

## INSTRUCTIONS FOR SUBMITTING AN IACUC AMENDMENT

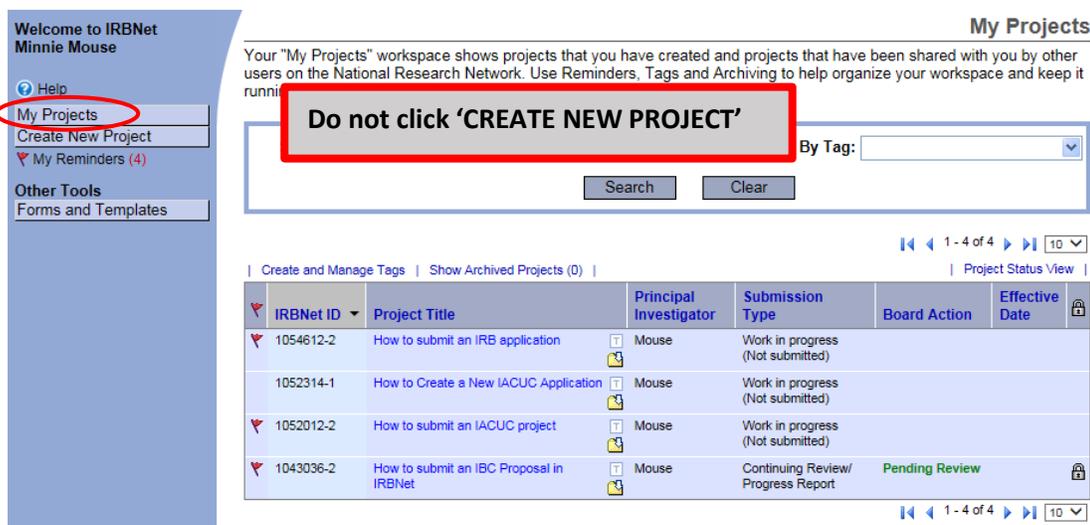
The PHS Policy (IV,B,7) and the AWAR (2.3,c,7) require PIs to seek IACUC approval for protocol modifications. The purpose of a protocol amendment is to modify a previously approved animal use protocol. All animal procedures, manipulations, and actions must have documented IACUC approval **prior** to beginning the proposed animal work. Initiating significant changes to IACUC-approved protocols without prior IACUC review is considered to be noncompliance with PHS Policy.

### Step 1: LOGIN

Login to IRBNet; [www.irbnet.org](http://www.irbnet.org) using your username and password.

### Step 2: SELECT THE PROJECT

Click on 'MY PROJECTS' tab. All of the studies that you have access to will be housed on this page.



Welcome to IRBNet  
Minnie Mouse

My Projects

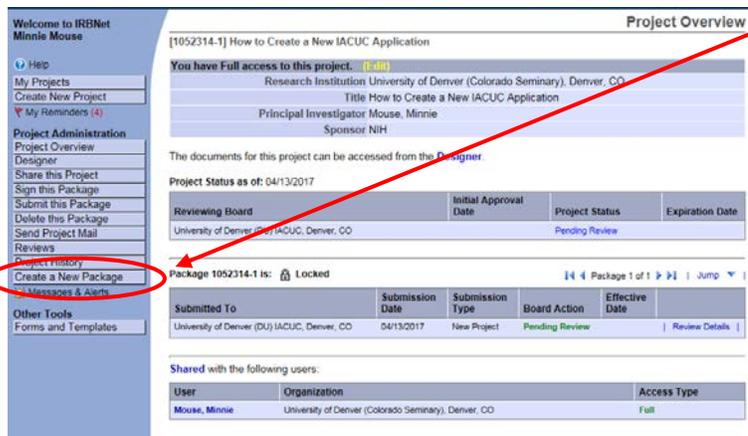
Your "My Projects" workspace shows projects that you have created and projects that have been shared with you by other users on the National Research Network. Use Reminders, Tags and Archiving to help organize your workspace and keep it running smoothly.

