

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: <u>www.irbnet.org</u> 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.



Login:	Username	Password
	🔔 New User Regis	stration (? Forgot Your 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							M	y Projects
Minnie Mouse	You	ur "My Projects ers on the Natio	workspace shows projects that you nal Research Network. Use Remine	u h der	ave created and s, Tags and Ard	d projects that have hiving to help organ	been shared with ize your workspa	you by other ce and keep it
My Projects Create New Project V My Reminders (4)		Do not	click 'CREATE NEW I	PF	ROJECT'	rch By Tag:		~
Forms and Templates	L					olour		
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	1.0	Create and Manag	e Tags Show Archived Projects (0)				Proje	ect Status View
	٣	IRBNet ID 👻	Project Title		Principal Investigator	Submission Type	Board Action	Effective Date
	٣	1054612-2	How to submit an IRB application	T V	Mouse	Work in progress (Not submitted)	·	
		1052314-1	How to Create a New IACUC Application	T V	Mouse	Work in progress (Not submitted)		
	٣	1052012-2	How to submit an IACUC project	T 74	Mouse	Work in progress (Not submitted)		
	٣	1043036-2	How to submit an IBC Proposal in IRBNet	T 74	Mouse	Continuing Review/ Progress Report	Pending Review	æ
							🚺 🖣 1 - 4 of 4	4 🕨 🚺 10 🗸



Step 3: CREATE NEW PACKAGE

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

Welcome to IRBNet							Proj	ect Overview
winnie wouse	[1052314-1] How to C	reate a New IACUC	Application				_	
😧 Help	You have Full access	to this project. 🜔	dit)					
My Projects	Re	search Institution U	Iniversity of Der	nver (Colorado	Semina	ry) Denve	r, CO	
Create New Project		Title	low to Create a	New IACUC A	pplicatio	n		
Y My Reminders (4)	Prir	cipal Investigator	louse, Minnie					
Project Administration		Sponsor N	IIH .					
Project Overview								
Designer	The documents for this	project can be acces	sect from the D	esigner.				
Share this Project	Project Status as of: 04	/13/2017						
Sign this Package				Initial Approv	al			
Submit this Package	Reviewing Board			Date	ui	Project St	tatus	Expiration Date
Sond Project Mail	University of Denver (DU)	ACUC, Denver, CO				Pending Re	view	
Reviews								
Preira: History								
Create a New Package	Package 1052314-1 is:					🚺 🖣 Pa	ackage 1 of 1	🕨 🔰 Jump 💌
Messages & Alerte			Submission	Submission			Effective	
Other Tools	Submitted To		Date	Туре	Board	Action	Date	
Forms and Templates	University of Denver (DU)	ACUC, Denver, CO	04/13/2017	New Project	Pendir	g Review		Review Details
	Shared with the followi	ng users:						
	User	Organization					Acc	ess Type
	Mouse, Minnie	University of Denver (C	olorado 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.

1	Designer
[1063000] How to submit an IBC project	
Package: 1063000-1 Work in progress (Not subn 1063000-1 (0) Work in progress (Not submitted)	nitted) Id a package description or notes.
Assemble you (0) All Documents	Need Forms? Show Form Libraries Id new project documents, revise existing project documents while m's Training & Credentials to your package. Learn more
Documents i Create a New Package	
There are	e 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?)
	SUBMITTING AN AMENDMEN IRBNet User's Guide for IBC Investigato

Office of Research Integrity & Education, v1, dated April 2017



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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 subr	<u>m</u> itted)
(0) 1063000-1 Work in progress (Not submitted)	d a package description or notes.
Assemble you (0) All Documents	d new project documents, revise existing project documents while m's Training & Credentials to your package. Learn more
Documents i Create a New Package	
There are	→ e no documents in this package.
Start a Wizard Referencing the diagram below, select ' Un Researchers' from the 'Select a Library' dr	OR Attach New Document (When should I do this?) iversity of Denver (DU) IBC, Denver, CO Documents for rop-down menu.
	Designe
[1063000] How to submit an IBC project	
Package: V1063000-1 Work in progress (Not submitted)	
	un lo aux a paunage description or notes.
Step 1: Download blank forms, document templates and reference materia	Is to assist you in assembling your document package.
Library: University of Denver (DU) IBC, Denver, CO	
Select a Form - IBC Amendment Document: Download	



