

SUBMITTING AN IBC AMENDMENT

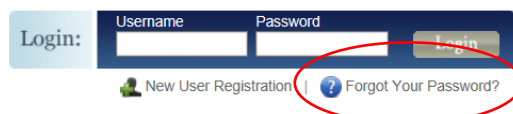
The submission of an amendment/modification to an approved IBC protocol requires the creation of a subsequent **PACKAGE** in a project.

After an IBC application is approved, the project may require modifications during the course of the research. The Principal Investigator (PI) is responsible for submitting an amendment/modification application to the DU IBC for review to obtain approval for any changes that may be requested or required. An example of a change that would require an amendment could include adding new personnel or revising the protocol to reflect removing or adding a new procedure.

To obtain IBC approval for changing anything to an approved protocol, the PI must submit an IBC Amendment Form. This is completed through submitting a new **PACKAGE, NOT PROJECT** through IRBNet.

Step 1: LOGIN

Login to IRBNet: www.irbnet.org using your username and password. If you forgot your password or username please click on the 'Forgot Your Password?' text in the upper right corner of the IRBNet home page.



Step 2: SELECT THE PROJECT

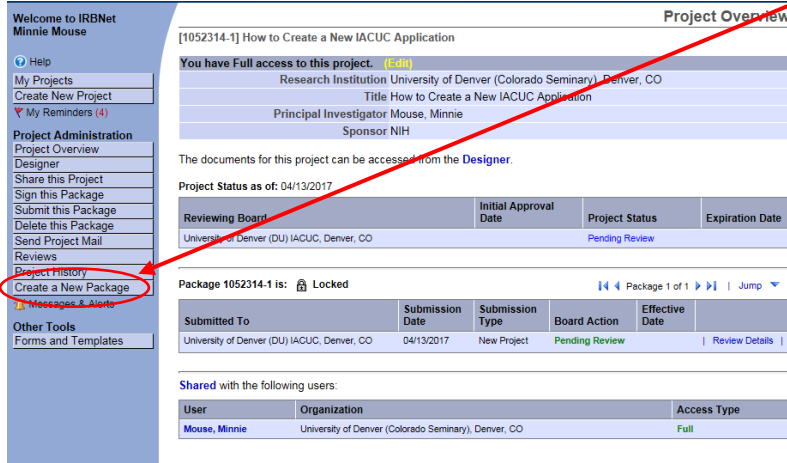
Click on '**MY PROJECTS**' tab. All of the studies that you have access to will be housed on this page.

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 Overview

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

You have Full access to this project. (Full)

Research Institution University of Denver (Colorado Seminary), Denver, CO
Title How to Create a New IACUC Application
Principal Investigator Mouse, Minnie
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	

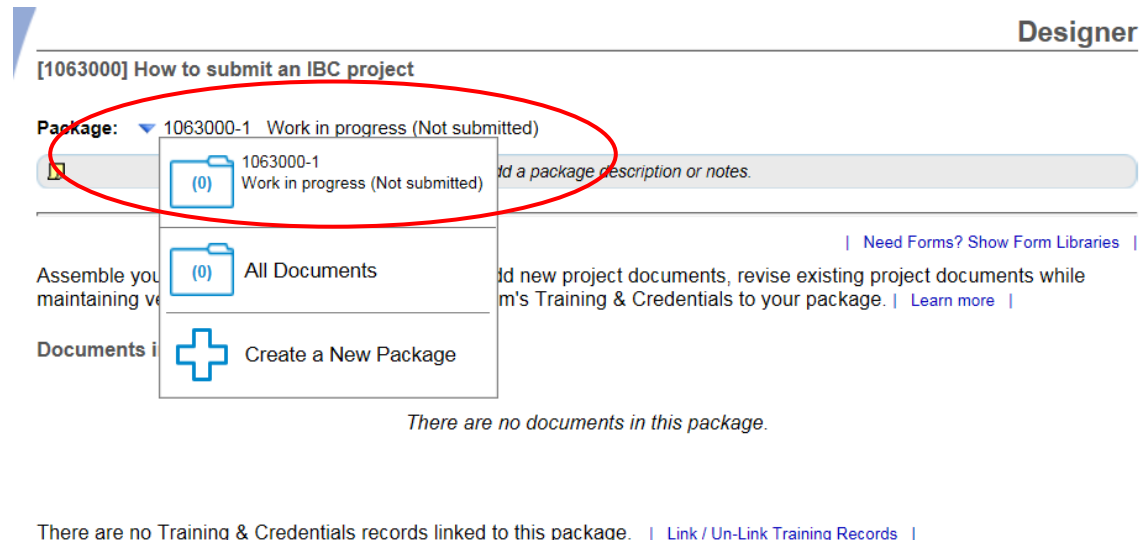
Shared with the following users:

