

User Guide: *How to Submit a New Application in PRIS3M*

Purpose: To provide the user with step-by-step instructions on how to complete/submit a new protocol application.

Last Update: February 2025

Important steps **prior** to application:

- ❑ Refer to **User Guide: *Getting Started and Navigating the Study Assistant Dashboard in PRIS3M*** before continuing.
- ❑ Any user creating a New Application **must** be selected as the Principal Investigator (PI) or be added as a team member in Section 3 of application.
- ❑ Team members must log into PRIS3M one time to create their account before they can be added to studies. If you can't find someone's name when adding team members, have that person log in with their Carilion credentials.

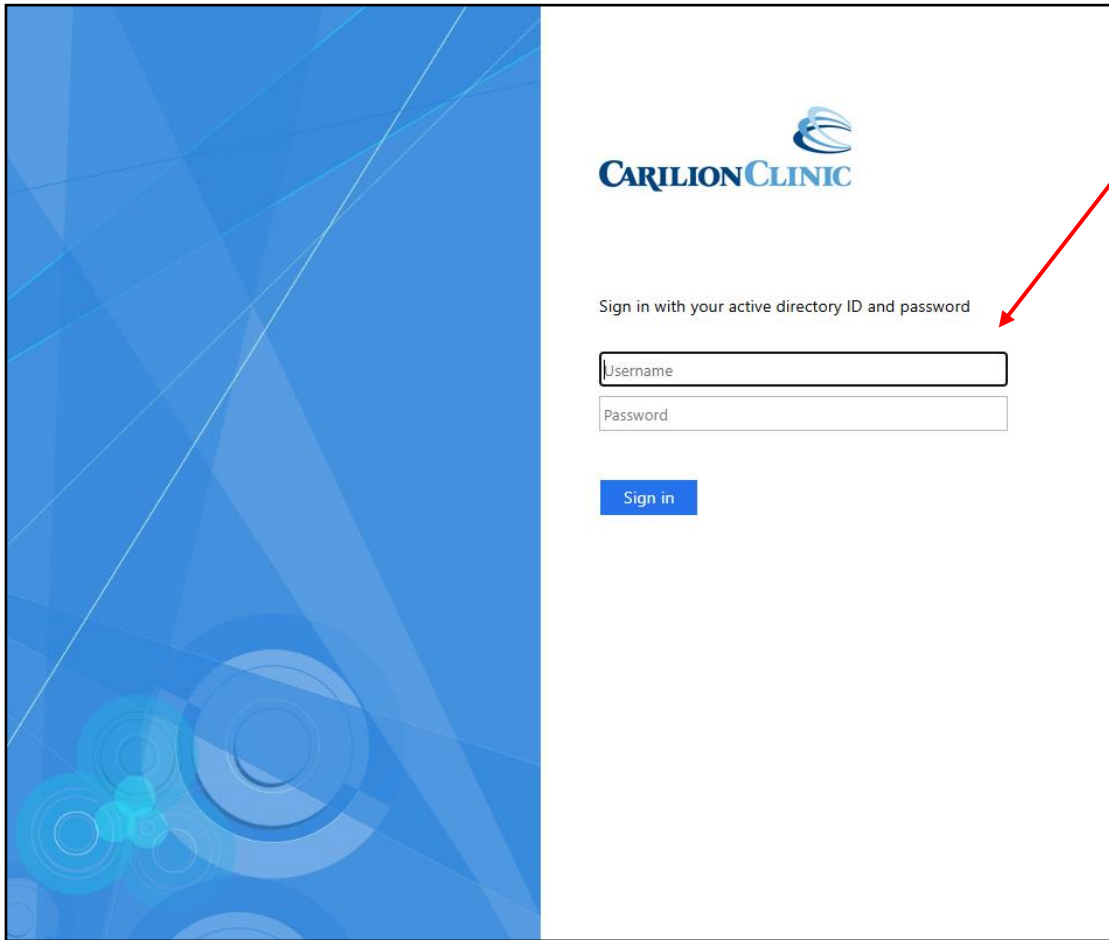
Carilion Clinic **PRIS3M**: Partnership in Research Integrity and Subject Safety Submission Module

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.

