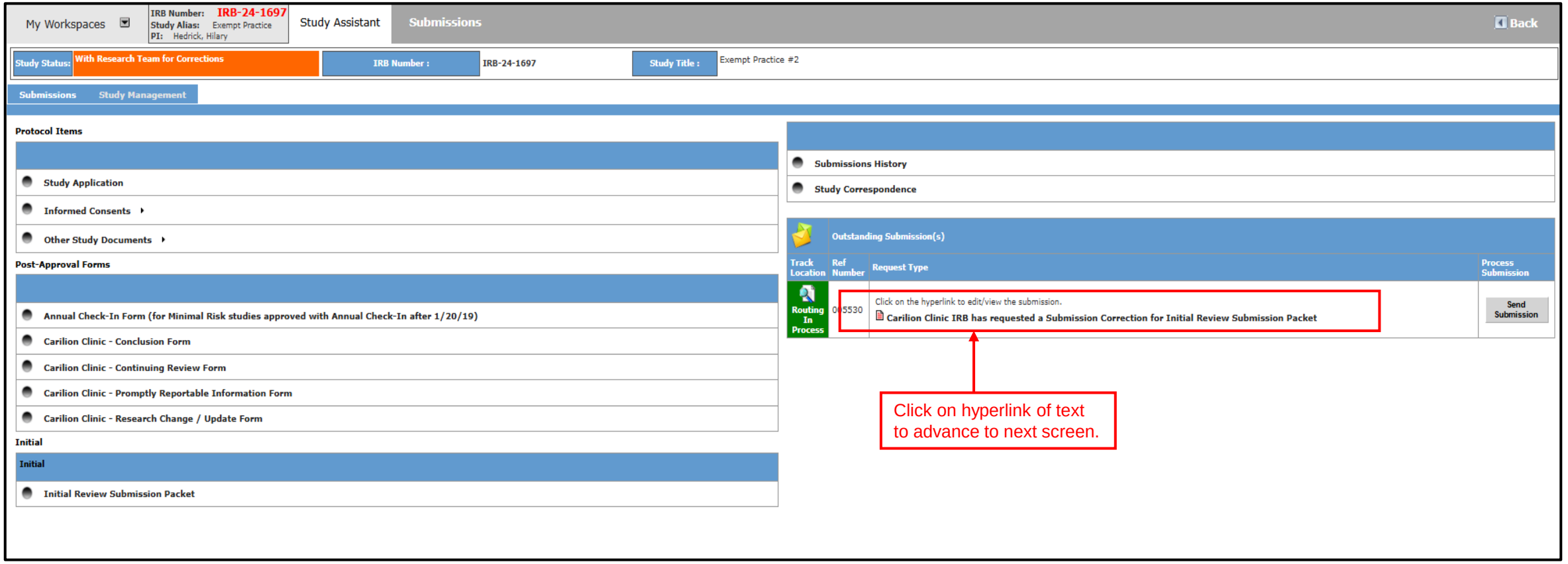
Main PRIS3M Dashboard (Under "Study Tasks")



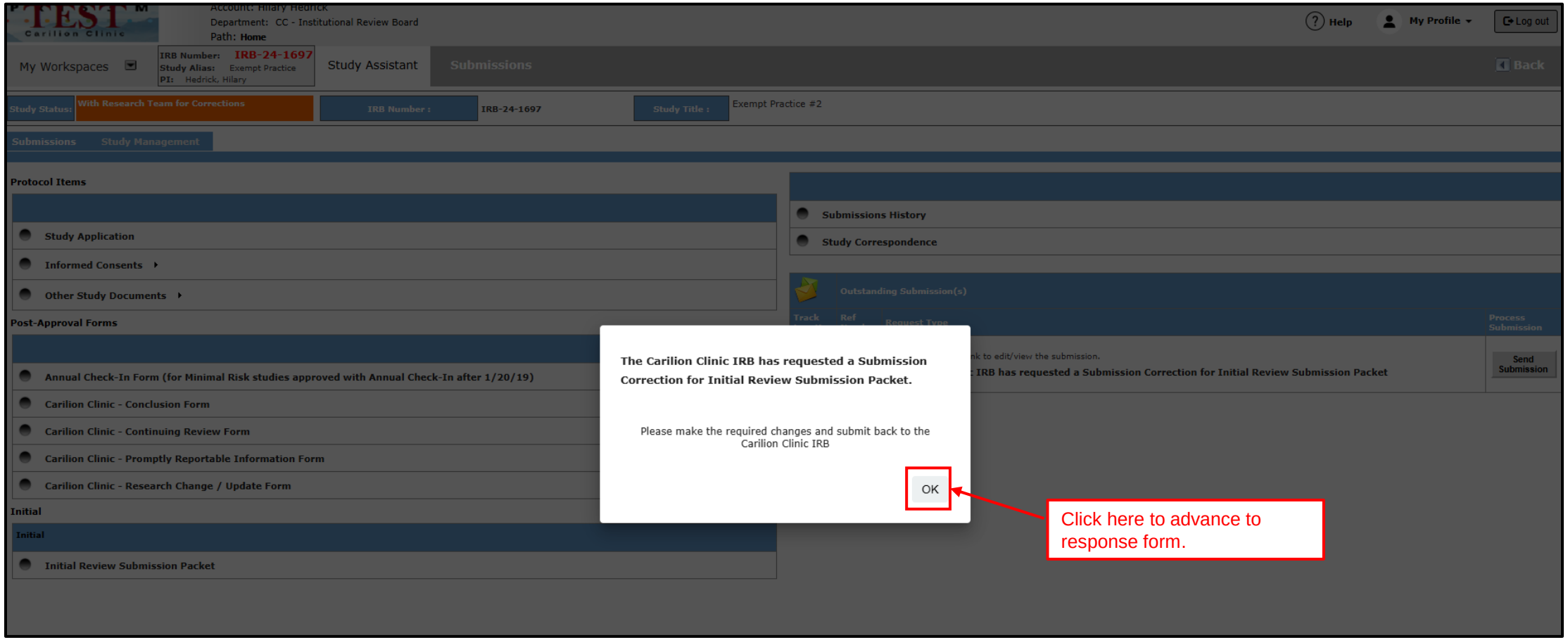
Another route in main PRIS3M Dashboard (Under "All Studies")



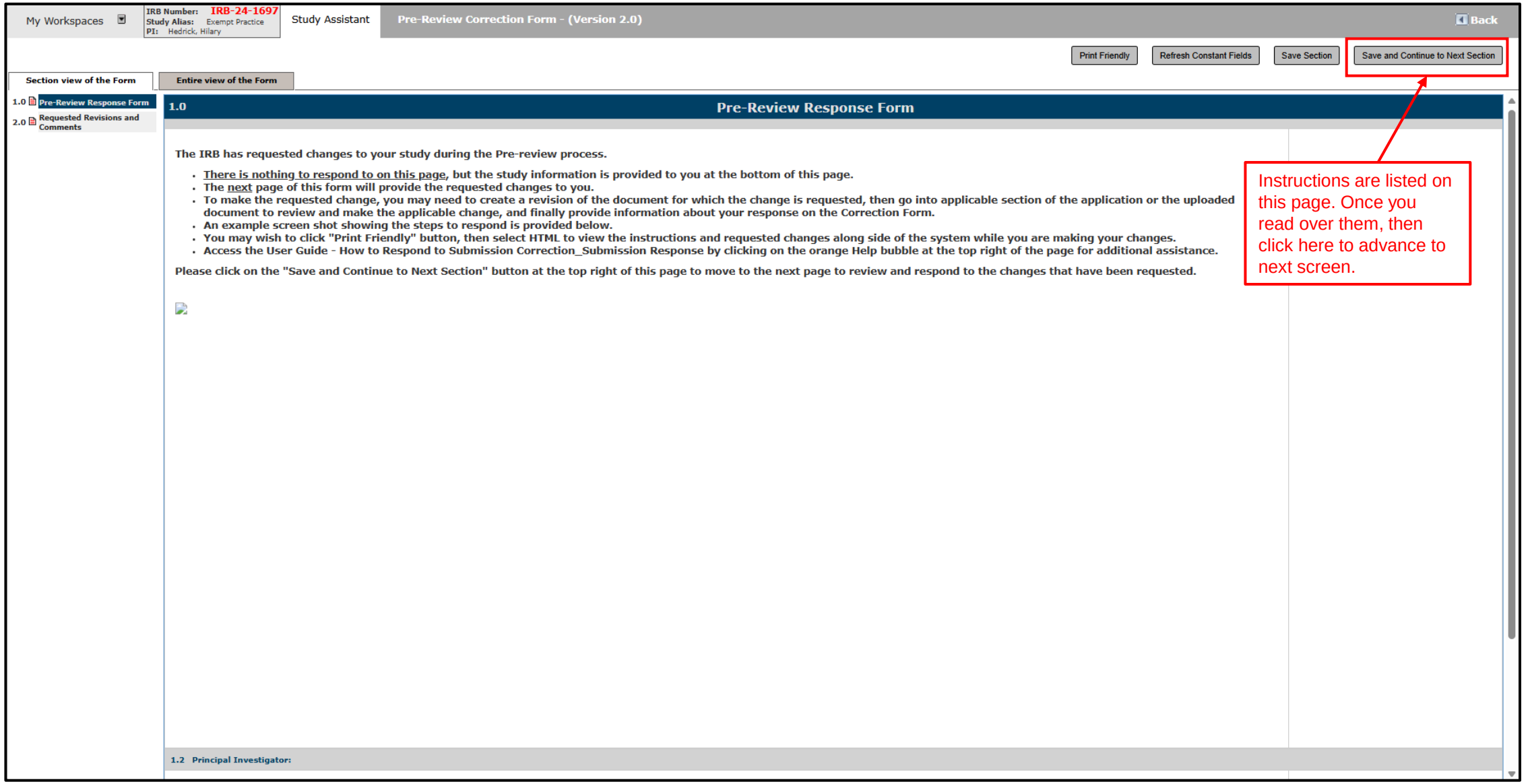
Study dashboard



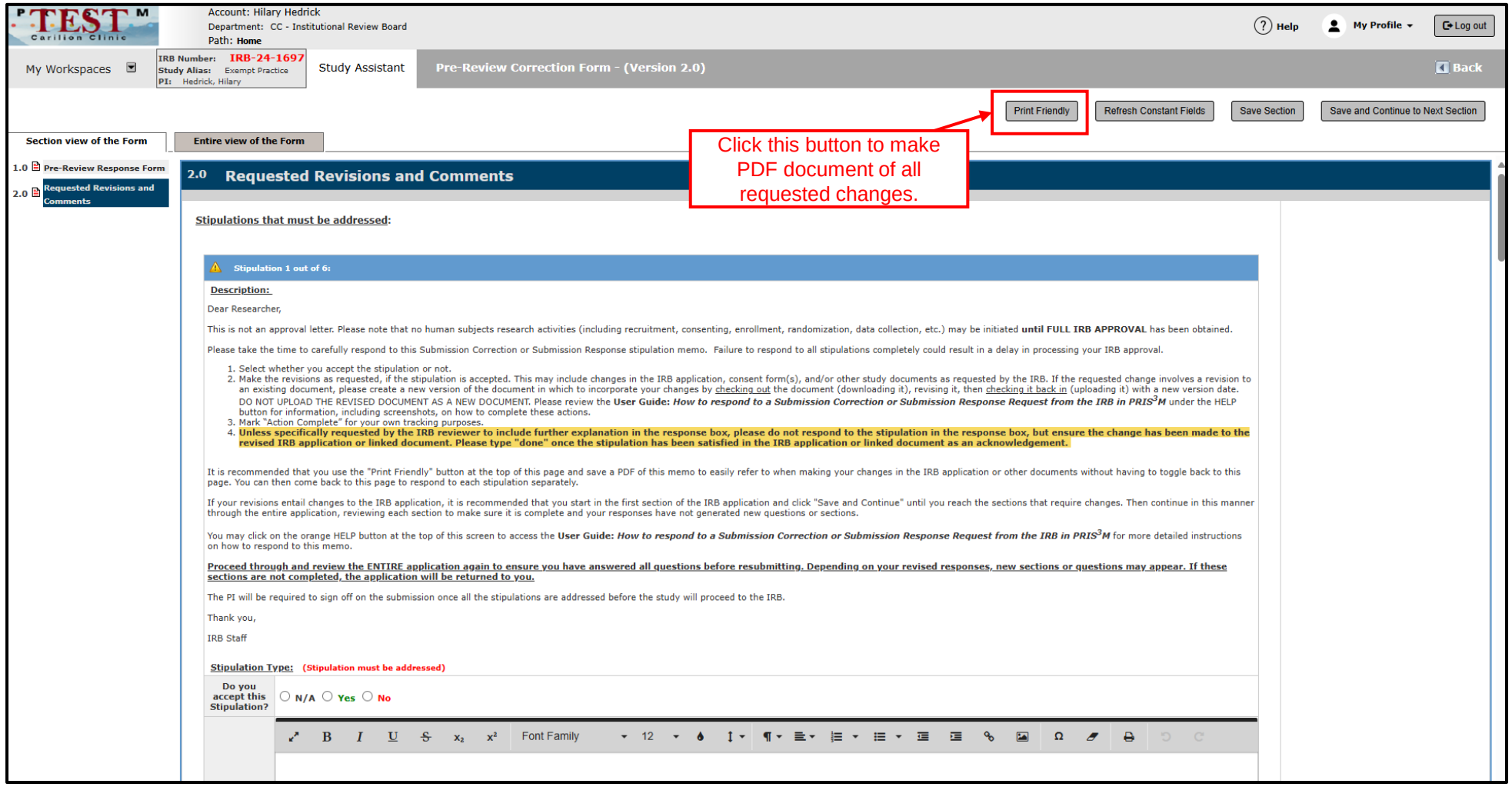
You will get a pop-up box informing you the IRB is requesting changes.