**Do not click 'CREATE NEW PROJECT'**

IRBNet ID	Project Title	Principal Investigator	Submission Type	Board Action	Effective Date
1054612-2	How to submit an IRB application	Mouse	Work in progress (Not submitted)		
1052314-1	How to Create a New IACUC Application	Mouse	Work in progress (Not submitted)		
1052012-2	How to submit an IACUC project	Mouse	Work in progress (Not submitted)		
1043036-2	How to submit an IBC Proposal in IRBNet	Mouse	Continuing Review/Progress Report	Pending Review	

### Step 3: CREATE NEW PACKAGE

To submit an **Amendment Application**, you need to create a new **PACKAGE**, not a new project.



Welcome to IRBNet  
Minnie Mouse

Project Administration

Project Overview

Designer

Sign this Package

Submit this Package

Delete this Package

Send Project Mail

Reviews

Project History

Create a New Package

Other Tools

Forms and Templates

[1052314-1] How to Create a New IACUC Application

You have Full access to this project. (Edit)

Research Institution University of Denver (Colorado Seminary), Denver, CO

Title How to Create a New IACUC Application

Principal Investigator Minnie Mouse

Sponsor NIH

The documents for this project can be accessed from the Designer

Project Status as of: 04/13/2017

Reviewing Board	Initial Approval Date	Project Status	Expiration Date
University of Denver (DU) IACUC, Denver, CO		Pending Review	

Package 1052314-1 is: Locked

Submitted To	Submission Date	Submission Type	Board Action	Effective Date
University of Denver (DU) IACUC, Denver, CO	04/13/2017	New Project	Pending Review	

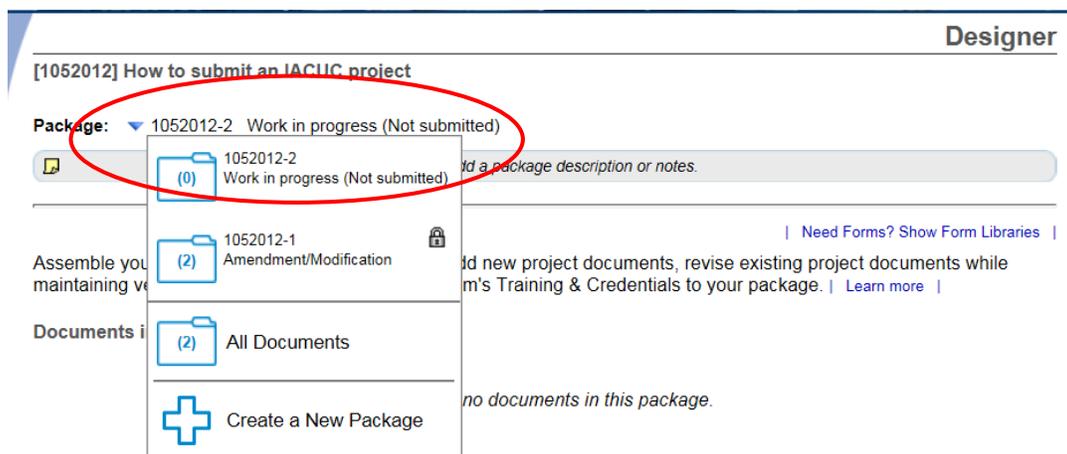
Shared with the following users:

User	Organization	Access Type
Mouse, Minnie	University of Denver (Colorado Seminary), Denver, CO	Full