Navigate to <https://carilionclinic.imedris.net/>



CARILION CLINIC

Sign in with your active directory ID and password

Username

Password

Sign in

Enter your **Carilion Clinic ID** and **password** to access the PRIS3M system.

Troubleshooting: If you cannot login due to incorrect credentials or missing access: Review USER GUIDE-Getting Access to PRIS3M.

If you are still unable to log in:

- Contact the IRB office directly at irb@carilionclinic.org
- Submit Help ticket at https://is.gd/PRIS3M_IRB_Help_Form

Study Assistant Dashboard

PRISM

Carillon Clinic

My Workspaces

Hello Hilary Hedrick
your last login was
02-12-2025 14:27

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 Process

0

Forms Pending Submission

0

Pending My Response

0

High

>

Tasks

All Tasks0

Study Assistant

Find a Study

All Tasks

Outstanding | Completed

Task List : All

Filter By : --none--

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

Click to open	Task Type	Date Received	Description	Priority	Complete By
No results found					

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

This activity button allows you to create a New Application



IRB number has now been generated

3. Click to proceed after adding departments

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

My Workspaces IRB Number: **IRB-25-1704** Study Assistant Carilion IRB Application (Version 1.0) 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

2.0 Add departments

2.1 Add the departments of all Key Study Personnel that will be involved with the design, conduct, or reporting on this project:

	Is Primary?	Department Name	
☐	☒	CC - Institutional Review Board	Add Department Remove Department

1. Click to add PI's department as primary department.
2. You **must also** add the other institutional departments of team members who will be involved with the design, conduct, or reporting of the study.

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](#)

3.0 Assign key study personnel(KSP) access to the study

1. Click here to add Key Study Personnel (KSP) to the study.

[Click Here to Setup Study Personnel](#)

3.1 * Please add a Principal Investigator for the study:

Name	Role	Training Record
No Principal Investigator has been added		

3.2 Please add the Research Staff, if applicable:

A) Additional Investigators

Name	Role	Training Record
No Additional Investigators have been added		

B) Research Support Staff

Name	Role	Training Record
No Research Support Staff have been added		

3.3 * Please add a Study Contact:

Name	Role	Training Record
No Study Contact have been added		

The Study Contact(s) will receive all important system notifications along with the Principal Investigator. (e.g. The project contact(s) are typically either the Study Coordinator or the Principal Investigator themselves).

The individuals added in these sections are defined as Key Study Personnel (KSP) who will have access to identifiable data and who will be involved with the design, conduct, or reporting of the study. Examples include:

- Principal Investigator
- Sub-Investigators
- Research Staff Personnel (research coordinator and other team members)

This screen will pop up to manually enter KSP. You must complete this process for each member of the study team.

Account: Hilary Hedrick

Setup Study Personnel

1. Type in name or partial name

2. Click find user

User Search by Study

Last Name: Hedrick First Name:

User Search by Study: All Departments

3. Click here to verify individual's CITI training

Select	Training	Name	Department	Email
☐	☐	Hedrick, Hilary	Institutional Review Board (primary)	hhhedrick@carilionclinic.org

4. Click here to select individual to add as KSP

IRB Policy: Review of submission cannot begin until all team members have completed required CITI training.

Selected Study Personnel:

Principal Investigator

Name	Role
No Personnel has been selected for this group.	

Additional Investigators

Name	Role
No Personnel has been selected for this group.	

Research Support Staff

Name	Role
No Personnel has been selected for this group.	

Contact

Name	Role
No Personnel has been selected for this group.	

5. Click here once you have added all KSP to the study.

This pop-up window will cue you to select the role for each team member.

Note the different pop-up screens from the application dashboard. The system will automatically do this for KSP.