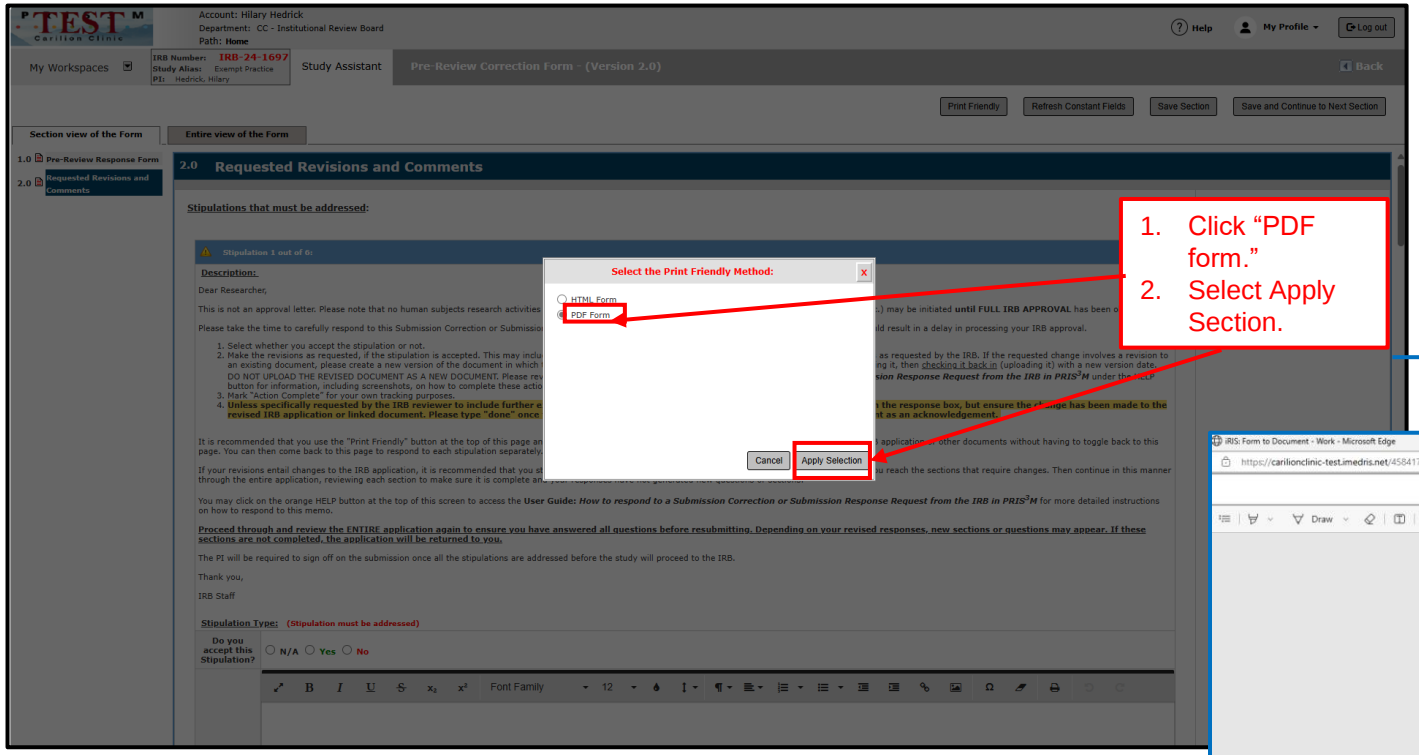
Next screen will automatically go to response form.



Tip from IRB Staff: To make the requested revisions process easier, make a PDF document of the requested revisions to view. The Pre-Review Correction Form is a SmartForm, so as you make changes, it will navigate away from this page to make the revisions live.

