

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”)

TEST

Carilion Clinic

Hello Hilary Hedrick
your last login was
03-18-2025 12:28

My Workspaces

Study Assistant

Help

Tutorial

My Profile

Log out

Featured Study Operations

Create a New Study

Start a Submission Form for one of My Studies

View the Current Approvals for one of My Studies

View the Submission History for one of My Studies

View and Manage My Studies

By the Numbers

Submissions in Process6

Forms Pending Submission1

Pending My Response1

High

Tasks

All Tasks6

Study Tasks6

Study Assistant

Find a Study

This section of main dashboard will take you **directly** to Pre-Review Correction Form.

Study Tasks

Outstanding | Completed

Search for RB Number, Title, Alias, Proposal Number

Search

Task List: All

Review Board: All

Filter By: --none--

All Tasks

Study Tasks

6 result(s) found...

Click to open	Task Type	Date Received	Study Status	Study Title	Principal Investigator	Review Board	Project Number	RB Expiration	Priority	Complete By
				Study Alias			RB Number			
	Submission Routing Signoff	03/18/2025 01:15:57 PM EDT	Draft	Blank					No Priority	
	Submission Correction	03/05/2025 11:47:51 AM EST	With Research Team for Corrections	Exempt Practice #2	Hedrick, Hilary	Carilion Clinic IRB	IRB-23-1794		No Priority	
	Reviewer Assignment	11/01/2024 02:37:21 PM EDT	EXPIRED	Development of home-based Pulmonary rehabilitation program using activity tracking devices with focus on self-efficacy	Hedrick, Hilary	Carilion Clinic IRB	IRB-24-1697	01/26/2025	No Priority	
	Reviewer Assignment	08/23/2024 11:38:21 AM EDT	With Research Team for Corrections	Home based PR	Aziz, Sameh	Carilion Clinic IRB	IRB-20-1079		No Priority	
	Reviewer Assignment	08/21/2024 11:10:28 AM EDT	With Research Team for Corrections	Test	Harmon, Tanner	Carilion Clinic IRB	IRB-24-1691		No Priority	
	Reviewer Assignment			Test	Harmon, Tanner	Carilion Clinic IRB	IRB-24-1691		No Priority	

Click here to open study submission correction and advance to Pre-Review Correction Form.

Another route in main PRIS3M Dashboard (Under “All Studies”)

TEST M
Carilion Clinic

Hello Hilary Hedrick
your last login was
04-03-2025 13:21

My Workspaces Study Assistant

0 result(s) found...

Help Tutorial My Profile Log out

All Studies Recently Used Study Status

Search for RB Number, Title, Alias, Project Number Search

All Draft Carilion Clinic IRB

13 result(s) found... 1 - 10

Click to open Study Dashboard	Study Status	Review Board	Project Number RB Number	RB Expiration	Study Title Study Alias	Principal Investigator	Actions
	With Research Team for Corrections	Carilion Clinic IRB	IRB-24-1697		Exempt Practice #2 Exempt Practice	Hedrick, Hilary	Applications Documents Forms Hide Exempt Copy Delete Correspond
	Corrections returned / IRB Reviewing	Carilion Clinic IRB	IRB-24-1698		Expedited Example #3 HH Example #3	Hedrick, Hilary	Applications Documents Forms Hide Exempt Copy Delete Correspond
	With Department Level Signoff	Carilion Clinic IRB	IRB-23-1794		Blank Blank	Hedrick, Hilary	Applications Documents Forms Hide Exempt Copy Delete Correspond
	Draft	Carilion Clinic IRB	IRB-25-1707		test test	Hedrick, Hilary	Applications Documents Forms Hide Exempt Copy Delete Correspond
	Corrections returned / IRB Reviewing	Carilion Clinic IRB	IRB-24-1696		NHSR Application Test Example #1 NHSR Example #1	Hedrick, Hilary	Applications Documents Forms Hide Exempt Copy Delete Correspond
	IRB Approved - Open	Carilion Clinic IRB	IRB-24-1695	02/23/2026	Exempt Practice Study Test #3	Hedrick, Hilary	Applications Documents Forms Hide Exempt Copy Delete Correspond
	Draft	Carilion Clinic IRB	IRB-25-1704		Application Guide Screenshots	Hedrick, Hilary	Applications Documents Forms Hide Exempt Copy Delete Correspond
	Draft	Carilion Clinic IRB	IRB-24-1693		Test #2 New, Categories	Hedrick, Hilary	Applications Documents Forms Hide Exempt Copy Delete Correspond
	Draft	Carilion Clinic IRB	IRB-25-1703		Training Screenshots	Hedrick, Hilary	Applications Documents Forms Hide Exempt Copy Delete Correspond
	Draft	Carilion Clinic IRB	IRB-25-1702		Screenshots capturing HH	Hedrick, Hilary	Applications Documents Forms Hide Exempt Copy Delete Correspond

Click here to advance to “Study Dashboard.”