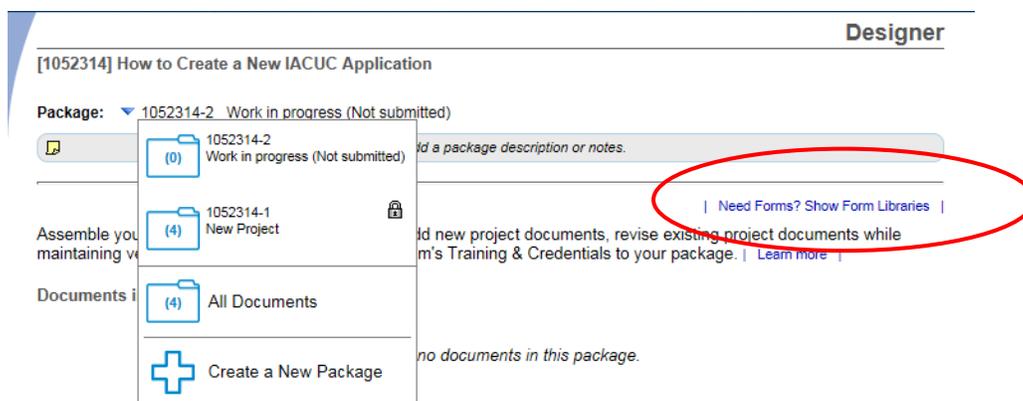
#### Step 4: SELECT FORMS

After clicking on 'Create New Package' your will be automatically directed to the **DESIGNER** screen where you can add documents for this package.

A **NEW DOCUMENT PACKAGE** will appear as a 'Work in progress (Not submitted)'. Click on the blue arrow next to the new project package number (example: 1052314-2) and select the icon folder **Work in progress (Not submitted)**. Please note that other project submissions (packages) are listed along with a folder of all documents that have been submitted for this research project.



The 'IACUC Amendment Form' and other relevant section documents are available through the DU IACUC Library of Forms & Templates. Click on the blue 'Need Forms? Show Form Libraries' link to view the document library.



There are no Training & Credentials records linked to this package. | [Link / Un-Link Training Records](#) |

[Start a Wizard](#) OR [Attach New Document](#) (When should I do this?)

Referencing the diagram below, select 'University of Denver (DU) IACUC, Denver, CO Documents for Researchers' from the 'Select a Library' drop-down menu.

**Designer**

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[1052012] How to submit an IACUC project

**Package:** ▼ 1052012-1 Work in progress (Not submitted)

 [Click to add a package description or notes.](#)

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**Step 1:** [Hide Form Libraries](#) |  
Download blank forms, document templates and reference materials to assist you in assembling your document package.

**Select a Library:** University of Denver (DU) IACUC, Denver, CO ▼

Select a Document: **Form- Amendment (Non-Personnel; Changes in procedures, locations, animal numbers)** ▼

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Next, **Select a Document:** choose either **Form – Amendment (Non-Personnel; Changes in procedures, locations, animal numbers)** or **Form - Amendment (Personnel Changes)**.

**Designer**

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[1052012] How to submit an IACUC project

**Package:** ▼ 1052012-1 Work in progress (Not submitted)

 [Click to add a package description or notes.](#)

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**Step 1:** [Hide Form Libraries](#) |  
Download blank forms, document templates and reference materials to assist you in assembling your document package.

**Select a Library:** University of Denver (DU) IACUC, Denver, CO ▼

**Select a Document:** **Form- Amendment (Non-Personnel; Changes in procedures, locations, animal numbers)** ▼

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Open or save 'Amendment Form' to your computer hard drive.

### Step 5: ATTACH FORMS

Complete the form and save it in a folder to store all research documents related to this protocol.

Go into IRBNet and click on '**Attach New Document**' on the **DESIGNER** page, select the correct document form from your hard drive and IRBNet will automatically post the document under Step 2: **Documents in this Package**.

As an **optional** feature - click on the yellow icon  to add a package description or notes (i.e. Amendment Application)

**Designer**

[1052314] How to Create a New IACUC Application

Package: 1052314-1 Work in progress (Not submitted)

 [Click to add a package description or notes.](#)

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**Step 1:** [Hide Form Libraries](#)  
 Download blank forms, document templates and reference materials to assist you in assembling your document package.

Select a Library: University of Denver (DU) IACUC, Denver, CO

Select a Document: Section L - Non-Survival Surgery

Download

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**Step 2:**  
 Assemble your document package here. You can add new project documents, revise existing project documents while maintaining version history, and link your project team's Training & Credentials to your package. [Learn more](#)

Documents in this Package:

*There are no documents in this package.*

There are no Training & Credentials records linked to this package. [Link / Un-Link Training Records](#)

Start a Wizard OR 
 Attach New Document [\(When should I do this?\)](#)

Continue to assemble your submission package through adding other forms from the IACUC Library relevant to your research project (i.e., *Section L – Non-Survival Surgery*) until all documents have been added.

