MICHIGAN STATE UNIVERSITY

Click: IRB

Quick Guide

How to Complete the Transfer of Legacy Non-Exempt Study to Click: At the Time of First Modification or Continuing Review

This quick guide provides information on how to complete the transfer of an active non-exempt study converted from the MSU IRB Online Application System into the Click IRB module (legacy study). **If are closing the study, you do not need to follow this transfer process; you may close the study without updating the study record or completing the required legacy protocol template.**

WHO:

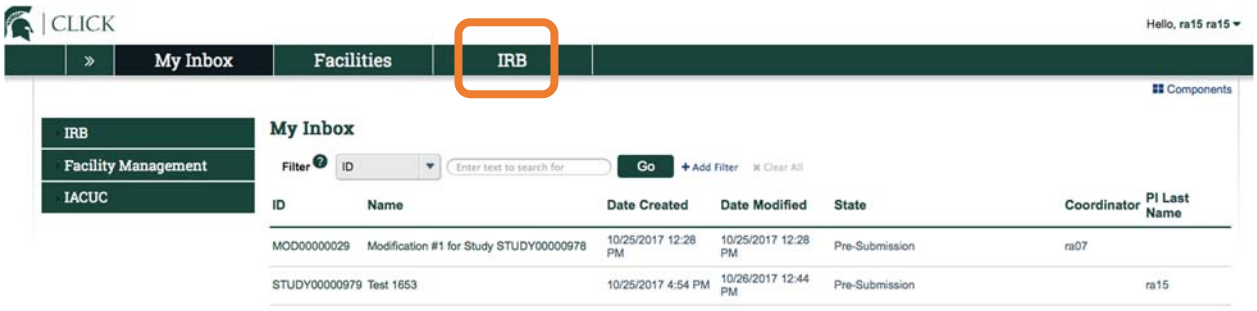
- Principal Investigators (PIs)
- Study Teams

WHEN:

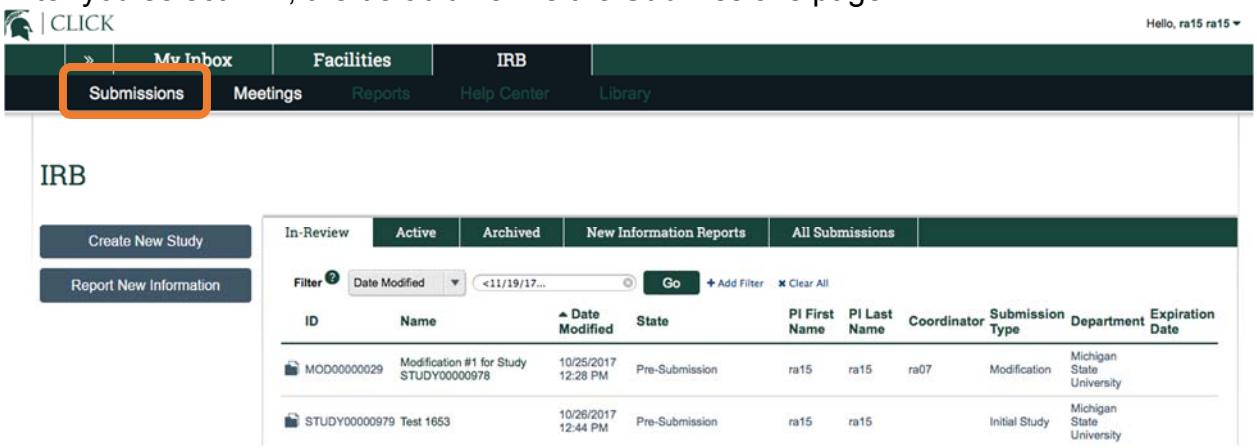
- At the time of first modification or continuing review for an active non-exempt study that was transferred from the MSU IRB Online System to Click (legacy study).

HOW:

