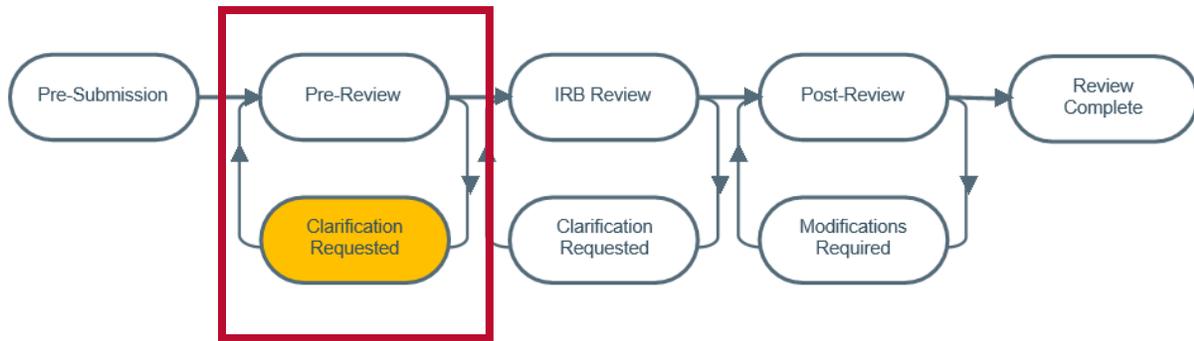


# Respond to a Clarification Request

After you submit your study, it goes to the ORRP staff for pre-review. The ORRP staff screen the submission and may ask for clarification if they notice inconsistencies or identify missing components. If this happens, they will send you a request for clarification.



## Navigation

Once you receive the request for clarification, you will log into Huron.

1. You will be on your dashboard.
2. The clarification request will be in your inbox. Select the request to open the study workspace.

The screenshot shows the Huron system dashboard for The Ohio State University. The user is logged in as 'STACE'. The dashboard has tabs for 'Dashboard', 'IRB', and 'Settings'. The 'My Inbox' tab is active, displaying a table of study requests. A red box highlights the first row, which is a 'Clarification Requested (Pre-Review)' for study ID 'STUDY20240302'. A red circle with the number '1' is placed over the 'Dashboard' tab, and another red circle with the number '2' is placed over the highlighted row in the table.

ID	Name	Date Created	Date Modified	State	Coordinator
STUDY20240302	An Open-Label Study of the Efficacy of Re-Retreatments with Ritumimab	12/10/2024 1:52 PM	2/28/2025 1:00 AM	Clarification Requested (Pre-Review)	
STUDY20240324	Multi Site testing	12/18/2024 2:45 PM	12/18/2024 3:11 PM	Pre-Submission	
STUDY20240318	ACE Inhibitors and Statins	12/16/2024 12:30 PM	12/16/2024 12:33 PM	Pre-Submission	
RNI00000080	ADH Withdrawal test	12/13/2024 8:45 AM	12/13/2024 9:12 AM	Pre-Submission	
STUDY20240196	Tish Testing Training Activity	10/17/2024 2:20 PM	10/17/2024 2:35 PM	Pre-Submission	

## Study Workspace

1. Click on the request for clarification for more details.
2. A pop-up window will appear with additional details for the request. For requests with multiple items, you will see an attached Word document uploaded here that lists the items that need to be addressed or clarified. You will be able to edit the study when it is in “Clarification Requested (Pre-Review)”.
3. Click on the “Edit Study” button to open the SmartForm.

Dashboard IRB Settings

Submissions Meetings Reports Library Help Center Central Actions

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

### Clarification Requested (Pre-Review)

Entered IRB: 3/5/2025 2:11 PM  
Last updated: 3/5/2025 2:30 PM

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

IRB off  
IRB co

## STUDY20240330: An Open-Label Study of t Ritumimab

**Ohio State Review Type:** Biomedical Sciences IRB

**Next Steps**

- 3 Edit Study
- Printer Version
- Submit Response
- Assign Primary Contact
- Assign PI Proxy
- Manage Ancillary Reviews
- Manage Guest List
- Add Related Grant
- Add Comment
- Copy Submission
- Withdraw

History Funding Contacts Documents Reviews Snapshots Training

Filter by Activity Enter text to search + Add Filter X Clear

Activity	Author
1 Clarification Requested	Hettler, Nicola

Please attach the subject recruitment advertisement to the Local Site Documents page of your submission.

Summary of Clarification Requested r, Nicola

### Clarification Requested

Pre-reviewer sends the submission back to the study team for clarifications.

