Click IRB **Quick Guide**
Tips for Migrated Studies

As open actions close out in the legacy system, current studies are being migrated into Click IRB. When you get to your study in Click, you will see a "shell" of your study. This shell contains the information that migrated with your study to Click.

Will this guide help me?

Refer to this as you manage your existing studies that have been migrated into Click IRB from the legacy IRB System.

Initially, only the PI / Primary Contact that were migrated from the legacy system will have access to a study. In order for other team members to view and act on the study, you (the PI or Primary Contact) must add them to the study record in Click by submitting a modification. For currently approved team members, it might seem odd to "modify" a study to add them, but this is the action that is necessary to give them study access in Click. This may be the first action you take in Click.

Before You Begin- Adding study Team Members

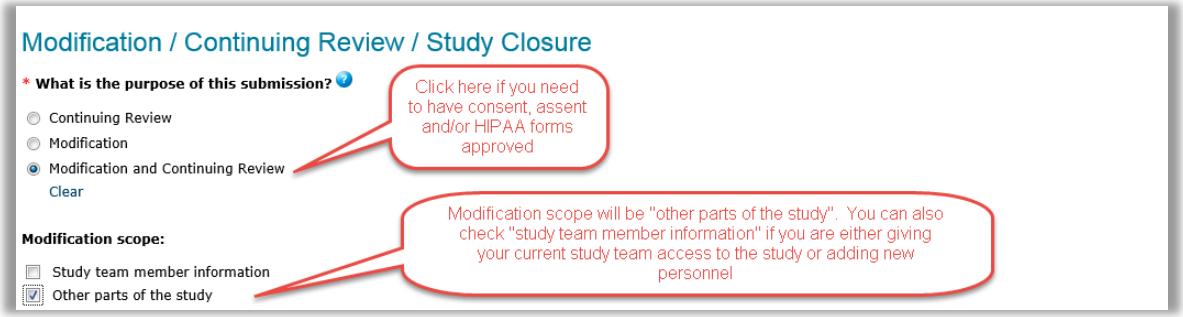
Step 1	When you are ready to take action in Click, first verify that you have no actions pending in the legacy system. If you submitted something to the IRB in the legacy system and have not yet been notified about it, that action is still pending. *Note: If you take action in Click on a study with open actions in the legacy system, you will be asked to withdraw and discard your Click submission and resubmit via the legacy process.*
Step 2	Be certain you and your team are ready to proceed with all actions on your study in Click IRB. If necessary, register for [additional] Click training in the Learning Center. **Once you begin using Click to manage your study, you will be unable to revert to the legacy system.** All study business must be done within Click from this point forward due to data integrity concerns. Your study is effectively transitioned into Click IRB when you click "Continue" in a SmartForm page or click "Save" the first page of a SmartForm even before the transaction is submitted to the IRB.
Step 3	Submit a modification to update your study shell with information for your current study team members. If you have new team members, you may add them in this modification.***** The PI or Primary Contact can prepare the modification, but only the PI can submit it to the IRB. It is very helpful to the IRB analysts to indicate that the study team members are already approved for the study and you are just adding them for purposes of obtaining access to the study in Click. Once your modification is approved, all study team members will be able to view and act on the study, and you can proceed with other actions in Click. If you wish to assign a PI Proxy at this time, you can follow the Quick Guide to learn how to do this.

*** Note:** If you are accompanying this study team modification with changes to "other parts of the study" (e.g. changes to add new names to the consent), **you should select both types of modifications at the time you**