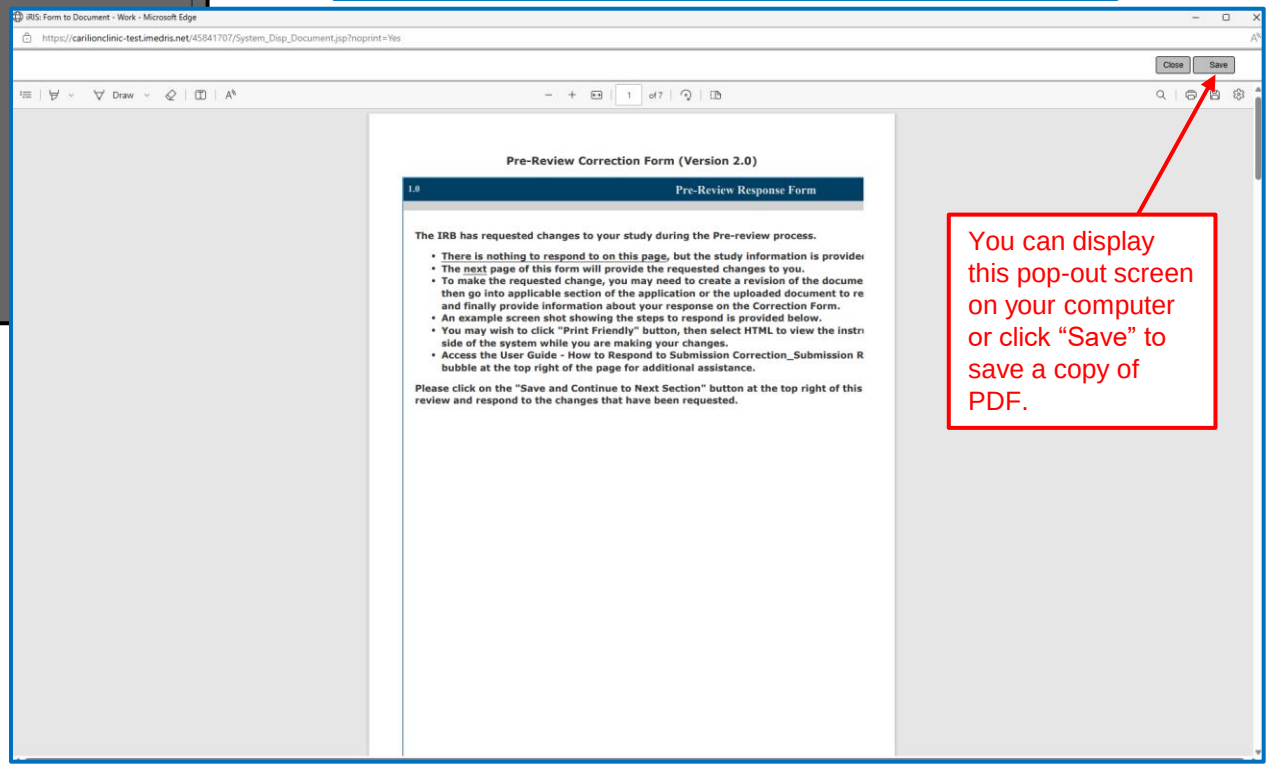


Creation of PDF reference document

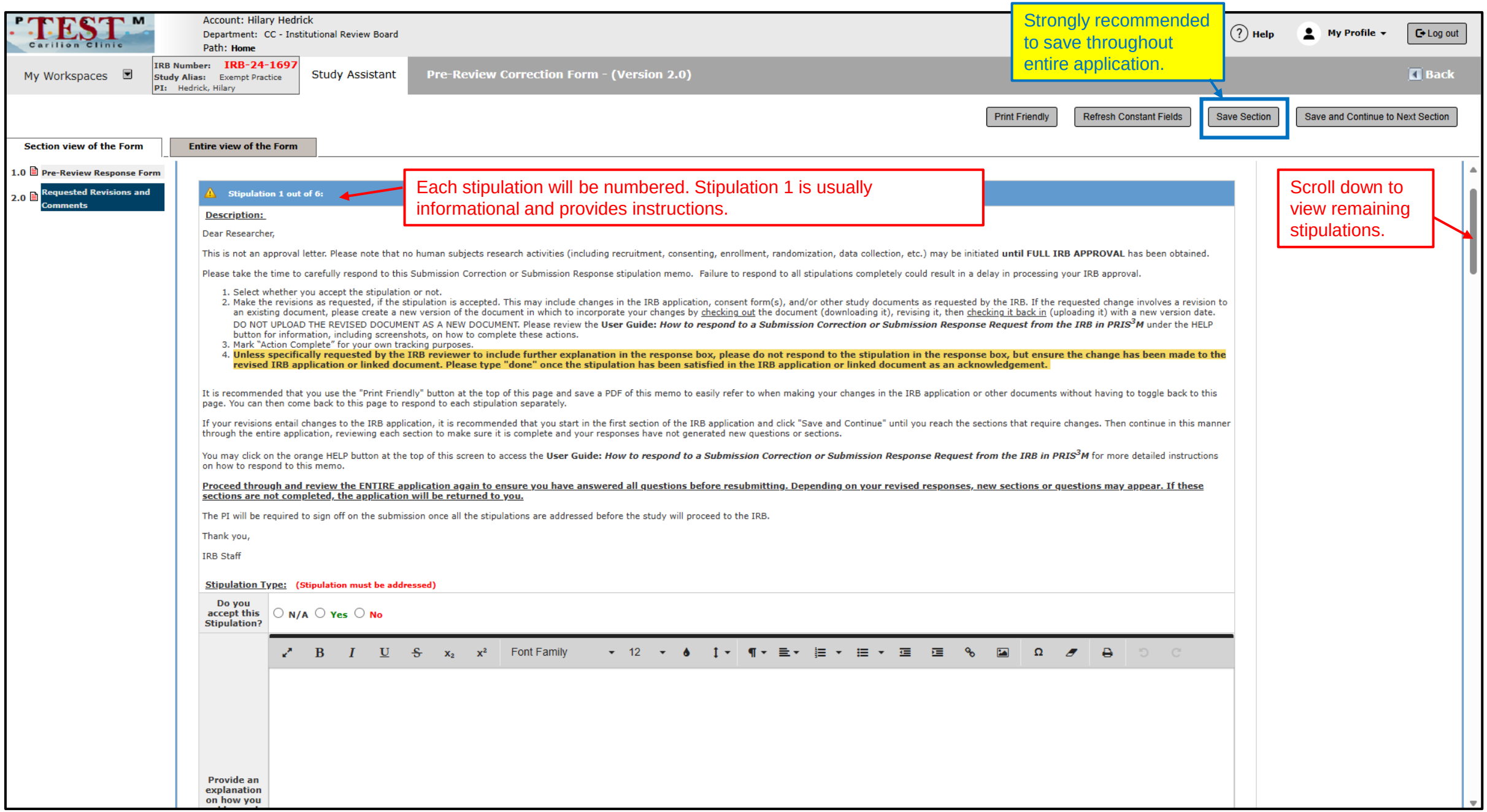


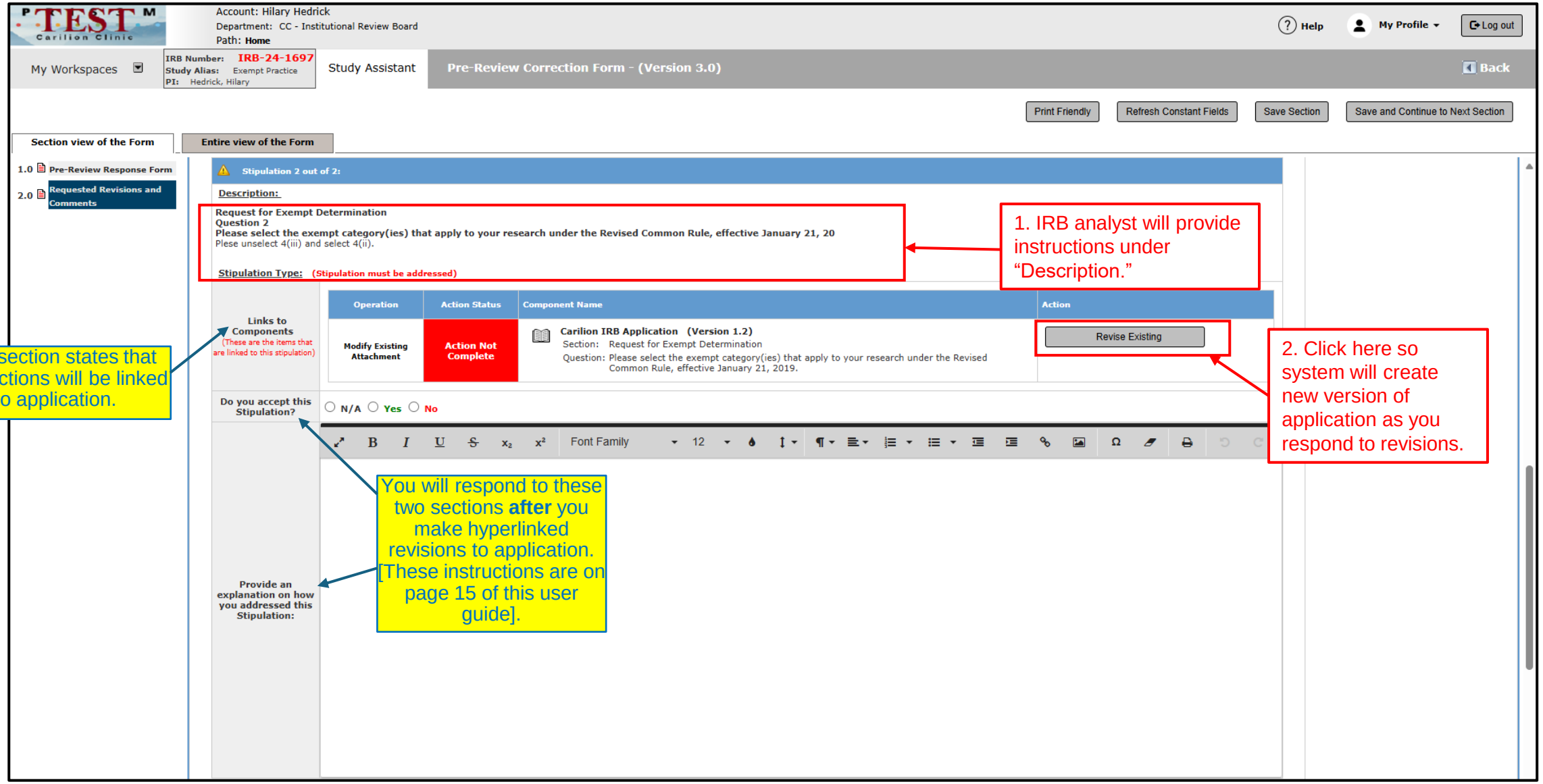
1. Click “PDF form.”
2. Select Apply Section.

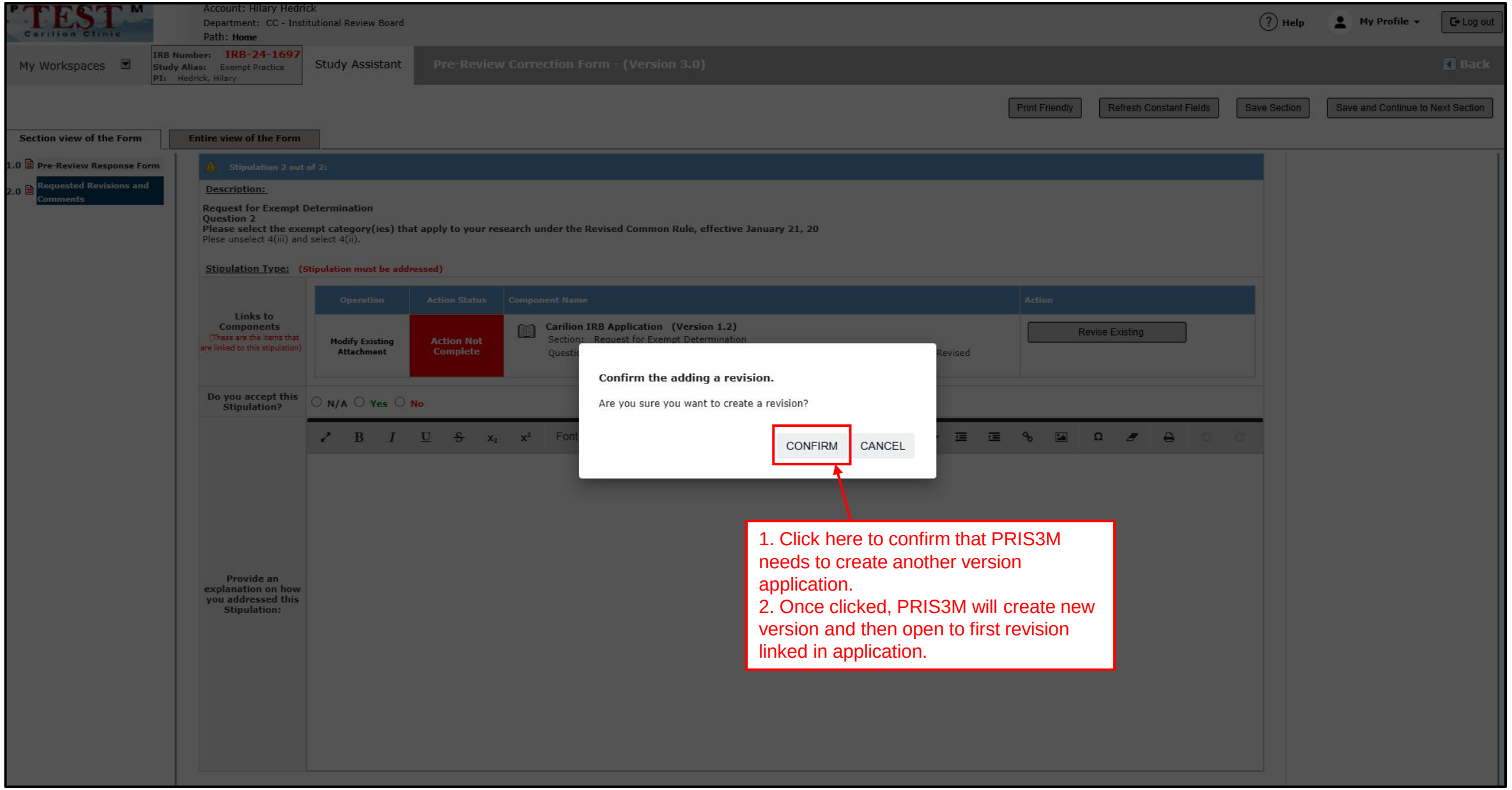
A pop-out screen will appear with PDF of all requested revisions.



You can display this pop-out screen on your computer or click “Save” to save a copy of PDF.


Account: Hilary Hedrick
Department: CC - Institutional Review Board
Path: Home
Help
My Profile
Log out
Strongly recommended to save throughout entire application.
My Workspaces
IRB Number: IRB-24-1697
Study Alias: Exempt Practice
PI: Hedrick, Hilary
Study Assistant
Pre-Review Correction Form - (Version 2.0)
Back
Print Friendly
Refresh Constant Fields
Save Section
Save and Continue to Next Section
Section view of the Form
Entire view of the Form
1.0 Pre-Review Response Form
2.0 Requested Revisions and Comments
Stipulation 1 out of 6:
Each stipulation will be numbered. Stipulation 1 is usually informational and provides instructions.
Scroll down to view remaining stipulations.
Description:
Dear Researcher,
This is not an approval letter. Please note that no human subjects research activities (including recruitment, consenting, enrollment, randomization, data collection, etc.) may be initiated until FULL IRB APPROVAL has been obtained.
Please take the time to carefully respond to this Submission Correction or Submission Response stipulation memo. Failure to respond to all stipulations completely could result in a delay in processing your IRB approval.
1. Select whether you accept the stipulation or not.
2. Make the revisions as requested, if the stipulation is accepted. This may include changes in the IRB application, consent form(s), and/or other study documents as requested by the IRB. If the requested change involves a revision to an existing document, please create a new version of the document in which to incorporate your changes by checking out the document (downloading it), revising it, then checking it back in (uploading it) with a new version date. DO NOT UPLOAD THE REVISED DOCUMENT AS A NEW DOCUMENT. Please review the User Guide: How to respond to a Submission Correction or Submission Response Request from the IRB in PRIS3M under the HELP button for information, including screenshots, on how to complete these actions.
3. Mark "Action Complete" for your own tracking purposes.
4. Unless specifically requested by the IRB reviewer to include further explanation in the response box, please do not respond to the stipulation in the response box, but ensure the change has been made to the revised IRB application or linked document. Please type "done" once the stipulation has been satisfied in the IRB application or linked document as an acknowledgement.
It is recommended that you use the "Print Friendly" button at the top of this page and save a PDF of this memo to easily refer to when making your changes in the IRB application or other documents without having to toggle back to this page. You can then come back to this page to respond to each stipulation separately.
If your revisions entail changes to the IRB application, it is recommended that you start in the first section of the IRB application and click "Save and Continue" until you reach the sections that require changes. Then continue in this manner through the entire application, reviewing each section to make sure it is complete and your responses have not generated new questions or sections.
You may click on the orange HELP button at the top of this screen to access the User Guide: How to respond to a Submission Correction or Submission Response Request from the IRB in PRIS3M for more detailed instructions on how to respond to this memo.
Proceed through and review the ENTIRE application again to ensure you have answered all questions before resubmitting. Depending on your revised responses, new sections or questions may appear. If these sections are not completed, the application will be returned to you.
The PI will be required to sign off on the submission once all the stipulations are addressed before the study will proceed to the IRB.
Thank you,
IRB Staff
Stipulation Type: (Stipulation must be addressed)
Do you accept this Stipulation?
N/A
Yes
No
Font Family
12
Provide an explanation on how you


Account: Hilary Hedrick
Department: CC - Institutional Review Board
Path: Home
Help
My Profile
Log out
My Workspaces
IRB Number: IRB-24-1697
Study Alias: Exempt Practice
PI: Hedrick, Hilary
Study Assistant
Pre-Review Correction Form - (Version 3.0)
Back
Print Friendly
Refresh Constant Fields
Save Section
Save and Continue to Next Section
Section view of the Form
Entire view of the Form
1.0 Pre-Review Response Form
2.0 Requested Revisions and Comments
Stipulation 2 out of 2:
Description:
Request for Exempt Determination
Question 2
Please select the exempt category(ies) that apply to your research under the Revised Common Rule, effective January 21, 20
Plese unselect 4(iii) and select 4(ii).
Stipulation Type: (Stipulation must be addressed)
1. IRB analyst will provide instructions under "Description."
Links to Components
(These are the items that are linked to this stipulation)
Operation
Action Status
Component Name
Action
Modify Existing Attachment
Action Not Complete
Carilion IRB Application (Version 1.2)
Section: Request for Exempt Determination
Question: Please select the exempt category(ies) that apply to your research under the Revised Common Rule, effective January 21, 2019.
Revise Existing
2. Click here so system will create new version of application as you respond to revisions.
This section states that your actions will be linked to application.
Do you accept this Stipulation?
N/A
Yes
No
Font Family
12
You will respond to these two sections after you make hyperlinked revisions to application. [These instructions are on page 15 of this user guide].
Provide an explanation on how you addressed this Stipulation:


