

SUBMITTING AN ANNUAL/PERIODIC ASSESSMENT REPORT

The submission of an annual/periodic assessment report of an open study requires the creation of a subsequent package in a project.

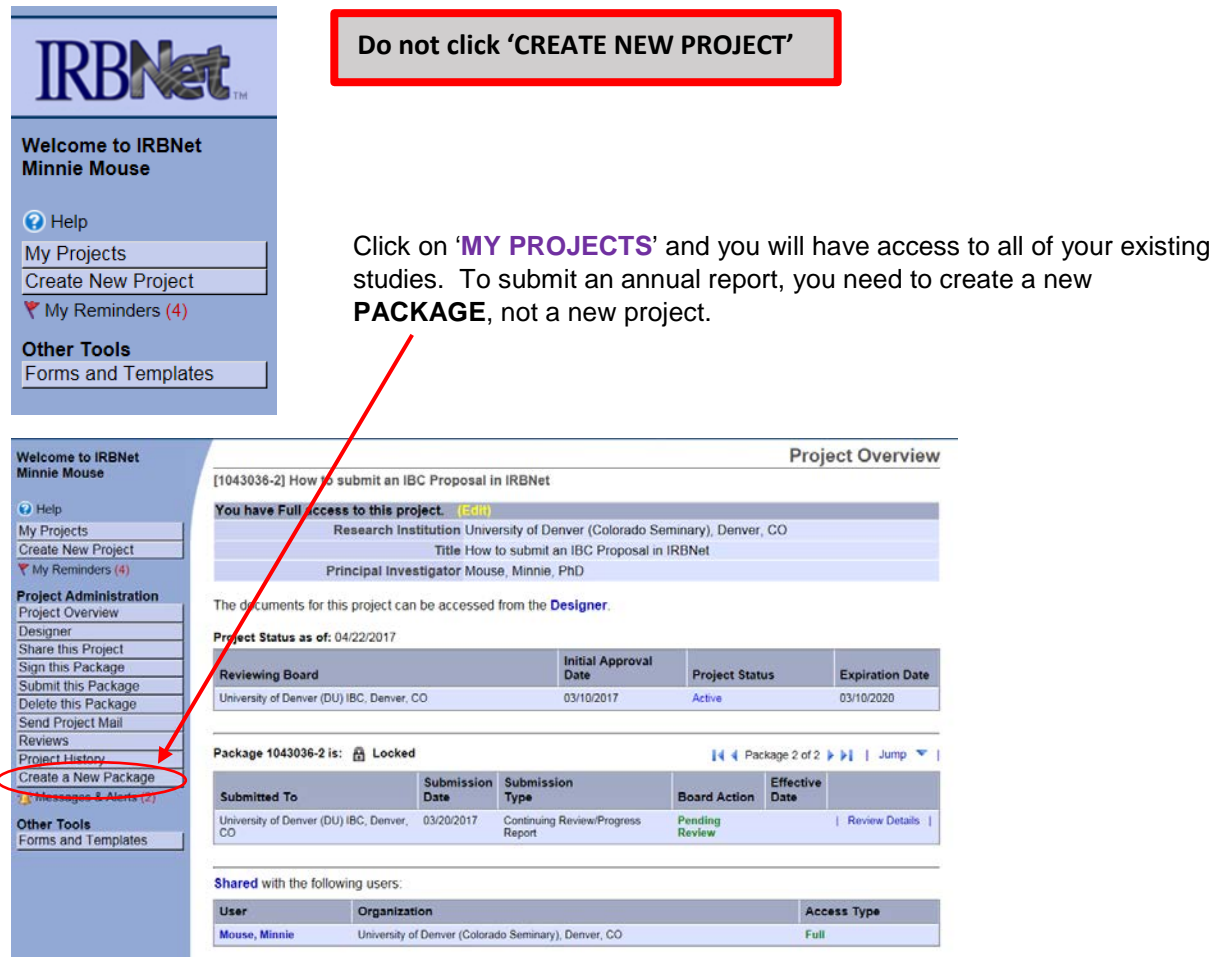
As part of the DU IBC post-approval monitoring program, all IBC-approved protocols must submit an annual periodic assessment report. Two electronic notices, at 60 day and 30 day intervals, are automatically generated by the IRBNet system to the PI reminding them to submit this report. The annual report must be posted in the IRBNet project at least 3 weeks prior to the anniversary date of the initial approval in order to allow sufficient time for IBC review.