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.



Designer

[1063000] How to submit an IBC project

Package: 1063000-1 Work in progress (Not submitted)

1063000-1 Work in progress (Not submitted) Add a package description or notes.

All Documents Add new project documents, revise existing project documents while maintaining v... m's Training & Credentials to your package. | Learn more |

Documents Create a New 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?)

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

Designer

[1063000] How to submit an IBC project

Package: ▼ 1063000-1 Work in progress (Not submitted)

(0) 1063000-1 Work in progress (Not submitted)

(0) All Documents

Documents

There are no documents in this package.

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

OR [\(When should I do this?\)](#)

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

Designer

[1063000] How to submit an IBC project

Package: ▼ 1063000-1 Work in progress (Not submitted)

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

Select a Library:

Select a Document:

Next, **Select a Document**: choose Form – IBC Amendment from the drop-down options to begin building your package.

Designer

[1063000] How to submit an IBC project

Package: ▼ 1063000-1 Work in progress (Not submitted)

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

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

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

Select a Document: **Form - IBC Amendment** ▼

[Download](#)

Open or save 'IBC Amendment Form' to you computer hard drive.

Step 5: ATTACH FORMS

Complete the form and save it in the research folder associated with this protocol.

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

Designer

[1063000] How to submit an IBC project

Package: ▼ 1063000-1 Work in progress (Not submitted)

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

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





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

Select a Document: Form - IBC Amendment ▼

[Download](#)

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	Form - IBC Amendment	04/24/2017 12:41 PM	   





The following records linked to this package: [Link / Un-Link Training Records](#)

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

If you need to modify or change a document, utilize the following icons:

Documents from Previous Packages that you can Revise: [\(When should I do this?\)](#)

Pkg #	Document Type	Description	Last Modified	Submission Date	
2	Continuing Review/Progress Report	IBC Annual Progress Report	03/20/2017 02:20 PM	03/20/2017	  
1	Application Form	IBC Protocol Application 2-10-17.docx	03/10/2017 04:11 PM	03/10/2017	  

- 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. Select 'Amendment/Modification' to label your document.

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

Designer


[1063000] How to submit an IBC project

Package: ▼ 1063000-1 Work in progress (Not submitted)

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





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

Select a Library:

Select a Document: 

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	Form - IBC Amendment	04/24/2017 12:41 PM	   

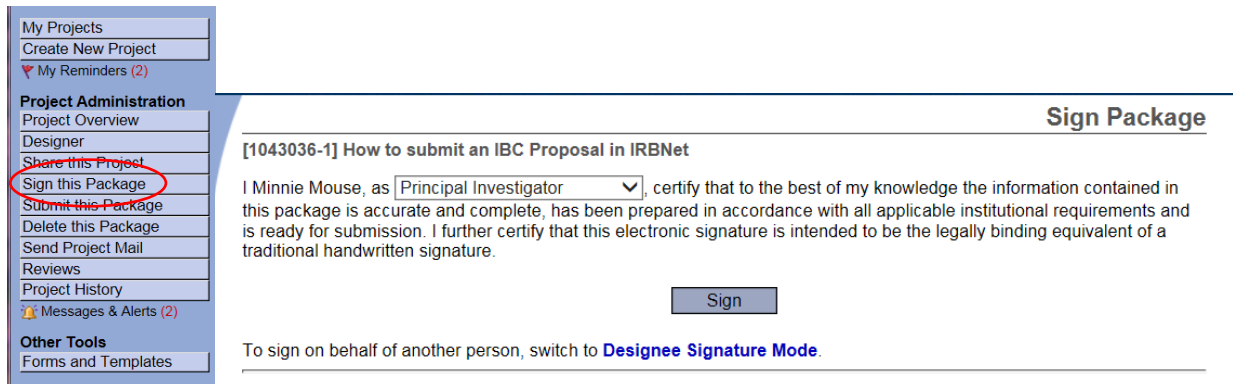
The documents linked to this package. [Link / Un-Link Training Records](#)