1. After login, the default view is the My Inbox page. Select “IRB” from the top navigation bar.

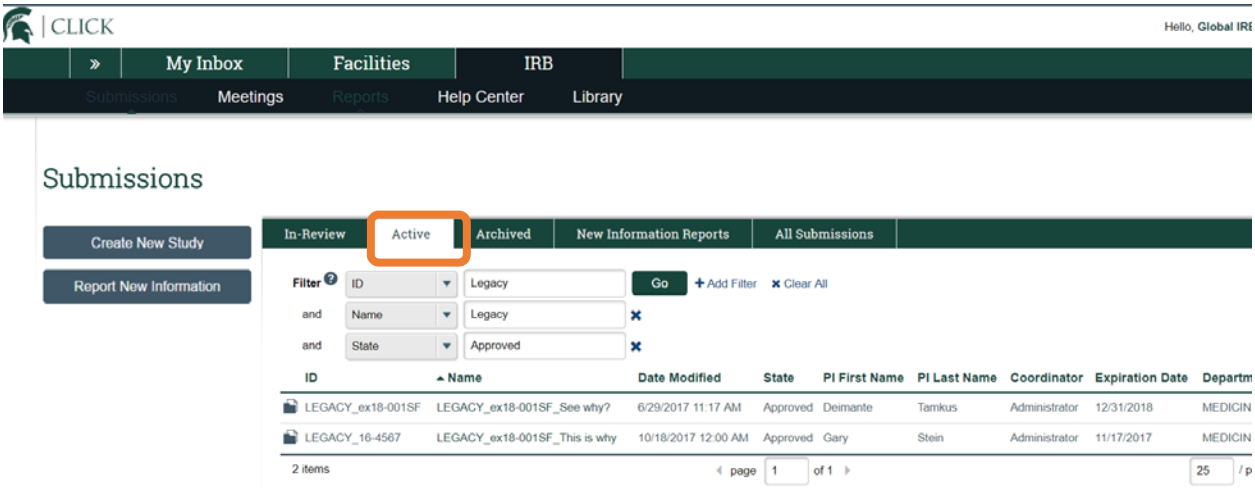


2. After you select IRB, the default view is the Submissions page.



How to Access a Study or Submission

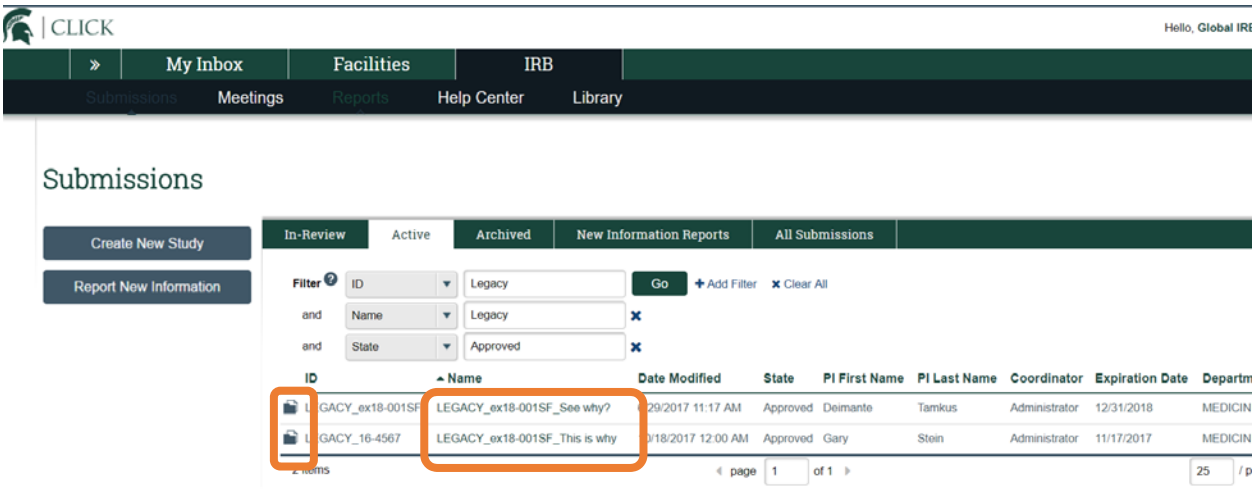
3. Select the “Active” tab in Submissions.



