

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:

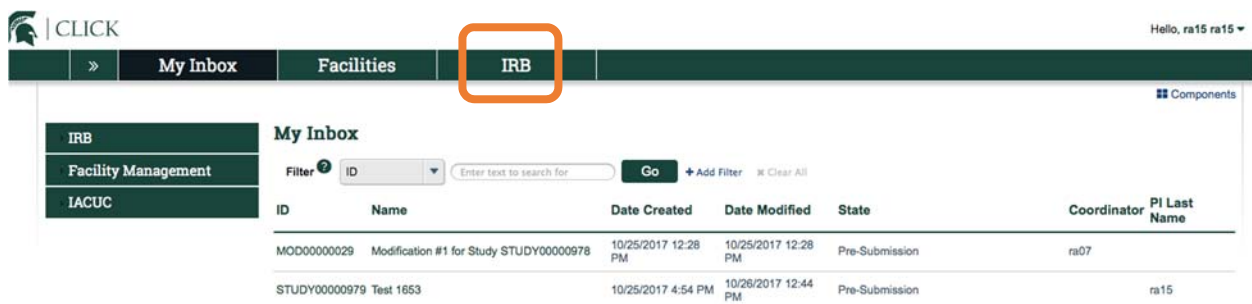
- Principal Investigators (PIs)
- Study Teams

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.



CLICK | Hello, ra15 ra15

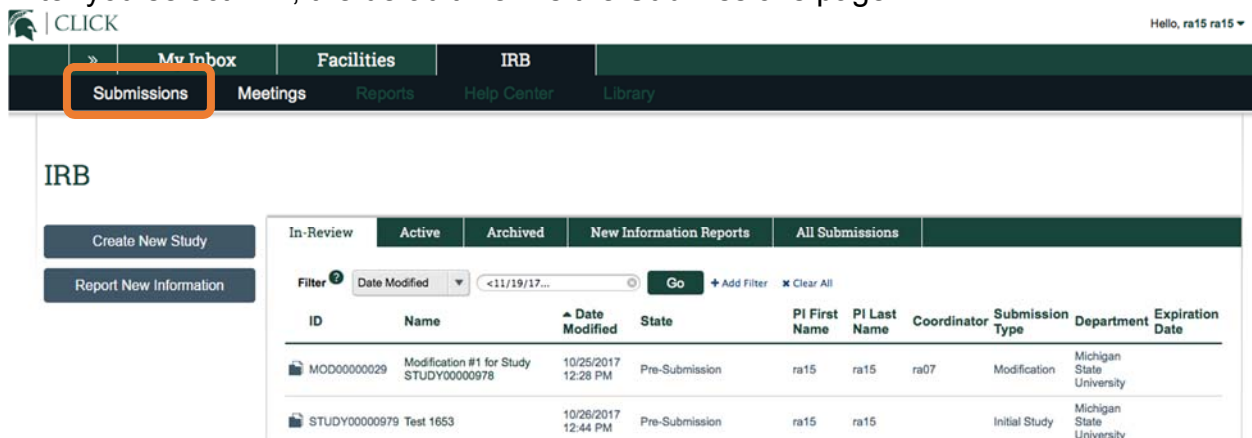
My Inbox

IRB | Facility Management | IACUC

Filter ID Enter text to search for Go + Add Filter x Clear All

ID	Name	Date Created	Date Modified	State	Coordinator	PI Last Name
MOD00000029	Modification #1 for Study STUDY00000978	10/25/2017 12:28 PM	10/25/2017 12:28 PM	Pre-Submission	ra07	
STUDY00000979	Test 1653	10/25/2017 4:54 PM	10/26/2017 12:44 PM	Pre-Submission		ra15

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



CLICK | Hello, ra15 ra15

My Inbox | Facilities | IRB | Submissions | Meetings | Reports | Help Center | Library

IRB

Create New Study | Report New Information

In-Review | Active | Archived | New Information Reports | All Submissions

Filter Date Modified <11/19/17... Go + Add Filter x Clear All

ID	Name	Date Modified	State	PI First Name	PI Last Name	Coordinator	Submission Type	Department	Expiration Date
MOD00000029	Modification #1 for Study STUDY00000978	10/25/2017 12:28 PM	Pre-Submission	ra15	ra15	ra07	Modification	Michigan State University	
STUDY00000979	Test 1653	10/26/2017 12:44 PM	Pre-Submission	ra15	ra15		Initial Study	Michigan State University	

How to Access a Study or Submission

3. Select the “Active” tab in Submissions.

The screenshot shows the 'Submissions' page in the CLICK system. The 'Active' tab is highlighted with an orange box. The page includes a navigation menu with 'My Inbox', 'Facilities', and 'IRB'. Below the navigation, there are buttons for 'Create New Study' and 'Report New Information'. A filter section is visible with the following criteria: ID (Legacy), Name (Legacy), and State (Approved). The main table displays two submission entries:

ID	Name	Date Modified	State	PI First Name	PI Last Name	Coordinator	Expiration Date	Departm
LEGACY_ex18-001SF	LEGACY_ex18-001SF_See why?	6/29/2017 11:17 AM	Approved	Deimante	Tamkus	Administrator	12/31/2018	MEDICIN
LEGACY_16-4567	LEGACY_ex18-001SF_This is why	10/18/2017 12:00 AM	Approved	Gary	Stein	Administrator	11/17/2017	MEDICIN

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.