The screenshot shows the 'Setup Study Personnel' interface. A pop-up window titled 'Add Personnel Role' is open, prompting the user to 'Select the Role for Hilary Hedrick :'. The pop-up includes four radio button options: 'Principal Investigator' (selected), 'Additional Investigators', 'Research Support Staff', and 'Study Contact'. Below these are two dropdown menus, both currently set to '--none--'. A checkbox question 'Would you like to include as a Study Contact ?' has 'Yes' selected. At the bottom of the pop-up are 'Cancel' and 'Save' buttons. A red callout box points to the 'Principal Investigator' option, another points to the first dropdown menu, and a third points to the 'Save' button.

1. Select the role of the team member. There may be additional identifiers based on their role.

2. PI is the default study contact. For additional investigators and staff, decide if they should also be a study contact.

3. Click here to save information for this specific team member.

4. System will return to "Setup Study Personnel" page (pg. 9) to enter more team members. Choose "close setup of study personnel" if all are entered.

Section 4—You will complete a new entry for each team member.

TEST
Carilion Clinic

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

My Workspaces

IRB Number: **IRB-25-1704**
Study Alias: Screenshots
PI: Hedrick, Hilary

Study Assistant

Carilion IRB Application (Version 1.0)

Help My Profile Log out

Back

Print Friendly Save Section Save and Continue to Next Section

Section view of 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

Entire view of the Application

4.1 Provide the following information below for each Carilion Clinic research team member: You will be asked to provide information about members of the research team that are outside Carilion at a later time.

Click "add another entry" to respond to this item.

*CITI Training in Human Subjects Research Biomedical Researchers and GCP (for FDA-regulated and NIH-funded) will be verified for each team member before the application will be reviewed by the IRB. Detailed instructions for Carilion's CITI training requirements can be found at <https://www.carilionclinic.org/irb/education>. Please ask all team members to ensure their Carilion email address is added to their CITI account profile so that their CITI training is pulled into this system. This feed occurs on a nightly basis.

Entry 1

Click here to add another entry

Research team member name: --none--

Degree:

Status: --none--

If other, specify:

Email address:

Phone number:

Alternate phone number (optional):

Affiliation: --none--

If other, specify:

Research Duties (check all that apply):

- ☐ PI: Ultimately responsible for the study including conduct by all study team members
- ☐ Identification of potential subjects
- ☐ Contacting potential subjects
- ☐ Screening of subjects, including assessing eligibility criteria
- ☐ Obtain Informed Consent
- ☐ Randomization
- ☐ Conduct of study procedures that result in research data
- ☐ Prepare or dispense study drug/device
- ☐ Research specimen collection/shipping
- ☐ Adverse Event documenting and reporting
- ☐ Data entry
- ☐ Data Analysis - Identifiable
- ☐ Data Analysis - De-identified
- ☐ Regulatory document maintenance
- ☐ Other (specify):

1. Select the name of the team member(s) from the drop-down menu.

2. Complete remaining entry for specified individual. Be sure to clarify duties of each person.

3. Make sure Section 3 & 4 match for KSP. Click button to advance to next application section.

Section 5: Identify the type of application for submission.

TEST
Carilion Clinic

Account: Hilary Hedrick
Department: CC - Institutional Review Board
Path: Home > study mgmt.

My Workspaces

IRB Number: **IRB-25-1704**
Study Alias: Screenshots
PI: Hedrick, Hilary

Study Assistant

Carilion IRB Application (Version 1.0)

Help

My Profile

Log out

Print Friendly

Save Section

Save and Continue to Next Section

Back

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

5.0

Application Type

IRB-25-1704

5.2 Select the application type:

☐ Human Subject Research Study

☐ Determination of Human Subjects Research (including QA/QI Determination)

☐ Establishing a prospective Data or Specimens Research Repository

☐ Humanitarian Use Device (non-research use)

☐ Expanded Access or Compassionate Use

☐ Single Patient Emergency Use

☐ Preparatory to Research Application

☐ IRB Grant Review ONLY for preliminary approval if required by funder

☐ Requesting Carilion Clinic RELY on another IRB of Record (WIRB, CIRB, VT, UVA, Advanra etc.)

☐ Conversion of a paper application due for Continuing Review or Annual Check-In

Additional guidance is provided to help with application type.

?

