

SUBMITTING A NEW IACUC PROJECT (INITIAL)

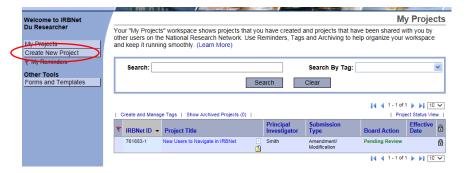
After you have established and activated your username and password, you can begin to create an IACUC application in IRBNet. To start building a new IACUC application, you must first **CREATE A NEW PROJECT** (Study) to hold your research documents. Any type of document can be uploaded, but your study MUST include all the required forms for a complete package before any action can be taken on behalf of the IACUC. Through referencing the 'IACUC New Project Submission Checklist', a list of required documents for submitting a new IACUC application is provided. This, and other checklists, 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 you username and password (for First Time Users, you must Register with IRBNet; please refer to the INSTRUCTIONS FOR REGISTERING WITH IRBNET)

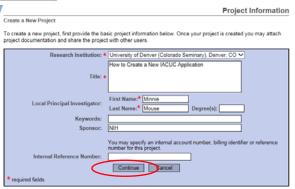
Step 2: CREATE NEW PROJECT

Initially, after logging into IRBNet, you will be guided to the default page MY PROJECTS, where you will have access to all of your existing studies as well as the ability to create new studies. Click CREATE NEW PROJECT (on the left side of your screen).



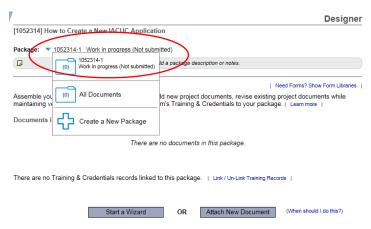
Fill in the relevant information about your project (title, PI name). Be sure to accurately enter the name of the project. All documents, including the approval letter, will utilize the project title entered at this step. Entering information in the 'Internal Reference Number', 'Keywords' and 'Sponsor' fields are not required but if the project is funded, the funding sponsor and grant protocol number could be entered here. After all required information is entered indicated by red asterisks (*), click 'Continue'





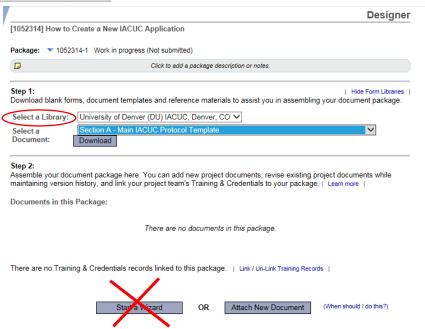
Step 3: SELECT FORMS

You will now be directed to the **DESIGNER** page where the new package for your project will appear as a **Work in Progress (Not submitted).** Click on the blue arrow next to the new project package number (example: 1052314-1) and select the icon folder **Work in progress (Not submitted)**. You will automatically be brought to the **DESIGNER** screen where you can begin to add documents for this package submission.

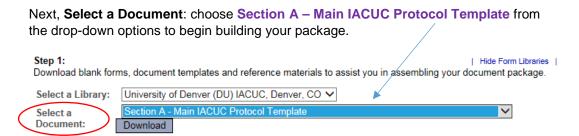


The 'Section A - Main IACUC Application' and other relevant section documents for completing a new study application are available through the DU IACUC Library of Forms & Templates. Referencing the diagram below, select 'University of Denver (DU) IACUC, Denver, CO – Documents for Researchers' from the 'Select a Library' dropdown menu.





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



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

Step 4: 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.

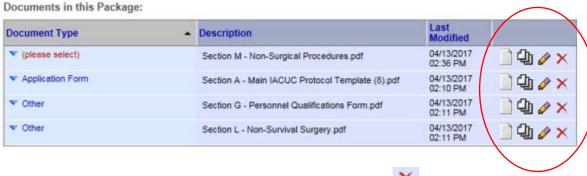


As an optional feature - click on the yellow icon to add a package description or notes (i.e. New Initial Application) Designer [1052314] How to Create a New IACUC Application Package: ▼ 1052314-1 Work in progress (Not submitted) **□** 🖈 Click to add a package description or notes Download blank forms, 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: 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: There are no documents in this package. There are no Training & Credentials records linked to this package. | Link/Un-Link Training Records |

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, referencing the $\underline{IACUC\ New\ Project\ Submission\ Checklist}$.

OR

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:



Attach New Document

To remove a document from this package, click on the red



To view the document click on the paper icon

ullet To view and manage different versions of a document click on the icon

NEW IACUC APPLICATION (INITIAL)
IRBNet User's Guide for IACUC Investigators
Office of Research Integrity & Education

(When should I do this?)



Step 2:

Step 5: 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.

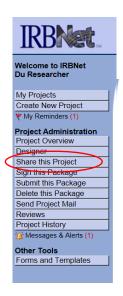
Label your document appropriately using the drop down list on the 'Document Type' (i.e. Application Form). You may use the label 'Other' for other Section forms (i.e., Section L – Non-Survival Surgery).

