Responding to a Request for Clarification

The goal, as always, is to submit IRB Protocol forms and documents that do not require clarification. Review by Alice Pasvogel in the Office of Research & Scholarship and for students by their DNP Project/Dissertation Chair will hopefully avoid the need for clarification once submitted to the IRB through eIRB.

If you receive a request for clarification, follow the steps below to review and respond to the request.

To review the request details

Click the study number link in the email. Log on to eIRB using your UANet ID and Password. You should be on the study page. Scroll down to see the Clarification Request. If it asks for revisions to the submission, click **Edit Study** to view the Smart Forms.

Next Steps



Look for the Smart Form(s) that have an icon indicating that a revision is needed.

E Compare	~
Basic Study Information	1
Study Funding Sources	
Local Study Team Members	
Study Scope	p
Local Research Locations	

Open the Smart Form and look for the icon next to the section that needs clarification/revision.



Click the icon to view the comment. Make the change requested and submit a response. If you are making changes to a document, download the document and make the changes requested. Always revise documents using Word's track changes feature. Once you have made the changes requested and/or responded to the comments, upload the revised document. Click **Update** next to the document you want to update. Only select '+Add' if the document is a brand-new document.

*	Attach the p	protocol: 🕜			
	+ Add				
		Document	Category	Date Modified	Document History
	C Update	Sample Protocol.docx(0.01)	IRB Protocol	11/2/2020	History

Select **Choose File** to upload the new version of the document.

Edit Attachment	
1. * File to attach:	
Protocol Attachment.docx(0.01)	
Choose File	
2. Name: (if not supplied, the file name will be shown)	
3. Version number:	

After you have uploaded the revised document, click 'Reply' and state, for example, that all requested revisions and comments have been addressed.

Exit the study when done.

To submit response

Once you have made all the revisions requested, on the submission workspace, click **Submit Response**.



In the Notes box, outline the changes that were made in response to the reviewer's comments or state that all requested revisions/comments have been addressed. Click **OK**.

The study has moved back to the reviewer's inbox to continue the review.

On the Workflow Map, your project should have moved from '**Clarification Requested**' back to '**Pre-Review**'. If you have addressed all the comments, your project is ready for review by the IRB Chair. Once this review is complete, you will be notified.

On the Workflow Map, your project will move to '**Review Complete**' and your Approval/Determination letter will be available to download.