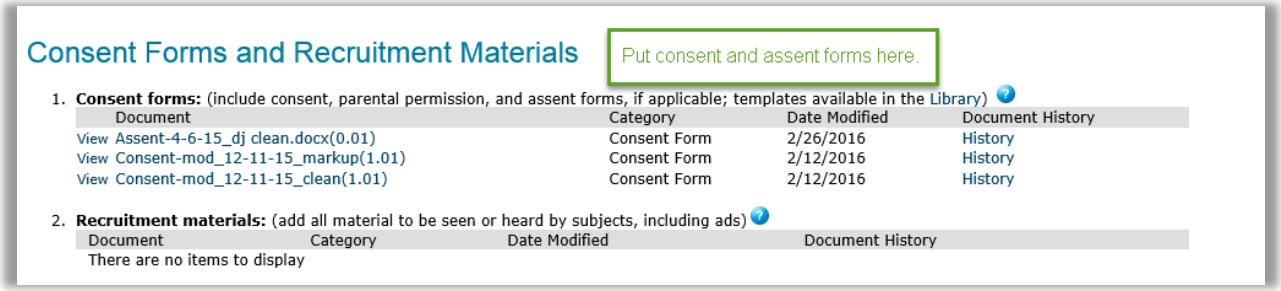
begin the modification submission process. Click will not let you alter the path of a modification request once you have saved the SmartForm in Pre-Submission.

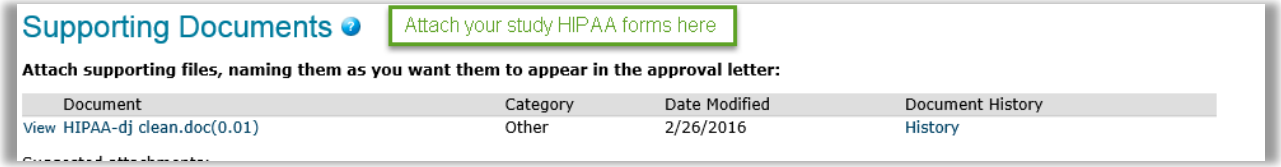
Submitting a Continuing Review for a Migrated Study

Step 1	When you are ready to submit a continuing review in Click for a migrated study, click on the **Create Modification / CR** button.



Step 2	Complete the CR SmartForm: read all questions thoroughly and include requested information. Be sure to add any consent and assent form to the "Consent Forms and Recruitment Materials" SmartForm page and HIPAA forms to the "Supporting Documents" SmartForm page for IRB approval/watermarking. For additional details, view the Attaching New and Revised Documents.





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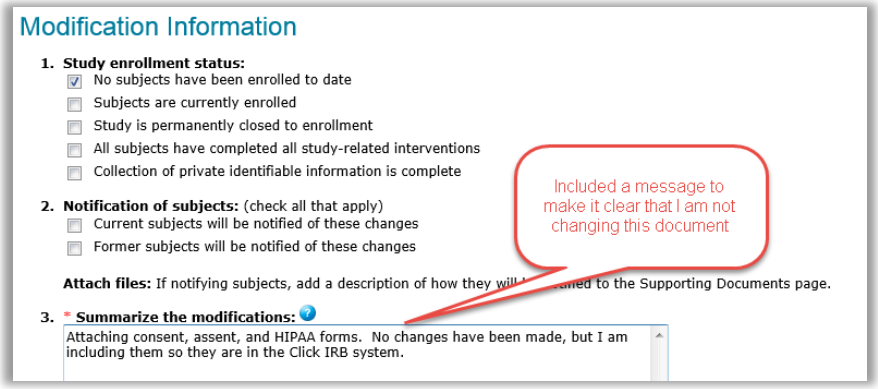
Step 3	Fill out relevant pages in the study SmartForm. **Note:** If you are attaching consent, assent, and HIPAA forms just to get them into Click (but not making other changes), a note is helpful for the analysts. If you do make changes to the documents or other study changes, revise relevant pages in the study SmartForm, and be sure that the "Summarize the modifications" box reflects these changes. Attach both clean and tracked documents to the appropriate SmartForm pages for IRB review.



Other Tips for Migrated Studies

- You should not up-load all of your legacy IRB documents into Click. As your study transitions from the Legacy System to Click IRB, you will only need to add documents as you modify them or if you need to have you consent, assent, and HIPAA forms approved at the time of Continuing Review.
- It is not required for you to update Click with study team members already approved in the Legacy IRB system. You should focus on adding team members that have a need to access the study in Click IRB.
- Why does my IRB number in Click IRB have the name "PIRO" in front? PIRO is the name of the legacy IRB database. Your legacy IRB study numbers were transitioned into Click IRB as "PIROSTUDY XXXXX".

More questions? Contact the Institutional Review Board by email or at x77804.