

## 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 later. Let's look at the Dashboard after our investigator John PI has logged in.

The screenshot shows the IRB Manager Dashboard for IACUC. The dashboard is divided into several sections:

- Home:** IACUC, Find Study (Ctrl+Q), Take a tour..., Help, John's Settings, Sign off
- Actions:** Actions for Researchers, Animal Use Protocol Form, Start xForm, Show Sponsor Ids
- Recent Items:** 300018-UT, 400025-UT, 400030-UT, 400006-UT, 400001-UT, TEST-IACUC-3-UT, TEST-IACUC-2-UT
- Useful Links:** All Projects Dashboard, IACUC Dashboard (coming soon), IBC Dashboard (coming soon)
- Studies (20 Active):** You are associated with 20 active Studies and 34 total Studies. You are the PI for 20 active and 34 total Studies. There are 8 studies expiring in the next 90 days. The next study to expire is 400004-UT.
- xForms (22 Active):** You have 8 unsubmitted xForms. You have 14 xForms being processed at a later stage. There are 3 xForms awaiting your attention.
- Events (15 Open):** Only show events where I am: [dropdown]. You have 2 IACUC Amendment Submission events. You have 13 IACUC New/Triennial Renewal Submission events. You have 15 Total Open events.
- Important Information:** Welcome to the new home of IACUC Research. IACUC research is open for testing and training. **IMPORTANT NOTE:** Do not put real Protocol applications here yet. All data entered will be wiped before the go-live on Monday February 24th at 5:00PM. For help with the transition or for question about a specific protocol, contact the IACUC office. For questions about the system email Jamie.Vannatta@utoledo.edu or call 419-530-6651.

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

1. Open the 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 IACUC Animal Use Protocol Form.

The screenshot shows the IRB Manager Study Detail page for Study 400004-UT (IACUC). The page is divided into several sections:

- Home:** Home, Find Study (Ctrl+Q), Help, John's Settings, Sign off
- Study 400004-UT (IACUC):** Comments, Study-Site, Location(s), Comments
- Study-Site:** Site(s): UT - University of Toledo, PI: PI, John M.D., Status: Approved, Additional: N, Approval: November 20, 2019, Expiration: January 7, 2020, Initial Approval: November 20, 2019, Other Expirations: Standard 3-Yr Expiration Date (IACUC) - 01/06/2020
- Study-Site Contacts (2):** Name, Role, CoInvestigator, Joe, Research Assistant, Student, Jane, Research Assistant
- Reference xForms (1):** Action, Form, Identifier, Stage, As Of, Ref Active, Inactivated
- Events (1):** Event, Att, FE, Instance/UDF, Start, Complete, Last Mtg

A red circle highlights the 'Copy' icon (a stack of papers) next to the 'Animal Use Protocol Form' in the Reference xForms section.

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 RENEW this study or start a new protocol using this protocol as template. Most answers will copy into the new protocol.

 **Copy for Amendment**

Use this option if you want to AMEND the current study. You will use this mechanism to request changes to the study, such as requesting additional animals or 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 ▼

Page 1 of 15

Next

---

**Animal Use Protocol Form -- AP. Amendment Purpose**

500

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

To complete the background information (back-fill) the original application for ease of amendment or renewal later.  
 To amend a study that has always lived in IRB Manager (native), or to amend a legacy study that has been previously back-filled.

**AP.2.1. Briefly summarize, in one or two sentences, the purpose of this amendment. This will be the identifier for your amendment so please be concise and clear.** (Required)

**AP.3. Are you adding a procedure(s) as part of this amendment?** (Required) [Add Note](#) [View Audit](#)

Yes  
 No

**AP.4. Are you adding animals as part of this amendment?** (Required) [Add Note](#) [View Audit](#)

Yes  
 No

**AP.5. Are you changing the PI?** [Add Note](#) [View Audit](#)

*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.* (Required)

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 ▾](#)