



**VCU**

Office of Research and Innovation

# **RAMS-IRB**

## **for**

# **Researchers**

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# CREATING A NEW STUDY

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## 1

Log-In

- Connect through RAMS [VPN](#) if off campus
- Log into RAMS-IRB by using your VCU eID and Password at <https://irb.research.vcu.edu>

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To create a new study in RAMS-IRB, click “New Study.”

## 2

Create a  
New  
Study

The screenshot shows the 'IRB Submissions' interface. At the top, there's a dark red header with 'IRB Submissions' in white. Below it, a light green sidebar contains 'My Roles' and 'IRB Submissions'. The main content area has a 'Create' section with a button labeled 'New Study' that is highlighted with a red rectangular box.

### Instructions for Submitting


1. Create a new Study by clicking the New Study button on the left. This is used for the following types
  - o Research projects
  - o EFIC submissions
  - o Emergency Use submissions
  - o External IRB submissions
  - o Grant Review submissions
  - o HUD submissions
  - o Treatment Use submissions
2. Complete the questions as required. Use the Jump To menu to navigate the form as needed
3. Upload all documents required for the IRB review at the document upload prompt questions or at the viewable from every document upload question.
4. Once complete, submit your study for review by the IRB

This screenshot shows the navigation and filtering area of the RAMS-IRB system. It includes tabs for 'Inbox', 'My IRB Studies', 'Archive', and 'Templates'. Below the tabs, there's a message: 'Displays all items in a state which require action by the study team. Click on links for more information.' At the bottom, there's a 'Filter by' dropdown menu set to 'ID', with 'Go' and 'Clear' buttons. Below the filter, there are columns for 'ID', 'Name', and 'Date Modified'.

## 3

Fill in  
Smart  
Form

Tips for filling out the smart form (content directions in a different guide):

- Fill out each question accurately, completely, and consistently.
- Use the  for additional guidance and directions.
- All the questions marked with a **\*** are mandatory.
- Refer to [Written Policies & Procedures \(WPPs\)](#)
- Do not use your browser’s “back/forward” buttons – instead, use the “Back” and “Continue” buttons, or drop down “Jump To” menu in RAMS IRB
- You can either click “Continue” to move to the next required page, or “jump to” to go to a specific page.
- Questions branch, so your answers will affect what other questions are required.
- ALWAYS click “SAVE” before “Exit”

Once you have finished filling out the form, click “Submit Study.” Only the PI can submit the study.

# 4

Submit Study

The screenshot shows the IRB Staging interface for a study titled "Study: Test Study for Guide (HM20005364)". The "Current State" is "In Development". Under "My Study Forms", there are buttons for "Edit Study", "Printer Version", and "View Differences". Under "My Activities", the "Submit Study" button is highlighted with a red box. Other activity buttons include "Withdraw", "Copy Study", "Edit Email List", and "Log Public Comment". A blue callout box with an arrow points left, stating: "Your IRB Study has NOT been submitted. to the left of this workspace to s NOTE: Access to the Submit button is limited to". Below the callout is a navigation bar with tabs: "History", "Comments", "Documents", "Reviewer Notes", "Change Log", and "IRB Inf". The "History" tab is active, showing a table with columns "Activity" and "Author". The table contains one entry: "Created Study" by "Wright, ...".

# 5

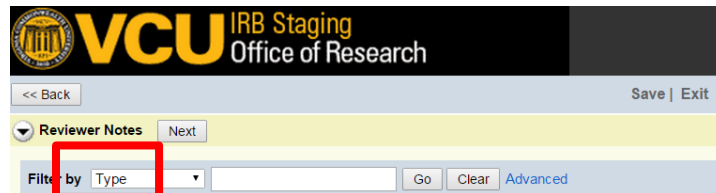
Departmental Approval

When you Submit Study, the form will prompt you request departmental approval.

