

## HOW TO AMEND A PROTOCOL IN IRB MANAGER

This short tutorial provides information on how to amend or update a protocol in IRB Manager. This type of amendment is appropriate for changing protocol information or Principal Investigator. Updating personnel is a different process, which is discussed elsewhere. Let's look at the Dashboard after our investigator John PI has logged in.

The dashboard displays the following sections:

- Home** | **My Studies** | All Projects | Find Study (Ctrl+Q)
- Actions for Researchers**: Animal Use Protocol Form, New IRB Research, Start xForm, Show Sponsor Ids
- Recent Items**: 500007-UT, 500010-UT, 500005-UT, 500008-UT, 500004-UT, 300018-UT, 400018-UT
- Useful Links**: All Projects Dashboard, IACUC Dashboard, IBC Dashboard (coming soon), IRB Dashboard
- My Docs & xForms**: 4 Attachments, 96 xForms
- Studies (63 Active)**:
  - You are associated with **63 active** Studies and **101 total** Studies.
  - You are the PI for **63 active** and **101 total** Studies.
  - There are **8 studies** expiring in the next 90 days.
  - The next study to expire is **200000-UT**.
- xForms (32 Active)**:
  - You have **22 unsubmitted** xForms.
  - You have **10 xForms** being processed at a later stage.
  - You have **1 xForm** in error.
  - There are **1 xForms** awaiting your attention.
- Events (19 Open)**:
  - You have **1 Activities Preparatory to Research** events.
  - You have **4 Central IRB Application Submission** events.
  - You have **1 Final Report Submission** events.
  - You have **1 FYI Submission** events.
  - You have **1 IBC Amendment Submission** events.
  - You have **6 IBC New Submission** events.
  - You have **3 IBC Renewal Submission** events.
  - You have **1 Initial Application Submission** events.
  - You have **1 Native Amendment Submission** events.
- Important Information**: Welcome to IRBManager. With the introduction of IACUC in February 2020, this message is now for all project types. Messages specific to IRB, IACUC and IBC will be found on their project-specific dashboards. In the left menu, under "Useful Links," click the appropriate "... Dashboard" link to go to a project-specific dashboard. Additionally, there is a drop-down in the blue bar at the top of the screen that will allow for quick transitions between the project dashboards.

Scroll to the bottom of the dashboard for a list of your currently active studies.

1. Open the IBC study you are looking at amending by clicking the study # link.
2. Scroll to the section of the study labeled "Reference XForms"
3. Click on the Copy Action (which looks like a stack of papers) next to the IBC Protocol Form.

The study details page for **Study 500009-UT (IBC)** shows the following information:

- Human/Animal Tissues & Cell Lines:** BSL2
- Animals : Biosafety Level:** ABSL3
- Study-Site:**
  - Site(s): **UT - University of Toledo**
  - PI: **PI, John M.D.**
  - Status: **Approved**
  - Approval: **March 20, 2020**
  - Initial Approval: **March 20, 2020**
  - Location(s):
  - Additional: **N**
  - Expiration: **March 19, 2025**
  - Other Expirations: **Standard 5-Yr Expiration Date (IBC) - 03/19/2025**
- Study-Site Contacts (2)**:
 

Name	Role
Coordinator, Clinical	IBC Study Personnel
Student, Jane	IBC Study Personnel
- Reference xForms (1)**:
 

Action	Form	Identifier	Stage	As Of	Ref Active	Inactivated
	IBC Protocol Form	Complex FCR	Complete	Friday at 3:04 PM	Friday at 3:04 PM	
- Study-Site Attachments (1)**:
 

Name	Type	Date	By
OLD Review IACUC Form.pdf	SOP	03/20/2020	john_pi
- Events (1)**:
 

Event	Att	FE	Instance/UDF	Start	Complete	Last Mtg
IBC New Submission	0		Complex FCR	03/20/2020		03/25/2020

The **Copy** action (represented by a stack of papers icon) is highlighted next to the **IBC Protocol Form** in the Reference xForms section.

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Billy Goat (2020.3.4323.0/Release/b411af5) | GCWAWS1 | 2020-03-25 13:32:38Z | 0.143s

4. You will then be given two options: Copy or Copy for Amendment. In this case, we are copying for amendment since this option allows you to amend or update the protocol.

### Choose an Action

 **Copy**

Use this option if you want to start a new application using this application as template. Most answers will copy, but attachments will need to be uploaded and certain questions will need to be re-answered.

 **Copy for Amendment**

Use this option if you want to AMEND OR RENEW the current study. You will use this mechanism to request changes to the study, such as changing protocol procedures. You will also use this amendment to request a change of PI, however, changes to other study personnel will be done through the Personnel Amendment.

5. This will give you a series of questions about the amendment and an editable version of the protocol upon which to make changes. Again, this type of amendment does not allow you to update personnel.



Collaborators

AP. Amendment Purpose

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\*\* you can use the drop-down list above to temporarily skip past error messages. \*\*

IMPORTANT! This application is for TESTING ONLY. Any applications entered now will be DELETED before go-live.  
 Please DO NOT put any real protocol information in the system.

**AP.1. IBC #** Add Note View Audit

500010

**Study Title**  
Common Scenario 1 (New Submission) - Renewal

**Current PI**  
PI, John M.D.  

Email: john.pi@utoledo.edu
Business: 419-530-6651

**Current Approval Period**  
3/30/2020 for 0 months - Expiration: 3/29/2025

**AP.2. What is the purpose of this form?** Add Note View Audit *(Required)*

To amend a study or to amend a legacy study that has been previously back-filled.

To renew a study

**AP.4. Are you changing the PI?** Add Note View Audit *(Required)*

*Note, you cannot make other study personnel changes on this amendment. Use the Personnel Amendment to add, change or remove study team members. Only the PI can be edited here.*

*Also note, both the current and the new PI will need to sign off on this amendment application.*

Yes  
 No

At the bottom of each page are directional buttons that allow you to move to the previous or next pages or sections, save the XForm for later, and a more button. If you press the more button you are given various options including the options to view the XForm as a pdf, which will allow you to print it for later use.

Yes  
 No

[Next](#) [Save for Later](#) [More ▾](#)

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