

Create a New Study

Prior to the Study

Studies can be entered by either the Principal Investigator (P.I.) or the Study Team. However, only the P.I. can submit the study.

Before you enter the study in Huron, you should first complete the appropriate protocol template for your category of study. This editable Word document can be found in Huron Library [IRB > Library > Templates].

Navigation

1. Make sure you are on the Dashboard
2. Click Create
3. A pop-up window will appear. Click Create New Study.

The screenshot displays the IRB Dashboard for Mary Kivel. At the top left is the Ohio State University logo and the text "THE OHIO STATE UNIVERSITY ENTERPRISE FOR RESEARCH, INNOVATION AND KNOWLEDGE". The main navigation bar includes "Dashboard" (marked with a red circle 1) and "IRB". Below the navigation bar, there are tabs for "My Inbox" and "My Reviews". A "Create" button (marked with a red circle 2) is visible in the top left of the main content area. A pop-up menu is open over the "Create" button, showing options: "IRB" (expanded), "Create New Study" (marked with a red circle 3), and "Report New Information". Below the pop-up, there is a search bar with "Enter text to search" and a search icon, and a table header with columns "Name", "Date Created", and "Date Modified". The table currently shows "No data t". At the bottom right, there is a pagination control showing "page 1".

SmartForm

Basic Study Information

1. **Title of study:** Enter your study title, this can be copied and pasted directly from your protocol document.
2. **Short title:** The short title is used to identify your study throughout the Huron system and is also the title that is used on participant documents, such as the consent form. The “Short Title” and the “Title of the Study” (1) should match, unless your title is longer than 277 characters. If your title is longer than 277 characters, you should shorten the title but try to remain as close to the original title as possible.
3. **Brief description:** Enter a brief description of your research. This can be copied and pasted directly from your protocol document.
4. **What kind of study is this?:** Identify whether your study is a multi-site or single-site study.
 - **Multi-site or Collaborative study:** Multiple institutions are involved in this study.
 - **Single-site study:** Ohio State is the only IRB of record on this submission.

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You Are Here: > IRBSubmission

Basic Study Information

Creating New: IRB Submission

Basic Study Information ?

1. * **Title of study:**
2. * **Short title:** ?
3. * **Brief description:** ?
4. * **What kind of study is this?** ?
 Multi-site or Collaborative study
 Single-site study
[Clear](#)
5. * **Will an external IRB act as the IRB of record for this study?** ?

5. **Will an external IRB act as the IRB of record for this study?** If another institution will be the IRB for your study, select “yes.” If Ohio State will serve as the IRB for your study, select “No.”
 - If you select “No,” an additional question should appear at the bottom of your form (9) asking you to identify the type of review required for your study.
6. **Local principal investigator:** This will default to the name of the person entering the study. If you are not the P.I. for this study, click on the ellipses and a full list of Ohio State investigators will appear. Select the P.I. from this list. If the P.I. is not listed, please contact ORRP.
7. **Financial Interest:** The P.I. is required to disclose and conflicts of interest related to this study. For questions related to conflicts of interest, please contact the Conflict of Interest team at conflictinfo@osu.edu.
8. **Attach Protocol:** Use the “Add +” button to upload your protocol document. A pop-up window will appear and allow you to upload your document. You also have the option to include an alternate file name and version number.
9. **What type of review is required for your project?:** This question will only appear if you selected “No” for question 5. Select the appropriate choice for your study.
 - **Exempt Research:** this category is for research that is no more than minimal risk and all of the research procedures fit within one or more of the exemption categories in the federal IRB regulations.
 - **Behavioral and Social Sciences IRB:** reviews research originating from a variety of disciplines; however, does not review FDA-regulated research or research otherwise involving medical procedures, drugs, or devices.
 - **Biomedical Sciences IRB:** reviews biomedical research, excluding cancer. research.
 - **Cancer IRB:** reviews all aspects of observational and interventional cancer research

● Single-site study
[Clear](#)

5. * Will an external IRB act as the IRB of record for this study? [?](#)
 Yes No [Clear](#)

6. * Local principal investigator: [?](#)
 Mary Kivel [...](#) [✕](#)