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



Step 6: SHARE THE PROJECT WITH RESEARCH TEAM

Under the Project Administration menu on the left side of the main screen, select the tab **SHARE THIS PROJECT**. Select the blue '**Share**' link. If you are completing this project on behalf of the Principal Investigator (PI), the PI must be granted '**Full**' access to the project.



You may share this project with other Researchers, Committee Members, Administrators and Sponsors. You may also send a complete copy of this project to a Principal Investigator at another site if this is a multi-site project. You may also transfer ownership of this project to another individual.

Share: Use this option if you wish to share your project with other Researchers, Committee Members, Administrators or Sponsors at your own institution or any other institution. For example, you may wish to share this project with other members of your research team so that you may collaborate in the design and development of the project, or with a selected Committee Member or Administrator to solicit feedback prior to submitting your project for review. You may provide any individual with Full, Write or Read access.

- Multi-site: Use this option only if your project is a multi-site project and you wish to send a complete and
 independent copy of this project to a Principal Investigator at another site. The local Principal Investigator will be
 able to obtain project documents from the lead site and may modify their copy of these documents (such as
 consent forms) to meet the requirements of their local Board. You will be able to monitor the progress of this
 project at every local site. The other local Principal Investigators will also be able to monitor the progress of this
 project at every local site (including your own).
- Transfer: Transfer your ownership of this project to another user. In doing so you will relinquish all access to this
 project and the designated user will be granted Full access.

To 'Share' your research with team members, they must be registered with IRBNet.org



Select "University of Denver (Colorado Seminary), Denver, CO' from the organization box; click 'Select Organization' and search for registered users with whom you'd like to share this project (i.e. Co-investigators, Faculty Advisor, Research Assistant, etc.) Grant each user a level of ACCESS: Signature Only, Read, Write or Full. To share this project with others, enter their last name and select 'Search'.

You may share this project with other users. Sharing a project consists of three steps:

- 1. Select an organization to display a list of users at that organization.
- Specify the access that you wish to grant each user at that organization.
- 3. Save your changes.



Specify the access that you wish to grant to each user at **University of Denver (Colorado Seminary)**. You should grant each user only the <u>minimum</u> level of access necessary to perform their work on this project.

- Signature Only (Read): Users whose only role is to sign off on project documentation should be granted "Read" access. Users with Read access can view project documentation, communicate with the project team and add their signature. This would typically include advisors, department heads, and other individuals who are required to sign off on the project documentation prior to submission but do not otherwise have a day-to-day role on the project.
- Read: Users that are granted "Read" access can view project documentation, collaborate with other users and add their signature, but may not edit project documents or perform any other administrative functions.
- Write: Users that are granted "Write" access can view and edit project documents, collaborate with other users and add their signature, but may not grant access to other users, submit packages for review or perform any other administrative functions.
- Full: Users that are granted "Full" access can perform all functions without restriction. This includes editing project
 documents, sharing the project with other users, submitting document packages for review and deleting document
 packages. Only Project Owners with day-to-day responsibility for the project should be granted Full access. Users
 with Full access will receive automatic email copies of all project notifications and alerts that are sent to the
 Project Owners.

Search for a User:			Search
	Save	Cancel	

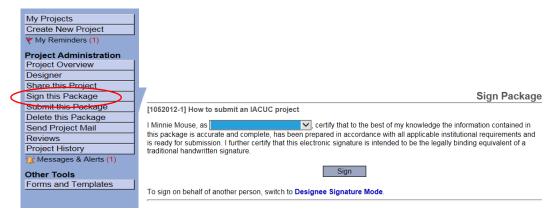
Selected users will be notified automatically via email that the project has been shared with them, and you may enter comments to be included within the email.

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 it is submitted.

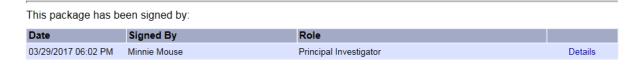


Click on **SIGN THIS PACKAGE** from the Project Administration Menu. Select your appropriate role from the dropdown box and click 'Sign'.



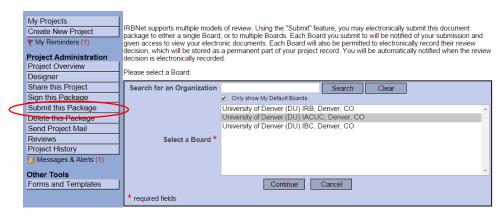
If a submission is submitted without the PI signature the submission will not be accepted for review. For example, if a graduate student completes the application on behalf of the PI, the PI still needs to electronically sign the submission. This requirement verifies that the PI has reviewed and approves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

<u>Please note: The IACUC Office only accepts the **Standard Signature Model** and does not utilized the Designee Signature Mode option.</u>



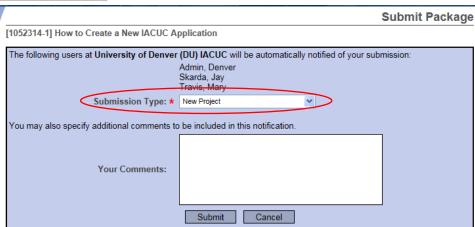
Step 8: SUBMIT PACKAGE

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).



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'.





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.

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.