Account: Hilary Hedrick
Department: CC - Institutional Review Board
Path: Home
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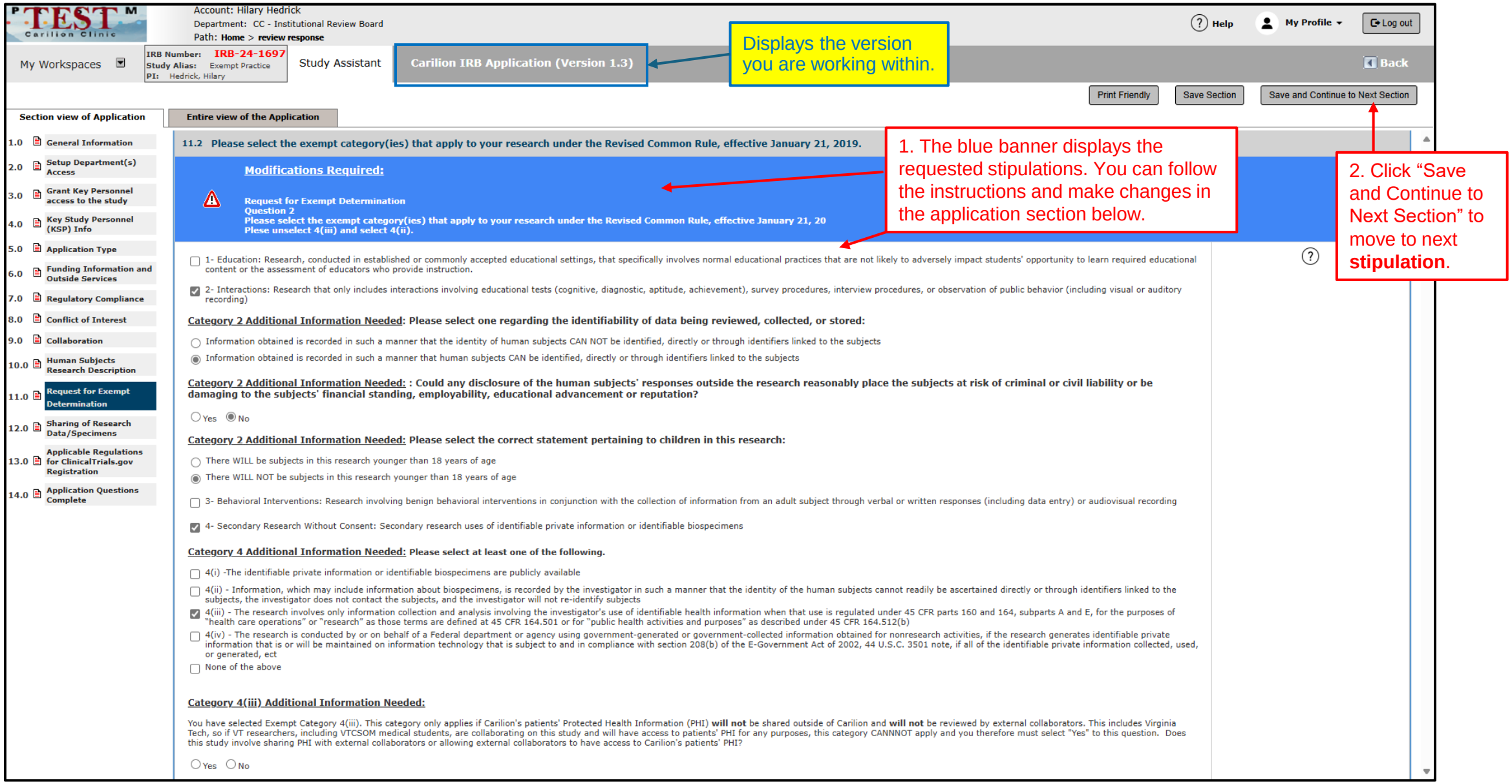
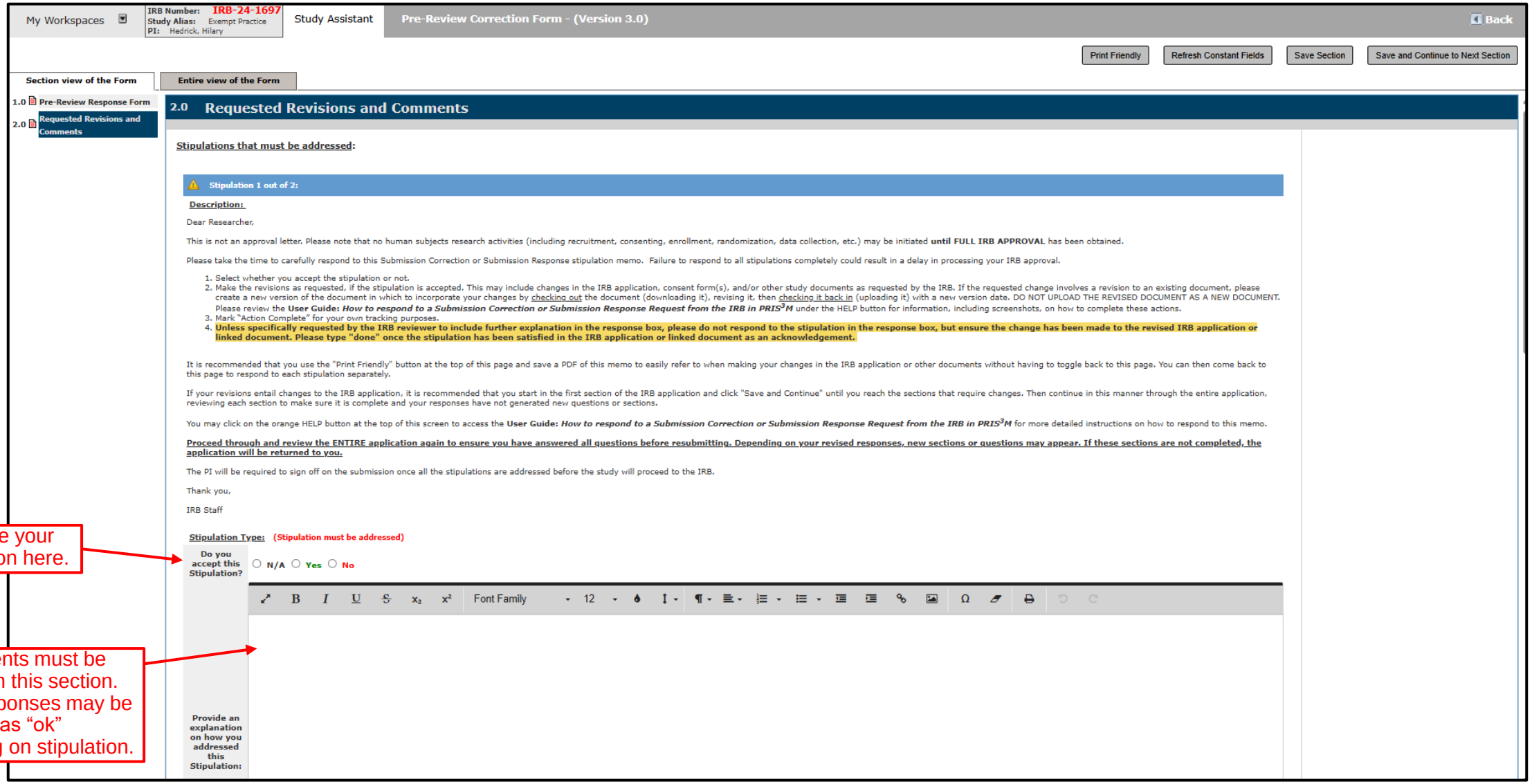
Log out
My Workspaces
IRB Number: IRB-24-1697
Study Alias: Exempt Practice
PI: Hedrick, Hilary
Study Assistant
Pre-Review Correction Form - (Version 3.0)
Back
Print Friendly
Refresh Constant Fields
Save Section
Save and Continue to Next Section
Section view of the Form
Entire view of the Form
1.0 Pre-Review Response Form
2.0 Requested Revisions and Comments
Stipulation 2 out of 2:
Description:
Request for Exempt Determination
Question 2
Please select the exempt category(ies) that apply to your research under the Revised Common Rule, effective January 21, 20
Plese unselect 4(iii) and select 4(ii).
Stipulation Type: (Stipulation must be addressed)
Links to Components
(These are the items that are linked to this stipulation)
Operation
Action Status
Component Name
Action
Modify Existing Attachment
Action Not Complete
Carilion IRB Application (Version 1.2)
Revise Existing
Do you accept this Stipulation?
N/A
Yes
No
Provide an explanation on how you addressed this Stipulation:
Confirm the adding a revision.
Are you sure you want to create a revision?
CONFIRM
CANCEL
1. Click here to confirm that PRIS3M needs to create another version application.
2. Once clicked, PRIS3M will create new version and then open to first revision linked in application.


Account: Hilary Hedrick
Department: CC - Institutional Review Board
Path: Home > review response
Help
My Profile
Log out
My Workspaces
IRB Number: IRB-24-1697
Study Alias: Exempt Practice
PI: Hedrick, Hilary
Study Assistant
Carilion IRB Application (Version 1.3)
Back
Displays the version you are working within.
Print Friendly
Save Section
Save and Continue to Next Section
Section view of Application
Entire view of the Application
1.0 General Information
2.0 Setup Department(s) Access
3.0 Grant Key Personnel access to the study
4.0 Key Study Personnel (KSP) Info
5.0 Application Type
6.0 Funding Information and Outside Services
7.0 Regulatory Compliance
8.0 Conflict of Interest
9.0 Collaboration
10.0 Human Subjects Research Description
11.0 Request for Exempt Determination
12.0 Sharing of Research Data/Specimens
13.0 Applicable Regulations for ClinicalTrials.gov Registration
14.0 Application Questions Complete
11.2 Please select the exempt category(ies) that apply to your research under the Revised Common Rule, effective January 21, 2019.
Modifications Required:
Request for Exempt Determination
Question 2
Please select the exempt category(ies) that apply to your research under the Revised Common Rule, effective January 21, 20
Plese unselect 4(iii) and select 4(ii).
1. The blue banner displays the requested stipulations. You can follow the instructions and make changes in the application section below.
2. Click “Save and Continue to Next Section” to move to next stipulation.
1- Education: Research, conducted in established or commonly accepted educational settings, that specifically involves normal educational practices that are not likely to adversely impact students' opportunity to learn required educational content or the assessment of educators who provide instruction.
2- Interactions: Research that only includes interactions involving educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior (including visual or auditory recording)
Category 2 Additional Information Needed: Please select one regarding the identifiability of data being reviewed, collected, or stored:
Information obtained is recorded in such a manner that the identity of human subjects CAN NOT be identified, directly or through identifiers linked to the subjects
Information obtained is recorded in such a manner that human subjects CAN be identified, directly or through identifiers linked to the subjects
Category 2 Additional Information Needed: : Could any disclosure of the human subjects' responses outside the research reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, educational advancement or reputation?
Yes No
Category 2 Additional Information Needed: Please select the correct statement pertaining to children in this research:
There WILL be subjects in this research younger than 18 years of age
There WILL NOT be subjects in this research younger than 18 years of age
3- Behavioral Interventions: Research involving benign behavioral interventions in conjunction with the collection of information from an adult subject through verbal or written responses (including data entry) or audiovisual recording
4- Secondary Research Without Consent: Secondary research uses of identifiable private information or identifiable biospecimens
Category 4 Additional Information Needed: Please select at least one of the following.
4(i) -The identifiable private information or identifiable biospecimens are publicly available
4(ii) - Information, which may include information about biospecimens, is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained directly or through identifiers linked to the subjects, the investigator does not contact the subjects, and the investigator will not re-identify subjects
4(iii) - The research involves only information collection and analysis involving the investigator's use of identifiable health information when that use is regulated under 45 CFR parts 160 and 164, subparts A and E, for the purposes of "health care operations" or "research" as those terms are defined at 45 CFR 164.501 or for "public health activities and purposes" as described under 45 CFR 164.512(b)
4(iv) - The research is conducted by or on behalf of a Federal department or agency using government-generated or government-collected information obtained for nonresearch activities, if the research generates identifiable private information that is or will be maintained on information technology that is subject to and in compliance with section 208(b) of the E-Government Act of 2002, 44 U.S.C. 3501 note, if all of the identifiable private information collected, used, or generated, ect
None of the above
Category 4(iii) Additional Information Needed:
You have selected Exempt Category 4(iii). This category only applies if Carilion's patients' Protected Health Information (PHI) will not be shared outside of Carilion and will not be reviewed by external collaborators. This includes Virginia Tech, so if VT researchers, including VTCSOM medical students, are collaborating on this study and will have access to patients' PHI for any purposes, this category CANNNOT apply and you therefore must select "Yes" to this question. Does this study involve sharing PHI with external collaborators or allowing external collaborators to have access to Carilion's patients' PHI?
Yes No