Description of Application Types - Work - Microsoft Edge

https://carilionclinic-test.imedris.net/39933022/System_Help_Win.jsp?s=101010101

Print

Close

Human Subject Research Study: This application type should be selected for work that is a systematic investigation, including research development, testing, and evaluation, that involves a living individual about whom a research investigator obtains data through intervention or interaction with the individual or from individually identifiable information, and which is designed to develop or contribute to generalizable knowledge.

Determination of Human Subjects Research (including QA/QI Determination): This application type should be selected if you are unsure if your project meets the definition of human subjects research, or if you wish to receive a formal determination from the IRB, as some journals and conferences will require a written statement from the IRB regarding their determination.

Establishing a prospective Data or Specimens Research Repository: This application type should be selected if your project will involve the collection and storage of information and/or biological specimens over time for future research.

Humanitarian Use Device (non-research use): This application type should be selected if a physician/clinician would like to use an approved HUD device according to its labeling for clinical treatment with the intent to benefit patients in the treatment and diagnosis of diseases or conditions that affect or is manifested in **fewer than 8,000 individuals** in the United States per year.

Expanded Access or Compassionate Use (non-research use): This application type should be selected for expanded access (sometimes called "compassionate use"), which provides a path to accessing investigational devices that have not received FDA approval or clearance for patients for whom the treating physician believes the device may provide a benefit in treating and/or diagnosing their disease or condition. Expanded access may be appropriate when all the following apply:

- Patient has a serious disease or condition, or whose life is immediately threatened by their disease or condition.
- There is no comparable or satisfactory alternative therapy to diagnose, monitor, or treat the disease or condition.
- Patient enrollment in a clinical trial is not possible.
- Potential patient benefit justifies the potential risks of treatment.
- Providing the investigational medical product will not interfere with investigational trials that could support a medical product's development or marketing approval for the treatment indication

Single Patient Emergency Use: This application type should be selected when a patient has a serious or life-threatening condition that is not addressed by current approved treatments (no other available alternatives), options exist to use an investigational medical device (i.e., one that has not been approved or cleared by FDA) to treat the patient, and there is no time to obtain FDA approval.

Preparatory to Research Application: This application type should be selected for activities involved in preparing for research. Under this, PHI may be used or disclosed to a researcher without an individual's authorization, a waiver or an alteration of authorization, or a data use agreement; however, The use or disclosure is requested **solely to review PHI as necessary to prepare a research protocol or for similar purposes preparatory to research.** the PHI will **not be removed from the covered entity** in the course of review, and the PHI for which use or access is requested is **necessary for the research.**

IRB Grant Review ONLY for preliminary approval if required by funder: This application type should be selected when Grant sponsors require that the grant be reviewed and approved by the IRB prior to submission of the grant. The principal investigator should verify the sponsor's requirements regarding IRB review prior to submission of a grant. Once the grant is funded, the principal investigator will need to submit another complete Human Subjects Research application to the IRB before work on the grant may begin.

Requesting Carilion Clinic RELY on another IRB of Record (WIRB, CIRB, VT, UVA, SMART IRB Reliance, etc.): This application type should be selected to request Carilion Clinic rely on another IRB. A reliance agreement (also called an IRB Authorization Agreement) is a document signed by two or more institutions engaged in human subjects research that permit one or more institutions to cede review to another IRB. A reliance agreement avoids duplicate IRB initial review and continued oversight when multiple IRBs have jurisdiction for the same multi-site research protocol. Once the agreement is executed, it can lessen the administrative burden and regulatory oversight of multiple institutions' IRBs.

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Section view of 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	Subject Population
12.0	Informed Consent for Adult Subjects
13.0	Privacy and Confidentiality
14.0	Request for Partial Waiver, Full Waiver, or Alteration of HI ...
15.0	Sharing of Research Data/Specimens
16.0	Research Settings/Performance Sites
17.0	Applicable Regulations for ClinicalTrials.gov Registration
18.0	Study Procedures
19.0	Research Review of Data/Records
20.0	Incidental Findings
21.0	Use of Internet
22.0	Identification/Recruitment of Subjects
23.0	Risks and Risk Minimization and Benefits
24.0	Costs and Compensation
25.0	Application Questions Complete

Navigate through & complete application sections

- Depending on the type of application for submission, there are **Sections 6-Section 25 [category preview]**
- Questions will branch depending on specifics of your study
- “Save Section” allows you to come back and finish section. It is recommended you hit this button frequently.
- “Save and Continue to Next Section” saves the entire form and advances to next section of application.

