





Job Aid Title	How to Submit a Modification
Relevant Users	Principal Investigator (PI), Additional Contact, Study Staff
Covered Topics	How to create and submit a Modification

! Note:

- You can only submit one Modification, Continuing Review, or Continuing Review/Modification submission at a time.
- If you have submitted a plain Modification that has not yet been approved and you need to submit additional Modifications to the study, or you need to submit a Continuing Review, please contact the IRB office for assistance (x6-4261).
- Create a Modification submission
 - Once in the "Parent" study (i.e. the study's initial submission in eIRB), select the **New CR/Modification** button as shown below.

Home IRB					
Home IRB IRB > IRB Studies > R01					
IRB > IRB Studies > R01					
Current State	H00006056: R01				
Approved IRB D IRB Studies D IRB Meeting D IRB Committee	Principal Investigator	PI Test			
	IRB Owner	Michelle Ferretti			
IRB		11/14/2014			
IRB Studies		11/14/2014			
IRB Meeting	Expiration Date	11/13/2015			
	Letter	Approved Letter_	H00006056pdf(0.01)		
View Submission					
View Submission Print Submission	Documents Project Personnel Follow-On	Submissions	Clarifications Requested RNI Full History Summary History	Respor	nd to IR
CR/Modification	Category		Original File Type	Date Modified	Stamp
CR/Modification New CR/Modification	Investigator Study Plan		eturbalan 14nov14 door - 0.02 Nieton	11/14/2014 10:54 AM	studyp
Reportable New Information	Consent Document(s)				Conse
Reportable New Information	Grant Application		researchportiongrant_2014.docx - 0.02 History	11/14/2014 10:54 AM	resear
My Current Actions	Grant Application		numansubjectsportiongrant_2014.docx - 0.02 History	11/14/2014 10:54 AM	numan
Summary	нірад		hipaawaiver_14hov14.doc - 0.02 History	11/14/2014 10:54 AM	nipaav
C Edit Research Staff	HIPAA			11/14/2014 10:54 AM	НІРАА

• In (1) Select **Modification**. Then review the **Current Protocol Status** in (2) and select any of the four statements that are true or not applicable. Click **Continue**.









- On the **Modification Summary** page, check any of the items in (1) that are true. Then in (2) provide a <u>description and a justification</u> of the modification. Include a list of all documents that have been modified. Click **Continue** to proceed to the next page.
 - **!Note:** Please avoid copying and pasting document text (e.g. text from a 'Summary of Changes' document) into the Modification Summary. Rather, please reference the relevant pages from the document in the Modification Summary.



- Once you have finished with the **Modification Summary**, click the **Continue** button and you will be taken to a copy of the currently approved study information. Edit the information in the various 'SmartForm' sections (Section 1.0 Study Information, Section 2.0 Funding Information, etc.) as needed.
 - If you would like to revise or add new study documents related to the modification, you may **Jump To** or **Continue** to Section **7.0 Attachments.**
 - Please refer to the <u>How to Manage Files in eIRB</u> Job Aid for steps on how to add or update study documents in Section 7.0 Attachments.
- When you have completed the Modification submission, click the **Finish** or **Exit** button to close.







• Submitting the Modification

- For Study Staff:
 - After clicking **Finish** or **Exit** in the submission, select **Ready for PI Review** under **My Current Actions** in the submission workspace. **The PI is the only member of the study team that may submit the Modification to the IRB office.**

IRB > IRB Studies > Trai	ning Study > Test: Mod		
Pre-submission	H00006049_1: Test: Mod		
RB	Principal Investigator	PI Test	
IRB Studies	IRB Owner Study Expiration Date	12/15/2015	
IRB Meeting	Submission Type	Modification	
IRB Committee	Submission Review Date		
Edit CR/Modification			
Print CR/Modification	Documents Clarifications Requested	Full History Summary History	
	Documents Clarifications Requested	Full History Summary History	
Print CR/Modification	Documents Clarifications Requested	Full History Summary History	[]
Print CR/Modification	Documents Clarifications Requested	Full History Summary History Original Submitted File	My Current Actions
Print CR/Modification y Current Actions Cancel	<u> </u>		My Current Actions
Print CR/Modification y Current Actions Cancel	UpdatedDocument Category	Original Submitted File	My Current Actions
Print CR/Modification IV Current Actions Cancel	Updated Document Category Investigator Study Plan	Original Submitted File Investigator Study Plan 11.7.14 - 0.02 Hi	

• For the PI:

• After clicking **Finish** or **Exit** in the submission, select **Submit** under **My Current Actions** in the submission workspace.

IRB > IRB Studies > Trai			
Pre-submission	H00006049_1: Test:	Mod	
RB	Principal Investigator IRB Owner	PI Test	
IRB Studies	Study Expiration Date	12/15/2015	
IRB Meeting	Submission Type	Modification	
IRB Committee	Submission Review Date		
Edit CR/Modification]		
Edit CR/Modification Print CR/Modification	Documents Clarifications Re	guested Full History Summary History	
Print CR/Modification	Documents Clarifications Re	guested Full History Summary History	_>
Print CR/Modification Ay Current Actions	Documents Clarifications Re	guested Full History Summary History Original Submitted File	-> My Current Actions
Print CR/Modification			0.02 Hi
Print CR/Modification	Updated Document Category	Original Submitted File	

• You will know that you have submitted successfully when the submission's "state" in the upper left-hand of the screen has changed from **Pre-submission** to **Pre-Review**.