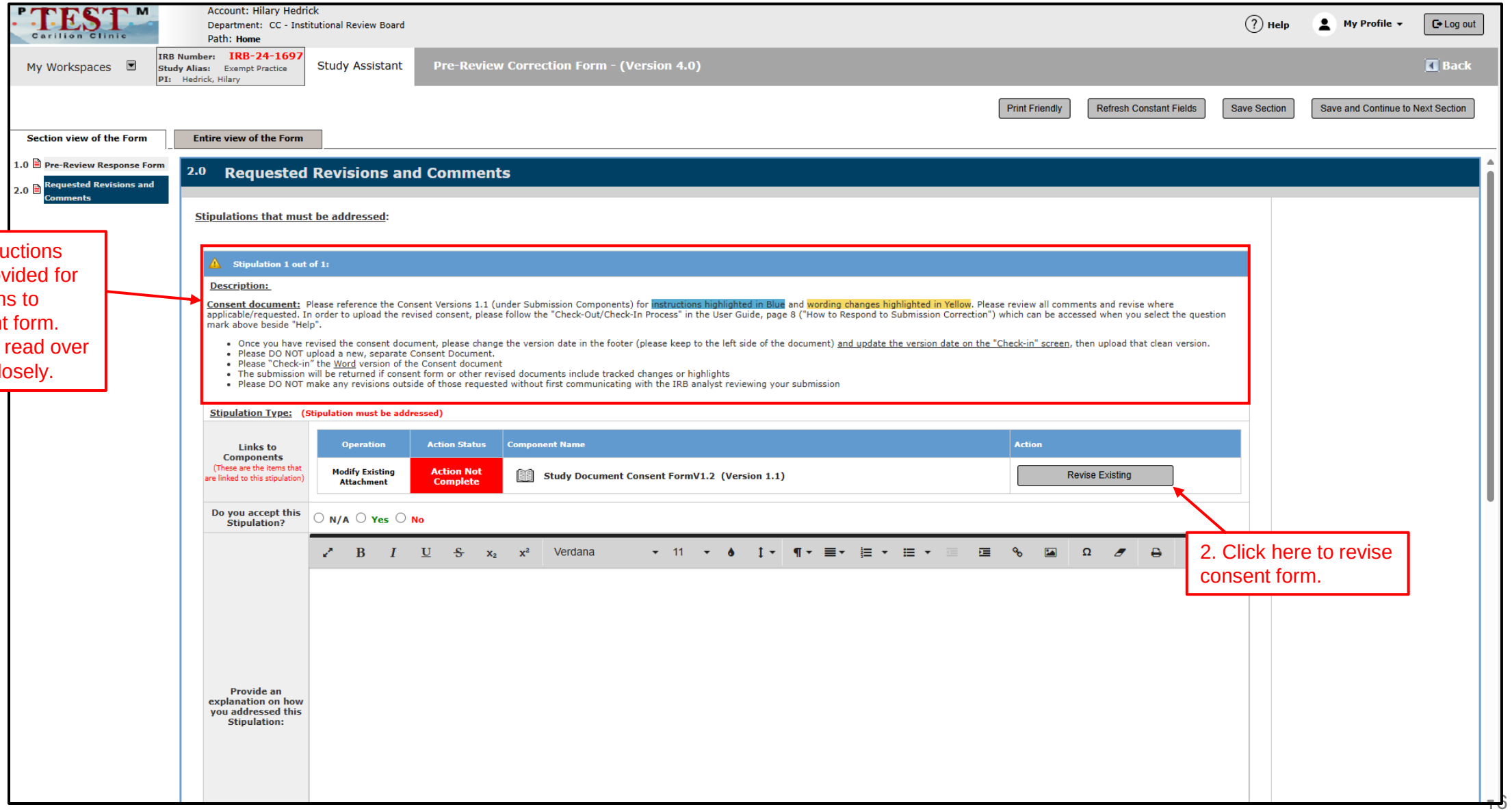
After you complete the linked stipulations in application sections, you will be taken back to the Pre-Review Correction Form [where you started].



1. Make your selection here.

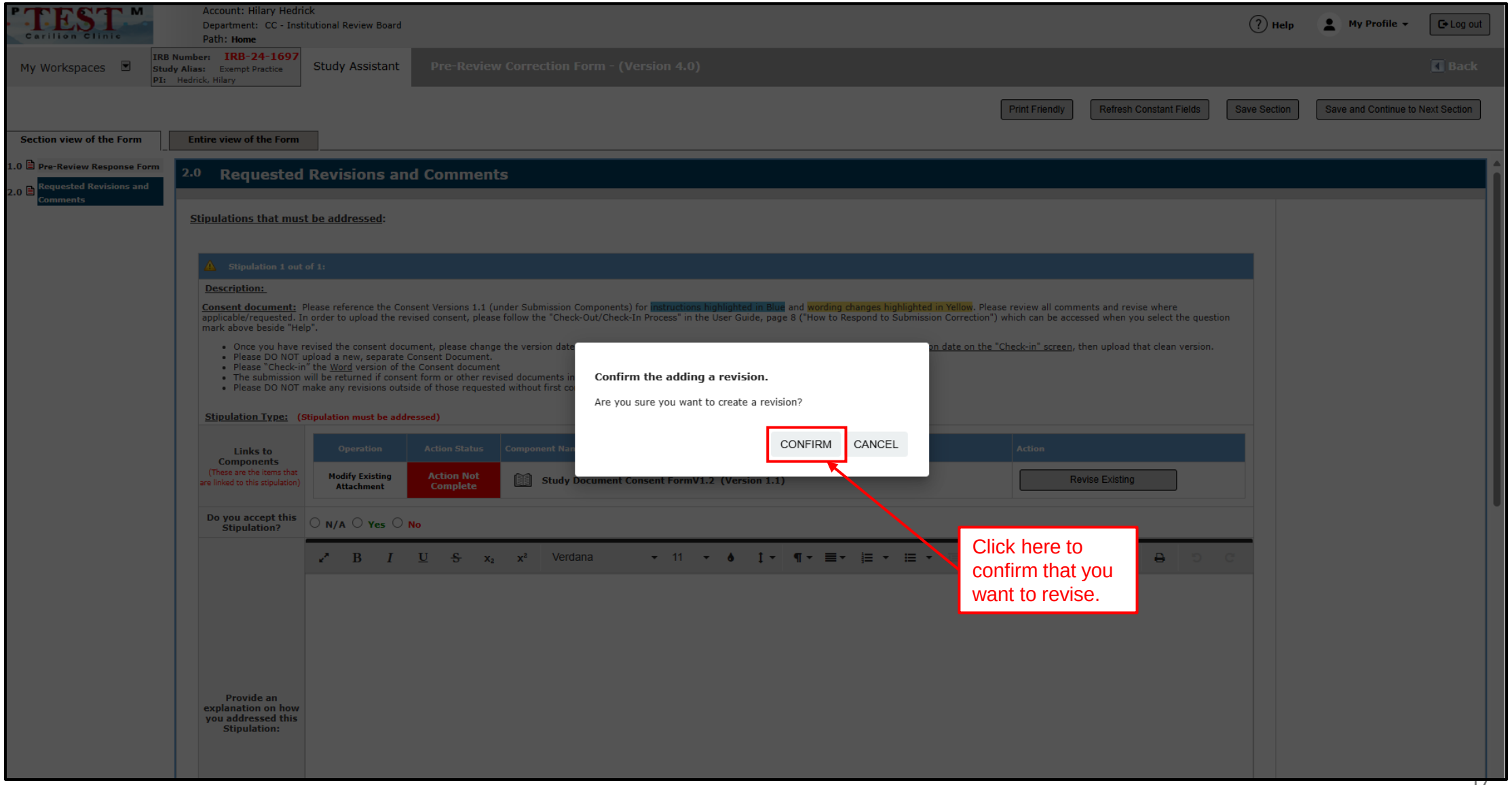
2. Comments must be included in this section. Some responses may be as simple as “ok” depending on stipulation.

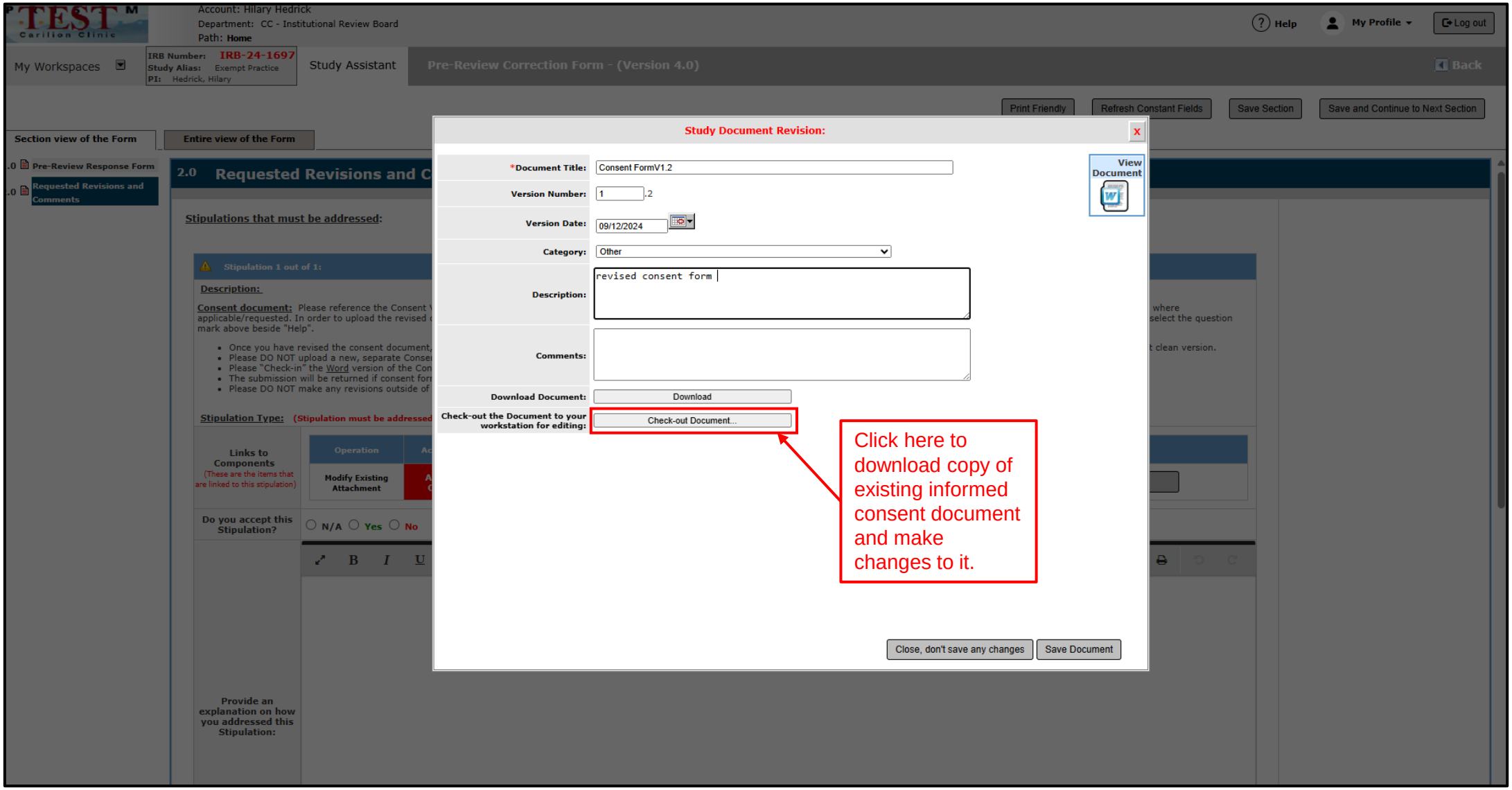
Revision to Consent Form



1. Instructions are provided for revisions to consent form. Please read over them closely.

2. Click here to revise consent form.


Account: Hilary Hedrick
Department: CC - Institutional Review Board
Path: Home
Help
My Profile
Log out
My Workspaces
IRB Number: IRB-24-1697
Study Alias: Exempt Practice
PI: Hedrick, Hilary
Study Assistant
Pre-Review Correction Form - (Version 4.0)
Back
Print Friendly
Refresh Constant Fields
Save Section
Save and Continue to Next Section
Section view of the Form
Entire view of the Form
1.0 Pre-Review Response Form
2.0 Requested Revisions and Comments
2.0 Requested Revisions and Comments
Stipulations that must be addressed:
Stipulation 1 out of 1:
Description:
Consent document: Please reference the Consent Versions 1.1 (under Submission Components) for instructions highlighted in Blue and wording changes highlighted in Yellow. Please review all comments and revise where applicable/requested. In order to upload the revised consent, please follow the "Check-Out/Check-In Process" in the User Guide, page 8 ("How to Respond to Submission Correction") which can be accessed when you select the question mark above beside "Help".
Once you have revised the consent document, please change the version date
Please DO NOT upload a new, separate Consent Document.
Please "Check-in" the Word version of the Consent document
The submission will be returned if consent form or other revised documents in
Please DO NOT make any revisions outside of those requested without first co
on date on the "Check-in" screen, then upload that clean version.
Stipulation Type: (Stipulation must be addressed)
Links to Components
(These are the items that are linked to this stipulation)
Operation
Action Status
Component Nam
Action
Modify Existing Attachment
Action Not Complete
Study Document Consent FormV1.2 (Version 1.1)
Revise Existing
Do you accept this Stipulation?
N/A
Yes
No
Verdana
11
Provide an explanation on how you addressed this Stipulation:
Confirm the adding a revision.
Are you sure you want to create a revision?
CONFIRM
CANCEL
Click here to confirm that you want to revise.


