

Responding to Issues & Modification Requests

How to respond when issues or modification requests are sent back to the study team to address

1. Receive email from ARROW indicating issues or modifications were returned

All members of the study team that have edit/email access to the a protocol application – including the PI, Point(s) of Contact, and any other study team member that has been granted edit/email access – will receive an email from ARROW when issues or modifications are sent back to be addressed. Study team members will not be able to address any issues visible in the application until it is sent back by the IRB Staff Reviewer. Therefore, it is important to wait for the email from ARROW before trying to address issues.

2. Review and respond to Reviewer Notes

Once the email has been received, access the appropriate protocol application from the ARROW Inbox by clicking on the appropriate protocol title to enter the protocol workspace.

The screenshot displays the ARROW web application interface. At the top, there is a red header with the ARROW logo and the text 'Application Review for Research Oversight at Wisconsin'. A navigation bar below the header contains links for 'My Home', 'IRB', 'IACUC', 'Biosafety', and 'SCRO', along with a 'HELP' button. The main content area is titled 'STUDY TEAM WORKSPACE' and includes a sub-header 'MY INBOX' with the text 'Submissions currently in progress.' Below this, there is a table of IRB submissions. The first submission, 'Sample Protocol Application', is circled in black. It has an ID of IRB00000827, is in the 'Pre-Submission' state, and has a 'TYPE: Initial Review' with a 'MODIFIED' date of 12/11/2017. To the right of this submission is a red warning icon and the text 'ACTION REQUIRED: Respond to issues from IRB staff and SUBMIT again.' The other two submissions, 'title' and 'test1', also have 'ACTION REQUIRED' messages to complete and submit the application to start IRB review.

| IRB | Submission Title | ID | STATE | TYPE | MODIFIED | Action Required |
|-----|---|-------------|----------------|----------------|------------|--|
| IRB | Sample Protocol Application <i>pi1, uwrb</i> | IRB00000827 | Pre-Submission | Initial Review | 12/11/2017 | Respond to issues from IRB staff and SUBMIT again. |
| IRB | title <i>Study Team Member 1, uwrb</i> | IRB00000820 | Pre-Submission | Initial Review | 12/7/2017 | Complete and SUBMIT application to start IRB review. |
| IRB | test1 <i>Study Team Member 1, uwrb</i> | IRB00000813 | Pre-Submission | Initial Review | 12/1/2017 | Complete and SUBMIT application to start IRB review. |

Open the Reviewer Notes tab to view the issues or modifications to be addressed. **If issues or modifications are sent back for a Change of Protocol, please see pages 6 & 7 for additional instructions.**

The screenshot shows the ARROW web application interface. At the top, there is a red header with the ARROW logo and the text 'Application Review for Research Oversight at Wisconsin'. A navigation bar below the header contains tabs for 'My Home', 'IRB', 'IACUC', 'Biosafety', and 'SCRO'. The 'IRB' tab is selected.

The main content area is titled 'Sample Protocol Application' and includes a sub-header 'Sample Protocol Application'. Below this, there are two sections: 'APPLICATION DETAILS' and 'MILESTONES'. The 'APPLICATION DETAILS' section lists: ID: 2017-0059, PI: uwirb pi1, Board: ED/SBS IRB, Staff Reviewer: uwirb irbd1, and Reviewer Contact: andrew.drinkwater@wisc.edu. The 'MILESTONES' section shows 'Date Submitted: 12/11/2017'.

A flowchart illustrates the review process: Pre-Submission → IRB Staff Pre-Review → IRB Committee Review → Review Complete. There are two 'Modifications Requested' boxes, one between IRB Staff Pre-Review and IRB Committee Review, and another between IRB Committee Review and Review Complete.

On the left side, there is a sidebar with 'ISSUES PENDING' (Action Required: Respond to issues from IRB staff and SUBMIT again.), 'EDIT APPLICATION', and 'ACTIVITIES' (Record Human Subjects Training Snapshot, Edit Administrative Access, Edit External Personnel Access, Preview Final Documents, Register a NetID, Withdraw).

