GW iRIS

Reference Guide: Submitting Amendments/Terminations/Renewals/Incident Reports for an IBC Study(s)

If you need to submit an additional form to an IBC study - including an amendment, termination, renewal or incident report - there are two ways to access the necessary forms:

Option 1: From "Submit a Form"

1) Go to "Submit a Form" (under "Study Assistant") and next to the study that requires an update/modification, click the icon under "Submit a New Form."

Form Submiss	sion				🖪 Back
Display my Studies by IBC Number ▼		ly Used Studies: Jdies by study status:	Find by IBC Number: Find by Short Title:		Find
11 result(s) found		Short Title	Derivering 1		1 - 11
Study Status	IBC Number	Study Title	Principal Investigator	Submit a New Form	Finish an Incomplete Form
Active IBC-19-15		Test IBC Protocol	Researcher, GW		4
		Test IBC Protocol			

2) A pop-up will then display requesting that you select a form to start. Click on the form you wish to submit



3) Complete the form by answering each question, clicking "Save and continue to next section" through the application, and signing off and submitting for review

Option 2: From "My Studies"

1) Go to "My Studies" (under "Study Assistant") and next to the study that requires an update/modification, click "Click to open"

Му	Studie	s						
by:	r my Studie	Filter	Recently Used Stud my Studies by stud le Studies that have		Find by IBC d an Number:			Find
IBC Nu	umber •	IBC N Show Hi	umber dden Studies 🔍 Ye		Find by Short Title:			Find
Click	View							
		Study		IBC	Short Title	Principal	Copy	
to open	Details	Study Status	IBC Number	IBC Expiration	Short Title Study Title	Principal Investigator	Copy Study	Hide
			IBC Number					Hide

2) Select the form that you would like to submit and click on it

IBC Number: IBC-19-15 PI: Researcher, GW	Submissio	ns				
Study Status: Active	IBC Number :	IBC-19-15	Study Title	: Test	IBC Proto	col
Submissions Study Ma	inagement					
		Current App	proval Packet			
Protocol Items				Su	bmission	s History
				Stu	udy Corre	sponden
Study Application						
Informed Consent	•			2	Outstand	ling Subm
Other Study Docume	nts 🕨			Track Location	Ref Number	Request
Submit a form below to rep	ort a change:			There are	no outsta	anding sub
IBC Amendment Form	n					
IBC Annual Renewal						
IBC Incident Reportion	ng					
IBC Protocol Termina	ntion					

3) Click "Add a New Form" to start a new form

IBC Number: IBC-19-15 IBC Amendment Form									
Study Status: Active IBC Number : IBC-19-15 Study Title : Test IBC Protocol									
					Copy Form	🕒 Add a New	Form	npare Two Versions	Delete Selected Form(s)
				orm: IBC Am in the folder i	endment Form icon <u> </u> .				
0 result	(s) found.								
F	Show Rev	Edit/ View	Form Number	Sub. Rounds	Track Location	Process Submission	Submission Date	Created By	Date Created

Submitting an IBC Amendment Form

If you selected 'IBC Amendment Form,' you will be brought to the GW IBC Amendment form. Make the necessary updates to each section of the application and click "Save and Continue to Next Section" to move through the form. In Section 2, you will select the type of protocol change and will update the associated information. For all changes except changes to Current Personnel, you will be asked to revise the application.



Revising the application

You revise the application in Section 2.2 – Revise the application to reflect all proposed changes.

• Select "Click here to attach the application"



• If you have already modified the existing application, you can select the updated application and click "Save Attachment"

Attaching Study Application						
0	Selec	t the a	pplication that you would like to attach and then click Save Attachment	Ø Save	e Attachment	
Select	Act Rev. View Form Name Form Name Create a Approved Revised Application					
۲	-		GW IBC Protocol (Version 1.1)	No		

• If you have not modified the existing application, you can modify it from the Amendment Form by selecting "Add Revision"



- You will then update the application (note that it will create a new version of the application 1.1 or 1.2, etc. and will save the prior version).
- To get back to the Amendment Form from the revised application, either click "Back" (in the upper right corner) or go to the final section "Application Complete" and click "Save and Continue to Next Section."
- Attach any other documentation in section 2.3 and confirm that the Amendment form has been updated properly, then select "Save and Continue to Next Section" and "Signoff and Submit". If you are completing the form on behalf of the PI, you will get the option to "Notify the PI to Signoff"
- On the Submission Routing Signoff page, you will need to check the box under "PI Assurance", select whether you "Approve" or "Deny" and click "Save Signoff"

Submission Routing Si	gnoff		🖪 Back
		1	Save Signoff
Study Title:	Test IBC Prot	ocol	
Submission Reference Number:	001808		
			Printable Version
Submission Form(s)	Include in PDF Packet	Submission Component Name - Version	
Sabinasion Form(s).	Submission	n Form(s)	
		IBC Amendment Form - (Version 1.0)	
	Application		
		GW IBC Protocol - (Version 1.1)	
Principal Investigator:			
by electronically signing the tems.	is form, you a	re indicating verification that all items on this form are accurate and you agree to ensure compliance with all	
GW Researcher as Principal Investigator do you Approve or Deny this submission?		Deny	
		Save Signoff	

Please note that once you have submitted an amendment form, you will need to wait for approval of the updated application before submitting another version. If you realize after submission that you have another modification to include, you can "retract" your application up until the review process begins (see instructions on p. 6 of this reference guide for how to retract).