Account: Hilary Hedrick
Department: CC - Institutional Review Board
Path: Home
Help
My Profile
Log out
My Workspaces
IRB Number: IRB-24-1697
Study Alias: Exempt Practice
PI: Hedrick, Hilary
Study Assistant
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2.0 Requested Revisions and C
Stipulations that must be addressed:
Stipulation 1 out of 1:
Description:
Consent document: Please reference the Consent
applicable/requested. In order to upload the revised
mark above beside "Help".
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Please DO NOT upload a new, separate Conse
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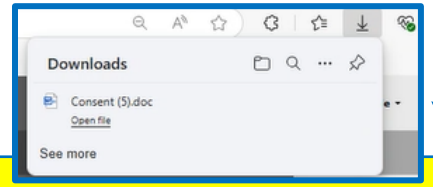
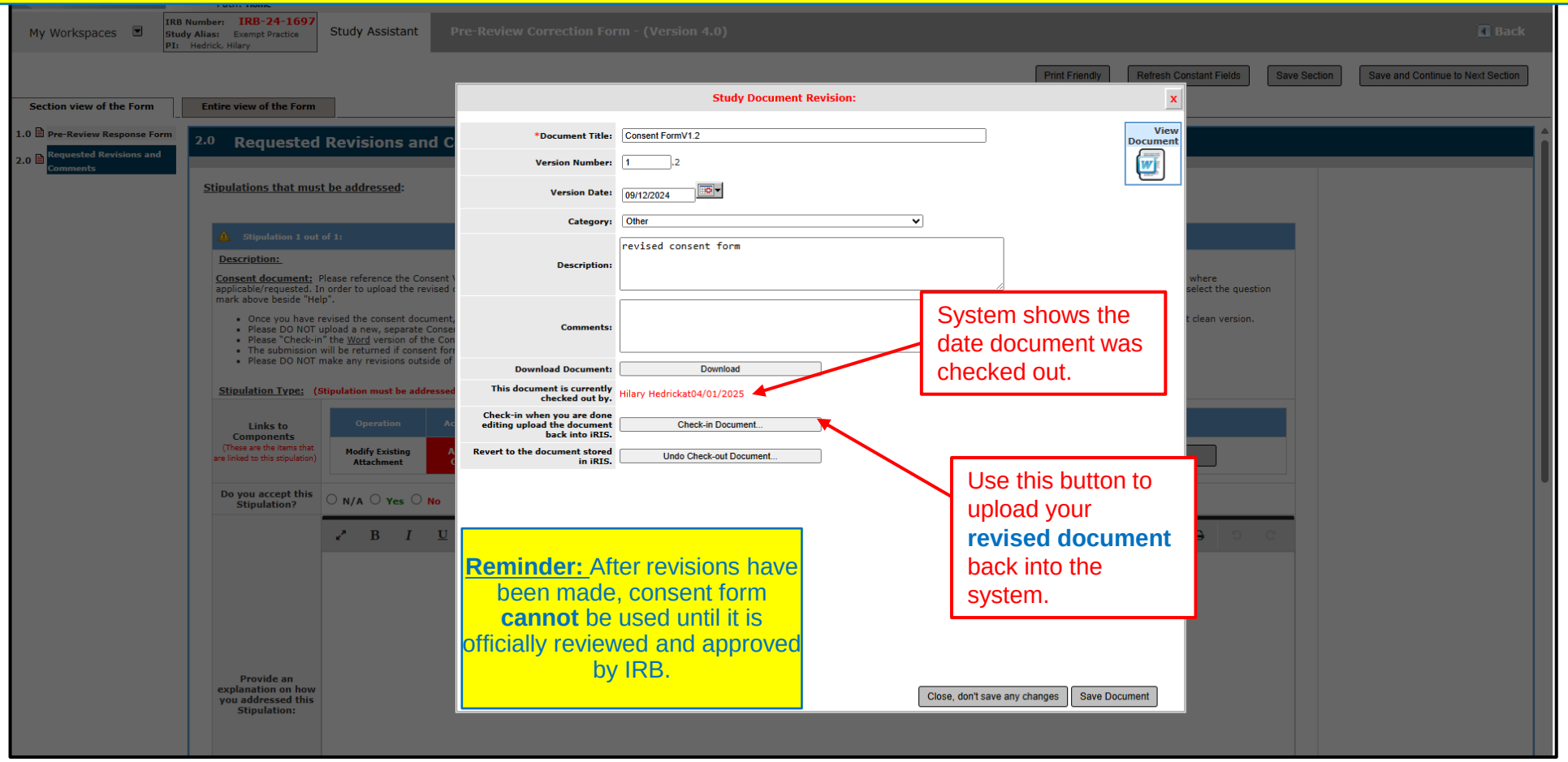
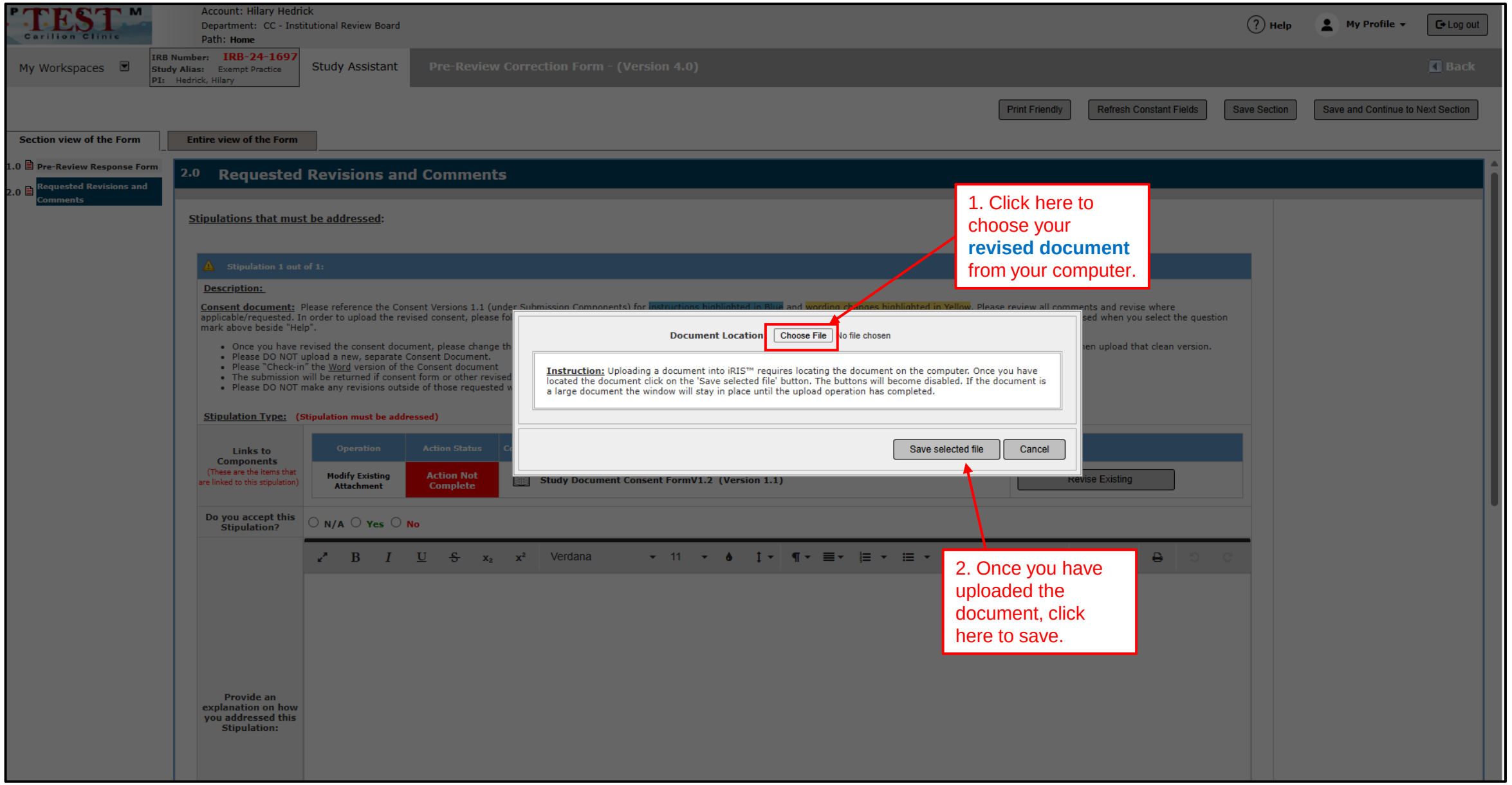
Please DO NOT make any revisions outside of
Stipulation Type: (Stipulation must be addressed
Links to Components
(These are the items that are linked to this stipulation)
Operation
Modify Existing Attachment
Do you accept this Stipulation?
N/A
Yes
No
Provide an explanation on how you addressed this Stipulation:
where
select the question
t clean version.
Study Document Revision:
*Document Title:
Consent FormV1.2
Version Number:
1
.2
Version Date:
09/12/2024
Category:
Other
Description:
revised consent form
Comments:
Download Document:
Download
Check-out the Document to your workstation for editing:
Check-out Document...
View Document
Click here to download copy of existing informed consent document and make changes to it.
Close, don't save any changes
Save Document



Wait a few moments, and “File Download” box will pop up on computer. Open a copy of the document as a Word file and start making the requested changes. Once all changes are complete, save the document to your computer with a document name to identify the correct version of informed consent form for you and your research team. Follow the instructions below to check back in revised document.