At the bottom, a 'History' table is visible with the 'Reviewer Notes' tab highlighted. The table contains the following data:

| Activity | Author | Activity Date |
|---|----------------------------|--------------------|
| Sent issues to study team 3 IRB questions require study team response. | irbd1, uwirb | 12/11/2017 2:18 PM |
| Assigned to IRBS and IRB Assigned to uwirb irbd1 | irbsm1, uwirb | 12/11/2017 2:11 PM |
| Submission submitted for review | pi1, uwirb | 12/11/2017 2:04 PM |
| Created study | Study Team Member 1, uwirb | 12/11/2017 1:50 PM |

Reviewer Notes may be in the form of IRB Requests, IRB Questions, or IRB Comments. Study team members can respond to the Reviewer Notes directly below each note. There is also a link provided to the specific page where the note was made (Jump To: [link]). **Study teams should respond to each Reviewer Note, and make the appropriate changes directly in the modified application and supporting research documents.**

The screenshot shows the IRB application interface. At the top, there are navigation tabs: My Home, IRB, IACUC, Biosafety, SCRO, and HELP. The main heading is 'Sample Protocol Application' with a sub-heading 'Sample Protocol Application'. Below this, there are two sections: 'APPLICATION DETAILS' and 'MILESTONES'. The 'APPLICATION DETAILS' section includes: ID: 2017-0059, PI: uwirb pi1, Board: ED/SBS IRB, Staff Reviewer: uwirb irbd1, and Reviewer Contact: andrew.drinkwater@wisc.edu. The 'MILESTONES' section shows 'Date Submitted: 12/11/2017'. A flowchart below these sections illustrates the review process: Pre-Submission leads to IRB Staff Pre-Review, which can lead to IRB Committee Review or Modifications Requested. IRB Committee Review can lead to Review Complete or Modifications Requested. IRB Staff Pre-Review can also lead to IRB Committee Review. Below the flowchart is a table of Reviewer Notes. The table has columns for Type, Reviewer, Date Created, and Date Modified. The first note is an IRB Question with a 'Jump To: Special Procedures' link circled in red. The note text is 'Please also check: "Creation of audio or video recordings or photographs" from the list below.' The reviewer is 'uwirb irbsm1', the date created is '12/11/2017 2:15 PM', and the date modified is '12/11/2017 2:17 PM'. A yellow arrow points to the 'Response Required! Click here to respond...' link. The second note is an IRB Question with a 'Jump To: Privacy/Confidentiality' link. The note text is 'Please describe storage on campus resources for both paper and electronic data in 1.3'. The reviewer is 'uwirb irbsm1', the date created is '12/11/2017 2:15 PM', and the date modified is '12/11/2017 2:15 PM'. The third note is an IRB Question with a 'Jump To: ED SBS Risks and Benefits General' link. The note text is 'Please state in 1.1 that there are no direct benefits from participation.' The reviewer is 'uwirb irbsm1', the date created is '12/11/2017 2:13 PM', and the date modified is '12/11/2017 2:13 PM'. A 'Report a Bug' link is visible at the bottom right of the table.

****Please do not respond to Reviewer Notes with questions. Contact the Staff Reviewer, listed under the Application Details, to address any questions that come up when responding to notes and making changes to the application.**

Example of how to respond to Reviewer Notes:

The screenshot shows the ARROW application interface. At the top, there is a red header with the ARROW logo and the text "Application Review for Research Oversight at Wisconsin". On the right side of the header, it says "Edit: IRB Application - 2017-0059". Below the header, there is a navigation bar with buttons for "Back", "Save", "Exit", "Hide/Show Errors", "Print", "Jump To", and "Continue".