Step 1: LOGIN

Log into IRBNet: www.irbnet.org using your username and password. If you forgot your username and password, please click on the 'Forgot Password?' text in the upper right corner of the IRBNet homepage.

Step 2: SELECT THE PROJECT

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



Do not click 'CREATE NEW PROJECT'

Click on '**MY PROJECTS**' and you will have access to all of your existing studies. To submit an annual report, you need to create a new **PACKAGE**, not a new project.

Project Overview

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

You have Full access to this project. (Edit)

Research Institution	University of Denver (Colorado Seminary), Denver, CO
Title	How to submit an IBC Proposal in IRBNet
Principal Investigator	Mouse, Minnie, PhD

The documents for this project can be accessed from the Designer.

Project Status as of: 04/22/2017

Reviewing Board	Initial Approval Date	Project Status	Expiration Date
University of Denver (DU) IBC, Denver, CO	03/10/2017	Active	03/10/2020

Package 1043036-2 is: Locked

Submitted To	Submission Date	Submission Type	Board Action	Effective Date
University of Denver (DU) IBC, Denver, CO	03/20/2017	Continuing Review/Progress Report	Pending Review	

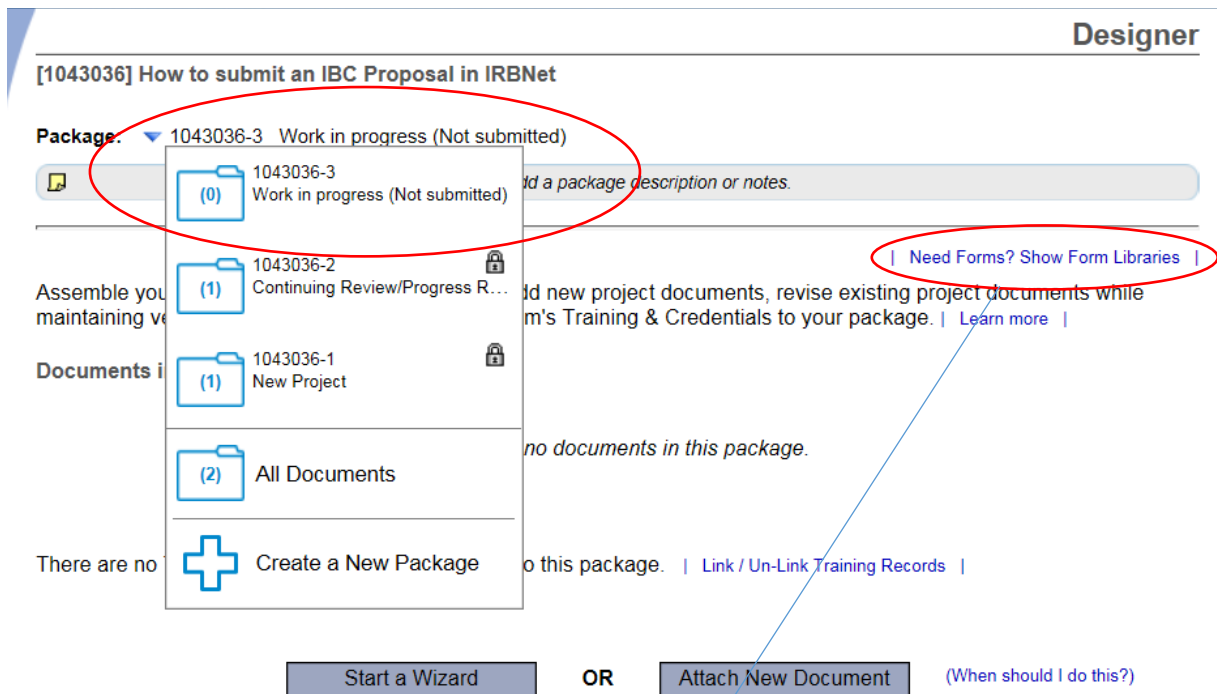
Shared with the following users:

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

Step 3: CREATE NEW PACKAGE

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

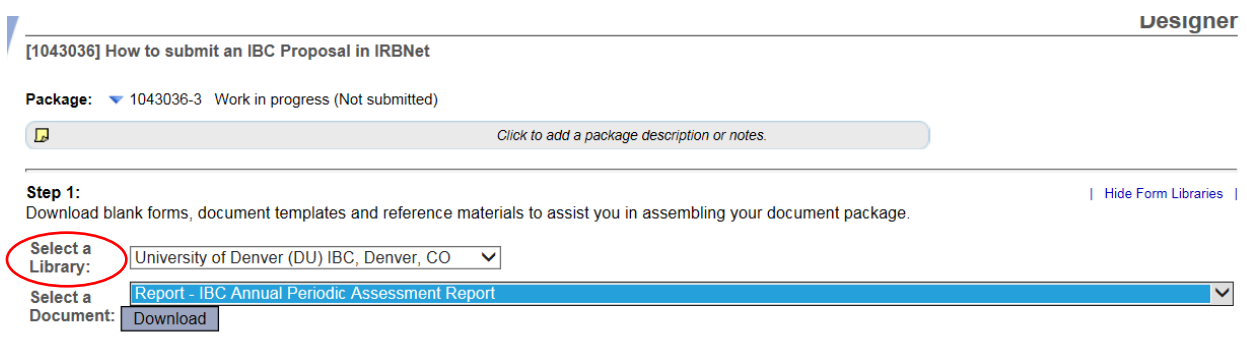
A **NEW DOCUMENT PACKAGE** will appear as a **'Work in progress (Not submitted)'**. Please note that the initial submission is listed along with a folder of all documents that have been submitted for this research project.



The screenshot shows the 'Designer' interface for package [1043036] 'How to submit an IBC Proposal in IRBNet'. A dropdown menu is open for package '1043036-3 Work in progress (Not submitted)'. The menu items are: '(0) 1043036-3 Work in progress (Not submitted)', '(1) 1043036-2 Continuing Review/Progress R...', '(1) 1043036-1 New Project', '(2) All Documents', and '+ Create a New Package'. A red circle highlights the package name and the first menu item. Another red circle highlights the link '| Need Forms? Show Form Libraries |'. Below the menu are buttons for 'Start a Wizard' and 'Attach New Document' (with a note '(When should I do this?)').

Step 4: SELECT FORMS

The IBC Annual Periodic Assessment Report form is available through the DU IBC Library of Forms & Templates. Click on the blue **'Need Forms? Show Form Libraries'** link to select a document. Referencing the diagram below, select **'University of Denver (DU) IBC, Denver, CO – Documents for Researchers'** from the 'Select a Library' drop-down menu.




The screenshot shows the 'Designer' interface for package [1043036] 'How to submit an IBC Proposal in IRBNet'. It shows 'Step 1: Download blank forms, document templates and reference materials to assist you in assembling your document package.' Below this, there are two dropdown menus: 'Select a Library:' with 'University of Denver (DU) IBC, Denver, CO' selected, and 'Select a Document:' with 'Report - IBC Annual Periodic Assessment Report' selected. A 'Download' button is visible below the document selection. A red circle highlights the 'Select a Library:' dropdown.

Next, **Select a Document**: choose **Report – IBC Annual Periodic Assessment Report** from the drop-down options to begin building your package.

Designer

[1043036] How to submit an IBC Proposal in IRBNet

Package: ▼ 1043036-3 Work in progress (Not submitted)

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

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

Select a Library: ▼

Select a Document: ▼

Open or save 'IBC Annual Periodic Assessment Report' form to your 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

[1043036] How to submit an IBC Proposal in IRBNet





Package: ▼ 1043036-2 Work in progress (Not submitted)

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

[Need Forms? Show Form Libraries](#)

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	
▼ Protocol	IBC Annual/Periodic Assessment Form.docx	03/20/2017 01:53 PM	   





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

OR (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.