This section of main dashboard will take you to “Study Dashboard” [page 6 instructions].

Study dashboard

My Workspaces

IRB Number: **IRB-24-1697**

Study Alias: Exempt Practice

PI: Hedrick, Hilary

Study Assistant

Submissions

Back

Study Status: With Research Team for Corrections

IRB Number : IRB-24-1697

Study Title : Exempt Practice #2

Submissions

Study Management

Protocol Items

Study Application

Informed Consents

Other Study Documents

Post-Approval Forms

Annual Check-In Form (for Minimal Risk studies approved with Annual Check-In after 1/20/19)

Carilion Clinic - Conclusion Form

Carilion Clinic - Continuing Review Form

Carilion Clinic - Promptly Reportable Information Form

Carilion Clinic - Research Change / Update Form

Initial

Initial Review Submission Packet

Submissions History

Study Correspondence

Outstanding Submission(s)

Track Location	Ref Number	Request Type	Process Submission
Routing In Process	05530	Click on the hyperlink to edit/view the submission. Carilion Clinic IRB has requested a Submission Correction for Initial Review Submission Packet	Send Submission

Click on hyperlink of text to advance to next screen.

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

The screenshot displays the Carilion Clinic IRB system interface. At the top, the user is logged in as Hilary Hedrick, a Study Assistant, with the IRB Number IRB-24-1697. The system shows the submission status as 'With Research Team for Corrections' and the study title as 'Exempt Practice #2'. A pop-up box in the center of the screen informs the user that the Carilion Clinic IRB has requested a Submission Correction for the Initial Review Submission Packet. The pop-up text reads: 'The Carilion Clinic IRB has requested a Submission Correction for Initial Review Submission Packet. Please make the required changes and submit back to the Carilion Clinic IRB'. An 'OK' button is visible in the bottom right corner of the pop-up. A red arrow points from a text box to the 'OK' button, with the text 'Click here to advance to response form.' The background interface includes sections for Protocol Items (Study Application, Informed Consents, Other Study Documents), Post-Approval Forms (Annual Check-In Form, Conclusion Form, Continuing Review Form, Promptly Reportable Information Form, Research Change / Update Form), and Initial Review Submission Packet.

Account: Hilary Hedrick
Department: CC - Institutional Review Board
Path: Home

My Workspaces ☒ IRB Number: **IRB-24-1697** Study Assistant Submissions ☐ Back

Study Status: With Research Team for Corrections IRB Number : IRB-24-1697 Study Title : Exempt Practice #2

Submissions Study Management

Protocol Items

- Study Application
- Informed Consents ▶
- Other Study Documents ▶

Post-Approval Forms

- Annual Check-In Form (for Minimal Risk studies approved with Annual Check-In after 1/20/19)
- Carilion Clinic - Conclusion Form
- Carilion Clinic - Continuing Review Form
- Carilion Clinic - Promptly Reportable Information Form
- Carilion Clinic - Research Change / Update Form

Initial

- Initial Review Submission Packet

Submissions History

Study Correspondence

Outstanding Submission(s)

Track	Ref	Request Type	Process Submission
			Send Submission

The Carilion Clinic IRB has requested a Submission Correction for Initial Review Submission Packet.

Please make the required changes and submit back to the Carilion Clinic IRB

OK

Click here to advance to response form.

Next screen will automatically go to **response form**.

My Workspaces IRB Number: **IRB-24-1697** 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

1.0 Pre-Review Response Form

The IRB has requested changes to your study during the Pre-review process.

