

TRIENNIAL (*de novo*) NEW APPLICATION
(required every three years & before the project expiration date)

Per PHS Policy (IV, C, 5), when protocols have reached the limit of their 3-year PHS approval period, a new IACUC application must be submitted for review. This new application is referred to as a Triennial (*de novo*) New Application. Principal Investigators must submit triennial new applications to the IACUC at least 30 days PRIOR to the protocol expiration date in order to allow the IACUC sufficient time to review and issue approval for the protocol.

PLEASE NOTE: Effective June 2017, the DU IACUC will no longer retire IRBNet protocol numbers when the protocols have reached their 3-year PHS approval period. Through the IRBNet system, the PI will create a new PACKAGE to their existing project. This process was implemented at the University of Denver to retain the original IRBNet protocol number though the life of the project for efficiency as well as to indicate the continuity and longevity of a research project.

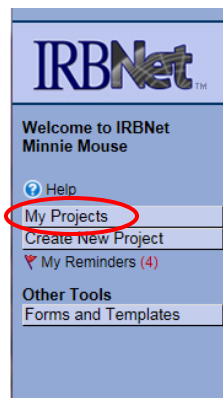
Through referencing the 'IACUC New Project Submission Checklist', a list of required documents for submitting a new IACUC application is provided. Other checklists and forms can be found under 'Other Tools' (Forms and Templates) on the left side of the main screen in IRBNet.

Step 1: LOG IN

Log into www.irbnet.org using your username and password.

Step 2: SELECT THE PROJECT

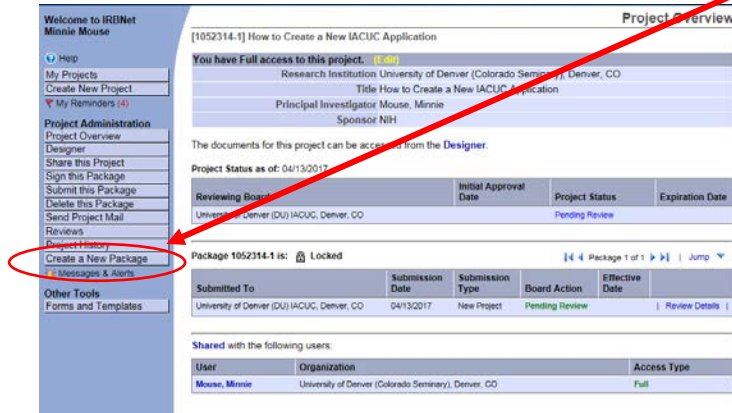
Click on '**MY PROJECTS**' tab. All of the studies that you have access to will be housed on this page.



Do not click 'CREATE NEW PROJECT'

Step 3: CREATE NEW PACKAGE

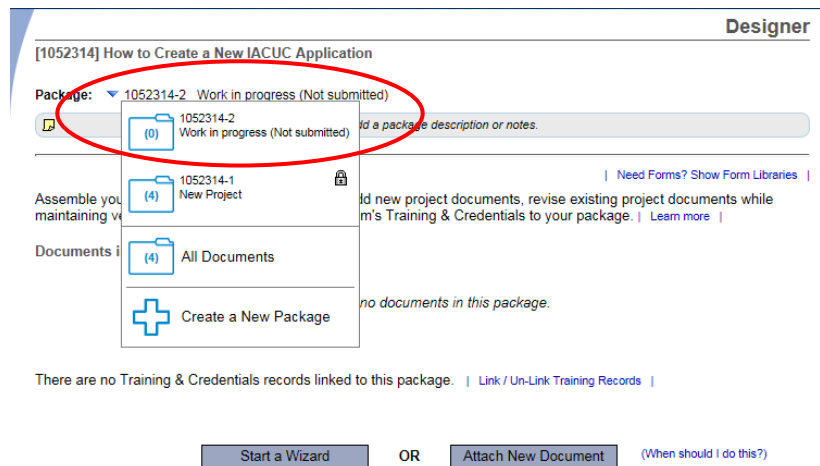
To submit a **Triennial New Application**, you need to create a new **PACKAGE**, not a new project.