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

Designer

[1043036] How to submit an IBC Proposal in IRBNet





Package: ▼ 1043036-2 Work in progress (Not submitted)

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

[Need Forms? Show Form Libraries](#) |

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	
<div style="border: 1px solid #ccc; padding: 5px;"> <ul style="list-style-type: none"> Protocol Conflict of Interest - Other Consent Form Consent Waiver Continuing Review/Progress Report Cover Sheet CV/Resume Data Collection </div>	IBC Annual/Periodic Assessment Form.docx	03/20/2017 01:53 PM	   

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

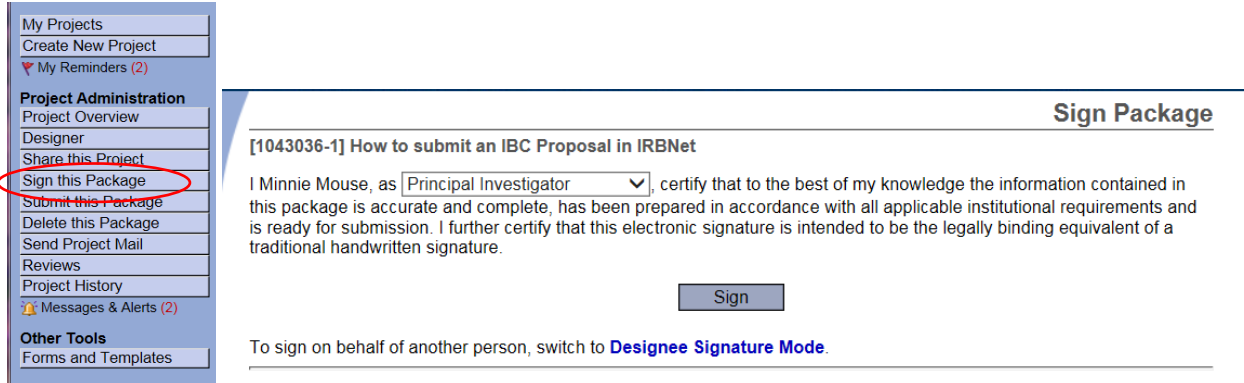
Wizard
OR
Attach New Document
[\(When should I do this?\)](#)

Step 7: SIGN 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'.

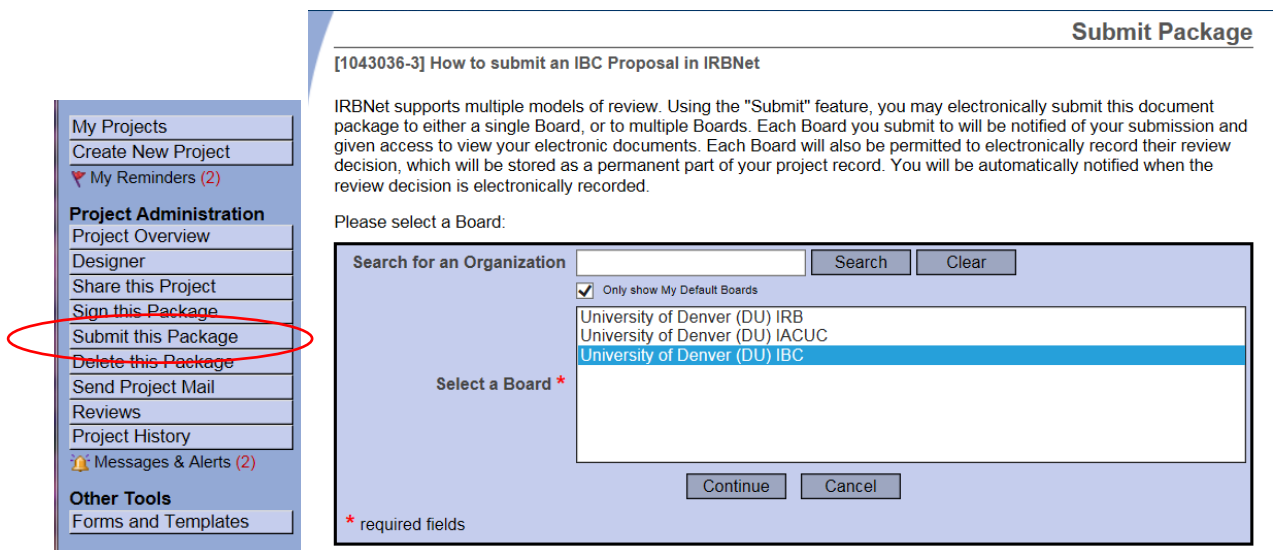


If a submission is submitted without a PI signature the submission will not be accepted for review. For example, if a graduate student completes that application on behalf of the PI, the PI still needs to electronically sign the submission. This requirement verifies that the PI has reviewed and approves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

[1043036-3] How to submit an IBC Proposal in IRBNet

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.