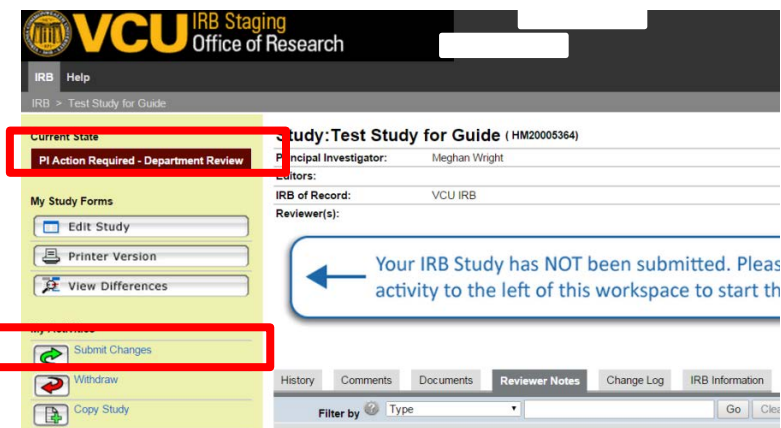
- Only PI may submit study and request approval
- Choose your department chair or the person designated by your department chair to review research applications.
- If you are the department chair, choose the dean of your department.

The screenshot shows the IRB Staging interface for the same study. The "Current State" is "Department Review", which is highlighted with a red box. Under "My Study Forms", there are buttons for "View Study", "Printer Version", and "View Differences". Under "My Activities", there are buttons for "Copy Study", "Edit Email List", and "Change Department Approver(s)". A blue callout box with an arrow points left, stating: "Your IRB Study has NOT been submitted. to the left of this workspace to s NOTE: Access to the Submit button is limited to". Below the callout is a navigation bar with tabs: "History", "Comments", "Documents", "Reviewer Notes", "Change Log", and "IRB Information". The "History" tab is active, showing a table with columns "Activity" and "Author". The table contains two entries: "Study Submitted for Review" by "Meghan Wright" and "Created Study" by "Wright, ...". A red box highlights the "Department Review" button in the "My Activities" section.

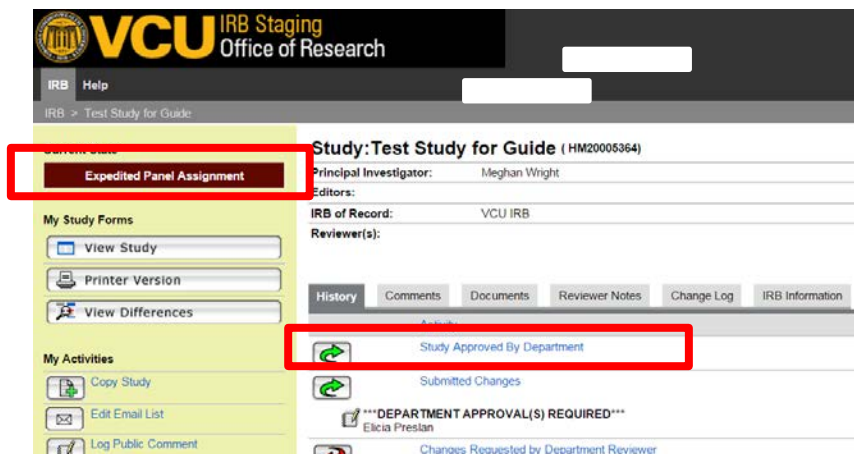
- Departments may request changes.
  - If changes are required, the **Current State** will signal “PI Action Required,” and you will receive an email.
  - You can view the department’s change requests under the “Reviewer Notes” Tab
  - Steps to make changes
    - Click “Edit Study” and click “next” – this will bring you to each reviewer note, and save any changes you’ve made.



- Make the requested changes in the Smart Form
- **Respond** to each note.
- Once you’ve responded to all notes, click “Save” & “Exit”



- Once you’ve made changes, click “Submit Changes” – this will send it back to the department for review.
  - Note: Department reviewers do not get reminder emails, so the PI will want to follow up.
- Once the department accepts the changes, they will accept it and it will move automatically to the IRB staff for pre-screening. You can see this in the **Current State**.
- See section “**IRB REVIEW PROCESS**” for next steps.