The main content area is titled "Reviewer Notes" and includes navigation buttons for "Previous" and "Next". There is a filter section with a "Filter by" dropdown set to "Type", a search input field, and "Go" and "Clear" buttons. Below this is a table with columns for "TYPE", "REVIEWER", "DATE CREATED", and "DATE MODIFIED".

| TYPE | REVIEWER | DATE CREATED | DATE MODIFIED |
|--------------|--------------|--------------------|--------------------|
| IRB Question | uwirb irbsm1 | 12/11/2017 2:13 PM | 12/11/2017 2:13 PM |

Below the table, there is a text area for the question: "Please state in 1.1 that there are no direct benefits from participation." A yellow arrow points to a link that says "Response Required! Click here to respond...".

Below the question, there is a section titled "Risks and Benefits: General" with a question: "1.1 Describe any potential direct benefits to subjects. If there are no direct benefits, state this." A text input field contains the text "Sample Protocol Application".

A Study Team Response of "Done." is generally sufficient, unless the IRB asks the study team to confirm or clarify something in their response.

This screenshot is similar to the one above, but it includes a dialog box titled "Respond to Reviewer Notes - Google Chrome" overlaid on the interface. The dialog box shows the details of the reviewer note and provides a form to enter a response.

The dialog box content includes:

- Author: uwirb irbsm1
- Please state in 1.1 that there are no direct benefits from participation.
- User: uwirb Study Team Member 1
- Type: Study Team Response (selected in a dropdown)
- Response: ENTER A RESPONSE AND UPDATE PAGE AS NECESSARY. (This text is circled in black in the image)

At the bottom of the dialog box, there are "OK" and "Cancel" buttons, and a note that "Response" is a required field.

The background of the screenshot shows the same ARROW interface as the first image, but with the "Response Required" link now disabled and the text "Response Required! Click here to respond..." replaced by "Response Required! Click here to respond...".

When all of the Reviewer Notes have been addressed, and the ARROW application and supporting documents updated as needed, the PI will need to press SUBMIT. This will not be possible until all of the required Reviewer Notes have been addressed. **Please note that ARROW will not automatically inform the PI when the application is ready to be resubmitted. PI must be notified outside of ARROW.**

Note: The Principal Investigator (PI), Point(s) of Contact (POC), and study team members with edit/email access all have the ability to respond to issues or modifications. However, only the PI has the ability to resubmit the application back to the IRB in ARROW.

The screenshot shows the ARROW web application interface. At the top, there is a red header with the ARROW logo and navigation tabs for My Home, IRB, IACUC, Biosafety, and SCRO. A user is logged in as 'uwirb pi1'. The main content area is titled 'Sample Protocol Application' and includes an 'ISSUES PENDING' section with an 'ACTION REQUIRED' message: 'Respond to issues from IRB staff and SUBMIT again.' Below this are buttons for 'EDIT APPLICATION' and 'SUBMIT' (circled in red). A flowchart illustrates the application process: Pre-Submission → IRB Staff Pre-Review → IRB Committee Review → Review Complete. It also shows paths for 'Modifications Requested' leading back to IRB Staff Pre-Review or IRB Committee Review. A 'History' table at the bottom lists activities such as 'Sent issues to study team', 'Assigned to IRBS and IRB', 'Submission submitted for review', and 'Created study'.

| Activity | Author | Activity Date |
|---|----------------------------|--------------------|
| Sent issues to study team 3 IRB questions require study team response. | irbd1, uwirb | 12/11/2017 2:18 PM |
| Assigned to IRBS and IRB Assigned to uwirb irbd1 | irbsm1, uwirb | 12/11/2017 2:11 PM |
| Submission submitted for review | pi1, uwirb | 12/11/2017 2:04 PM |
| Created study | Study Team Member 1, uwirb | 12/11/2017 1:50 PM |

The application is returned to the IRB office for review of the addressed issues or modifications made.

Responding to Issues for a Change

Responding to issues in ARROW regarding Changes to modify research procedures and/or documents is different than responding to issues or modifications from an Initial Review. A Change request involves two parts: a Change App to describe the proposed changes, and the Modified App where the proposed changes to the application are actually made.

Directions for reviewing issues for a Change:

Step 1

If there are issues or modifications that need to be addressed in the Change App, from the Change workspace, you can see the issues or modifications by clicking on the Change Form Reviewer Notes tab.