Repeat the steps to attach new documents until all documents have been uploaded to your package. If you need to **modify** or **change** a document, utilize the following icons:

Documents in this Package:

Document Type	Description	Last Modified	
▼ (please select)	Section M - Non-Surgical Procedures.pdf	04/13/2017 02:36 PM	   
▼ Application Form	Section A - Main IACUC Protocol Template (8).pdf	04/13/2017 02:10 PM	   
▼ Other	Section G - Personnel Qualifications Form.pdf	04/13/2017 02:11 PM	   
▼ Other	Section L - Non-Survival Surgery.pdf	04/13/2017 02:11 PM	   

- To remove a document from this package, click on the red 
- To revise document click on the pencil icon 
- To view the document click on the paper icon 
- To view and manage different versions of a document click on the icon 

## Step 6: LABEL FORMS

Once you have attached all the necessary documents to your study package, a list of your documents will be posted under Step 2: on the **DESIGNER** page.

Label your document appropriately using the drop down list on the 'Document Type' (i.e. Application Form). You may use the label 'Other' for other Section forms (i.e., Section L – Non-Survival Surgery).

If documents are not labeled, your application cannot be submitted in IRBNet.

### Step 2:

Assemble your document package here. You can add new project documents, revise existing project documents while maintaining version history, and link your project team's Training & Credentials to your package. | [Learn more](#) |

#### Documents in this Package:

Document Type	Description	Last Modified	
(please select)	Section M - Non-Surgical Procedures.pdf	04/13/2017 02:36 PM	   
Application Form	Section A - Main IACUC Protocol Template (8).pdf	04/13/2017 02:10 PM	   
Other	Section G - Personnel Qualifications Form.pdf	04/13/2017 02:11 PM	   
Other	Section L - Non-Survival Surgery.pdf	04/13/2017 02:11 PM	   

### Step 2:

Assemble your document package here. You can add new project documents, revise existing project documents while maintaining version history, and link your project team's Training & Credentials to your package. | [Learn more](#) |

#### Documents in this Package:

Document Type	Description	Last Modified	
Amendment/Modification	IACUC Amendment Form (Non-Personnel; Changes in procedures, locations, animal numbers).pdf	03/29/2017 05:18 PM	   

There are no Training & Credentials records linked to this package. | [Link / Un-Link Training Records](#) |

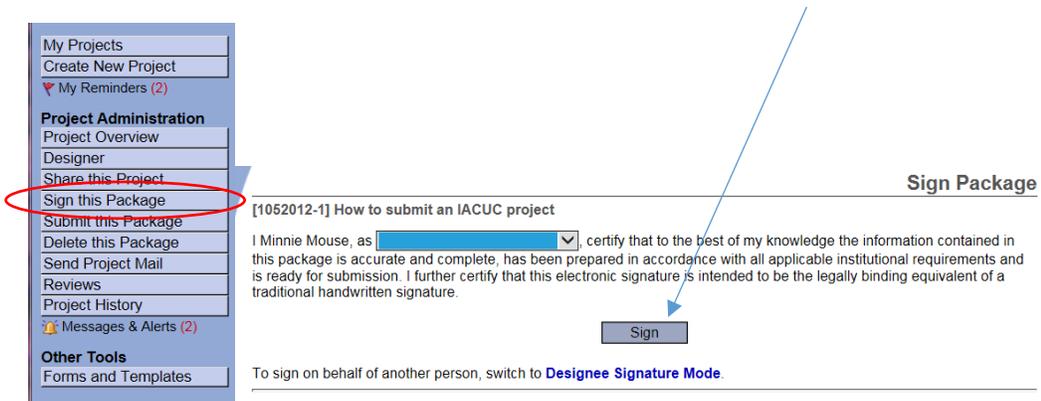


Please disregard the 'Start a Wizard' tab. This IRBNet tab feature is used only for IRB (Human Subjects) applications.