7. * Does the local principal investigator have a financial interest related to this research? [?](#)
 Yes No [Clear](#)

8. ** Attach the protocol: [?](#)

Document	Category	Date Modified
<input type="button" value="Update"/> Re-Treatments with Ritumimab Protocol.docx(0.01)	IRB Protocol	12/9/2024

9. * What type of review is required for your project?
 Exempt Research
 Behavioral and Social Sciences IRB
 Biomedical Sciences IRB
 Cancer IRB
[Clear](#)

Study Funding Sources

1. Click on the “+Add” button to add funding sources for the study.
2. A pop-up screen will appear. Use this tab to enter both internal and external funding sources. Click on the ellipses [...] to access an extensive list of over 13,000 funding sources
3. Use the second pop-up to add your funding sources.
 - a. Use the wild card “%” to search for your funding source.
 - b. For all award internal to OSU, use “SPN-0006020 Ohio State University Internal Award”
4. Upload a grant application for external funding sources.
5. Check to make sure your funding source is correct.

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Validate Compare <<

You Are Here: An Open-Label Study of the Eff...

Editing: STUDY20240302

Study Funding Sources

1. Identify each organization supplying funding for the study:

1 + Add

Funding Source	Sponsor's Funding ID	Grants Office ID	Attachments
Arthritis National Research Foundation			

5

Add Funding Source

1. * Funding organization: ?

Arthritis Fdn ... 2

2. Sponsor's funding ID: (assigned by external sponsor)

3. Grants office ID: (assigned internally)

4. Attach files: (include any grant applications) ?

4 + Add

Document

Update GrantApplication.docx(0.01)

Add Funding Source

1. * Funding organization: ?

3

ID	Name	Category	Parent Organization
2. Academic_Affairs_CCH6	Academic Affairs CCH6	Division	OSU
Administration_and_Planning_CCH6	Administration and Planning CCH6	Division	OSU
Arts_and_Sciences_CCH6	Arts and Sciences CCH6	Division	OSU
Athletics_and_Business_Advancement_CCH6	Athletics and Business Advancement CCH6	Division	OSU
3. SPN-0004497	Breath of Hope Lung Foundation	Sponsor	
SPN-0001655	O. Smith Corporation	Sponsor	
SPN-0001205	123 Systems, Inc.	Sponsor	
SPN-0004790	AAA Foundation for Traffic Safety	Sponsor	
4. SPN-0006044	Aadi Bioscience, Inc.	Sponsor	
SPN-0007920	AAPlasma	Sponsor	

Document Category Date Modified Document History

There are no items to display

Local Study Team Members

Add study team members

1. Click on the “+Add” button after the statement “Identify each additional person involved in the design, conduct, or reporting of the research.”
2. A pop-up window will appear. For each team member, indicate their role in the research, the consent process, and disclose any financial interests related to the research. Once you have completed all fields for your first team member, you can select "OK and Add Another" to continue adding the rest of your study team.
3. The ellipses [...] will allow you to access a list of Ohio State affiliated individuals. The help text provides additional information for external members. Collaborating individuals must have an active Ohio State ID and complete required training. There is an [Ohio State job aid for creating a guest account](#). This step will need to be completed for external members before they can be added in Huron. In addition to an Ohio State ID, a CV should also be added for any external members (step 6).
4. After you have added all of your study team members, click okay and then check to make sure that they are listed correctly.
5. There is an additional entry field for external members that will allow you to upload the CV for an external member. Click the “+Add” button.
6. Use the pop-up window to add a CV for external members.

The screenshot displays the 'Local Study Team Members' section of the Huron system. The main interface includes a sidebar with navigation options and a central table of team members. A red circle '1' highlights the '+ Add' button at the top of the table. A red circle '4' highlights the 'Involved in Consent' column for the first member, Tish Denlinger. Below the table, a red circle '5' highlights the '+ Add' button for external team member information.