- There is nothing to respond to on this page, but the study information is provided to you at the bottom of this page.
- The next page of this form will provide the requested changes to you.
- To make the requested change, you may need to create a revision of the document for which the change is requested, then go into applicable section of the application or the uploaded document to review and make the applicable change, and finally provide information about your response on the Correction Form.
- An example screen shot showing the steps to respond is provided below.
- You may wish to click "Print Friendly" button, then select HTML to view the instructions and requested changes along side of the system while you are making your changes.
- Access the User Guide - How to Respond to Submission Correction_Submission Response by clicking on the orange Help bubble at the top right of the page for additional assistance.

Please click on the "Save and Continue to Next Section" button at the top right of this page to move to the next page to review and respond to the changes that have been requested.

1.2 Principal Investigator:

Instructions are listed on this page. Once you read over them, then click here to advance to next screen.

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.

Account: Hilary Hedrick
Department: CC - Institutional Review Board
Path: Home

My Workspaces ☒ IRB Number: **IRB-24-1697**
Study Alias: Exempt Practice
PI: Hedrick, Hilary

Study Assistant

Pre-Review Correction Form - (Version 2.0)

Help My Profile Log out

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 6:

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

Creation of PDF reference document

Account: Hilary Hedrick
Department: CC - Institutional Review Board
Path: Home

My Workspaces

IRB Number: **IRB-24-1697**
Study Alias: Example Practice
PI: Hedrick, Hilary

Study Assistant

Pre-Review Correction Form - (Version 2.0)

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 6:

Description:

Dear Researcher,

This is not an approval letter. Please note that no human subjects research activities may be initiated until FULL IRB APPROVAL has been obtained. Any research activity initiated without IRB approval may result in a delay in processing your IRB approval.

Please take the time to carefully respond to this Submission Correction or Submission Response Request from the IRB in PRISTM.

1. Select whether you accept the stipulation or not.
2. Make the revisions as requested, if the stipulation is accepted. This may include creating a new version of the document in which you have made the requested changes. If you are revising an existing document, please create a new version of the document in which you have made the requested changes. DO NOT UPLOAD THE REVISED DOCUMENT AS A NEW DOCUMENT. Please refer to the User Guide 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 information, please type "done" once you have completed the requested changes.

It is recommended that you use the "Print Friendly" button at the top of this page and 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 go through the entire application, reviewing each section to make sure it is complete and accurate before submitting your response.

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 PRISTM 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

Cancel Apply Selection

1. Click "PDF form."
2. Select Apply Section.

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

Pre-Review Correction Form (Version 2.0)

Pre-Review Response Form

The IRB has requested changes to your study during the Pre-review process.

- There is nothing to respond to on this page, but the study information is provided.
- The next page of this form will provide the requested changes to you.
- To make the requested change, you may need to create a revision of the document then go into applicable section of the application or the uploaded document to re-upload and finally provide information about your response on the Correction Form.
- An example screen shot showing the steps to respond is provided below.
- You may wish to click "Print Friendly" button, then select HTML to view the instructions of the system while you are making your changes.
- Access the User Guide - How to Respond to Submission Correction_Submission Response Request from the IRB in PRISTM for more detailed instructions.

Please click on the "Save and Continue to Next Section" button at the top right of this review and respond to the changes that have been requested.

Close Save

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

PRIS3M

Carilion Clinic

Account: Hilary Hedrick
Department: CC - Institutional Review Board
Path: Home

My Workspaces

IRB Number: **IRB-24-1697**
Study Alias: Exempt Practice
PI: Hedrick, Hilary

Study Assistant

Pre-Review Correction Form - (Version 3.0)

HelpMy ProfileLog out

Back

Print FriendlyRefresh Constant FieldsSave SectionSave 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
Please unselect 4(iii) and select 4(ii).

Stipulation Type: (Stipulation must be addressed)

Operation	Action Status	Component Name	Action
Modify Existing Attachment	Action Not Complete	Carilion IRB Application (Version 1.2) Section: Request for Exempt Determination Question 2	Revise Existing

Do you accept this Stipulation? ☐ N/A ☒ Yes ☐ No

Links to Components
(These are the items that are linked to this stipulation)

Provide an explanation on how you addressed this Stipulation:

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.

13

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)

Displays the version you are working within.

Back

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, 2019. Please unselect 4(iii) and select 4(ii).

☐ 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 VTCOSOM medical students, are collaborating on this study and will have access to patients' PHI for any purposes, this category CANNOT 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

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.