# CREATING AN AMENDMENT

## 1

Create New Amendment

1. Log In
2. Go to “My IRB Studies”
3. Click on study title
4. Click “New Amendment”
5. Read the directions and click “Continue”

**VCU IRB Staging Office of Research**

IRB Help

IRB > Test Study for Guide for the PI

**Current State**

Approved

**My Study Forms**

- View Study
- Printer Version
- View Differences
- Create**
- New Amendment
- New Continuing Review
- New Report to IRB
- New Study Closure

**Study: Test Study for Guide for the PI (HM20005364)**

Principal Investigator:	Meghan Wright	IRB Coordinator:	E
Editors:		IRB Panel:	IF
Approval Date:	8/24/2015	Approved Review Type:	E
Expiration Date:	7/31/2016	IRB of Record:	V
Continuation Due Date:	6/26/2016		
Reviewer(s):	Elicia Preslan		

History | Comments | Amendments | Continuing Reviews | Closures | Reports to IRB | Documents | Change Log | IRB Information

1 loading...

## 2

Fill out Amendment Cover Sheet

Under the “Amendment Details” page, make sure to fully explain why these changes are being requested. Make your responses as detailed as possible.

\* Explain why these changes are being requested.

Check the box on this page, and click finish.

**VCU IRB Staging Office of Research**

You Are Here: Test Study for Guide for the P... Amendment 1 for IRB Study #HM2...

<< Back Save | Exit | Hide/Show Errors | Print... | Jump To: SF - Certification

**Certification**

After you have finished describing the changes here, the appropriate changes should be made to the Study SmartForms.

1. If you are ready to start making edits to your Study and want to go directly to the Modified Study Smart Forms, check the box below. Otherwise click finish and you will go to the Amendment Workspace:

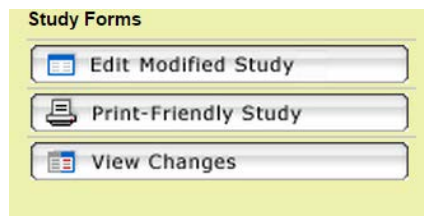
# 3

## Make Changes

- Use the “Jump To” drop down menu to go to the page(s) where you need to make changes.
- When you’re done making changes, click “Save” & “Exit.”
- Note: RAMS-IRB is automatically tracking all changes made in smart form.

## Changing Documents – Stacking Documents

1. When you’re done making changes, either go to the Documents page (or any other section requiring documents, or if you’ve left the smart form, click “Edit Modified Study” on the workspace page.



- New Document: Click “Add”
- Updating Document: Click “Update”
  - Upload your red-line version by clicking “Choose File”
  - Then, click “update” again, and upload the clean version
- **DO NOT CLICK DELETE**
- Click “Save” & “Exit”

## Add Document

1. \* Document Name:

2. \* Type:

3. \* File: [Getting Started.docx\(0.02\)](#) | [History](#)   
 No file chosen

Once you’re done making changes, click “Submit Changes.”

The amendment will then be reviewed by the IRB staff and reviewer.

IRB staff and reviewers look for consistency within the study.

Note: You may only submit one amendment at a time.

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# CONTINUING REVIEW

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Continuing Review reminders are sent prior to study expiration. Please submit your continuing review on time to avoid expiration. If your study expires, all study activities, including data analysis must stop.

To submit a continuing review, click “New Continuing Review.”

The screenshot shows the VCU IRB Staging Office of Research web application. The top navigation bar includes the VCU logo and 'IRB Staging Office of Research'. Below this, there is a breadcrumb trail: 'IRB > Test Study for Guide for the PI'. The main content area is divided into a left sidebar and a main panel. The sidebar has sections for 'Current State' (Approved), 'My Study Forms' (View Study, Printer Version, View Differences), and 'Create' (New Amendment, New Continuing Review, New Report to IRB, New Study Closure). The 'New Continuing Review' option is highlighted with a red box. The main panel displays study details for 'Study: Test Study for Guide for the PI (HM20005364)'. It lists the Principal Investigator (Meghan Wright), IRB Coordinator (E), Editors, Approval Date (8/24/2015), Expiration Date (7/31/2016), Continuation Due Date (6/28/2016), and Reviewer(s) (Elicia Preslan). At the bottom, there are tabs for History, Comments, Amendments, Continuing Reviews | Closures, Reports to IRB, Documents, Change Log, and IRB Information. A 'loading...' indicator is visible at the bottom right.