The screenshot displays the ARROW web application interface. At the top, the ARROW logo and navigation tabs (My Home, IRB, IACUC, Biosafety, SCRO) are visible. The user is logged in as 'uwirb Study Team Member 1'. The main content area shows details for application 'CP001 for IRB Study 2017-0059'. A flowchart illustrates the review process: Pre-Submission → IRB Staff Pre-Review → IRB Committee Review → Review Complete. Two 'Modifications Requested' boxes are shown between IRB Staff Pre-Review and IRB Committee Review. The 'Change Form Reviewer Notes' tab is selected and circled. Below the flowchart, a table lists reviewer notes:

| Type | Reviewer | Date Created | Date Modified |
|--|-------------|--------------------|--------------------|
| IRB Question Jump To: Consent Continued Please explain in 2.1.1 why re-consent from subjects who have completed participation is not necessary. | uwirb irbd1 | 12/27/2017 1:25 PM | 12/27/2017 1:25 PM |
| IRB Question Jump To: Full Changes ED SBS It seems that Recruitment materials are also being modified as part of this change, please select that option below. | uwirb irbd1 | 12/27/2017 1:24 PM | 12/27/2017 1:24 PM |

Note: The Principal Investigator (PI), Point(s) of Contact (POC), and study team members with edit/email access all have the ability to respond to issues or modifications. However, per normal IRB procedure, only the PI has the ability to resubmit the Change back to the IRB in ARROW.

Step 2

In addition to responding to issues or modifications listed in the Change App, if there are issues or modifications in the Modified App, those will also need to be addressed. To do this, click on the tab for the Modified App Reviewer Notes.

The screenshot shows the ARROW application review interface. At the top, there is a navigation bar with tabs for My Home, IRB, IACUC, Biosafety, and SCRO. The user is logged in as 'Hello, uwirb Study Team Member 1'. The main content area displays 'CP001 for IRB Study 2017-0059' with the initial application type as 'Sample Protocol Application'. Below this, there are sections for 'APPLICATION DETAILS' (ID: 2017-0059-CP001, PI: uwirb_pi1, Board: ED/SBS IRB, Staff Owner: uwirb_irbd1) and 'MILESTONES' (Date Submitted: 12/27/2017). A workflow diagram shows the process from Pre-Submission to IRB Staff Pre-Review, IRB Committee Review, and Review Complete, with 'Modifications Requested' boxes indicating feedback loops. Below the diagram, there are tabs for History, Correspondence, and Modified App Reviewer Notes (which is circled). A table below the tabs shows a list of reviewer notes with columns for Type, Reviewer, Date Created, and Date Modified.

| Type | Reviewer | Date Created | Date Modified |
|--|-------------|-----------------------|-----------------------|
| IRB Question Jump To: Research Design General Please update 1.2 to include the proposed changes. | uwirb_irbd1 | 12/27/2017 1:27 PM | 12/27/2017 1:27 PM |

Once all issues or modifications have been addressed in the Change Form and/or Modified Application, refer to page 5 for how to submit. The SUBMIT activity will be in the Change workspace.

Administrative Hold Response

A study may be approved with Administrative Hold (conditional approval) when the study team is waiting on additional pieces for final IRB approval (ie. site permission, finalized agreement, etc.). Do not submit any other applications when your study is in Administrative Hold, instead, once you have the documents contingent on final approval, send them to your PI along with these instructions.

Directions for completing an Administrative Hold Response:

Step 1

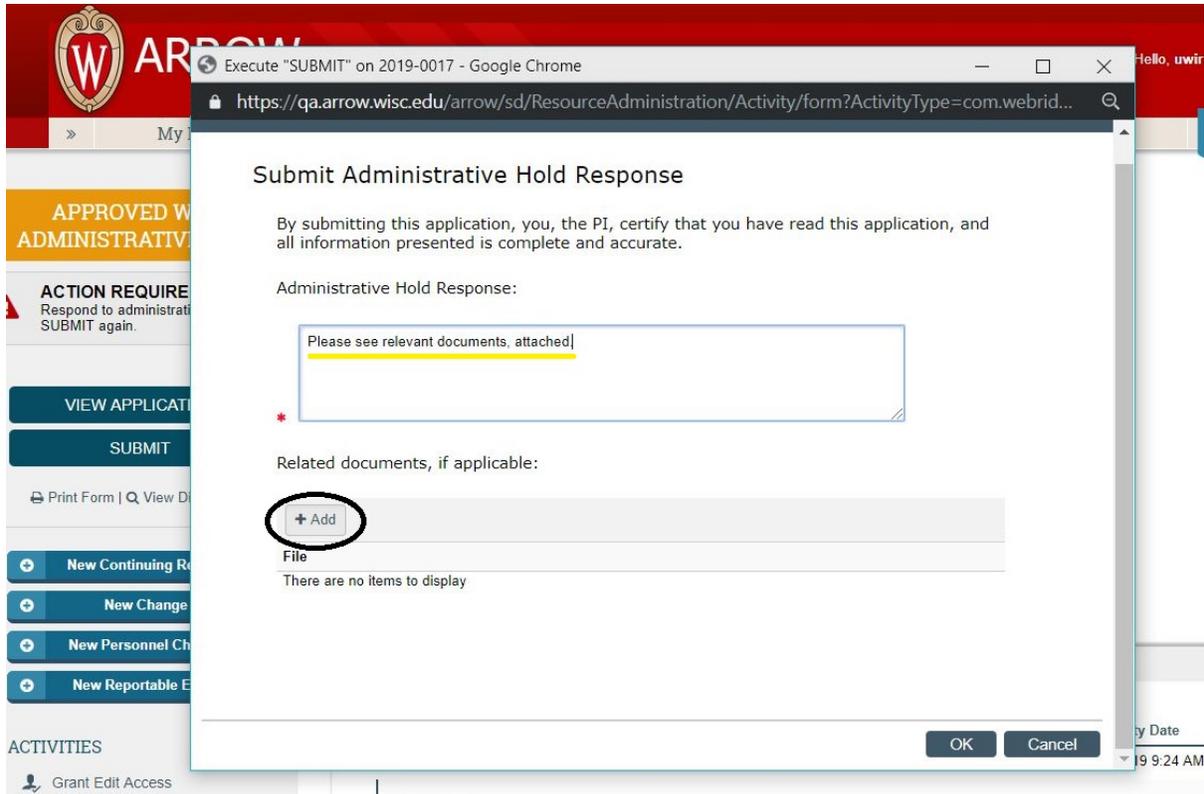
Only your PI will have the SUBMIT option, as with other applications. Once you have sent them any relevant documents for the Administrative Hold, ask them to click SUBMIT in the main study workspace.

The screenshot displays the ARROW web application interface. At the top, the ARROW logo and navigation tabs (My Home, IRB, IACUC, Biosafety, SCRO) are visible. The main content area is titled 'Sample Protocol Application' and shows the application is 'APPROVED WITH ADMINISTRATIVE HOLD'. A red warning icon indicates 'ACTION REQUIRED: Respond to administrative hold and SUBMIT again.' The 'SUBMIT' button is circled in red. Below the application details, a flow diagram shows the review process: Pre-Submission, IRB Staff Pre-Review, IRB Committee Review (highlighted in orange), and Review Complete. A 'History' table at the bottom shows an activity: 'Sent correspondence to study team: Approved with Administrative Hold' by 'irbd1, uwirb' on '7/17/2019 9:24 AM'.

| Activity | Author | Activity Date |
|---|--------------|-------------------|
| Sent correspondence to study team: <i>Approved with Administrative Hold</i> | irbd1, uwirb | 7/17/2019 9:24 AM |

Step 2

The Submit Administrative Hold Response window will pop-up where they can note what documents are being submitted and upload them in the response.



Once all relevant documents are attached, the PI should click OK on both windows to save and submit the response. Now the application is back under review by the IRB. Please contact your staff reviewer with any questions about your Administrative Hold Response.