Special note for existing studies (open prior to 2/1/2019): If you had a study approved prior to 02/01/2019, only the title and a few basic data points have been added to iRIS. In order to have an application to update/add for an amendment form, you will first need to build your application in the iRIS system. Steps to do this:

1) Go to "My studies" (under "Study Assistant")

Study Assistant 🕕					\$
Add a New Study	My Studies	Submit a Form	My Current Approvals	Upcoming Renewals	

2) Find the study for which you would like to submit a form, clicking the link to open the study (found under the "Click to open" column)

	Click	View	Study	IBC Number	IBC	Short Title	Principal		Сору	
	to open	Details	Status	IBC Number	Expiration	Study Title	Investigator	5	Copy Study	Hide
	X	Ŧ	Active	IBC-19-15		Test IBC Protocol	Researcher, GW		P	Ð
						Test IBC Protocol				
) Sel	ect S	I	Applicati BC Number: PI: Researcher	IBC-19-15 ; GW	Submissi	ons				
			Study Status:	Active		IBC Number :	IBC-19-15	Study Title :		
		ĺ	Submission	s Study Ma	inagement					
							Curre	ent Approval Packe	et	
			Protocol Ite	ms						
					-					
			Study	Application						
			Infor	med Consent	•					
			-	med Consent					_	

4) Click "Add a new Application" (on right side of screen)

🔁 Add a new Application

- 5) Select "GW IBC Protocol" and click "Start selected Application." Some basic information about the protocol (title, PI, department) will be pre-populated but should be confirmed and/or updated as necessary. All other sections will need to be populated.
- 6) Once you have completed the application, you will go through approving the application as you do when initially building an application.
- 7) You can then add an amendment and when you get to section 2.2 and "Click here to attach the application", select the application you just built to add to the study and click "Save attachment"

Checking the status of a form or retracting a submitted form can be done by going to My Studies and either selecting the '+' under "View Details" then clicking "Track Location" <u>or</u> by clicking the icon under "Click to Open" under "My studies". In the bottom right corner of the Submissions page, it will show

outstanding submissions. You can click the is icon to see the current status or "Retract Submission" to retract the submission

Click to View		w	s	tudv			lumber	IB	с	Sho	ort Title	Pr
open	Det	ails	S	tatus		IBC	umber	Ex	piration	Stu	dy Title	In
X	E			Active		IBC-1	9-15				IBC Protoco ng update	l- Res
										Test	IBC Protoco	1
Subi	niss	ions in P	rocess		Comple	ted Su	bmissio	ns	Submis	sion	s Returned	with Chan
Referer Numb		Track ocation	Status	F	Request Ty	pe	Details	F	Review Board	1	View Outcome Letters	Revie Proce
001808				IBC /	Amendment	Form						
			0		BC Amendi orm	nent	₫	IBC				

View of the "My studies" page



"Outstanding submissions" section of the "Submissions" page. You get to this by clicking the icon under "Click to open" from the "My studies" page

Submitting an IBC Annual Renewal Form

1) Select the IBC Annual Renewal Form

Subn	Submit a form below to report a change:					
۲	IBC Amendment Form					
۲	IBC Annual Renewal					
۲	IBC Incident Reporting					
۲	IBC Protocol Termination					

 Respond to the questions. In Section 2.0, you will be asked to update personnel and information on controls. If you indicate you are making a change to the current protocol, you will be asked to submit a modified application (following the instructions for "submitting an IBC Amendment Form").

IBC Number: IBC-19-15 PI: Researcher, GW	C Annual Renewal - (Version 1.0)	💽 Back
Print F	riendly ORefresh Constant Fields Save Section	Save and Continue to Next Section
George Washington 1.0 University Annual Renewal of a Biosafet	2.0 Annual Update Inform 2.1 Personnel Information:	nation

 Click the "Save and Continue" button in the upper right corner and go through the steps to "Signoff and Submit" the form

Submitting an IBC Incident Report

1) Select the IBC Incident Reporting



- 2) Respond to the questions in Sections 1.0 and 2.0
- Click the "Save and Continue" button in the upper right corner and go through the steps to "Signoff and Submit" the form

Submitting an IBC Protocol Termination

1) Select the IBC Protocol Termination

Subm	Submit a form below to report a change:						
	IBC Amendment Form						
•	IBC Annual Renewal						
۲	IBC Incident Reporting						
۲	IBC Protocol Termination						

- 2) Respond to the questions in Sections 1.0 and 2.0
- Click the "Save and Continue" button in the upper right corner and go through the steps to "Signoff and Submit" the form

Starting a Form and Returning to it at a Later Date

If you start one of the IBC forms and want to return to it later to complete and/or submit it, you can access it one of two ways:

1) From the homescreen, go to "Submit a Form" and select "Finish an Incomplete Form". Find the form you want to complete and click the icon under "Edit/View"

ľ	Show Rev	Edit/ View	Form Number	Sub. Rounds	Track Location	Process Submission	Submission Date	
			1.0			> Send		

 From the homescreen, go to "My Studies" and click the icon under the "Click to Open" column. In the bottom right corner, under "Outstanding Submissions", click the link to the form to access it again

2	Outstanding Submission(s)					
Track Location	Ref Number	Request Type	Process Submission			
	001811	Click on the hyperlink to edit/view	Send			
		IBC Protocol Termination	Submission			

If you have any questions or need any additional assistance, please contact the Office of Lab Safety at 202-994-8258 or email <u>labsafety@gwu.edu</u>.