Please provide as much information as possible as to what has happened with the study within the last approval period.

Once you have completed the form, click “Save” & “Exit.”

Then, click “Submit Continuing Review”

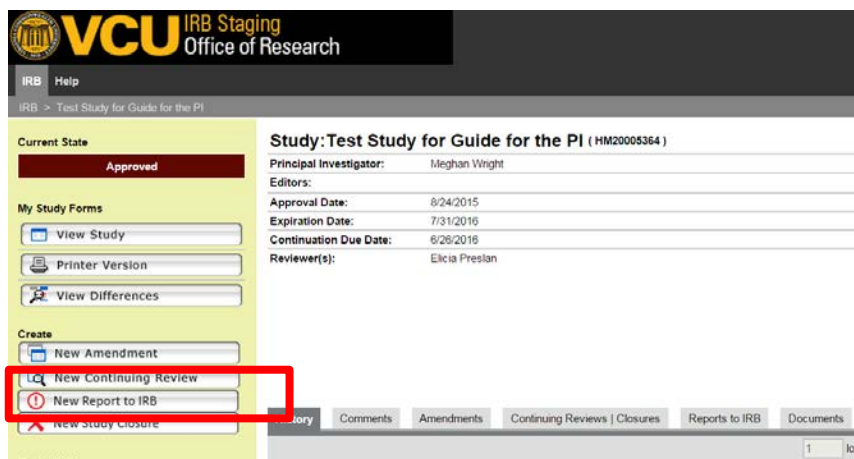
The image shows a close-up of the 'My Activities' section. It features three buttons: 'Submit Continuing Review' (with a green circular arrow icon), 'Withdraw' (with a red circular arrow icon), and 'Log Public Comment' (with a notepad icon). The 'Submit Continuing Review' button is highlighted with a red rectangular box.

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# CREATING A REPORT

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- Events such as unanticipated problems, protocol deviations or violations, and noncompliance need to be reported to the VCU IRB.
- Most other events occurring in a research study do not need to be reported to the IRB unless they are unanticipated problems. However, there may be times when a sponsor requires reporting to the IRB or there is other information the investigator feels the IRB should know, in which case a report may be submitted on a Non-Prompt paper form or using the reporting function in RAMS-IRB.




- Click “New Report to IRB”
- Use best judgement and give as much information as possible in the smart form.
- Once you’re done, click “Submit Report”

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# CLOSING A STUDY

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1. Click “New Study Closure”
2. To close the study, all three of these must be true:

1. \* To close this project, verify the following: 

- Enrollment is permanently closed
- All interactions/interventions with subjects, or access to identifiable private information for the purpose of research data collection is complete
- All use, study, and/or analysis of identifiable private information at the research site(s) under the VCU IR approval is complete

3. Click “Submit Closure Report”



# IRB REVIEW PROCESS

## 1

IRB Staff

Pre-Screen

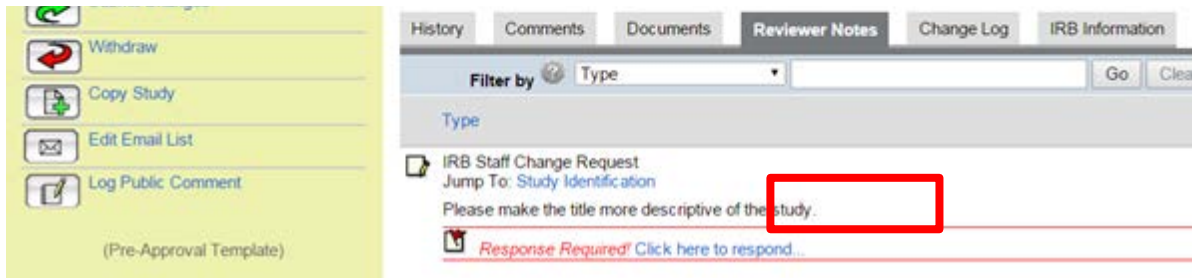
The IRB staff will pre-screen the study to make sure it is ready for IRB review. IRB staff may request changes, similarly to departmental changes.