2

Summary

Mar  
5  
2025

Author: Nicola Hettler (ERIK | Office of Responsible Research Practices)  
Logged For (IRB Submission): An Open-Label Study of the Efficacy of Re-Retreatments with Ritumimab  
Activity Date: 3/5/2025 2:30 PM

Form

**1. Make the following changes or provide the requested information:**

Please attach the subject recruitment advertisement to the Local Site Documents page of your submission.

**2. Supporting documents:**

Name

There are no items to display

# SmartForm

## Edit the SmartForm

Navigate to the area of the SmartForm relevant to your required changes. Make the requested changes.

## Review Changes

Any time you make a change in the SmartForm, you can use the compare feature to compare changes.

1. Click on Compare at the top of the left navigator to compare your changes.
2. A pencil icon will appear next to any section that has been changed.
3. Any changes will be detailed and will include the time and date of the change and the name of the person who made the changes.

**1** Compare

Compare current state of version:  
0.2 Submit to IRB  
with  
0.1 [No description]  
12/30/2024 12:41:53 PM

Changes found on 1 step:

- Basic Study Information
- Study Funding Sources
- Local Study Team Members
- Study Scope
- Local Research Locations
- Drugs
- Devices
- Local Site Documents**
- Departmental Approval

### Local Site Documents ?

- 1. Consent forms:** (include an HHS-approved sample consent document, if applicable) ?  
Document  
View Consent form (LOCAL SITE DOCUMENT).docx(0.01)
- 2. Recruitment materials:** (add all material to be seen or heard by subjects, including ads)  
Document  
View Recruitment Flyer (LOCAL SITE DOCUMENT).docx(0.01)

**3**

**Differences**

**Mary Kivel** • modified a minute ago • version 0.2+ (Submit to IRB)

- ▶ **Added:** Recruitment Flyer (LOCAL SITE DOCUMENT).docx

- 3. Other attachments:** ?  
Document      Category      Date Modified  
There are no items to display

**i** Suggested attachments:

- Completed checklist of meeting Department of Energy requirements, if applicable
- Other site-related documents not attached on previous forms

## Submit Clarification Request

1. After making the required changes and exiting the SmartForm, you will be back in the study workspace. You will complete the clarification request by submitting the response. Click on “Submit Response” and a pop-up window will appear.
2. Use the “Submit Response” pop-up window to detail your changes. If your Clarification Request involved a Word document with multiple items that needed to be addressed or clarified, you should upload a document detailing those changes. Once you have described your changes or uploaded your document, click “OK.”

The screenshot shows the IRB system interface for a study titled "STUDY20240330: An Open-Label Study of the Efficacy of Re-Retreatments with Ritumimab". The page is divided into several sections:

- Navigation:** Dashboard, IRB, Settings, Submissions, Meetings, Reports, Library, Help Center, Central Actions.
- Study Information:** Entered IRB: 3/5/2025 2:11 PM, Last updated: 3/5/2025 2:33 PM. Principal investigator: Mary Kivel, Submission type: Initial Study, Primary contact: Mary Kivel, PI proxies: (empty). IRB office: Office of Res, IRB coordinator: Nicola Hettle.
- Next Steps:** Edit Study, Printer Version, **Submit Response** (highlighted with a red box and a red circle with the number 1), Assign Primary Contact, Assign PI Proxy.
- Flowchart:** A process flow diagram showing the stages of an IRB review: Pre-Submission, Pre-Review, IRB Review, Post-Review, and Review Complete. A "Clarification Requested" box is shown below the Pre-Review stage, and another "Clarification Requested" box is shown below the IRB Review stage. A "Modifications Required" box is shown below the Post-Review stage.

The "Submit Response" pop-up window is shown with the following fields and options:

- 1. Notes:** A large text area for entering notes, currently empty.
- 2. Supporting documents:** A section for uploading documents, featuring an "+ Add" button and a table with the following structure:

Name
There are no items to display
- Buttons:** "OK" and "Cancel" buttons are located at the bottom right of the window.

- After submitting your response, you will notice that the status of the submission is now “Pre-Review” and your study can move forward to IRB Review.

Dashboard | IRB | Settings

Submissions | Meetings | Reports | Library | Help Center | Central Actions

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

### Pre-Review

Entered IRB: 3/5/2025 2:11 PM  
Last updated: 3/5/2025 2:35 PM

## STUDY20240330: An Open-Label Study of the Efficacy of Re-Retreatments with Ritumimab

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

**IRB office:** Office of Research  
**IRB coordinator:** Nicola Hettler

**Ohio State Review Type:** Biomedical Sciences IRB

**Next Steps**

- View Study
- Printer Version

- Assign Primary Contact
- Assign PI Proxy
- Manage Ancillary Reviews
- Manage Guest List
- Add Related Grant

**Flowchart:**

```
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;
```