After completing each section of application, click “**Save and Continue to Next Section**” to access the [Initial Submission packet](#). This is where you’ll upload all your study-related documents. The submission packet is like a central storage folder for all study materials.

The screenshot shows a web application interface for IRB applications. On the left is a sidebar with a list of sections: 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 Expanded Access For Treatment Use, 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 Applicable Regulations for ClinicalTrials.gov Registration, and 13.0 Application Questions Complete. The 13.0 section is highlighted in blue. At the top right are three buttons: 'Print Friendly', 'Save Section', and 'Save and Continue to Next Section'. A green arrow points from the text 'Initial Submission Packet' in the main content area to the 'Save and Continue to Next Section' button. The main content area has a dark blue header '13.0 Application Questions Complete' and a light blue sub-header '13.1 You have now completed the IRB Application. Please click Save & Continue to proceed to the [Initial Submission Packet](#).' Below this is a form with a 'Date Completing Form:' label, a date input field showing '08/02/2022', and a calendar icon. The form contains three paragraphs of text explaining the 'Initial Submission Packet' and the next steps in the process.

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 Expanded Access For Treatment Use
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 Applicable Regulations for ClinicalTrials.gov Registration
13.0 Application Questions Complete

Print Friendly | Save Section | Save and Continue to Next Section

13.0 Application Questions Complete

13.1 You have now completed the IRB Application. Please click Save & Continue to proceed to the [Initial Submission Packet](#).

Date Completing Form:
08/02/2022

The [Initial Submission Packet](#) is a short form filled out after the IRB application has been completed and is where you will attach protocol-related documents, such as consent forms and recruitment materials. You will also be able to conduct a final review of the IRB application.

The PI will be required to sign off on the final [Initial Submission Packet](#). The study may then proceed to the Department Signoff, if necessary based on the application type selected, and may require COI review before proceeding to the IRB.

You can view the Submission History of the study at any time to determine the status.

Submission Packet Study Dashboard

The screenshot shows the 'Submission Packet to the Review Board' form. At the top right, there are four buttons: 'Print Friendly', 'Refresh Constant Fields', 'Save Section', and 'Save and Continue to Next Section'. A red arrow points from a red-bordered box containing the text '2. Save and Continue to Next Section.' to the 'Save and Continue to Next Section' button. On the left side, there is a sidebar with a red-bordered box containing the text '1. Write summary of your study using simple language (1-2 paragraphs).'. The form itself has sections for '1.1 IRB Number (Auto Applied):' (with value 'IRB-22-596'), '1.2 Study Title:' (with value 'Screenshots for the user manual'), '1.3 Principal Investigator:' (with value 'Patricia Winter'), and '1.4 Lay Summary:' (with a rich text editor). The rich text editor has a toolbar with various formatting options and a large text area below it.

Next, you will be taken to the Application summary page. You can complete your final review and edits of your IRB application from this page.

Section view of the Form

Entire view of the Form

1.0 Submission Packet to the Review Board

2.0 Application

2.0 Application

2.1 * Attach / Review your completed application for this study:

Deattach	Revise/ Attach	Edit/ View	Title
			Carilion IRB Application (Version 1.0)

Print Friendly

Refresh Constant Fields

Save Section

Save and Continue to Next Section

Click to continue to next section.

Click here to view or edit application before submission.

WARNING: Clicking here will permanently disconnect your application. This action cannot be undone.

Upload your required consent and assent documents, as applicable to your study.