Note

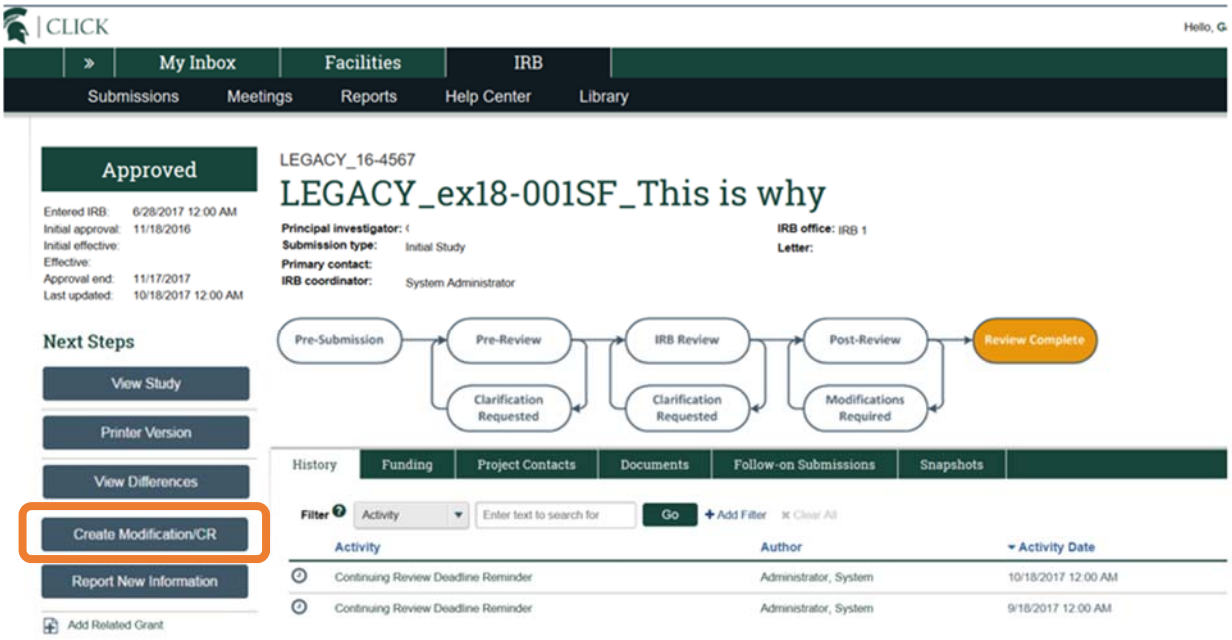
- You will be able to view active, non-exempt studies transferred into Click on which you were listed in the MSU IRB Online System as the principal investigator, secondary investigator and/or study coordinator.
- Legacy study IDs include “LEGACY” and the previously assigned MSU IRB#.

4. Locate the study and select the folder icon or name (title) to open the study workspace.



How to Access a Study or Submission

5. From the study workspace, click Create Modification/CR.



Follow Step 6 if you are submitting a renewal or renewal revision.

Follow Step 7 if you are submitting a revision (modification) only.

6. If submitting a renewal or a renewal revision:

   a. Select "Modification and Continuing Review" (*even if you are not proposing modifications, you must select "Modification and Continuing Review" to upload document(s) and to update any data in the SmartForm, if needed*).

Note:

- After you select the submission purpose and continue to the next SmartForm page, you **cannot** change the submission purpose so be sure to select "Modification and Continuing Review."

b. For the Modification Scope, there are two options: “Other Parts of the Study” and “Study Team Members.” Select:

   i. For ALL renewals, you must select “Other Parts of the Study.”

   ii. If you want to modify the study team, also select “Study Team Members.”

Note

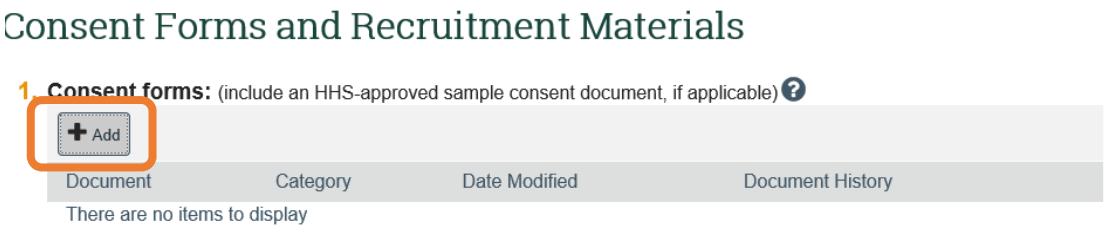
- You may want to view the “Project Contacts” tab in the study workspace to determine if individuals need to be added or removed from the study before selecting the modification scope. As part of the transfer, only the principal investigator, secondary investigator, and the study coordinator (as appropriate) were transferred to the Click study record.

c. Complete the Modification and Continuing Review / Study Closure SmartForms.

Note:

- If you have no proposed modifications, indicate that this is a legacy study in the Modification Summary text box.

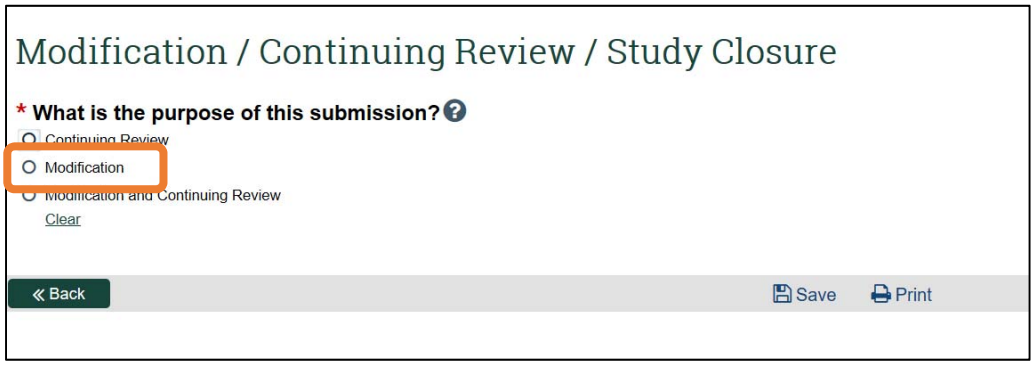
d. Upload any current IRB approved consent documents (including parental permission forms, assent forms, translated consent forms) in the Consent Forms and Recruitment Materials SmartForm page, Question 1.