OR [\(When should I do this?\)](#)

Step 7: SIGN YOUR PACKAGE

When all the necessary documents are uploaded to the package, the Principal Investigator must sign the package electronically. If you are completed this package on behalf of the PI, send an email to the PI using the 'Send Project Mail' function and request that the PI sign the package. The Principal Investigator MUST sign the package before it is submitted.

Click on **SIGN THIS PACKAGE** from the Project Administration Menu. Select your appropriate role from the dropdown box and click 'Sign'.

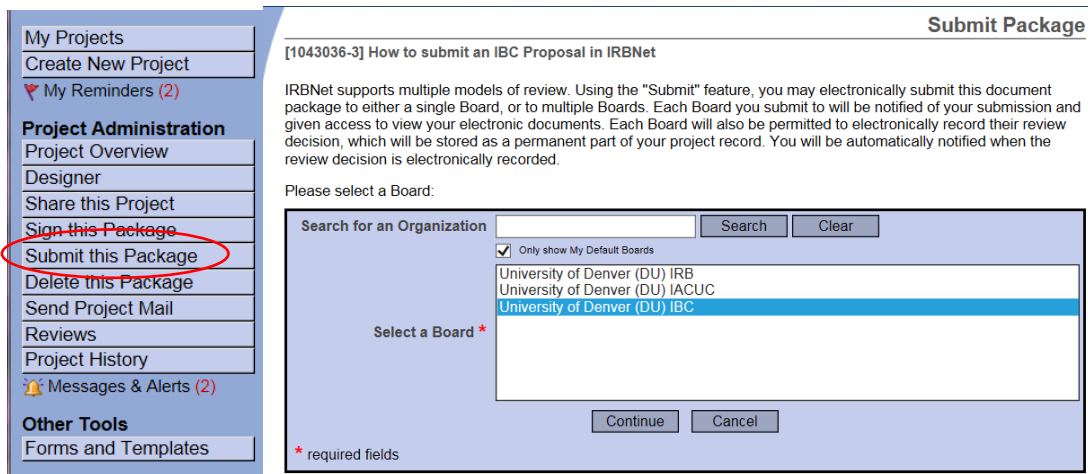


If a submission is submitted without a PI signature the submission will not be accepted for review. For example, if a graduate student completes that application on behalf of the PI, the PI still needs to electronically sign the submission. This requirement verifies that the PI has reviewed and approves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

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

Step 8: **SUBMIT PACKAGE**

Once the PI has signed the package, click **SUBMIT THIS PACKAGE**. The DU IBC cannot see any submissions until the 'Submit' button has been selected. Select '**University of Denver (DU) IBC, Denver, CO**' in the "Search for Organization" drop down menu (this will be your default location and should be highlighted already).



Then click the 'Continue' button. In the Submission Type drop-down menu, select 'Continuing Review/Progress Report' and click 'Submit'. You may also send any comments or special request to the IACUC before clicking 'Submit'.

Submit Package

[1063000-1] How to submit an IBC project

The following users at **University of Denver (DU) IBC** 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:

Step 9: SUBMISSION CONFIRMATION

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

Submit Package

Submission Confirmation - [1043036-2] How to submit an IBC Proposal in IRBNet

This package has been successfully submitted for review.

Submitted by Minnie Mouse to Denver Admin; Jay Skarda; Mary Travis; at University of Denver (DU) IBC, Denver, CO on 03/20/2017.

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 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 IBC Office at 303-871-2121 to request to have the package unlocked.*

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

Step 10: [PROJECT OVERVIEW](#)

To review what has been sent, click [PROJECT OVERVIEW](#). **The submission will be under 'Pending Review' status until a decision by the board 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 copied or printed.