Section view of the Form | Entire view of the Form

1.0 Submission Packet to the Review Board

2.0 Application

3.0 Informed Consent, Assent, and Parental Permission

3.0 Informed Consent, Assent, and Parental Permission

3.1 * Attach the Inform Consent Document(s), including Parental Permission and Assent, for this study:

Add a New Consent

1. Click here to upload consent documents

Detach	Version	Title	Category	Language	Expiration Date	Consent Outcome	Checked Out	View Document
No Consent(s) have been attached to this form.								

This screen will open after "Add a New Consent" button is clicked.

Click here to upload consent Word document.

Study Consent Add:

*Consent Title: Provide a title that clearly and adequately explains what the document is (eg. consent, assent, info sheet, study population).

*Select the consent to upload:

*Version Number: 1.0

*Version Date: 08/02/2022

Category: Consent

*Language: English

Description: You can provide more details about the document here which were not included in the title, such as consent, assent, information sheet, population, etc. |

Comments:

Fill out each required section of the "Study Consent Add" entries that are marked with an asterisk(*).

After completing form and uploading document, click here.

Close, don't save any changes | Save Consent

Double-check uploaded consent document

Section view of the Form

1.0 Submission Packet to the Review Board

2.0 Application

3.0 Informed Consent, Assent, and Parental Permission

Entire view of the Form

Print Friendly

Refresh Constant Fields

Save Section

Save and Continue to Next Section

3.0 Informed Consent, Assent, and Parental Permission

3.1 * Attach the Inform Consent Document(s), including Parental Permission and Assent, for this study:

Select or Revise Existing

Add a New Consent

Detach	Version	Title	Category	Language	Expiration Date	Consent Outcome	Checked Out	View Document
	1.0	Provide a title that clearly and adequately explains what the document is (eg. consent, assent, info sheet, study population).	Consent	English				 10.69 KB

Click here to revised and/or add additional comments to previously uploaded document.

Verify that the correct document was uploaded by clicking icon.

Upload all required supplemental documents (as applicable):

5. Click here when all documents are uploaded and have been verified and clearly labeled.

The screenshot shows a web application interface for uploading supplemental study documents. On the left, a sidebar lists sections: 1.0 Submission Packet to the Review Board, 2.0 Application, 3.0 Informed Consent, Assent, and Parental Permission, and 4.0 Supplemental Study Documents. The main area is titled '4.0 Supplemental Study Documents' and includes a sub-instruction: '4.1 Click the Help bubble to the right for a list of documents that must be uploaded for IRB Review.' Below this, there are buttons for 'Add a New Document' and 'Add Multiple Documents'. A table with columns 'Detach', 'Version', 'Title', and 'Category' is shown, with a message: 'No Document(s) have been attached to this form.' A modal window titled 'Study Document Add:' is open, containing fields for 'Version Number' (set to 1.0), 'Version Date' (08/02/2022), 'Category' (set to --none--), 'Description', and 'Comments'. At the bottom of the modal are buttons for 'Close, don't save any changes' and 'Save Document'. A red arrow points from the 'Add a New Document' button to a list of instructions. Another red arrow points from the 'Save Document' button to a final instruction. A third red arrow points from the 'Save and Continue to Next Section' button in the top right to a final instruction.

Section view of the Form Entire view of the Form

1.0 Submission Packet to the Review Board

2.0 Application

3.0 Informed Consent, Assent, and Parental Permission

4.0 Supplemental Study Documents

4.0 Supplemental Study Documents

4.1 Click the Help bubble to the right for a list of documents that must be uploaded for IRB Review.

Add a New Document Add Multiple Documents

Detach	Version	Title	Category
No Document(s) have been attached to this form.			

Study Document Add:

*Select the document to upload:

*Version Number: 1.0

Version Date: 08/02/2022

Category: --none--

Description:

Comments:

Close, don't save any changes Save Document

1. Add other supporting documents—recruitment materials, eligibility checklists, case report forms, full protocol, grant application, etc.

2. Be sure the document is clearly labeled and does not include any special characters. The title will display in the system as it is labeled when uploaded.

3. Assign a category to the document for easy identification. *Clear labeling of documents is important for ease of access later and IRB review & approval.