Note:

- It is important that consent forms are uploaded to the Consent Forms and Recruitment Materials SmartForm page so a footer can be applied. Please leave document footer blank with a 1 inch bottom margin.

7. If submitting a revision (modification):
    a. For the purpose of the submission, select “Modification.”



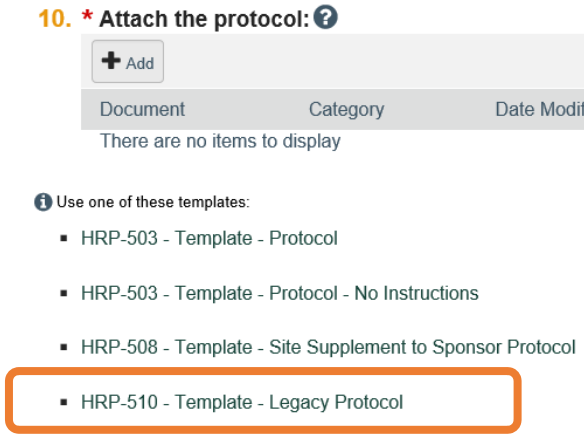
    b. For the Modification Scope, there are two options: “Other Parts of the Study” and “Study Team Members.” Select:
        i. For all revisions, you must select “Other Parts of the Study.”
        ii. If you want to modify the study team, also select “Study Team Members”

Note

- You may want to view the “Project Contacts” tab in the Study Workspace to determine if individuals need to be added or removed from the study before selecting the modification scope. As part of the transfer, only the principal investigator, secondary investigator, and the study coordinator (as appropriate) were transferred to Click.

    c. Complete the Modification and Continuing Review / Study Closure SmartForms.
    d. Update any SmartForm pages relevant to the modification, including adding, replacing, or removing documents.
8. For ALL submissions (revisions or renewals):

a. Complete and upload **HRP-510 – Template – Legacy Protocol** to the Basic Information SmartForm page, Question 10.

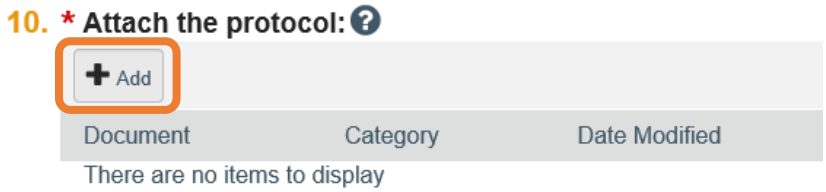


Note:

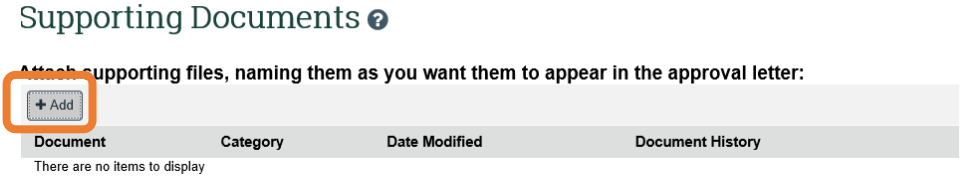
- The HRP-510 – Template – Legacy Protocol is accessible in Click as a link on the Basic Information SmartForm page; this links to SharePoint and requires a MSU NetID login.
- The HRP-510 – Template – Legacy Protocol is also accessible on https://hrpp.msu.edu/protocol-templates (no password required).
- Legacy studies DO NOT need to complete the full protocol template (503).

b. For FDA regulated studies:

i. Upload the currently approved protocol in the Basic Information SmartForm page, Question 10.

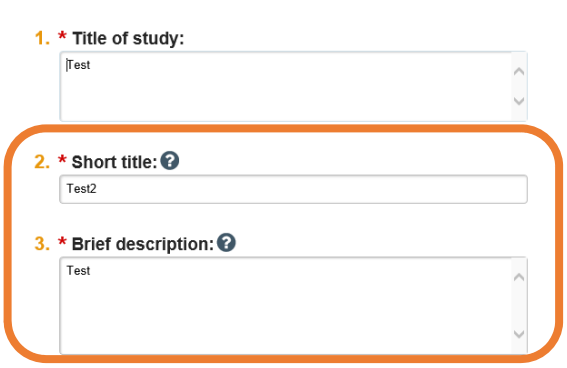


ii. Upload the currently approved Investigator Brochure in the Supporting Documents SmartForm page.