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

TEST
Carilion Clinic

Account: Hilary Hedrick
Department: CC - Institutional Review Board
Path: Home

My Workspaces

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

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 in the footer (please keep to the left side of the document) and update the version date on the "Check-in" screen, then upload that clean version.
- 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 include tracked changes or highlights
- Please DO NOT make any revisions outside of those requested without first communicating with the IRB analyst reviewing your submission

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	Study Document Consent FormV1.2 (Version 1.1)	Revise Existing

Do you accept this Stipulation?
☐ N/A ☒ Yes ☐ No

Provide an explanation on how you addressed this Stipulation:

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

2. Click here to revise consent form.

TEST

Carilion Clinic

Account: Hilary Hedrick
Department: CC - Institutional Review Board
Path: Home

My Workspaces

IRB Number: **IRB-24-1697**
Study Alias: Exempt Practice
PI: Hedrick, Hilary

Study Assistant

Pre-Review Correction Form - (Version 4.0)

HelpMy ProfileLog out

Print FriendlyRefresh Constant FieldsSave SectionSave and Continue to Next Section

Section view of the FormEntire 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 on the "Check-in" screen, then upload that clean version.
- 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

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	Study Document Consent FormV1.2 (Version 1.1)	Revise Existing

Do you accept this Stipulation?

☐ N/A ☒ Yes ☐ No

Provide an explanation on how you addressed this Stipulation:

CONFIRM

CANCEL

Click here to confirm that you want to revise.

TEST
Carilion Clinic

Account: Hilary Hedrick
Department: CC - Institutional Review Board
Path: Home

My Workspaces

IRB Number: **IRB-24-1697**
Study Alias: Exempt Practice
PI: Hedrick, Hilary

Study Assistant

Pre-Review Correction Form - (Version 4.0)

HelpMy ProfileLog out

Print FriendlyRefresh Constant FieldsSave SectionSave and Continue to Next Section

Section view of the Form

Entire view of the Form

Pre-Review Response Form

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 Y applicable/requested. In order to upload the revised mark above beside "Help".

- Once you have revised the consent document,
- Please DO NOT upload a new, separate Consent
- Please "Check-in" the Word version of the Con
- The submission will be returned if consent for
- 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:

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:

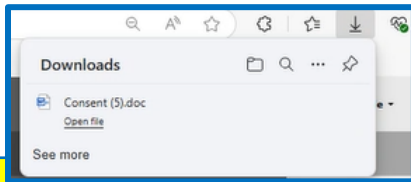
Check-out Document...

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.

My Workspaces | IRB Number: **IRB-24-1697** | Study Assistant | Pre-Review Correction Form - (Version 4.0) | Back

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 applicable/requested. In order to upload the revised mark above beside "Help".

- Once you have revised the consent document.
- 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 is not uploaded.
- Please DO NOT make any revisions outside of the system.

Stipulation Type: (Stipulation must be addressed)

Links to Components (These are the items that are linked to this stipulation)

Operation	Action
Modify Existing Attachment	+

Do you accept this Stipulation? ☐ N/A ☐ Yes ☐ No

Provide an explanation on how you addressed this Stipulation:

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

This document is currently checked out by: Hilary Hedrickat04/01/2025

Check-in when you are done editing upload the document back into IRIS. Check-in Document...

Revert to the document stored in IRIS. Undo Check-out Document...

View Document

Close, don't save any changes | Save Document

Reminder: After revisions have been made, consent form **cannot** be used until it is officially reviewed and approved by IRB.

System shows the date document was checked out.

Use this button to upload your revised document back into the system.

TEST
Carilion Clinic

Account: Hilary Hedrick
Department: CC - Institutional Review Board
Path: Home

My Workspaces

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

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 instructions below. Once you have revised the consent document, please change the version number in the document title. 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 are uploaded outside of those requested. Please DO NOT make any revisions outside of those requested.

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

Do you accept this Stipulation?

☐ N/A ☐ Yes ☐ No

Provide an explanation on how you addressed this Stipulation:

⌵ B I U ⌵ x₂ x² Verdana 11

Study Document Consent FormV1.2 (Version 1.1)

Revise Existing

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.

TEST
Carilion Clinic

Account: Hilary Hedrick
Department: CC - Institutional Review Board
Path: Home

My Workspaces

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

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 document applicable/requested. In order to upload the revised document, please check the "Check-in" button above beside "Help".

