EIRB+ Application Guide

Responding to IRB Requests

When a submission is returned to the study team for Clarifications, access reviewer notes by clicking



Edit Study

- IRB Requests are indicated by the following symbol:
- IRB Requests that require a typed response:



RUTGERS UNIVERSITY Office for Research • In the workspace, the IRB Request symbol appears in the left navigation bar and in the Study Workspace. Clicking the symbol in the navigation bar will ONLY bring you to that section on the main page.

	4 Go to forms menu 🔒 F	Print - Dicons O Help
▼ 1 - General Information		this project and is displayed in the "All IRB
1.0 General Project		Submissions" workspace where all activity is listed. This field is limited to 100 characters
1.1 Submission Type		
1.3 Emergency Use	3.0 * Enter the Principal Investigator / Repository Administrator:	For more information on who may be a principal
1.3.1 Emergency Use - Drugs		investigator (PI) click HERE
1.3.2 Emergency Use -	* Indicate the current institutional status of the listed Principal Investigator:	Required training for researchers and the
No Consent Form (drug)	Rutgers Faculty (Full-Time)	research team members click HERE
=10 Attachments and Additional	Rutgers Volunteer Faculty/Adjunct Faculty	 PI Institutional Status Guidance
Supporting Information	Rutgers Graduate Student (Masters and Doctoral Level)	
10.0 Attachments	Staff (permanent, non-faculty staff positions at Rutgers)	
Final Page	O RWJBH Employee	
	O Other	
	<u>Clear</u>	
	4.0 Study Coordinator / Contact Person:	In addition to the listed
		PI, select the individual who will be responsible for the day - to - day
		administrative requirements of the
		protocol.
	5.0 Co-Investigators:	Please refer to your
		school policies to check who must be included in
	Last Name First Name Department/Division School/Unit Institutional Status Restricted	Investigator
	6.0 Other Study Staff: (Click on the ADD button below to add Other Staff. Click on the Person's name link	
	below to edit/update)	Select each additional personnel or individual to
	Name Dant Bole Interaction or Accesse Institutional Status Beatricted Data Madified	person's name link to
	There are no items to display	 Additional
	70	Information:
	* Is this IRB submission related to an existing OnCore record? ○ Yes ● No Clear	Guidance for OnCore:
	0-5-1 Do	0
i i	Exit Save	Continue 🤿

• **CLICK** the IRB Request symbol within the eIRB+ application to view the note:

1.1 Submission Type O RWJBH Employee 1.1 Submission Type O Other 1.3 Emergency Use Clear
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Change history « Reviewer Notes persons name link to efficiency and the second state and the
Kyle Manley Response Required IRB Staff Change Request Information:
Example - Kequred comment - please address and type a response.
posted an hor region of other small of OnCore: OnCore:
Reply

- CLICK 'Reply' to type a response,
- **CLICK** 'OK' to post/save the response.

Once all IRB Requests have been addressed, RESUBMIT by returning to the Study Workspace and • A Submit Changes





A final window will open:

test-eirb.rutgers.edu	eiR8/sd/ResourceAdministration/Activity/form?ActivityType=com.webridge.entity.Entity[0/D[31C68D4E9C]	121C428293A89C794888F4[]8.Activit 9,
etenit Changes		
Submit Change	es/Clarifications to IRB	
1 addition to your response to th	e Reviewer Notes, rokase socials and allow summary advantation double reviewer. To add or update documents related to this project PLAction Required - No errors when submitting.jpg	please use the "Upload Attachments" activity
Comments		
		DX Deve

• Once completed, the Study Workspace will reflect that the study is in IRB Office Review and that the changes were submitted.

Proje	ct Informatio	n	
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Tips and Suggestions

• If the IRB requests a new document or that a document is revised, DO NOT only upload the requested document in the IRB Request pop-up box. All documents should be **UPLOADED** to section 10.0 Attachments of the eIRB+ application.

Specifically, when the IRB requests that a document is revised, upload two versions: a 'tracked' and a 'clean' version.

A 'tracked' document is a version where the track changes feature in Microsoft Word is turned on (<u>Microsoft Instructions for</u> <u>turning on this feature</u>). A 'tracked' version facilitates the IRB review and re-review process because it enables the IRB to easily identify the updates made to address the IRB's requests.

A 'clean' document is a version where all tracked changes have been accepted.

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• If you receive an error message when resubmitting, you most likely have not addressed all required IRB Requests. The Error/Warning Message will indicate which section(s) have an IRB Request that needs a response.