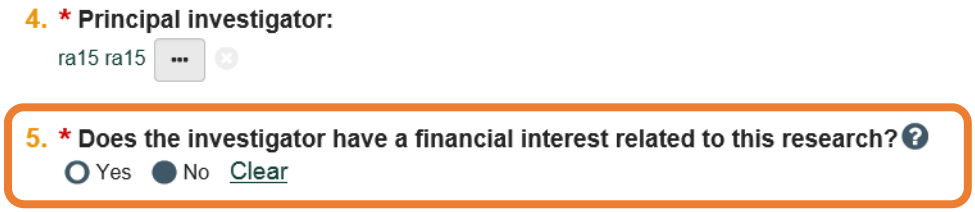


9. Before submitting, confirm, update, and/or add information in the SmartForm pages. Included below are examples of SmartForm pages that may require updates.

   a. Basic Information SmartForm:
      i. Update the short title and brief description, if needed.

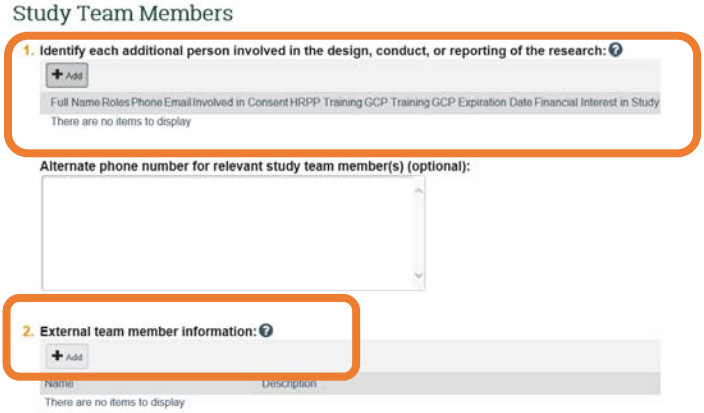


      ii. Confirm that the conflict of interest question is answered appropriately.



   b. Funding Sources SmartForm: Update funding information (if any) on the Funding Sources SmartForm page.

   c. Study Team Members SmartForm: Update study team members if needed (only the secondary investigator and study coordinator were transferred over as part of the partial data conversion).



Note:

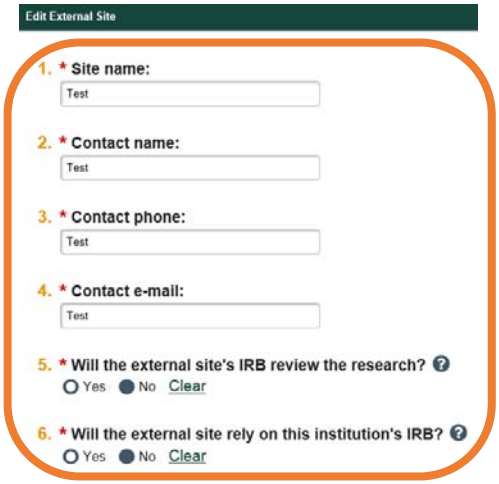
- For individuals that are listed on the study team as part of the transfer of the study, update the conflict of interest and involvement in the consent process questions.
- Non-MSU individuals should be indicated in a document uploaded to Question 2. If a non-MSU individual requires log in access to Click, they will need to obtain a departmentally sponsored NetID to access Click.

d. External Sites SmartForm: If the study involves external site, update data as needed.

i. If updates are needed:

1. Click the name of the external site.

2. This will open a window that will allow you to edit the External Site information.



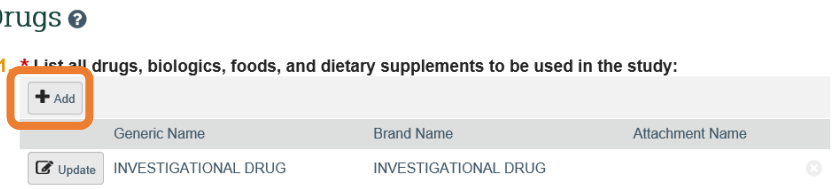
Note:

- Contact information may need updating; “data conversion” was populated in several fields for some studies.

