

SUBMITTING REQUESTED CHANGES

(BEFORE EXPEDITED OR FULL BOARD REVIEW)

Request for changes by the RSRB specialist can be made to a new application, an amendment, a continuing review, and an adverse event. The following are examples of screen shots from a new application.

While the application is in “Changes Required by IRB Specialist” state, the research study personnel should perform the following tasks:

1. Go to your home page - **My Inbox** tab
2. Find the **Application** that was returned to you by IRB Specialist with request for changes, and click on its **name**

Home page

My Inbox Applications Adverse Events Continuing Reviews Amendments						
Your inbox displays Applications, Amendments, Continuing Reviews and Adverse Events requiring action by the PI or study team.						
Note: The Inbox contains all items that you have permission to view. Not all will require action from you.						
ID	Name	Date Modified	Type	State	Last State Change	
CR00001533	Continuing Review 1 for RSRB Application #RSRB00023206	3/5/2008 12:34 PM	Continuing Review	Pre Submission	3/5/2008 12:34 PM	
Ame2_RSRB00023206	Amendment 2 for RSRB Application #RSRB00023206	3/5/2008 12:33 PM	Amendment	Pre Submission	3/5/2008 12:33 PM	
RSRB00023165	Application with Stipulations	1/17/2008 1:34 PM	Application	Stipulations Pending	1/17/2008 1:34 PM	
RSRB0002316	Application Returned by IRBS	1/17/2008 1:29 PM	Application	Changes Required By IRB Specialist	1/17/2008 1:29 PM	
RSRB00023144	Application 1 Pre Submission	1/16/2008 3:15 PM	Application	Pre Submission	1/16/2008 3:15 PM	

3. Review the proposed changes from IRB Specialist by clicking on the appropriate link in the **Clarifications** section under **Required Actions** tab with comments from the RSRB Specialist

Study home page

IRBS			
Application Returned by IRBS			
Description:	Returned for changes required by IRBS		
PI:	training pi1	Coordinator:	training user1
RSRB Case Number:	RSRB00023157	IRB Specialist:	Carla Caves
Date Submitted:	1/17/2008	Date Returned to PI:	1/17/2008 10:45 AM
<i>form 591</i>			
This application has been returned to you. Either changes are required to the application or more information or clarifications are requested.			
Important:			
<ul style="list-style-type: none"> If you have completed all the requested changes from the RSRB. Click "Submit Changes to IRBS" or "Submit Exempt Changes to IRBS" button to send the application back to the RSRB specialist for continuing with the review process. 			
Required Actions		Documents	
Clarifications			
Activity		Author	Activity Date
Changes Requested by IRB Staff during initial review of Please answer all the questions		Carla Caves	1/17/2008 10:45 AM
Stipulations			
Stipulations:			
Description			
There are no items to display.			
<i>form 152</i>			

Clarifications screen

Activity Details (Changes Requested by IRB Staff during initial review) Changes to the item were requested.

Author:	Carla Caves (RSRB Staff)	Activity Date:	1/17/2008 10:45 AM
For Person:		Created Date:	1/17/2008 10:45 AM
Logged For (Application):	Application Returned by IRBS		

Activity Form | Property Changes | Documents / Tasks / Notifications

Instructions:

- Use this form to send the application back to the PI with a request for changes
- Upload a document specifying the required changes
- In the Comments section, you may add a note (e.g. Please review the attachment)
- When finished, click the **OK** button, this will send a notification to the PI

Comments - Type in a note for the PI, if applicable:
Please answer all the questions

Documents - Upload your document specifying the required changes:
name: _____ version: _____
There are no items to display.

4. Review all items listed under **Comments**

Study home page

Current State
Changes Required by IRB Specialist

Application Forms

My Activities
Submit Changes to IRBS
Withdraw
Edit Guest List

(Changes Required Template)

Application Returned by IRBS

Description: Returned for changes required by IRBS
 PI: training user1
 RSRB Case Number: RSRB00023157
 Date Submitted: 1/17/2008
 Coordinator: training user1
 IRB Specialist: Carla Caves
 Date Returned to PI: 1/17/2008 10:45 AM

This application has been returned to you. Either changes are required to the application or more information or clarifications are requested.

Important:

- If you have completed all the requested changes from the RSRB. Click "Submit Changes to IRBS" or "Submit Exempt Changes to IRBS" button to send the application back to the RSRB specialist for continuing with the review process.

Required Actions | Documents

Clarifications

Activity: Changes Requested by IRB Staff during inbal review	Author: Carla Caves	Activity Date: 1/17/2008 10:45 AM
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Stipulations
Description: There are no items to display.

5. Go back to the study home page

6. Click the **Application Forms** button

7. Use the scroll-down menu to navigate within the application to the relevant section

8. Make the required change(s)

9. Click on **Save**

10. Click on **Exit**

Application form

<< Back | Save | Exit | Help/Show Errors | Print... | Jump

01. Study Personnel Information. Protocol and Measures

01. Study Identification Information. Protocol and Measures

02. Conflict of Interest

03. Sponsorship (Part 1)

04. Study Info (Part 1)

05. Study Info (Part 2)

06. Sponsorship (Part 2)

07. Just In Time (Part 1)

07. Just In Time (Part 2)

08. Coordinating Center Studies, Concepts and Umbrellas

09. Exempt

10. WIRB

1.1 * Study Working (short) Title:
Application Returned by IRBS

1.2 * Study Full Title:
Returned for changes required by IRBS

1.3 If the Study Protocol is available electronically, click **Add** to upload. **Important:** If you're revising or replacing the previously uploaded document, use the **Replace** link next to the file name. Do not delete any document after the study has been submitted to the RSRB.

Add

name	Revision	Modified Date
There are no items to display.		

Study home page

11. After all changes have been completed, click on **Submit Changes to IRBS**



12. Type in a brief summary of changes

13. **Optional** - upload a memo explaining the changes (for additional instructions go to p. 14 - Adding a Document)

14. Click the **OK** button

Note: This will send the application back to the RSRB specialist.

Submit changes to IRB specialist window