Step 4: SELECT FORMS

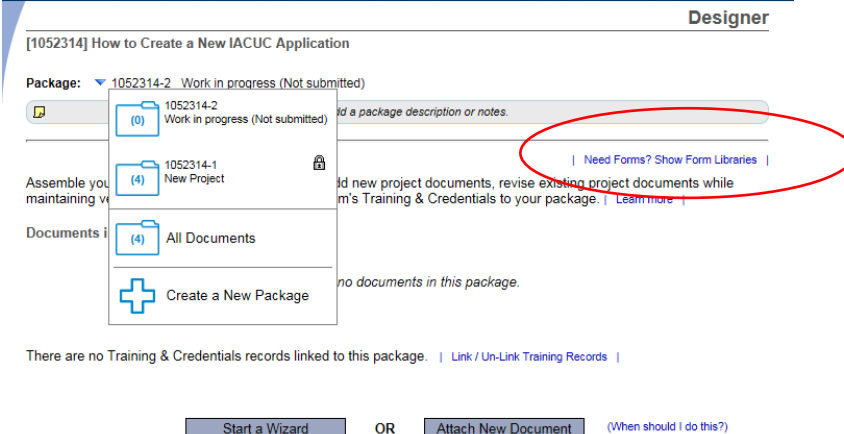
After clicking on 'Create New Package', you will be automatically directed to the **DESIGNER** screen where you can add documents for this package.

A **NEW DOCUMENT PACKAGE** will appear as a **'Work in progress (Not submitted)'**. 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.



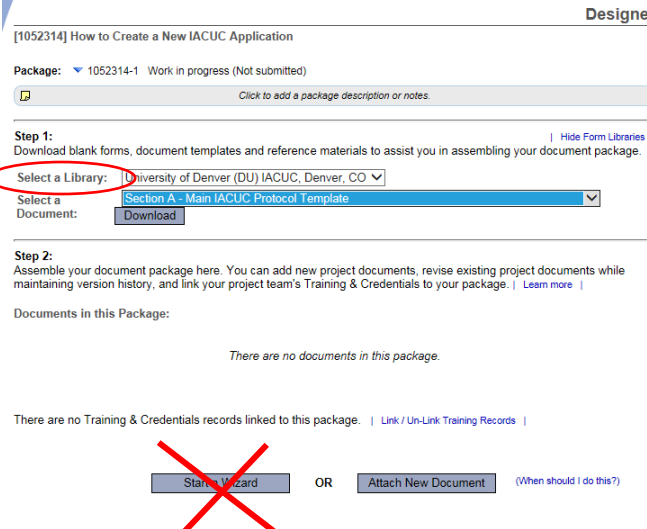
Institutional Animal Care and Use Committee (IACUC)
Office of Research Integrity & Education

The **'Section A – Main IACUC Application'** 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.



The screenshot shows the 'Designer' interface for creating a new IACUC application. The package name is '1052314-2 Work in progress (Not submitted)'. On the left, there are folders for '1052314-2 Work in progress (Not submitted)', '1052314-1 New Project', and 'All Documents'. A red circle highlights the blue link 'Need Forms? Show Form Libraries' located in the right-hand pane. Below the package information, there are buttons for 'Start a Wizard' and 'Attach New Document'.

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



The screenshot shows the 'Designer' interface for creating a new IACUC application. The package name is '1052314-1 Work in progress (Not submitted)'. The 'Select a Library' dropdown menu is open, and 'University of Denver (DU) IACUC, Denver, CO' is selected. A red circle highlights the dropdown menu. Below the dropdown, there is a 'Download' button. The 'Start a Wizard' button is crossed out with a red X. Below the package information, there are buttons for 'Start a Wizard' and 'Attach New Document'.

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

**Institutional Animal Care and Use Committee (IACUC)
Office of Research Integrity & Education**

Next, **Select a Document:** choose **Section A – Main IACUC Protocol Template** from the drop-down options to begin building your package.