If changes are required (most likely), PIs and study editors receive an email notification. IRB staff may also log a comment explaining that changes are requested.

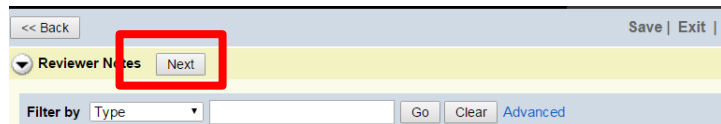
When you log into RAS-IRB, the *Current State* will reflect PI Action Required.



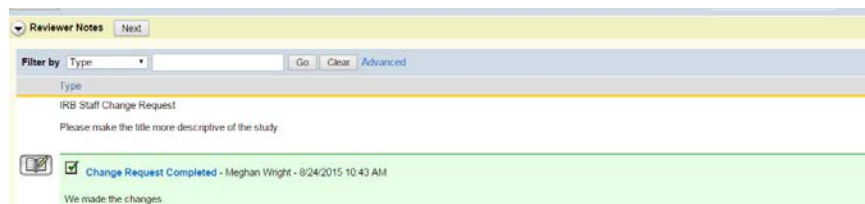
To view the list of changes that are requested, click on the “Reviewer Notes” tab.



Click “Edit Study” and click “next” – this will bring you to each reviewer note, and save any changes you’ve made to previous notes.



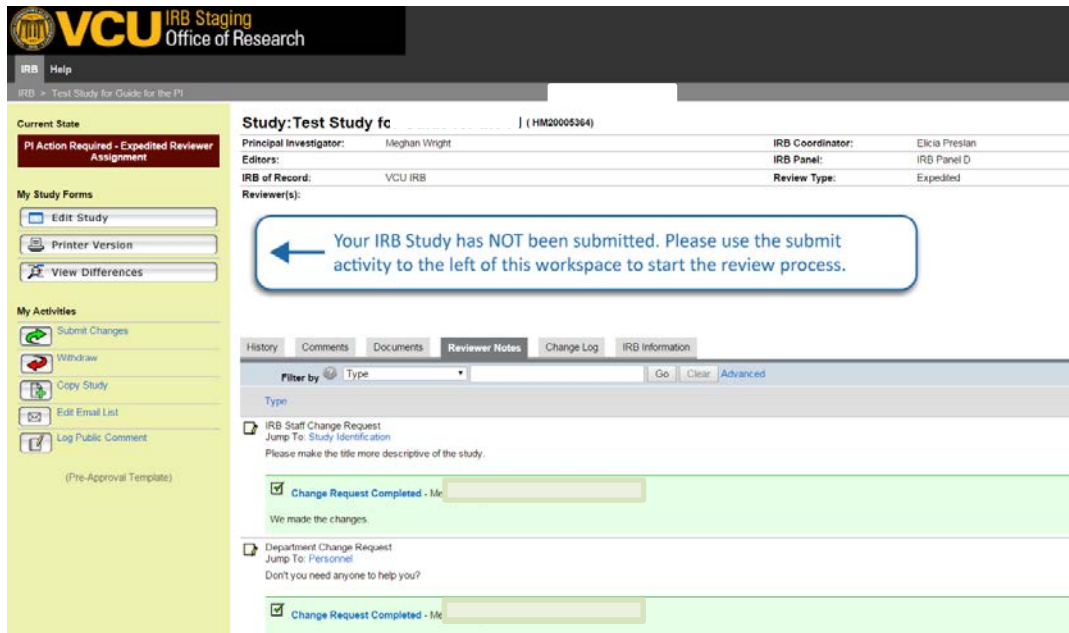
- Make the requested changes in the Smart Form
- **Respond** to each note.



