



Job Aid Title	Change of PI
Relevant Users	Principal Investigator (PI), Additional Contact, Study Staff
Covered Topics	How to submit a Modification to change the PI of an approved study

- Active study staff or the outgoing PI must create a Modification to change the Principal Investigator for an approved study. The incoming PI then submits the Modification. Changing the PI cannot be done using Edit Research Staff.
- 1. Create a modification submission
 - If you are the new PI and are ready to **submit**, skip to Step 3: Submit the Modification.
 - Once in the "Parent" study (i.e. the study's initial submission in eIRB) select the **New CR/Modification** button shown below.



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

<< Ba	ick	Save Print	Continue >>
Con	tinuing Review and Modification		1
	* Submission Nickname:		
	Protocol ID:		
	Study Title:		
1.	Continuing Review/Modification: Continuing Review Modification Continuing Review and Modification Clear		
		K	
2.	Current Protocol Status. Check all that are true or n		
	related to collection of long-term follow-up data.	eted all-research related interventions and interactions, including intervention the subjects is being obtained by this institution's investigator.	and interactions
		nstitution is completed. (This can be checked even if a statistical center at anot	ther institution will

On the Modification Summary page, check off Changes to PI and any items in (1) that are true. Then in (2) provide a description and a justification of the modification. List any documents that are being added/modified with this submission (i.e. informed consent form, assent form, required letter regarding change of PI, etc.).



<< Bac	k	Save Exit Hide/Show Errors Print Jump To: Modification Summary +	Continue >>
Mod	ification Summary		1
1.	Check all of the following that are true:		
-	Changes to PI	(For a change in principal investigator (PI), upload a letter from the previous PI agreeing to the change or from the department chair or sup without the previous PI's agreement.)	ervisor explaining the reason to pro
	Subjects are currently enrolled		
	Current subject will be notified of these changes	(If checked, ensure that the submitted documents, describe how current or former subjects will be notified, provide justification for why no	1)
	Former subject will be notified of these changes	(If checked, ensure that the submitted documents describe how current or former subjects will be notified. If they will not be notified, provi	de justification for why not.)
2.	* Provide a description and justification	of the modifications. Please include a list of the documents that have been modified:	
	PI will be leaving UMass. The following docum submission:	nents have been modified with this	
	Informed consent form		
	Assent form		
	Also attached is a letter from the previous PI	agreeing to the change	

- Once you have finished with the **Modification Summary**, click the **Continue** button. This allows you to edit a copy of the study's current approved submission.
- In section **1.0 Study Information**, click **Update** next to the current PI's name. When the **Add Principal Investigator** window opens, click on **Select** in (1). Select the name of the new PI from the list and click **OK**.



• This will bring you back to the Add Principal Investigator window.

• Review (2) and (3) to make sure the questions about consent and financial interest are answered correctly for the new PI. Edit if necessary. Then, click **OK** at the bottom of the window.







• At the top of the page, click **Continue** or use the **Jump To** menu to navigate to any other section(s) requiring editing.

Jump To:	1.0 Study Information +	Continue >>
	1.0 Study Information	1
	2.0 Funding Information	•
	3.0 UMass Information	
	5.0 Drugs	
	6.0 Devices	
	7.0 Attachments	
	8.0 Final Page	

- In section 7.0 Attachments, add a letter from the outgoing PI agreeing to the change or a letter from the department chair or supervisor explaining the reason to proceed without the previous (outgoing) PI's agreement. Following the steps in the <u>How to Manage Files in eIRB</u> Job Aid, add or update any other study documents.
- When you have completed the Modification, either click the **Finish** button on 8.0 Final Page or click **Save** and then **Exit** at the top of the page.



2. Notify the New PI:

 If you if you are active study staff or if you are listed as an Additional Contact on the study, click on **Ready for PI Review** under My Current Actions on the submission workspace to notify the <u>new</u> PI.

Home IRB			
IRB > IRB Studies > Trainin	g Study > Test: Change of P1		
Pre-submission	H00006049_1: Test: Char	nge of PI	
IRB b IRB Studies b IRB Meeting b IRB Committee Edit CR/Modification Print CR/Modification My Current Actions	Principal Investigator PI Test IRB Owner Study Expiration Date 12/15/2015 Submission Trype Modification Submission Review Date Documents Clarifications Requested Full History Summary History		
Cancel Cancel Ready for PI Review	Updated Document Category	Original Submitted File	My Current Actions
c	Investigator Study Plan	Investigator Study Plan 11.7.14 - 0.0	Cancel
-	Advertisements	Flyer 11.7.14 - 0.01 History	
	Consent Document(s)	Informed Consent Form Version 1 da	🔇 Ready for PI Review 🗲







! TROUBLESHOOTING: If you are <u>missing</u> the Ready for PI Review button or if the new PI cannot see the submission in All Studies, then active Study Staff must perform the following steps:

- Go to the main study (parent) and click on **Edit Research Staff**. Click OK at the bottom of the window.
- Then, return to your Modification submission (under the follow-on submissions tab) and you should see the button **Ready for PI Review** under My Current Actions. It is advised that you also contact the new PI directly (outside of the system) to let them know it is ready for their review and submission.

Try the above steps before contacting the IRB office. If you continue to have issues, contact the IRB office.

3. Submit the Modification (New PI only):

- If you are the new PI, you will receive a notification in the email listed in your user profile indicating that the submission is ready for your review once active study staff or the additional contact has clicked Ready for PI Review. You will need to submit the modification to change the PI. *The previous PI will not be able to submit.*
- Click on **Submit** under My Current Actions.



 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.**









TIPS:

- Once study staff has prepared the submission for your review, you can find the submission under ALL STUDIES.
- Refer to the <u>How to Navigating to Find Existing Studies</u> Job Aid that describes how to find your eIRB studies.
- If you need to update your contact information (e.g. email address), refer to the <u>How to</u> <u>Edit User Profile</u> Job Aid that describes how to edit your eIRB user profile.