This screenshot is identical to the previous one, but with orange boxes highlighting the folder icons and the study names in the table. The highlighted entries are:

	LEGACY_ex18-001SF	LEGACY_ex18-001SF_See why?	6/29/2017 11:17 AM	Approved	Deimante	Tamkus	Administrator	12/31/2018	MEDICIN
	LEGACY_16-4567	LEGACY_ex18-001SF_This is why	10/18/2017 12:00 AM	Approved	Gary	Stein	Administrator	11/17/2017	MEDICIN

How to Access a Study or Submission

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

The screenshot shows the CLICK IRB system interface. At the top, there is a navigation bar with 'My Inbox', 'Facilities', and 'IRB'. Below this, there are tabs for 'Submissions', 'Meetings', 'Reports', 'Help Center', and 'Library'. The main content area displays the study workspace for 'LEGACY_16-4567' with the title 'LEGACY_ex18-001SF_This is why'. On the left, there is a sidebar with 'Next Steps' including 'View Study', 'Printer Version', 'View Differences', 'Create Modification/CR' (highlighted with an orange box), and 'Report New Information'. The main area shows a flowchart of the review process: Pre-Submission, Pre-Review, IRB Review, Post-Review, and Review Complete. Below the flowchart, there is a 'History' section with tabs for 'Funding', 'Project Contacts', 'Documents', 'Follow-on Submissions', and 'Snapshots'. A table of activities is shown below, with columns for 'Activity', 'Author', and 'Activity Date'. The 'Create Modification/CR' button is highlighted with an orange box.

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).*

The screenshot shows the 'You Are Here' breadcrumb: 'LEGACY_ex18-001SF_This is why > IRBSubmission'. Below the breadcrumb are navigation buttons: '<< Back', 'Save', and 'Print'.

Modification / Continuing Review / Study Closure

* What is the purpose of this submission? ?

- Continuing Review
- Modification
- Modification and Continuing Review

[Clear](#)

The screenshot shows navigation buttons: '<< Back', 'Save', and 'Print'. To the right of the 'Print' button is the label 'Note'.

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.”

How to Access a Study or Submission

- 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.”

Modification scope:

- Study team member information
- Other parts of the study

Active Modification for This Study Modification Type

◀ Back Save Print

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

1. Consent forms: (include an HHS-approved sample consent document, if applicable) ?

Document	Category	Date Modified	Document History
There are no items to display			

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.

How to Access a Study or Submission

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):

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: ?

Document	Category	Date Modified
There are no items to display		

Use one of these templates:

- HRP-503 - Template - Protocol
- HRP-503 - Template - Protocol - No Instructions
- HRP-508 - 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> (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.

10. * Attach the protocol: ?

Document	Category	Date Modified
There are no items to display		

- 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:

Document	Category	Date Modified	Document History
There are no items to display			

How to Access a Study or Submission

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 ?

1. * Title of study:

Test

2. * Short title: ?

Test2

3. * Brief description: ?

Test

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

4. * Principal investigator:

ra15 ra15 ...

5. * Does the investigator have a financial interest related to this research? ?

Yes No [Clear](#)

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

Funding Sources ?

Find Now

1. Related Funding Sources: ?

PI First Name	PI Last Name	Institutional Proposal Number	Award Number	Prime Sponsor Name	Sponsor Name	Project Title	Project Start Date	Co Investigator
There are no items to display								

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

1. Identify each additional person involved in the design, conduct, or reporting of the research: ?

+ Add

Full Name	Roles	Phone	Email	Involved in Consent	HRPP	Training	GCP	Training	GCP	Expiration Date	Financial Interest in Study
There are no items to display											

Alternate phone number for relevant study team member(s) (optional):

2. External team member information: ?

+ Add

Name	Description
There are no items to display	

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 

1. External Sites:

Site	Contact	Phone	Email	External IRB Review	Rely on This IRB
Test	Test	Test	Test	no	no

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

Edit External Site

1. * Site name:
2. * Contact name:
3. * Contact phone:
4. * Contact e-mail:
5. * Will the external site's IRB review the research? 
 Yes No [Clear](#)
6. * Will the external site rely on this institution's IRB? 
 Yes No [Clear](#)

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).

Drugs 

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

	Generic Name	Brand Name	Attachment Name
			
	INVESTIGATIONAL DRUG	INVESTIGATIONAL DRUG	

How to Access a Study or Submission

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

Add Drug

Add Drug Information

1. Select the drug: ?

If you cannot find the drug in the list above, enter its information here:

Generic name:

Brand name:

2. Attach files related to this drug:

+ Add

Document	Category	Date Modified	Document History
There are no items to display			

* Required

OK

OK and Add Another

Cancel

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:

+ Add

	Generic Name	Brand Name	Attachment Name
Update	INVESTIGATIONAL DRUG	INVESTIGATIONAL DRUG	✕
Update	Study Drug X	Investigational Drug	✕

- 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).

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?

- 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

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

How to Access a Study or Submission

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.”

STUDY00001086
Test2

Entered IRB:
Last updated: 12/4/2017 10:46 AM

Principal investigator: ra15 ra15
Submission type: Initial Study
Primary contact: ra15 ra15
IRB coordinator:
IRB office: IRB 1

Next Steps

- Edit Study
- Printer Version
- View Differences
- Submit**
- Add Related Grant
- Discard
- Assign PI Proxy
- Assign Primary Contact
- Manage Ancillary Reviews
- Manage Guest List
- Copy Submission
- Add Comment
- msuKcIntegration

Flowchart: Pre-Submission (highlighted) → Pre-Review → IRB Review → Post-Review → Review Complete. Clarification Requested and Modifications Required are shown as feedback loops between stages.

History	Funding/Training	Project Contacts	Documents	Reviews	Snapshots
Filter	Activity	Author	Go	+ Add Filter	✖ Clear All
Activity	Author	Activity Date			
Study Created	ra15, ra15	11/19/2017 1:35 PM			

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.