If you have questions regarding the change requests, you may log a public comment to the IRB coordinator, or contact the IRB staff.

- Once you’ve responded to all notes, click “Save” & “Exit”

Once you've made all the requested changes, go to the "Reviewer Notes" tab on the home page to make sure all notes are **green**. Then click "Submit Changes" to re-submit the study.

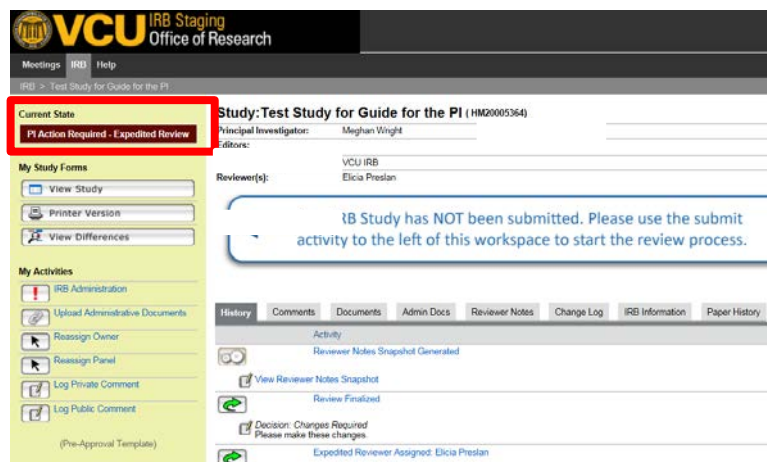


It is not uncommon for this process to happen a few times. After all appropriate changes have been made, the study will be assigned to an IRB reviewer. The PI will get an email notification when this occurs, and the **Current State** will also reflect this phase.

# 2

## IRB Review

The IRB Reviewer will most likely request changes, as with the department review and pre-screen. The PI will receive a system notification, and PI Action Required will be reflected in the **Current State**.



Make changes and respond to reviewer notes following the same procedure as the pre-screen. Make sure to re-submit the study by clicking "Submit Changes."

# 3

## IRB Determination

Once the requested changes have been made (this may happen multiple times), the IRB Reviewer or IRB Panel will make a determination, the IRB Coordinator will write a letter informing the PI of the determination, and the IRB Chairperson will approve the letter and the determination. The IRB Chairperson may request additional changes. The approval of a study is not final until you receive an approval letter.

The PI will receive an email regarding the status, and may also view the status of the review at any time by looking at the *Current State*

The screenshot shows the VCU IRB Staging Office of Research web application. The 'Current State' is highlighted with a red box and shows 'Approved'. The study title is 'Study: Test Study for Guide for the PI (HM20005364)'. The Principal Investigator is Meghan Wright. The Approval Date is 8/24/2015, the Expiration Date is 7/31/2016, and the Continuation Due Date is 6/26/2016. The Reviewer(s) is Elicia Preslan. The interface includes tabs for History, Comments, Amendments, Continuing Reviews | Closures, Reports to IRB, and Documents. A 'Project Snapshot Generated' notification is visible at the bottom.

## Reminders:

- Go to the “Documents” tab, and download the stamped consent form to use.
- You may edit the email list for those people who will need to be able to view the study (not edit)

The screenshot shows the VCU IRB Staging Office of Research web application with the 'Edit Email List' dialog box open. The dialog box title is 'Execute "Edit Email List" on HM20005364 - Google Chrome'. The URL is 'irbstage.research.vcu.edu/irbstage/ResourceAdministration/Activity/form?ActivityType=com.webbridge.ent'. The dialog box contains the following information: 'HM20005364 - Meghan Wright Test Study for Guide for the PI'. The 'Edit Email List' section includes a note: 'Note: specifying someone to receive email notifications will automatically give them access to the study file and its contents. The principal investigator and editors (listed below) will receive notifications.' The Principal Investigator is Meghan Wright. The Editors section is empty. The dialog box has 'OK' and 'Cancel' buttons.