The 'Add Study Team Member' pop-up window (red circle '2') contains the following fields:

- 1. * Study team member: (input field with ellipsis, red circle '3')
- 2. Role in research: (check all that apply)
 - Co-investigator
 - Key Personnel
- 3. * Is the team member involved in the consent process?
 - Yes No [Clear](#)
- 4. * Does the team member have a financial interest related to this research?
 - Yes No [Clear](#)

The 'Submit a Document' pop-up window (red circle '6') contains the following fields:

- Title: (input field)
- If not provided, the name of the file will be used
- * File: (input field with 'Choose File' button)
- Show Advanced Options (button)
- * Required

Study Scope

1. **Drugs and biologics:** This first question asks “Does the study specify the use of an approved drug or biologic, use of an unapproved drug or biologic, or use a food or dietary supplement to diagnose, cure, treat, or mitigate a disease or condition? If the protocol requires one or more subjects to use the drug, biologic, dietary supplement, or food as part of study participation, you should answer yes to this question. This will add an additional tab titled “drugs” in the left navigator.
2. **Devices:** This second question asks “Does the study evaluate the effectiveness of a device or use of a humanitarian use device (HUD)?” If you are unsure if your device qualifies as a HUD, please reach out to IRBinfo@osu.edu. Answering yes to this question will add an additional tab titled “devices” in the left navigator.

You Are Here: [Re-Treatments with Ritumimab](#)

Editing: STUDY20240288 [Go to forms menu](#) [Print](#) [Help](#)

Study Scope [?](#)

1. * Does the study specify the use of an approved drug or biologic, use an unapproved drug or biologic, or use a food or dietary supplement to diagnose, cure, treat, or mitigate a disease or condition? [?](#)
 Yes No [Clear](#)
2. * Does the study evaluate the safety or effectiveness of a device or use a humanitarian use device (HUD)?
 Yes No [Clear](#)

Local Research Locations

This question asks you to identify research locations where research activities will be conducted or overseen by the local investigator.

1. Click on the “+Add” button and the “Add Research Location” pop-up window will appear.
2. Use the ellipses [...] to access a list of local research locations.
3. Use the selection field to identify your location. Use the wild card “%” to search for your site.
 - a. If your study involves a medical facility, please search for the specific location.
 - b. For non-medical sites on the OSU campus, please use "Ohio State Columbus Campus."
 - c. You should also include any other local, off-campus sites, such as a local elementary school, nursing home, or a private physician's office.
 - d. If you have a multi-site study, you do NOT need to list the participating sites, because those sites would rely on the reviewing IRB.
4. If you cannot find your local research location in the research location list, manually enter the location.
5. Check to make sure your location is correct.

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Local Research Locations

1. Identify research locations where research activities will be conducted or overseen by the local investigator:

Location	Contact	Phone	Email
Ohio State University Hospital			

5

Add Research Location

Add Research Location Information

1. Select the research location:

2

If you cannot find the research location in the list above, enter its information here:

4

a. Location name:

b. Location address:

Address line 1

Address line 2

Address line 3

City

Select Research Location SEL

3

Filter by Location Name

Go Clear

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Location Name

- African American and African Studies Community Extension Center (AAAS CEC)
- Agricultural Technical Institute (ATI)
- Alum Creek Columbus Southside
- Biodynamics Laboratory
- Brain and Spine Hospital
- Camelot Women's Health Center

Drugs

This page will only appear if you answered "yes" to the first question on the study scope page.

1. Click on the add button for a pop-up window that will allow you to enter in any drug, biologic, food product, or dietary supplements used in the study.
2. Use the responsive text to identify the items listed in your protocol. Huron maintains a robust list in this category, however if your item is not on this list, please enter it on the line provided.
3. Next, specify your item type, and attach any related files. Click okay and then look to make sure your entry is correct.

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Editing: STUDY20240302

Drugs

- * List all drugs, biologics, foods, and dietary supplements to be used in the study:**
+ Add

Generic Name	Brand Name	Drug Type	Attachment Name
	Ritumimab	Drug	

Update
- * Will the study be conducted under any IND numbers?**
 Yes No [Clear](#)
- Attach files:** (such as IND or other information that was not attached for a specific drug)
+ Add

Document	Category	Date Modified	Document History
There are no items to display			

Add Drug

Add Drug Information

- Select the drug:**
Ritumimab ... + Add
If you cannot find the drug in the list above, enter its information here:
Generic name:
Brand name:
- Specify the type:**
 Drug
 Biologic
 Food Product
 Dietary Supplement
 Other
[Clear](#)
- Attach files related to this drug:**
+ Add

Document	Category	Date Modified	Document History
There are no items to display			

* Required

OK OK and Add Another Cancel

Devices

The devices tab will only appear if you answered “yes” to question two on the study scope page.