4. Be sure to save after each upload.

5. Click here when all documents are uploaded and have been verified and clearly labeled.

Select your Department Approval Signatory

Section view of the Form

Entire view of the Form

1.0 Submission Packet to the Review Board

2.0 Application

3.0 Informed Consent, Assent, and Parental Permission

4.0 Supplemental Study Documents

5.0 Signoff

Print Friendly

Refresh Constant Fields

Save Section

Save and Continue to Next Section

5.0 Signoff

5.1 Please add the Department Chair, Division Chief, or Vice President of the Principal Investigator below. DO NOT ADD THE NAME OF THE PI.

- To determine the appropriate signoff, please click the help bubble to the right for EVERY SUBMISSION to view the designated signoff for your department/unit. It is important to check as the signoff may change. Failure to do so could delay your submission if the submission is routed to the incorrect person.
- The application will be routed to this individual(s) for signoff after the application is submitted by the PI and before it is routed to the IRB. If there are two individuals listed for signoff, it will be routed to each at the same time. Once both have signed off, the submission will proceed to the next step in the process.
- If the PI is also the department chair, please select the supervisor of the Chair for signoff. If the department the PI is in does not have a department chair, select the supervisor of the PI.
- You can view the study Submission History to determine where in the process the application is sitting.

If you unable to find your Department Signatory within PRISM3M, they do not currently have an account in PRISM3M, so please ask them to log into the system one time.

Add Selected User

No Users have been selected.

5.2 Once the Initial Submission Packet has been submitted, please do not make revisions to ANY documents unless requested!

Once the Initial Review Submission Packet is submitted by the PI, the study status will change to "Pending - Submitted for Initial Review". Please do not make revisions or create any new versions of any documents within the packet, including the IRB Application Form, until you are requested to do so. If you need to make immediate changes, please request that the Initial Review Submission Packet be returned to you for revisions.

- If new versions are created while the application is in the "Pending - Submitted for Initial Review" study status, they will not be attached to the Initial Review Submission Packet that was submitted and therefore will not be reviewed by OIC or the IRB.
- At best, the Initial Review Submission Packet will need to be returned to you to incorporate the new changes, or it could cause major issues with version control.
- This will significantly delay the review of your application.

☐ Acknowledged

- PI with department: Find your department's designated signatory
- PI without department: Select your PI's direct supervisor
- Click "Help" button to find your department's designated signatory

- Review and click "Acknowledge"

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For Team Members:

1. Notify your PI that the study application is ready for submission
2. The PI must log in and click submit the application to begin the review process

Important to note: Only the PI can submit the application to begin the review process.

This screenshot shows the 'Form has been Completed!' screen. At the top, there are buttons for 'Print Friendly' and 'Notify PI to Signoff'. A red callout box points to the 'Notify PI to Signoff' button with the text: 'Click on either button to send prompt to PI that the application is ready for signoff. The PI will receive an email from the system.' Another red callout box points to the 'Create PDF Packet' button with the text: 'Click here to create PDF of your entire submission that you will be able to save to your computer.' The left sidebar shows a list of sections: 1.0 Submission Packet to the Review Board, 2.0 Application, 3.0 Informed Consent, Assent, and Parental Permission, 4.0 Supplemental Study Documents, and 5.0 Signoff. The main content area has a blue header with the text 'Form has been Completed!' and 'Instruction of Form has Been Completed Screen'. Below this, there are three buttons: 'Notify PI to Signoff', 'Create PDF Packet', and 'Exit Form'.

This screenshot shows the Carilion Clinic Submissions screen. At the top, there is a header with the Carilion Clinic logo, user information (Emerson, Carley), and navigation links (Home, My Profile, Log out). Below the header, there is a section for 'My Workspaces' with a dropdown menu. The main content area is titled 'Submissions' and shows a list of 'Outstanding Submission(s)'. A red callout box points to the 'Outstanding Submission(s)' section with the text: 'Screenshot of confirmation screen that PI has been notified.' A confirmation dialog box is displayed in the center of the screen with the text: 'The Principal Investigator has been notified to complete the submission.' and an 'OK' button. The 'Outstanding Submission(s)' table has columns for 'Track Location', 'Ref Number', 'Request Type', and 'Process Submission'. The table contains one row with the following data: 'Waiting for PI signoff', '000169', 'Click on the hyperlink to edit/view the submission. Initial Review Submission Packet', and 'Retract Submission'.