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:

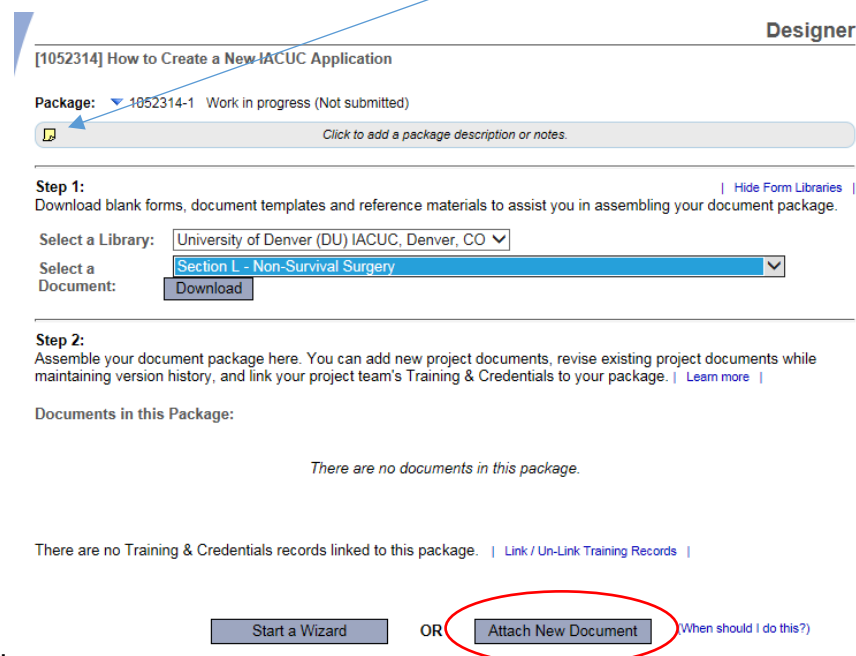
Open or save 'Section A – Main IACUC Protocol Template' to your computer hard drive.

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. New Application - Triennial)









The screenshot shows the 'Designer' interface for a package titled '[1052314] How to Create a New IACUC Application'. It includes a 'Package' dropdown menu, a 'Step 1' section with a 'Select a Document' dropdown menu, and a 'Step 2' section. A yellow icon with a document symbol is circled in red, and a blue arrow points from the text above to it. At the bottom, there are two buttons: 'Start a Wizard' and 'Attach New Document', with the latter circled in red. The text '(When should I do this?)' is visible next to the 'Attach New Document' button.

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](#) |

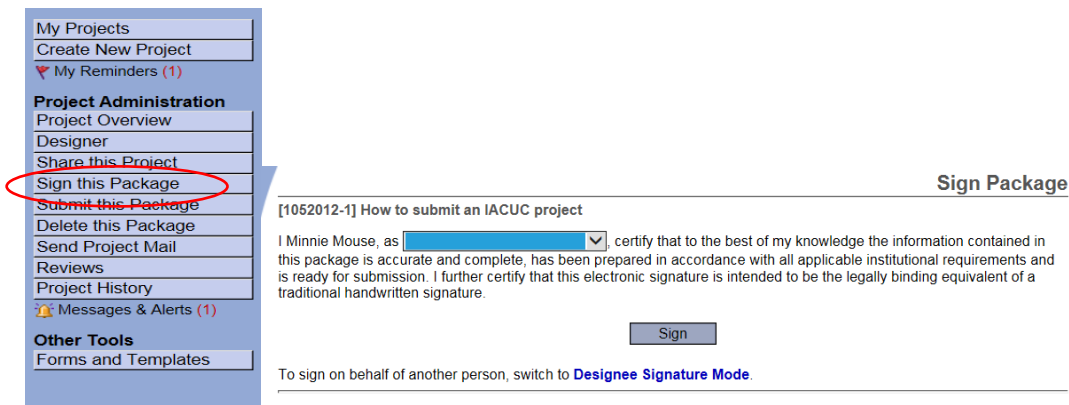
Documents in this Package:

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 7: SIGN PACKAGE

When all the necessary documents are uploaded to the package, the Principal Investigator must sign the package electronically. If you are completing 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 the IACUC will review it.