- Once you have revised the consent document, 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 is not a Word document.
- Please DO NOT make any revisions outside of the "Check-in" button.

Stipulation Type: (Stipulation must be addressed)

Links to Components

(These are the items that are linked to this stipulation)

Do you accept this Stipulation?

☐ N/A ☒ Yes ☐ No

Operation

Modify Existing Attachment

Provide an explanation on how you addressed this Stipulation:

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

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.

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

TEST
Carilion Clinic

Account: Hilary Hedrick
Department: CC - Institutional Review Board
Path: Home

My Workspaces 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

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 in the footer (please keep to the left side of the document) and update the version date on the "Check-in" screen, then upload that clean version.
- 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 include tracked changes or highlights
- Please DO NOT make any revisions outside of those requested without first communicating with the IRB analyst reviewing your submission

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	Study Document Consent FormV1.2 (Version 1.2)	Compare Document Version
			Study Document Consent FormV1.2 (Version 1.1)	☐ Complete Action ☒ Incomplete Action

Do you accept this Stipulation? ☐ N/A ☒ Yes ☐ No

Provide an explanation on how you addressed this Stipulation:

3. Comments must be included in this section. Some responses may be as simple as "ok" depending on stipulation.

1. Click "complete action to confirm revision was made and uploaded."

2. Make your selection here.

Shows that new version has been created.

TEST

Carilion Clinic

Account: Hilary Hedrick
Department: CC - Institutional Review Board
Path: Home

My Workspaces

IRB Number: IRB-24-1697
Study Alias: Exempt Practice
PI: Hedrick, Hilary

Study Assistant

Pre-Review Correction Form - (Version 2.0)

Help

My Profile

Log out

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

If additional study documents need to be upload, follow these steps below.

⚠ Stipulation 6 out of 6:

Description:
Please upload your recruitment email draft with a subject line included.

Stipulation Type: (Stipulation must be addressed)

Operation	Action Status	Component Name	Action
Add New Attachment	Action Not Complete	Please add the Study Document	Add Document

Do you accept this Stipulation?

☐ N/A ☒ Yes ☐ No

Provide an explanation on how you addressed this Stipulation:

B I U S x₂ x² Font Family 12

TEST
Carilion Clinic

Account: Hillary Hedrick
Department: CC - Institutional Review Board
Path: Home

My Workspaces

IRB Number: **IRB-24-1697**
Study Alias: Exempt Practice
PI: Hedrick, Hillary

Section view of the Form

Entire view of the Form

1.0 Pre-Review Response Form
2.0 Requested Revisions and Comments

Stipulation 6 out of 6:
Description:
Please upload your recruitment em
Stipulation Type: (Stipulation r
Links to Components
(These are the items that are linked to this stipulation)
Do you accept this Stipulation?
Provide an explanation on how you addressed this Stipulation:

Study Document Add Verification

Select Category: --none--
Version #:
Version Date: between
Document Outcome: --none--
Title:
Search level: ☒ Top ☐ All
Expiration Date: between
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.
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

Upload a New Document Not on the List

Cancel Document Add

Click here to upload additional document.

TEST

Carilion Clinic

Account: Hilary Hedrick
Department: CC - Institutional Review Board
Path: Home

My Workspaces

IRB Number: **IRB-24-1697**
Study Alias: Exempt Practice
PI: Hedrick, Hilary

Study Assistant

Pre-Review Correction Form - (Version 2.0)

HelpMy ProfileLog out

Back

Print FriendlySignoff 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.

The screenshot shows a web application interface for a study. At the top, the header includes the 'TEST' logo, account information for Hilary Hedrick, and navigation links like 'Help', 'My Profile', and 'Log out'. Below the header, there's a section for 'My Workspaces' and a table with study details, including the IRB Number 'IRB-24-1697'. The main content area displays a 'Pre-Review Correction Form - (Version 2.0)' with a 'Back' button. A large blue banner in the center reads 'Form has been Completed!' with the subtitle 'Instruction of Form has Been Completed Screen'. A white notification box is centered on the screen, containing the text: 'You are required to signoff on the submission.', 'You will now be redirected to the signoff screen to apply your electronic signature.', and 'You can monitor the submission progress with the Submission Status - In Progress.' An 'OK' button is at the bottom of this box. A red arrow points from a red-bordered box containing the text 'Click here to move to signoff screen.' to the 'OK' button.