1. Click on the add button for a pop-up window that will allow you to enter in your device information.
2. Click on the ellipses [...] to access an extensive device list.
3. Use this list to locate your device. Use the wildcard, “%”, to easily find your device in this list.
4. If your device was not on that list, manually enter in the name of your device and indicate whether it is a humanitarian use device.
5. If you have any files relating to your device, enter them here. Click okay and check again to confirm that your device information is correct.
6. Question two is a required field, asking you about possible device exemptions. Use the help text for additional clarification. If you still have a question pertaining to device exemptions, you can reach out to ORRP at IRBinfo@osu.edu.
7. The final question on this page is optional and provides a space for you to attach any documents related to any device exemptions. This attachment field is for documents relating to any potential investigational device exemptions or any humanitarian device exemptions. Attachments for general device information should be added in the device pop-up window.

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Validate Compare

You Are Here: An Open-Label Study of the Eff...
Editing: STUDY20240302

Devices

1. * Select each device the study will use as an HUD or evaluate for safety or effectiveness:

+ Add

Device	Humanitarian Use Device	Attachment Name
Splint, Extremity, Inflatable, External	no	

Update

2. * Device exemptions applicable to this study:

IDE number
 HDE number
 Claim of abbreviated IDE (nonsignificant risk device)
 Exempt from IDE requirements
[Clear](#)

3. Attach files: (such as IDE, HDE, or other information that was not attached for a specific device)

+ Add

Document	Category	Date Modified	Document History
There are no items to display			

Add Device

Add Device Information

1. Select the device:

2

If you cannot find the device in the list above, enter its information here:

Device name:

4

Is this a humanitarian use device (HUD)?

Yes No [Clear](#)

2. Attach files related to this device:

+ Add

5

Document	Category	Date Modified	Document History
----------	----------	---------------	------------------

There are no items to display

Attachments may include a copy of investigator brochure and the product labeling/device instructions.

Select Device Selection

3

Filter by

Device Name

Go

Clear

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Device Name

- 11.7 tesla micro mri
- 11-Dehydro Thromboxane B2 Kit, Urinary
- 1-Nitroso-2-Naphthol (Fluorometric), Free Tyrosine
- 2,4-Dinitrofluorobenzene (Spectroscopic), Nitrogen (Amino-Nitrogen)
- 2,4-Dinitrophenylhydrazine, Lactate Dehydrogenase
- 2009 H1n1 Influenza Virus (Swine Origin), Nucleic Acid Or Antigen, Detection And Identification
- 21-Hydroxylase Antibody (21-Ohab)
- 25-Oh-Vitamin D Mass Spectrometry Test System

Department Approval

Ohio State requires departmental endorsement of all regulated research protocols, including those for human subjects research.

1. Once a new protocol is ready for review by the department endorser, check the box labeled 'I certify that this submission is ready to be routed for departmental approval.' By checking this box and then clicking save, your protocol has now been routed for approval to your departmental approver.
2. You cannot proceed any further until you have the signed approval. The approval process happens outside the Huron system, so you can save and exit for now.

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Hello, Mary Kivel

You Are Here: Re-Treatments with Ritumimab

Editing: STUDY20240288

Departmental Approval

Instructions:
All initial submissions require departmental approval before the pre-review process. To initiate the departmental routing, check the box below, then click "Save" and exit this form. Upon exiting the form, a departmental approval document will be automatically routed to the department signatory via DocuSign. The study team will receive an email when the departmental review is created which will provide the signatory name. If you have any questions about the status of the review, please contact the signatory directly.

On completion of the departmental review, the study team will receive a copy of the endorsed departmental approval via email. Upload a copy of the approval below and click "Save" or "Continue" to complete the rest of the form. Click "Submit" to complete the submission process.

1. * I certify that this submission is ready to be routed for departmental approval.