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



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 subm	itted)		
	Click to add a package description or notes.		
Step 1: Download blank forms, document templates and refu	erence materials to assist you in assembling your docum	ent package.	Hide Form Libraries
Select a Library: University of Denver (DU) IBC, Denve	er, CO 🗸		
Select a Form - IBC Amendment Document: Download			~
Step 2: Assemble your document package here. You can ac project team's Training & Credentials to your packag Documents in this Package:	dd new project documents, revise existing project docume je. Learn more	ents while maintaining version	history, and link your
Document Type	Description	Last Modified	
Amendment/Modification Abstract/Summary	Form - IBC Amendment	04/24/2017 12:41 PM	📄 4 🖉 🗙
Adverse Event Report Advertisement Amendment/Modification	o this package. Link / Un-Link Training Records		
Application Form Budget Child Assent	Start a Wizard OR Attach New Docum	(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 imes
- 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 $extsf{Q}$

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.

							Desigr
[1063000] H	low to submit an If	BC project					
Package: 🕚	▼ 1063000-1 Work	in progress (Not submit	ted)				
D			Click to add a	a package di	escription or notes.		
Step 1: Download b	lank forms, docume	ent templates and refe	rence materials to assi	ist you in a	ssembling your document (package.	Hide Form Librar
Select a Library:	University of Der	nver (DU) IBC, Denve	r, CO 🗸				
Select a	Form - IBC Ame	ndment					
Document	Download						
Assemble yo project team	our document packa I's Training & Crede	age here. You can add antials to your package	J new project documer	nts, revise e	existing project documents	while maintaining version h	istory, and link your
Document 1	Гуре		 Description 			Last Modified	
Amendmedia	ent/Modification		Form - IBC Amendme	ent		04/24/2017 12:41 PM	📄 🕘 🤌 🗙
Abstract/	Summary Event Report	^					
The Advertise	ment	ords linked to	this package. Link /	Un-Link Trai	ining Records		
Amendm	ent/Modification						
Applicatio	n Form					_	
Budget			Start a Wizard	OR	Attach New Document	(When should I do this?)	
0.11.1			otarea		Fillaci How Document		

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'.

My Projects	
Create New Project	
Y My Reminders (2)	
Project Administration	
Project Overview	Sign Package
Designer	10/43036-11 How to submit an IBC Proposal in IRRNet
Share this Project	
Sign this Package	I Minnie Mouse, as Principal Investigator
Submit this Package	this package is accurate and complete, has been prepared in accordance with all applicable institutional requirements and
Delete this Package	is ready for submission. I further certify that this electronic signature is intended to be the legally binding equivalent of a
Send Project Mail	traditional handwritten signature.
Reviews	
Project History	Sign
1 Messages & Alerts (2)	
Other Tools	To sign on bobalf of another person, switch to Designed Signature Mode
Forms and Templates	ro sign on benan or another person, switch to besignee signature would.

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.

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

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).

	My Projecto	Submit Package
	Create New Project	[1043036-3] How to submit an IBC Proposal in IRBNet
	W Perminders (2)	IDPNat supports multiple models of review. Using the "Submit" feature, you may electronically submit this document
	Y My Reminders (2)	package to either a single Board, or to multiple Boards. Each Board you submit to will be notified of your submission and
	Project Administration	given access to view your electronic documents. Each Board will also be permitted to electronically record their review
	Project Overview	review decision is electronically recorded.
	Designer	Please select a Board
	Share this Project	
	Sign this Package	Search for an Organization Search Clear
¢	Submit this Package	Only show My Default Boards
	Delete this Package	University of Denver (DU) IRB University of Denver (DU) IACUC
	Send Project Mail	University of Denver (DU) IBC
	Reviews	Select a Board *
	Project History	
	1 Messages & Alerts (2)	
	Other Tools	Continue Cancel
	Forms and Templates	* required fields



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 submit Admin, Denver	ission:
	Skarda, Jay Travis, Mary	
Submission Type: *	Amendment/Modification	
You may also specify additional comments to	be included in this notification.	
Your Comments:		
	Submit Cancel	

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 De 03/20/2017.	enver (DU) IBC, Denver, CO on
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.