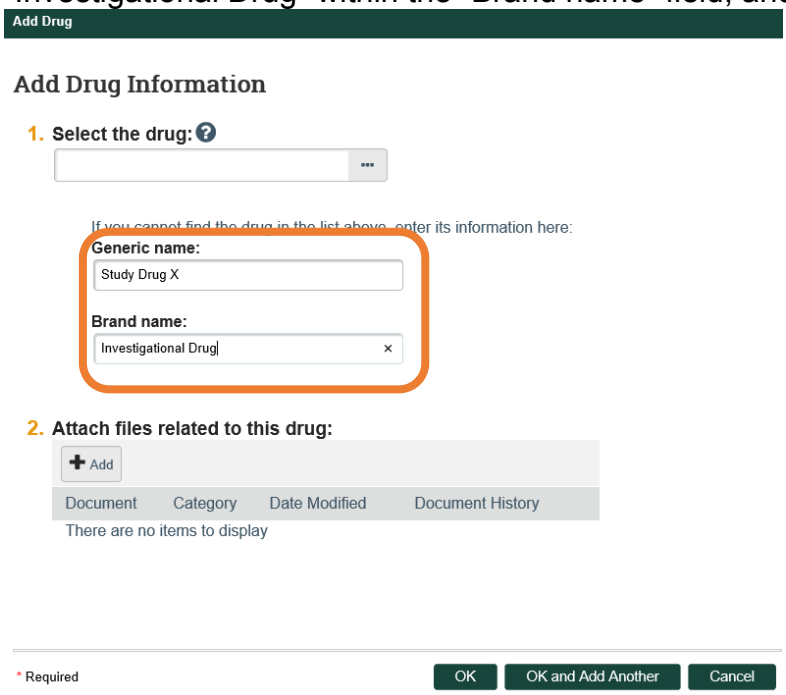
e. Drugs SmartForm: If the study involves use of an investigational drug, the drug was entered as “Investigational Drug.” Please update to the specific drug name.

i. To update the study drug name:

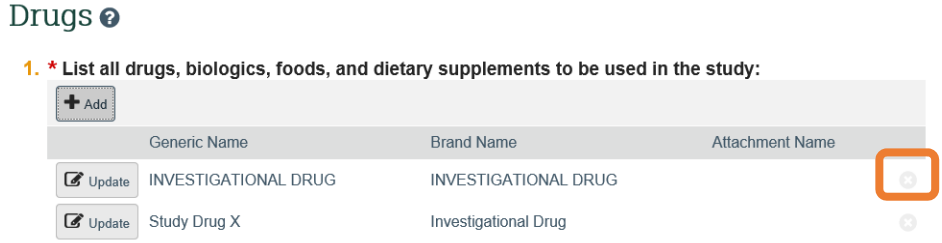
1. Click “Add” (update will only allow you to select from a pre-populated list).



2. Enter the study drug name within the “Generic name” field, enter “Investigational Drug” within the “Brand name” field, and click “OK.”