Account: Hilary Hedrick
Department: CC - Institutional Review Board
Path: Home

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

You are required to signoff on the submission.

You will now be redirected to the signoff screen to apply your electronic signature.

You can monitor the submission progress with the Submission Status - In Progress.

OK

Click here to move to signoff screen.

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

P-TEST M
Carilion Clinic

Account: Hilary Hedrick
Department: CC - Institutional Review Board
Path: [Home](#)

[Help](#) [My Profile](#) [Log out](#)

[My Workspaces](#) [Study Assistant](#) **Submission Routing Signoff** [Back](#)

[Save Signoff](#)

Study Title: Exempt Practice #2
Submission Reference Number: 005530

Show submission component(s) in round: 3 Current Round [Items in Folder View](#) [Create PDF Packet](#)

Include in PDF Packet	Compare to Last Approved	View in Separate Window	Submission Component Name - Version
Submission Form(s)			
☐			Pre-Review Correction Form - (Version 2.0)
☐			Initial Review Submission Packet - (Version 1.0)
Application			
☐			Carilion IRB Application - (Version 1.2)
Document(s)			
Category : Other			
☐			Recruitment email - (Version 1.0)
☐			Consent FormV1.2 - (Version 1.1)

Submission Form(s):

Hilary Hedrick as Principal Investigator
Do you Approve or Deny this submission?

☐ **Approve** ☐ **Deny**

Comments: [Click here to add comments.](#)

[Save Signoff](#)

PI should review each document before signing off on revisions.

PI will need to approve then hit "save signoff."

Hello Hilary Hedrick
your last login was
03-31-2025 13:28

? Help
Tutorial
My Profile
Log out

My Workspaces
Study Assistant

0 result(s) found...
1 - 0

All Studies
Recently Used
Study Status

Search for RB Number, Title, Alias, Project Number
Search

All
Draft
Carilion Clinic IRB

13 result(s) found...
1 - 10

Click to open Study Dashboard	Study Status	Review Board	Project Number RB Number	RB Expiration	Study Title Study Alias	Principal Investigator	Actions
	Corrections returned / IRB Reviewing	Carilion Clinic IRB	IRB-24-1697		Exempt Practice #2 Exempt Practice	Hedrick, Hilary	Applications Documents Forms Hide Exempt Copy Delete Correspond
	Corrections returned / IRB Reviewing	Carilion Clinic IRB	IRB-24-1698		Expedited Example #3 HH Example #3	Hedrick, Hilary	Applications Documents Forms Hide Exempt Copy Delete Correspond
	With Department Level Signoff	Carilion Clinic IRB	IRB-23-1794		Blank Blank	Hedrick, Hilary	Applications Documents Forms Hide Exempt Copy Delete Correspond
	Draft	Carilion Clinic IRB	IRB-25-1707		test test	Hedrick, Hilary	Applications Documents Forms Hide Exempt Copy Delete Correspond
	Corrections returned / IRB Reviewing	Carilion Clinic IRB	IRB-24-1696		NHSR Application Test Example #1 NHSR Example #1	Hedrick, Hilary	Applications Documents Forms Hide Exempt Copy Delete Correspond
	IRB Approved - Open	Carilion Clinic IRB	IRB-24-1695	02/23/2026	Exempt Practice Study Test #3	Hedrick, Hilary	Applications Documents Forms Hide Exempt Copy Delete Correspond
	Draft	Carilion Clinic IRB	IRB-25-1704		Application Guide Screenshots	Hedrick, Hilary	Applications Documents Forms Hide Exempt Copy Delete Correspond
	Draft	Carilion Clinic IRB	IRB-24-1693		Test #2 New, Categories	Hedrick, Hilary	Applications Documents Forms Hide Exempt Copy Delete Correspond
	Draft	Carilion Clinic IRB	IRB-25-1703		Training Screenshots	Hedrick, Hilary	Applications Documents Forms Hide Exempt Copy Delete Correspond
	Draft	Carilion Clinic IRB	IRB-25-1702		Screenshots capturing HH	Hedrick, Hilary	Applications Documents Forms Hide Exempt Copy Delete Correspond

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