Account: Hilary Hedrick
Department: CC - Institutional Review Board
Path: Home
Help
My Profile
Log out
My Workspaces
IRB Number: IRB-24-1697
Study Alias: Exempt Practice
PI: Hedrick, Hilary
Study Assistant
Pre-Review Correction Form - (Version 4.0)
Back
Print Friendly
Refresh Constant Fields
Save Section
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Section view of the Form
Entire view of the Form
1.0 Pre-Review Response Form
2.0 Requested Revisions and Comments
2.0 Requested Revisions and Comments
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Stipulation 1 out of 1:
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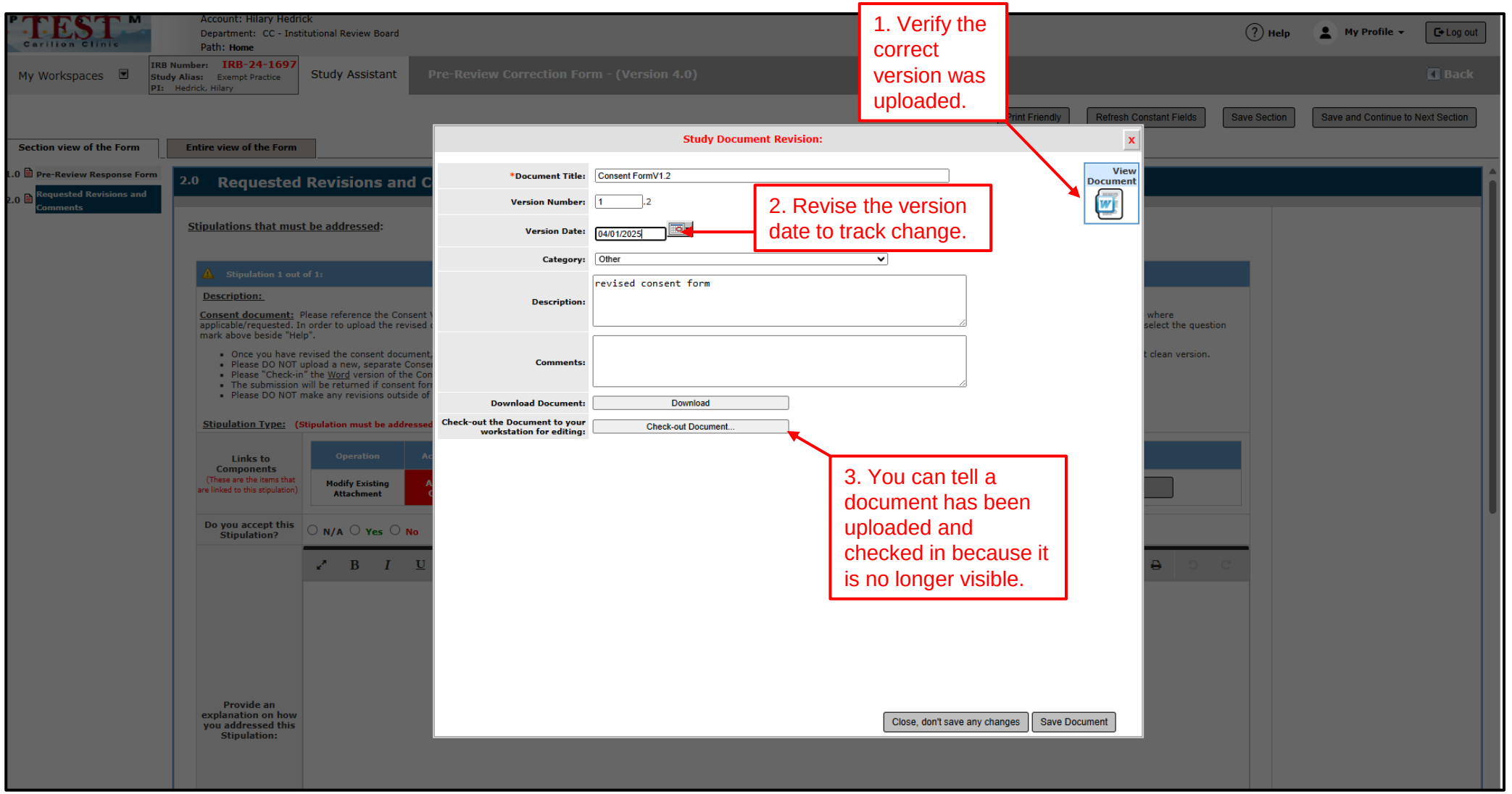
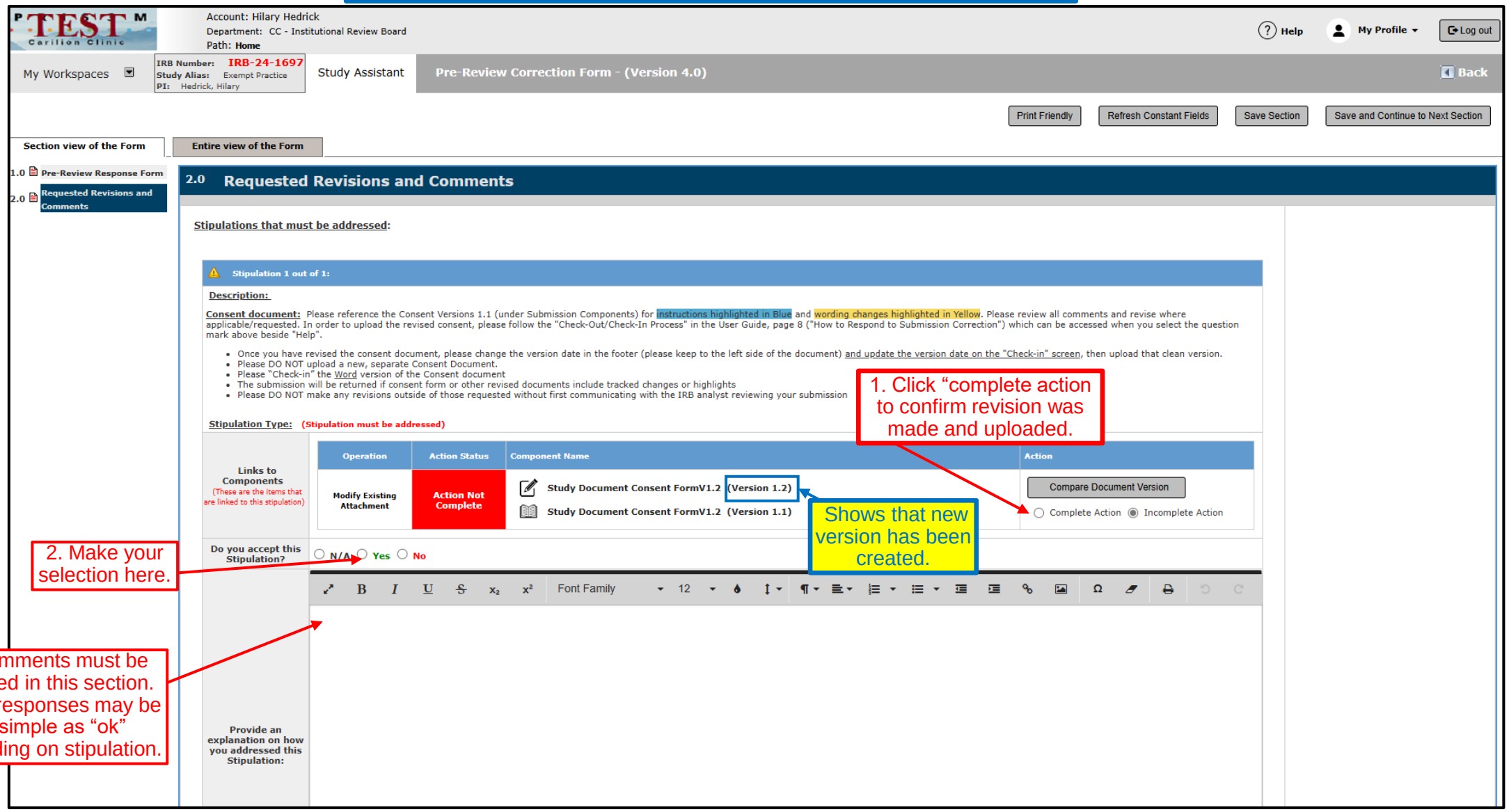
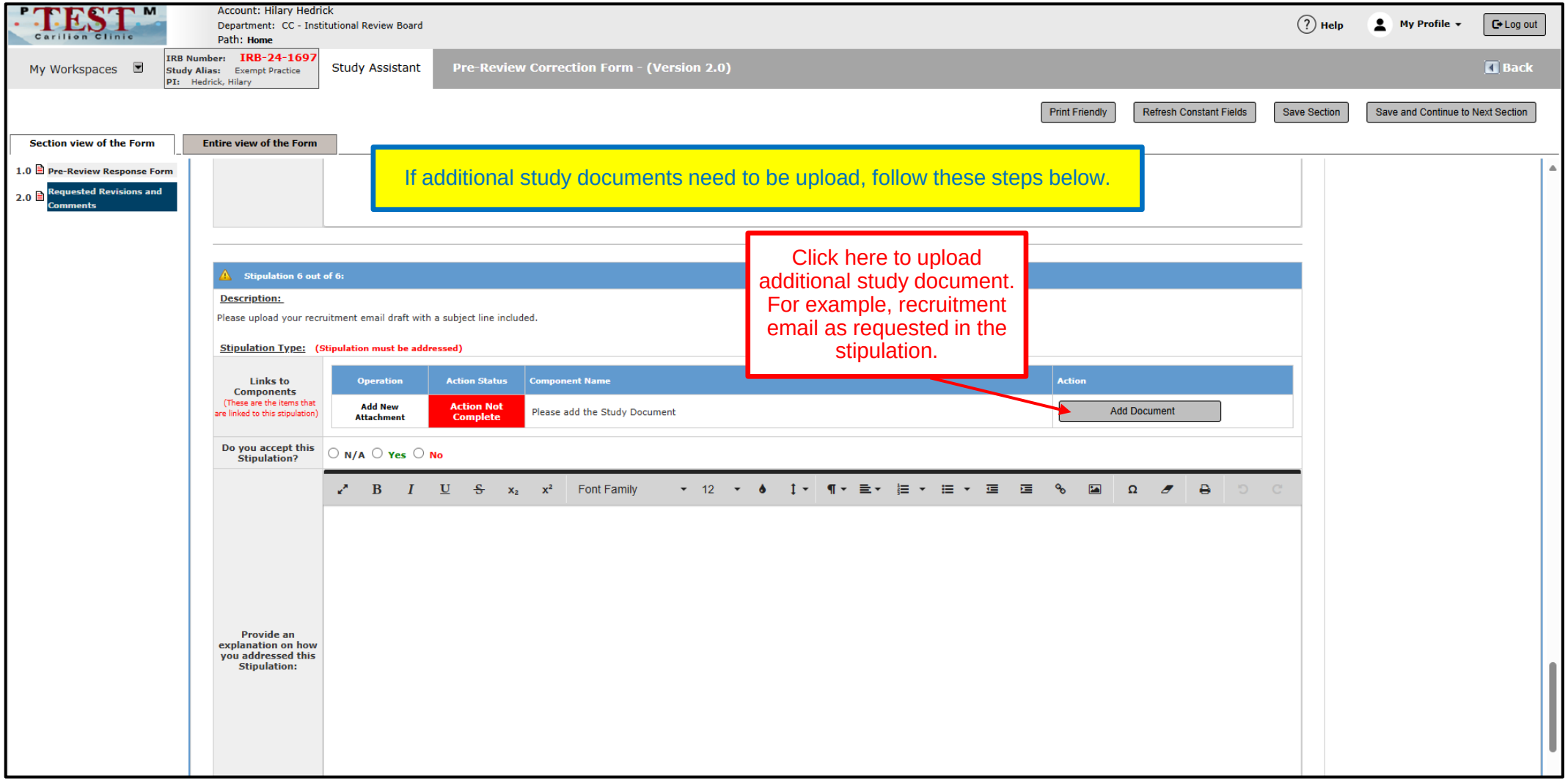
Consent document: Please reference the Consent Versions 1.1 (under Submission Components) for instructions highlighted in Blue and wording changes highlighted in Yellow. Please review all comments and revise where applicable/requested. In order to upload the revised consent, please fo
sed when you select the question mark above beside "Help".
Once you have revised the consent document, please change th
Please DO NOT upload a new, separate Consent Document.
Please "Check-in" the Word version of the Consent document
The submission will be returned if consent form or other revised
Please DO NOT make any revisions outside of those requested w
en upload that clean version.
Stipulation Type: (Stipulation must be addressed)
Links to Components
(These are the items that are linked to this stipulation)
Operation
Action Status
Modify Existing Attachment
Action Not Complete
Study Document Consent FormV1.2 (Version 1.1)
Revise Existing
Do you accept this Stipulation?
N/A
Yes
No
Verdana
11
Provide an explanation on how you addressed this Stipulation:
Document Location
Choose File
No file chosen
Instruction: Uploading a document into iRIS™ requires locating the document on the computer. Once you have located the document click on the 'Save selected file' button. The buttons will become disabled. If the document is a large document the window will stay in place until the upload operation has completed.
Save selected file
Cancel
1. Click here to choose your revised document from your computer.
2. Once you have uploaded the document, click here to save.

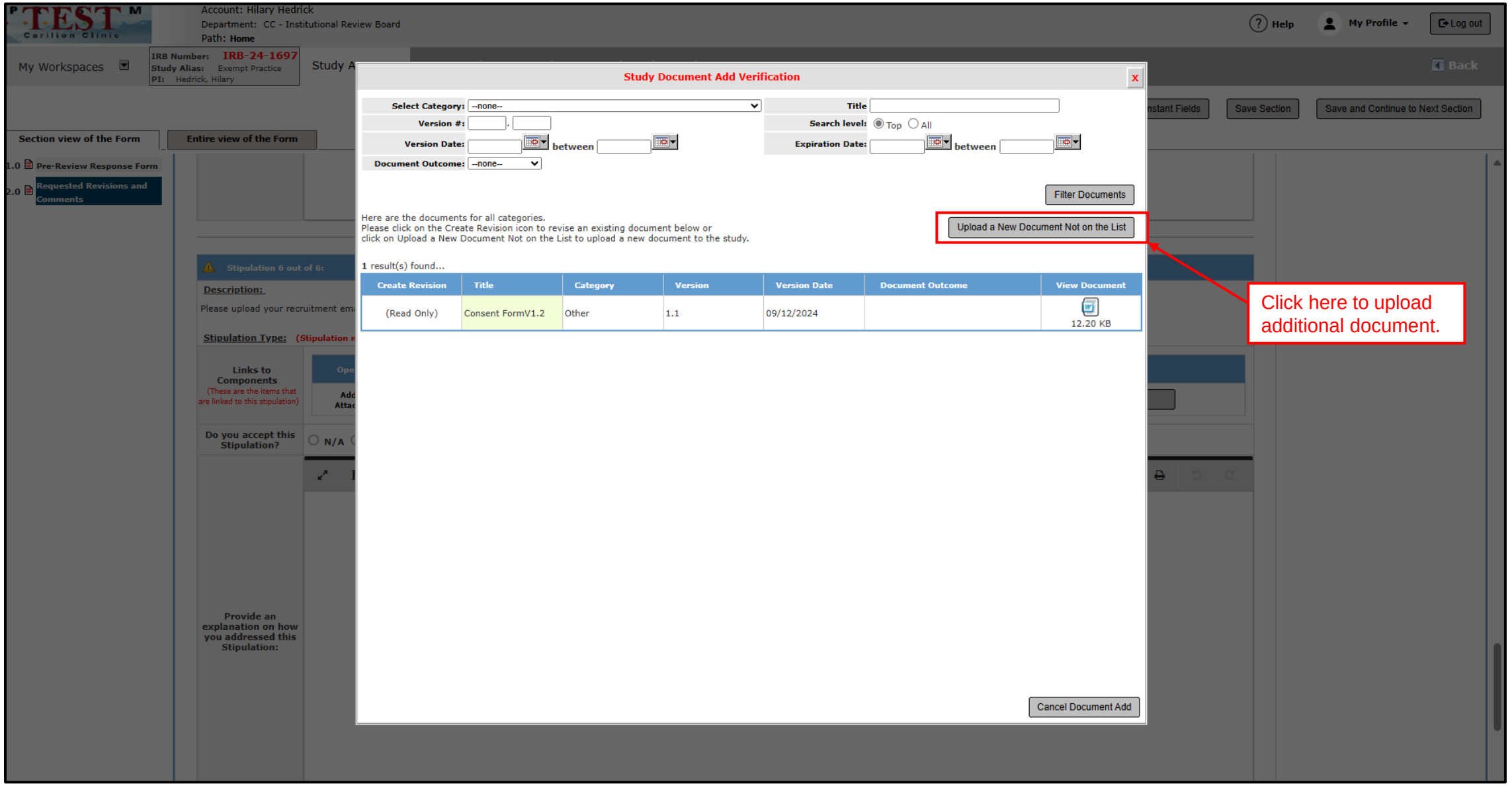

1. Verify the correct version was uploaded.
2. Revise the version date to track change.
3. You can tell a document has been uploaded and checked in because it is no longer visible.
Study Document Revision:
*Document Title:
Consent FormV1.2
Version Number:
1
.2
Version Date:
04/01/2025
Category:
Other
Description:
revised consent form
Comments:
Download Document:
Download
Check-out the Document to your workstation for editing:
Check-out Document...
View Document
Close, don't save any changes
Save Document
Requested Revisions and C
Stipulations that must be addressed:
Stipulation 1 out of 1:
Description:
Consent document:
Stipulation Type:
Links to Components
Modify Existing Attachment
Do you accept this Stipulation?
N/A
Yes
No
Provide an explanation on how you addressed this Stipulation:
Account: Hilary Hedrick
Department: CC - Institutional Review Board
Path: Home
IRB Number: IRB-24-1697
Study Alias: Exempt Practice
PI: Hedrick, Hilary
Study Assistant
Pre-Review Correction Form - (Version 4.0)
Help
My Profile
Log out
Back
Refresh Constant Fields
Save Section
Save and Continue to Next Section
Section view of the Form
Entire view of the Form
Pre-Review Response Form
Requested Revisions and Comments