### Step 7: SIGN PACKAGE

When all documents are uploaded the PI needs to **SIGN THIS PACKAGE** found under the Project Administration menu, to be accepted as a complete application.

Select your appropriate role from the dropdown box and click 'Sign'.



To sign a package, click **SIGN THIS PACKAGE**. The Principal Investigator **MUST** sign the package before it is submitted. Select 'Principal Investigator' role from the dropdown box and click 'Sign'.

*If a submission is submitted without a PI signature the submission will not be accepted for review. For example, if a graduate student completes the application on behalf of the PI, the PI still needs to electronically sign the submission. This requirement verifies that the PI has reviewed and approves the application.*

Please note: The IACUC Office only accepts the **Standard Signature Mode** and does not utilize the Designee Signature Mode option.

This package has been signed by:

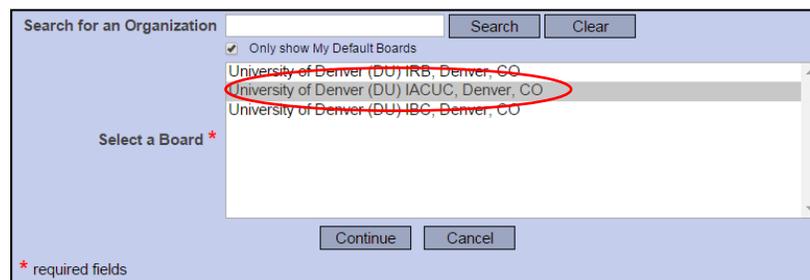
Date	Signed By	Role	Details
03/29/2017 06:02 PM	Minnie Mouse	Principal Investigator	<a href="#">Details</a>

### Step 8: SUBMIT PACKAGE

Once the package has been signed, click **SUBMIT THIS PACKAGE**. Select "DU IACUC, Denver, CO" in the "Search for Organization" drop down menu (This will be your default location and should be highlighted already).

IRBNet supports multiple models of review. Using the "Submit" feature, you may electronically submit this document package to either a single Board, or to multiple Boards. Each Board you submit to will be notified of your submission and given access to view your electronic documents. Each Board will also be permitted to electronically record their review decision, which will be stored as a permanent part of your project record. You will be automatically notified when the review decision is electronically recorded.

Please select a Board:



Then click the **'Continue'** button. In the Submission type drop-down menu, select **'AMENDMENT/MODIFICATION'** and click **'Submit'**. You may also send any comments or special requests to the IACUC before clicking **'Submit'**.

**Submit Package**

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[1052314-2] How to Create a New IACUC Application

The following users at **University of Denver (DU) IACUC** will be automatically notified of your submission:

Admin, Denver  
Skarda, Jay  
Travis, Mary

**Submission Type:** \*

You may also specify additional comments to be included in this notification.

**Your Comments:**

Once you hit the **'Submit'** button, you will be given a confirmation showing the date and the individuals who received your submission.

**Submit Package**

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**Submission Confirmation - [1052012-1] How to submit an IACUC project**

This package has been successfully submitted for review.

Submitted by Minnie Mouse to Denver Admin; Jay Skarda; Mary Travis; at University of Denver (DU) IACUC, Denver, CO on 03/29/2017.

These users will automatically receive notification of this submission.

Return to the [Project Overview](#).

*Keep in mind that once you click **'Submit'** your study is now locked and you are not allowed to attach any other documents or make revisions. Take the time to be sure all documents are attached and in the final version prior to submitting. Any incomplete submissions will not be reviewed by the IACUC and will be returned for corrections. If you need to make any changes after the package has been submitted and locked, please contact the IACUC Office at **303-871-2121** to request to have the package unlocked.*

*The IACUC Office does not have the administrative ability to load document in an IRBNet package on behalf of the PI or any other research team member.*

### Step 9: **SUBMISSION CONFIRMATION**

To review what has been sent, click **PROJECT OVERVIEW**. **The submission will be under 'Pending review' status until a decision has been made.** Once a decision letter is formulated, an email will be sent to everyone who has full access and the letter and any supporting documents can be printed.