2. * Departmental Approval: (upload a departmental approval document)

+ Add

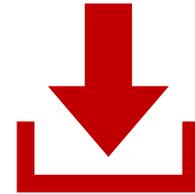
Document Name	Modified Date
There are no items to display	

Exit Save Continue

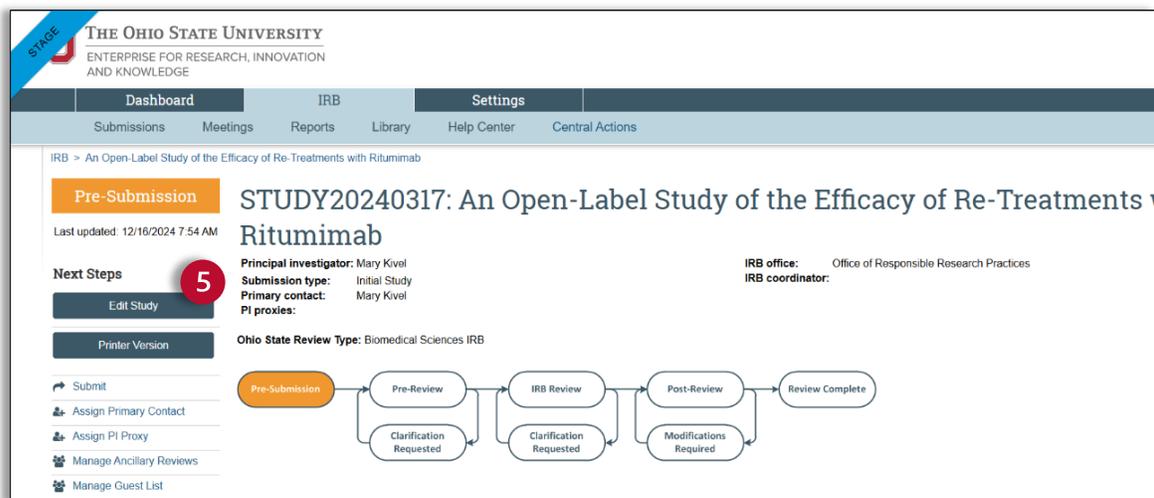
3. The departmental approver will receive a notification email letting them know that a summary of the protocol information is ready for review in DocuSign. The P.I. will also receive a verification email letting them know that the protocol has been routed for departmental review. The approver will log into DocuSign to review and approve the protocol. Check with your department for their approval process and timelines. Your department approver may ask the research team for more information prior to endorsing the protocol.



- Once the departmental approver signs the protocol, the P.I. will receive a confirmation email from DocuSign, letting them know that the approval is complete. The P.I. can now download a P.D.F. copy of the signed approval from DocuSign.



- Once the P.I. has downloaded the departmental approval, they are now ready to submit. Log back into the Huron system. Once back in Huron, navigate to your dashboard, find your study, and click on edit study.



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Dashboard IRB Settings
Submissions Meetings Reports Library Help Center Central Actions

IRB > An Open-Label Study of the Efficacy of Re-Treatments with Ritumimab

Pre-Submission STUDY20240317: An Open-Label Study of the Efficacy of Re-Treatments with Ritumimab
Last updated: 12/16/2024 7:54 AM

Next Steps **5**
Edit Study
Printer Version

Submit
Assign Primary Contact
Assign PI Proxy
Manage Ancillary Reviews
Manage Guest List

Principal investigator: Mary Kivel
Submission type: Initial Study
Primary contact: Mary Kivel
PI proxies:

IRB office: Office of Responsible Research Practices
IRB coordinator:

Ohio State Review Type: Biomedical Sciences IRB

Pre-Submission -> Pre-Review (Clarification Requested) -> IRB Review (Clarification Requested) -> Post-Review (Modifications Required) -> Review Complete

6. Once you have opened the SmartForm, navigate to the Departmental Approval tab.
7. Click on the “+Add” button to access a document submission window.
8. Use the “Submit a Document” pop-up window to find and upload the Departmental Approval from your device.
9. Check to make sure your approval has uploaded correctly and click continue.

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Hello, Mary Kivel ▾

You Are Here: An Open-Label Study of the Eff...