For Principal Investigators (PIs):
Click "Signoff and Submit" to send your study to IRB review

TEST M
Carilion Clinic

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

? Help My Profile Log out

My Workspaces System Administration **Submission Routing Signoff** Back

Save Signoff

Study Title: NHSR Application Test Example #1
Submission Reference Number: 005529

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 1.1)

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

1. Designated Principal Investigator needs to click "Approve" to route to IRB.

2. Click button to save signoff.

Study Dashboard

You can view the **Submissions History** to determine the status of application.

The screenshot displays the 'TEST M' Study Dashboard for Carilion Clinic. The top navigation bar includes the user account 'Hilary Hedrick', department 'CC - Institutional Review Board', and a 'Home' path. The main header shows 'My Workspaces' with a dropdown, 'Study Assistant', and 'Submissions' tabs. The 'Submissions' tab is active, showing a table with columns for 'Study Status', 'IRB Number', and 'Study Title'. The 'Study Status' is 'With Research Team for Corrections', 'IRB Number' is 'IRB-24-1696', and 'Study Title' is 'NHRS Application Test Example #1'. Below this, the 'Submissions History' section is visible, showing a table with columns for 'Track Location', 'Ref Number', 'Request Type', and 'Process Submission'. The table contains one entry with 'Track Location' 'Waiting for PI signoff', 'Ref Number' '005529', and 'Request Type' 'Carilion Clinic IRB has requested a Submission Correction for Initial Review Submission Packet'. A 'Retract Submission' button is present next to the entry. Red callout boxes provide instructions: 'View more details about submission.' points to the 'Submissions History' link, 'Shows status of study.' points to the 'Waiting for PI signoff' status, and 'Click here if you need to withdraw the submission. The submission can only be withdrawn until the IRB begins processing. Once processing begins, it cannot be withdrawn. You will need to contact the IRB to request withdraw.' points to the 'Retract Submission' button.

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

My Workspaces ☒ IRB Number: **IRB-24-1696** Study Assistant Submissions Back

Study Status: **With Research Team for Corrections** IRB Number: IRB-24-1696 Study Title: NHRS Application Test Example #1

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
Waiting for PI signoff	005529	Click on the hyperlink to edit/view the submission. Carilion Clinic IRB has requested a Submission Correction for Initial Review Submission Packet	Retract Submission

View more details about submission.

Shows status of study.

Click here if you need to withdraw the submission. The submission can only be withdrawn until the IRB begins processing. Once processing begins, it cannot be withdrawn. You will need to contact the IRB to request withdraw.

This page can be found under the **Submissions History** tab.

TEST
Carillon Clinic

Account: Hilary Hedrick
Department: CC - Institutional Review Board
Path: Home > study mgmt.

My Workspaces

IRB Number: **IRB-24-1696**
Study Alias: NHSR Example #1
PI: Hedrick, Hilary

Study Assistant

Submissions

Study Status: With Research Team for Corrections

IRB Number: IRB-24-1696

Study Title: NHSR Application Test Example #1

Submissions in Process

Completed Submissions

Submissions Returned with Changes

Print Friendly

Reference Number	Track Location	Status	Request Type	Details	Review Board	View Outcome Letters	Review Process	Meeting Date	Review Outcome	Date Received
005529			Initial Review Submission Packet							
			Submission Correction for Initial Review Submission Packet		Carillon Clinic IRB Committee C and/or Minimal Risk		Returned for Corrections			09/16/2024 10:36:45 AM EDT
			Initial Review Submission Packet		Carillon Clinic IRB Committee C and/or Minimal Risk		Returned for Corrections			09/09/2024 09:45:38 AM EDT
			Submission Correction for Initial Review Submission Packet							

Shows you the application in process.

Click here for more details of study.

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Need more help? Contact the
HRPO team to assist.

Email IRB@carilionclinic.org