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



The screenshot shows a sidebar menu on the left with the following items: My Projects, Create New Project, My Reminders (1), Project Administration (expanded), Project Overview, Designer, Share this Project, **Sign this Package** (circled in red), Submit this Package, Delete this Package, Send Project Mail, Reviews, Project History, Messages & Alerts (1), and Other Tools (Forms and Templates). The main content area is titled 'Sign Package' and contains a form with a dropdown menu set to 'Minnie Mouse'. The text reads: 'I Minnie Mouse, as [Minnie Mouse], certify that to the best of my knowledge the information contained in this package is accurate and complete, has been prepared in accordance with all applicable institutional requirements and is ready for submission. I further certify that this electronic signature is intended to be the legally binding equivalent of a traditional handwritten signature.' Below the text is a 'Sign' button. At the bottom, it says 'To sign on behalf of another person, switch to [Designee Signature Mode](#)'.

If a submission is submitted without the 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.

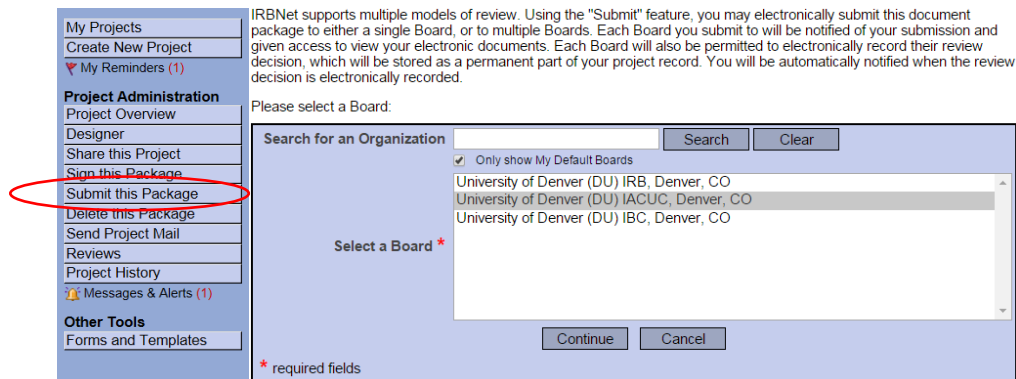
Please note: The IACUC Office only accepts the **Standard Signature Model** and does not utilize the Designee Signature Mode option.

This package has been signed by:

Date	Signed By	Role	
03/29/2017 06:02 PM	Minnie Mouse	Principal Investigator	Details

Step 8: **SUBMIT PACKAGE**

Once the PI has signed the package, click **SUBMIT THIS PACKAGE**. Select 'University of Denver (DU), 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:

Search for an Organization

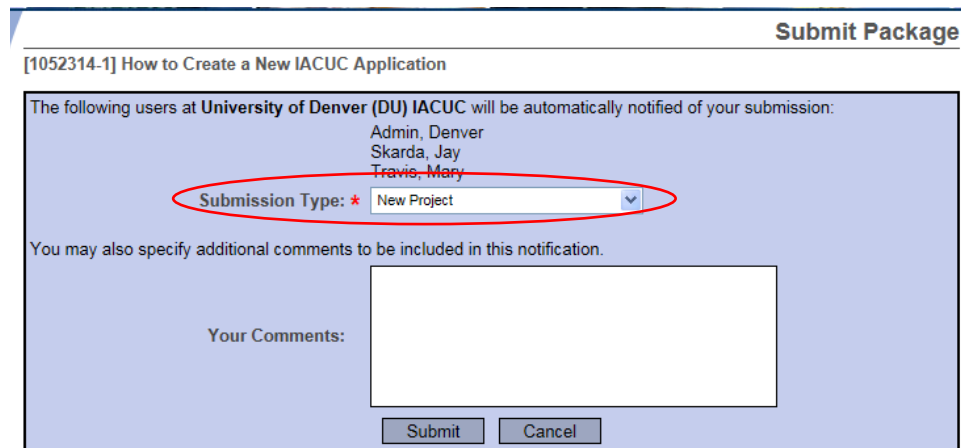
Only show My Default Boards

- University of Denver (DU) IRB, Denver, CO
- University of Denver (DU) IACUC, Denver, CO
- University of Denver (DU) IBC, Denver, CO

Select a Board *

* required fields

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



Submit Package

[1052314-1] 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:

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 - [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 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.*

Please note: The IACUC 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.