Editing: STUDY20240317

Departmental Approval

Instructions:
All initial submissions require departmental approval before the pre-review process. To initiate the departmental routing, check the box below, then click "Save" and exit this form. Upon exiting the form, a departmental approval document will be automatically routed to the department signatory via DocuSign. The study team will receive an email when the departmental review is created which will provide the signatory name. If you have any questions about the status of the review, please contact the signatory directly.

On completion of the departmental review, the study team will receive a copy of the endorsed departmental approval via email. Upload a copy of the approval below and click "Save" or "Continue" to complete the rest of the form. Click "Submit" to complete the submission process.

1. * I certify that this submission is ready to be routed for departmental approval.

2. * Departmental Approval: (upload a departmental approval document)

Document Name	Modified Date
DOCUSIGN Departmental Approval.pdf(0.01)	12/16/2024 7:51 AM

6 Departmental Approval

7 + Add

9

Exit Save Continue →

Submit a Document

8 Title:
If not provided, the name of the file will be used

* File:

* Required

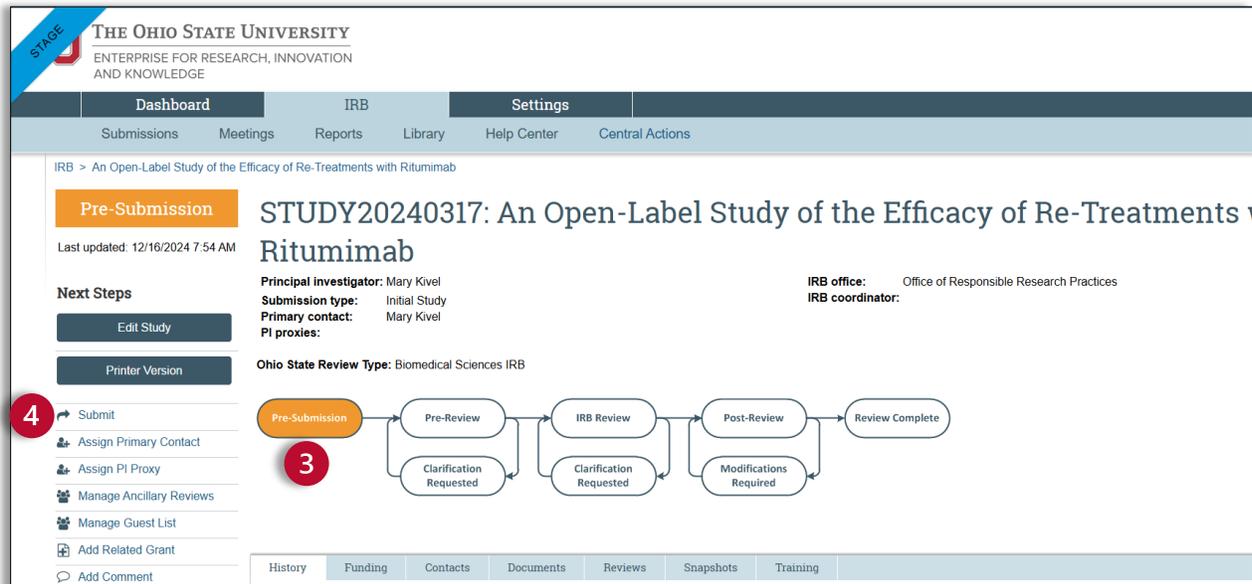
OK OK and Add Another Cancel

Finalize and Submit

1. After you have clicked “Continue” on the Departmental Approval page, the final page of the Smart Form will appear. Before you finish the SmartForm, check your study for errors using the validate button at the top of the left navigator.
2. After you have corrected any errors, you are now ready to finish the SmartForm. You will notice that the SmartForm now has a finish button. Click finish and exit the SmartForm.

The screenshot shows the 'Final Page' of an IRB submission form for 'Re-Treatments with Ritumimab' (STUDY20240288). The page includes a left sidebar with navigation options like 'Validate' and 'Compare'. The main content area contains instructions: '1. Click Finish to exit the form.' and '2. Important! To send the submission for review, click Submit on the next page.' A 'Finish' button is visible in the bottom right corner, highlighted with a red circle '2'. A red circle '1' is placed over the 'Validate' button in the sidebar.