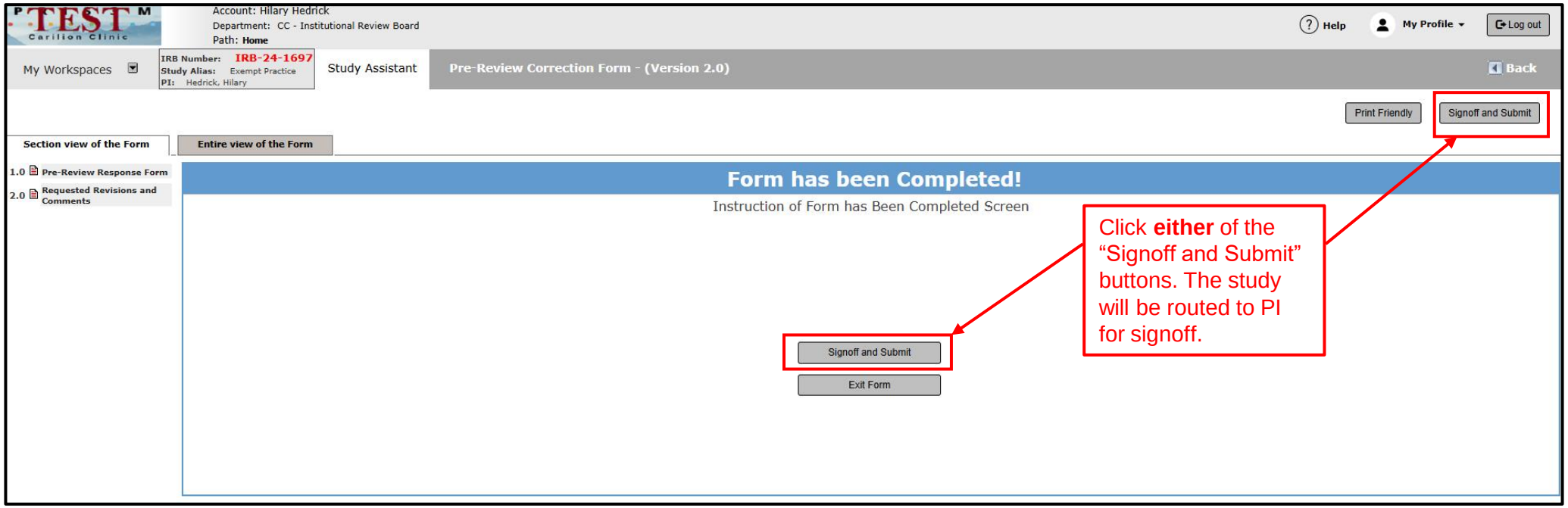
You will be taken back to the Pre-Review Correction Form.



Add supplemental study document

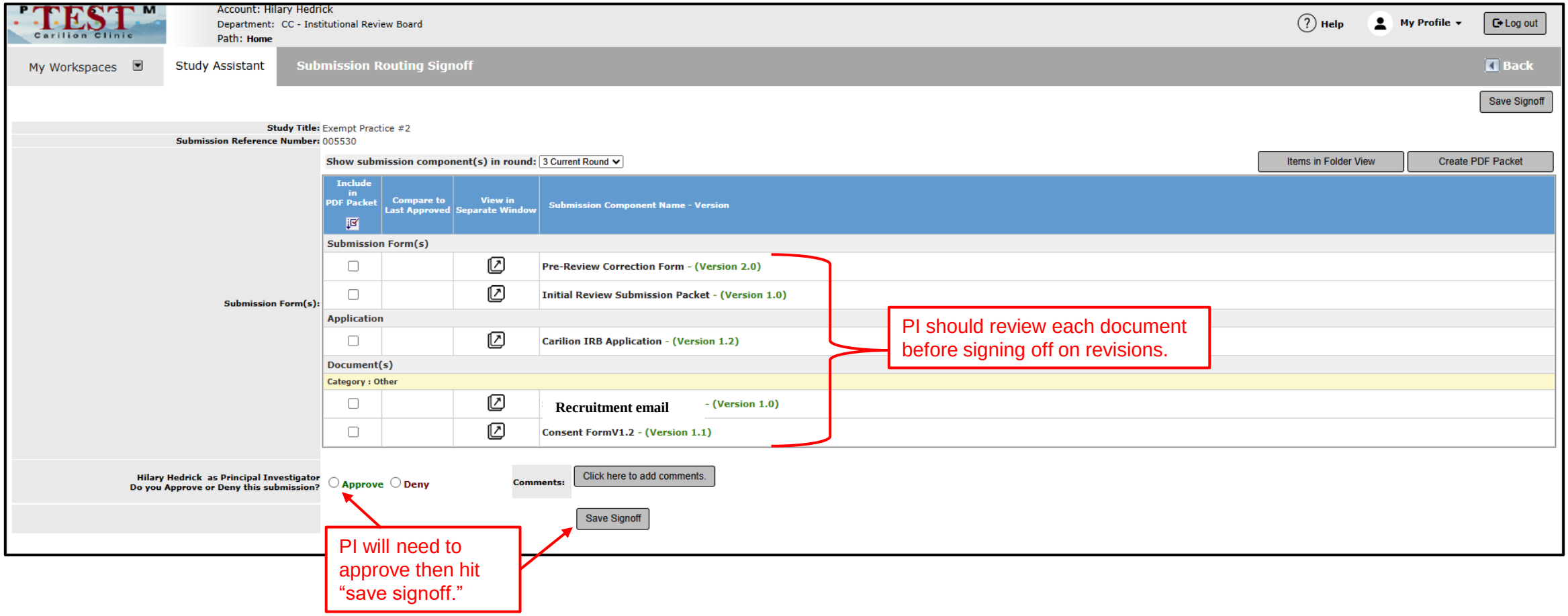


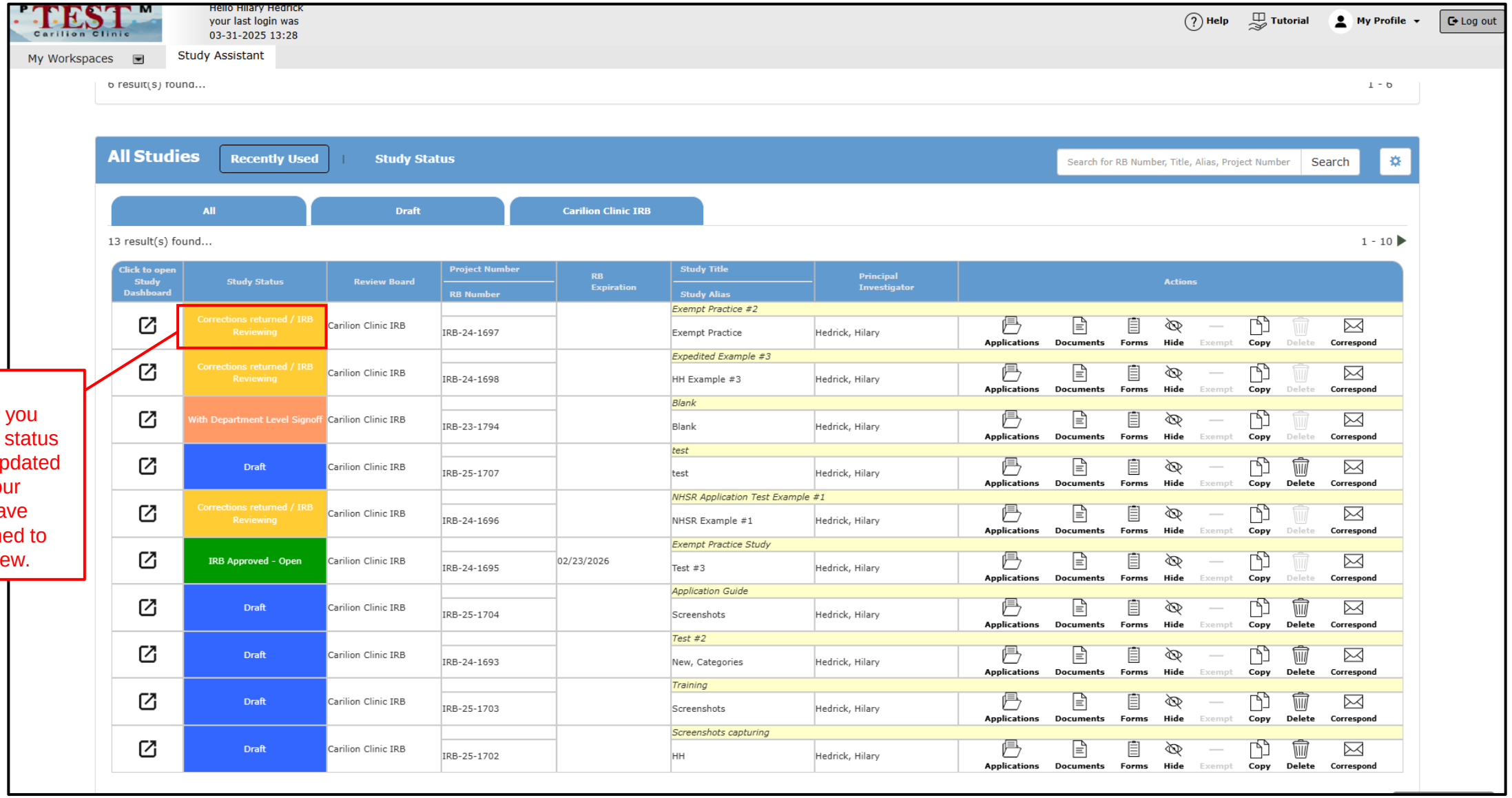

Study Document Add Verification
Select Category: --none--
Title
Version #:
Search level: Top All
Version Date: between
Expiration Date: between
Document Outcome: --none--
Filter Documents
Here are the documents for all categories.
Please click on the Create Revision icon to revise an existing document below or
click on Upload a New Document Not on the List to upload a new document to the study.
Upload a New Document Not on the List
1 result(s) found...
Create Revision
Title
Category
Version
Version Date
Document Outcome
View Document
(Read Only)
Consent FormV1.2
Other
1.1
09/12/2024
12.20 KB
Cancel Document Add
Click here to upload additional document.


Account: Hilary Hedrick
Department: CC - Institutional Review Board
Path: Home
Help
My Profile
Log out
My Workspaces
IRB Number: IRB-24-1697
Study Alias: Exempt Practice
PI: Hedrick, Hilary
Study Assistant
Pre-Review Correction Form - (Version 2.0)
Back
Print Friendly
Signoff and Submit
Section view of the Form
Entire view of the Form
1.0 Pre-Review Response Form
2.0 Requested Revisions and Comments
Form has been Completed!
Instruction of Form has Been Completed Screen
Signoff and Submit
Exit Form
Click either of the "Signoff and Submit" buttons. The study will be routed to PI for signoff.

If you are PI of study, this notification box will appear.

This is the screen a PI will view. It displays the documents that are attached with the stipulations.





On your dashboard, you will see the status has been updated to reflect your revisions have been returned to IRB for review.

Need more help? Contact the HRPO team to assist.

Email IRB@carilionclinic.org