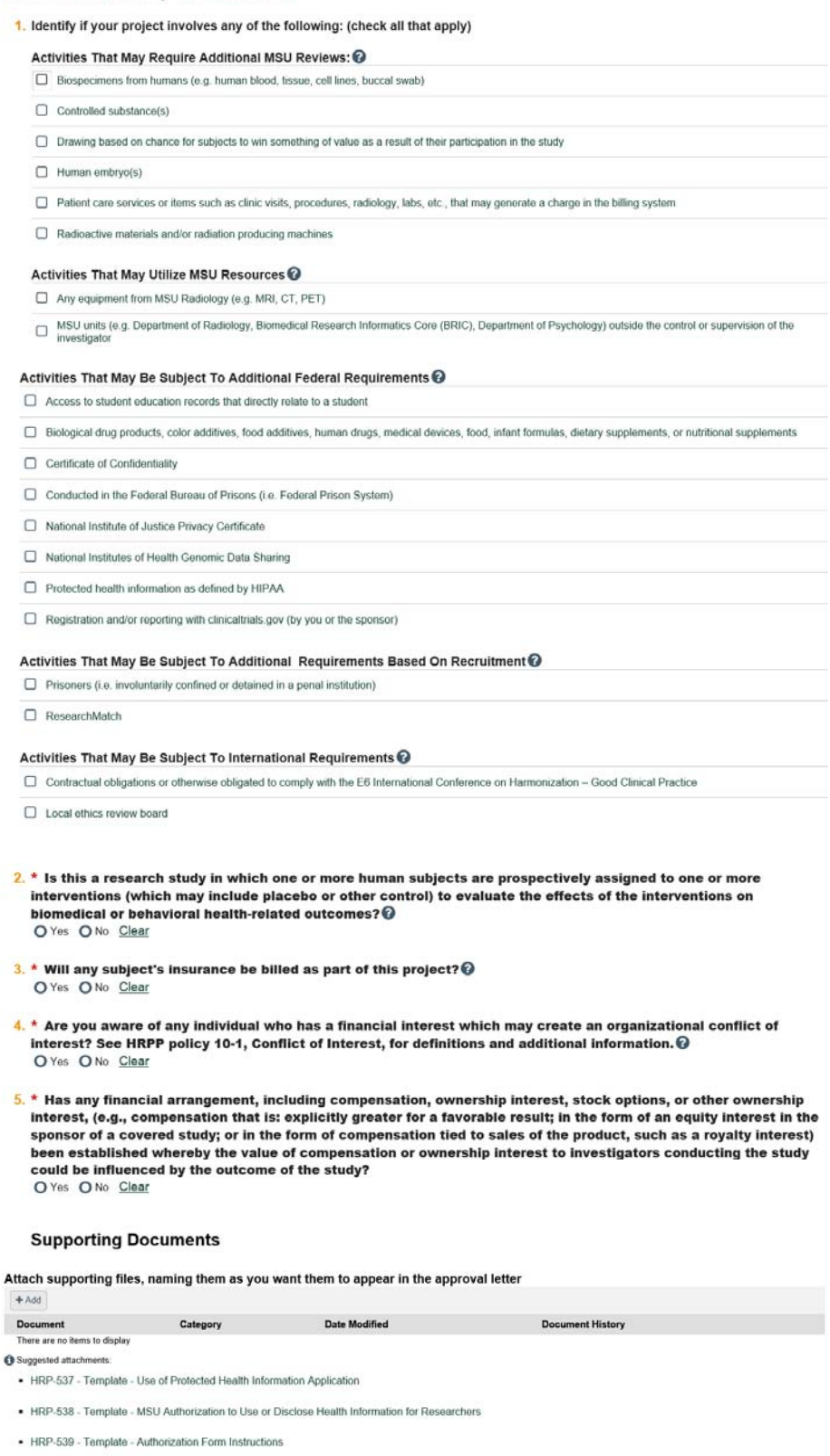


3. Delete the original “Investigational Drug” entry by clicking the “x” at the right side of the row.



f. Devices SmartForm page: If the study involves use of an investigational device, the device was entered with “Investigational Device” (follow the steps for Drugs to update in the same manner).

g. Complete the MSU Additional Study Information SmartForm page.



Additional Study Information

1. **Identify if your project involves any of the following: (check all that apply)**

Activities That May Require Additional MSU Reviews:

- ☐ Biospecimens from humans (e.g. human blood, tissue, cell lines, buccal swab)
- ☐ Controlled substance(s)
- ☐ Drawing based on chance for subjects to win something of value as a result of their participation in the study
- ☐ Human embryo(s)
- ☐ Patient care services or items such as clinic visits, procedures, radiology, labs, etc., that may generate a charge in the billing system
- ☐ Radioactive materials and/or radiation producing machines

Activities That May Utilize MSU Resources

- ☐ Any equipment from MSU Radiology (e.g. MRI, CT, PET)
- ☐ MSU units (e.g. Department of Radiology, Biomedical Research Informatics Core (BRIC), Department of Psychology) outside the control or supervision of the investigator

Activities That May Be Subject To Additional Federal Requirements

- ☐ Access to student education records that directly relate to a student
- ☐ Biological drug products, color additives, food additives, human drugs, medical devices, food, infant formulas, dietary supplements, or nutritional supplements
- ☐ Certificate of Confidentiality
- ☐ Conducted in the Federal Bureau of Prisons (i.e. Federal Prison System)
- ☐ National Institute of Justice Privacy Certificate
- ☐ National Institutes of Health Genomic Data Sharing
- ☐ Protected health information as defined by HIPAA
- ☐ Registration and/or reporting with clinicaltrials.gov (by you or the sponsor)

Activities That May Be Subject To Additional Requirements Based On Recruitment

- ☐ Prisoners (i.e. involuntarily confined or detained in a penal institution)
- ☐ ResearchMatch

Activities That May Be Subject To International Requirements

- ☐ Contractual obligations or otherwise obligated to comply with the E6 International Conference on Harmonization – Good Clinical Practice
- ☐ Local ethics review board

2. * **Is this a research study in which one or more human subjects are prospectively assigned to one or more interventions (which may include placebo or other control) to evaluate the effects of the interventions on biomedical or behavioral health-related outcomes?**
   ○ Yes ○ No Clear

3. * **Will any subject's insurance be billed as part of this project?**
   ○ Yes ○ No Clear

4. * **Are you aware of any individual who has a financial interest which may create an organizational conflict of interest? See HRPP policy 10-1, Conflict of Interest, for definitions and additional information.**
   ○ Yes ○ No Clear