3. After exiting the SmartForm, you will now be back in the study workspace. The study is complete but has not yet been sent to the IRB. If you look at the workflow map, you can see that the study is still in pre-submission.
4. The study staff can enter a study, but only the P.I. can submit a study. The P.I. will click “Submit.”



- After clicking “Submit,” an agreement page will appear. After reading this page, the P.I. or P.I. Proxy can click OK.

Submit

I agree to follow all applicable Ohio State policies and procedures and federal, state, and local laws and guidance regarding the protection of human subjects in research, as well as professional practice standards and generally accepted good research practice guidelines for investigators, including, but not limited to, the following:

- Perform approved research by appropriately trained and qualified personnel under my direction and with adequate resources,
- Initiate the research only after written notification of IRB approval or exempt determination has been received,
- Obtain and document (unless waived) informed consent (and HIPAA research authorization, when applicable) from participants (or their legally authorized representatives) prior to their involvement in the research using the currently approved consent form(s) and process,
- Promptly report to the IRB events that may represent unanticipated problems involving risks to subjects or others,
- Provide significant new findings that may relate to the participants' willingness to continue to participate,
- Inform the IRB of any proposed changes in the research or informed consent process before changes are implemented, and agree that no changes will be made until approved by the Ohio State IRB (except where necessary to eliminate apparent immediate hazards to participants),
- Complete and submit a continuing review application before the deadline for review at intervals determined by the IRB to be appropriate to the degree of risk (but not less than once per year) to avoid expiration of IRB approval and cessation of all research activities,
- Maintain research-related records (and source documents) in a manner that documents the validity of the research and integrity of the data collected, while protecting the confidentiality of the data and privacy of participants,
- Retain research-related records for audit for a period of at least three years after the research has ended (or longer, according to sponsor or publication requirements) even if I leave the university,
- Contact the Office of Responsible Research Practices for assistance in amending (to request a change in principal investigator) or terminating the research if I leave the university or am unavailable to conduct or supervise the research personally (e.g., sabbatical, or extended leave),
- Provide a final study report to the IRB when all non-exempt research activities have ended (including data analysis with individually identifiable or coded private information), and
- Inform all co-investigators, research staff, employees, and students assisting in the conduct of the research of their obligations in meeting the above commitments.

Incomplete study team training and COI requirements prevent submission of initial applications. Continuing reviews and modifications can be submitted but are checked for requirements by ORRP staff. Modification submissions adding new personnel will not be forwarded for review until they have satisfied the requirements.

The following personnel have training or COI requirements that have not been met:

There are no outstanding/incomplete trainings.

Ensure that all requirements have been met or remove personnel from the study and add them later once their training and COI are complete.

To notify study personnel of their unmet training or COI requirements, execute the Check CITI-COI activity.

5
OK
Cancel

- The study is now submitted. Congratulations. You will notice the state has changed to pre-review on the study workspace, indicating that it is now In-Review.

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Hello, M Sw

Dashboard
IRB
Settings

Submissions
Meetings
Reports
Library
Help Center
Central Actions

Pre-Review

Entered IRB: 12/16/2024 7:56 AM
Last updated: 12/16/2024 7:56 AM

Next Steps

View Study

Printer Version

- + Assign Primary Contact
- + Assign PI Proxy
- + Manage Ancillary Reviews
- + Manage Guest List
- + Add Related Grant
- + Add Comment
- + Copy Submission
- ← Withdraw

STUDY20240317: An Open-Label Study of the Efficacy of Re-Treatments with Ritumimab

Principal investigator: Mary Kivel
Submission type: Initial Study
Primary contact: Mary Kivel
PI proxies:

IRB office: Office of Responsible Research Practices
IRB coordinator:

Ohio State Review Type: Biomed Sciences IRB

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graph LR
    A[Pre-Submission] --> B[Pre-Review]
    B --> C[IRB Review]
    C --> D[Post-Review]
    D --> E[Review Complete]
    B --> B1[Clarification Requested]
    B1 --> B
    C --> C1[Clarification Requested]
    C1 --> C
    D --> D1[Modifications Required]
    D1 --> D
          
```

History Funding Contacts Documents Reviews Snapshots Training

Filter by Activity Enter text to search + Add Filter × Clear All