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 you 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.
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.
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.

Consent Forms and Recruitment Materials

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.”

   ![Modification SmartForm Image]

   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”

   ![Modification Scope Image]

   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):
How to Access a Study or Submission

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

10. *Attach the protocol:

<table>
<thead>
<tr>
<th>Document</th>
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There are no items to display.

Use one of these templates:
- HRP-503 - Template - Protocol
- HRP-503 - Template - Protocol - No Instructions
- HRP-501 - Template - Site Supplement to Sponsor Protocol
- **HRP-510 - Template - Legacy Protocol**

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](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.

Supporting Documents

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

<table>
<thead>
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</tbody>
</table>

There are no items to display.
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.
      ![Basic Information SmartForm]
   ii. Confirm that the conflict of interest question is answered appropriately.
      ![Principal investigator]

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

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).
   ![Study Team Members SmartForm]
Quick Guide

How to Access a Study or Submission

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.
        
        ![External Sites SmartForm](image)
        
        2. This will open a window that will allow you to edit the External Site information.

        ![Edit External Site](image)

        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.”

Add Drug Information

1. Select the drug:

   *Generic name:*
   - Study Drug X

   *Brand name:*
   - Investigational Drug

2. Attach files related to this drug:

   There are no items to display

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

Drugs

1. List all drugs, biologics, foods, and dietary supplements to be used in the study:

<table>
<thead>
<tr>
<th>Generic Name</th>
<th>Brand Name</th>
<th>Attachment Name</th>
</tr>
</thead>
<tbody>
<tr>
<td>INVESTIGATIONAL DRUG</td>
<td>INVESTIGATIONAL DRUG</td>
<td></td>
</tr>
<tr>
<td>Study Drug X</td>
<td>Investigational Drug</td>
<td></td>
</tr>
</tbody>
</table>

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).
Quick Guide

How to Access a Study or Submission

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:
   - Biopsies from humans (e.g. human tissues, organs, body fluids)
   - Controlled substance(s)
   - Drawing blood from animals
   - Human embryos
   - Patient care services or items such as clinic visits, office visits, radiology, lab, 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)
   - NIH grants (i.e., 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-use products; e.g. additives, food additives, food, finished products, 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 Genetic Data Sharing
   - Federally funded 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. involuntary 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 E8 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 controls) 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.

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There are no items to display.

Suggested attachments:
- HRSP 637 - Template: Use of Protected Health Information Application
- HRSP 638 - Template: MSU Authorization to Use or Disclose Health Information for Research
- HRSP 639 - 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.