5. * **Has any financial arrangement, including compensation, ownership interest, stock options, or other ownership interest, (e.g., compensation that is: explicitly greater for a favorable result; in the form of an equity interest in the sponsor of a covered study; or in the form of compensation tied to sales of the product, such as a royalty interest) been established whereby the value of compensation or ownership interest to investigators conducting the study could be influenced by the outcome of the study?**
   ○ Yes ○ No Clear

Supporting Documents

Attach supporting files, naming them as you want them to appear in the approval letter

+ Add

Document	Category	Date Modified	Document History

There are no items to display

Suggested attachments:

- HRP-537 - Template - Use of Protected Health Information Application
- HRP-538 - Template - MSU Authorization to Use or Disclose Health Information for Researchers
- HRP-539 - Template - Authorization Form Instructions

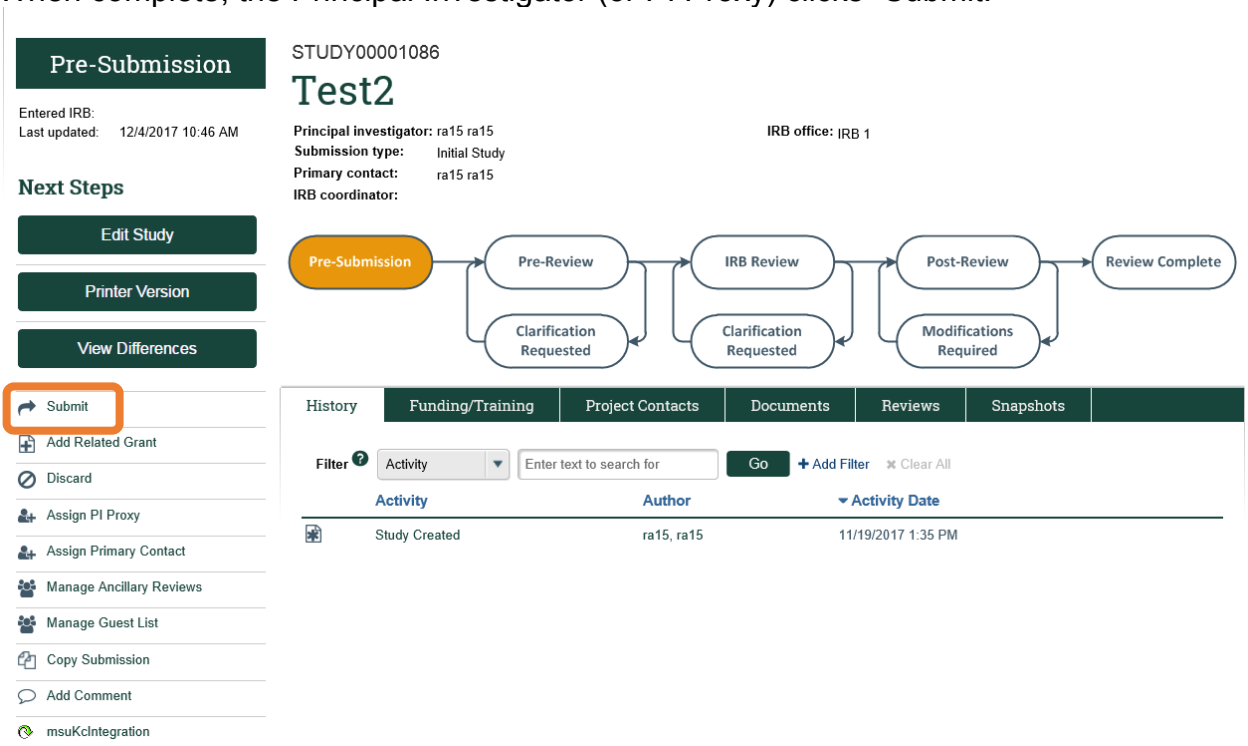
Note:

- If you select “Protected Health Information as defined by HIPAA,” the SmartForm will require you to upload a document. You can upload a blank use of PHI form (you do not need to re-complete).

h. Confirm data on all other SmartForm pages and update as needed.

i. Upload new or revised document(s) (if any) in the relevant SmartForm pages.

10. When complete, the Principal Investigator (or PI Proxy) clicks “Submit.”



Note:

- The PI can assign PI proxy(ies) by clicking “Assign PI Proxy” and selecting study team individual(s). With legacy studies, if the individual was not part of the study team transferred from the MSU IRB Online System, they will need to be added through a modification submission before they can be assigned as a PI proxy. Once the modification submission is approved, they can then be assigned as a PI proxy.