

VERAS Guide - IBC Amendment Manual

Introduction

This manual will guide you through the process of creating and submitting an IBC Amendment to an already approved protocol. Any change to the protocol must be approved by the IBC prior to implementation. Amendments may include but are not limited to, changes in procedures/methods, personnel, agents used, lab location, etc. Not all amendments require full committee review. Some may be approved administratively in accordance with the IBC policy. Contact the IBC (208-885-7258 or ibc@uidaho.edu) if you have any questions.

Please Note: questions with a red asterisk * are required for submission and sign-off. Validation checks at the end will take you back to any items missed for completion.

If you need to add personnel AND submit an amendment to your protocol, you must submit an *IBC - Personnel Change Only* form and receive approval for the personnel change before submitting an *IBC - Amendment Form*.

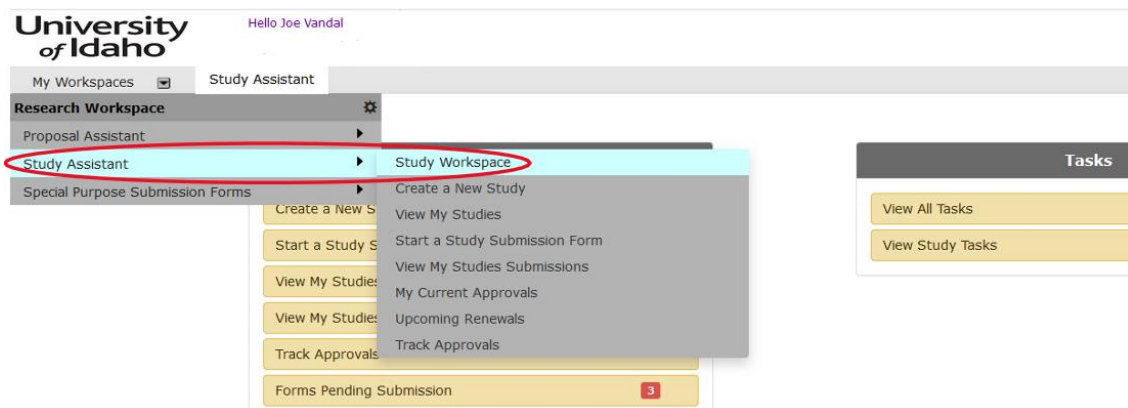
Let's get started!

Login

<https://veras.uidaho.edu/>, use your UI Network ID and password to login.

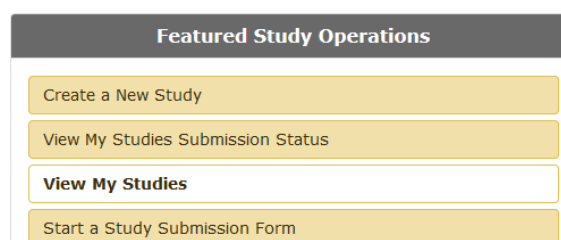
My Workspaces

You will need to work under the Study Assistant workspace. If you are not there, place your cursor over "My Workspaces", then highlight and select Study Assistant.



Amendment Form Location

1. Under the Featured Study Operations panel, select "View My Studies" or scroll down to "All Studies"



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IBC Studies		Recently Used	Study Status		Search for RB Number, Title, Alias		Search	
All		Draft		IRB		IACUC		
5 result(s) found...								1 - 5
Click to open Study Dashboard	Study Status	Review Board	RB Number	RB Expiration	Study Title	Principal Investigator	Actions	
					Short Reference Title			
	Open	IBC	IBC-20027	06/10/2023	Test 5/4	Vandal, Joe		
	Pending - Submitted for Initial Review	IBC	IBC-20020	06/10/2023	Test 5/4	Vandal, Joe		
					Test 5/8/2020 BME			
					5/8/2020 - test 5.9			



2. Locate the protocol row you want to amend, select **Forms** under the **Action** column.
3. A pop-up window will appear showing *IBC Renewal, Amendment & Closure Forms*, locate the *IBC – Amendment Form* or if you are making any personnel changes (additions or removals), you must submit an *IBC - Personnel Change Only* form, select the option below that applies:

- to start a new Submission for the form you want
- to finish an incomplete form
- to see the versions of the form you currently have

IBC - Amendment Form Components

The *IBC - Amendment Form* has five sections, and you will need to address all required components before completing and submitting the form to the IBC. If you are making any personnel changes you must submit an *IBC - Personnel Change Only* form and receive approval for the personnel change before submitting an *IBC - Amendment Form* updating their roles and materials they will be handling.

Section 1.0 Institutional Biosafety Committee Application for Protocol Modification

Section 1 auto-populates most of the study's general information: PI, Study Contact, IBC Protocol #, Study Title, Original Approval Date, Full Renewal Expiration Date, and the date the amendment is prepared. Select **Save and Continue to Next Section**, to move forward in the form.

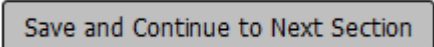
Section 2.0 Modification Request

In section 2, you will identify what category of changes you are requesting. Changes in:

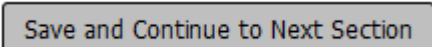
- Protocol Title
- Funding Source
- Location
- Animal Activities/Materials
- Biological Agents (Not Recombinant DNA)
- Biological Toxins (Not CDC Select Toxins)
- CDC Select Agents & Toxins
- EAR / ITAR Cat XIV

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- Human Subjects Research
- Plant Activities (Including Plant Pathogens and Pests)
- Recombinant DNA
- Permits (e.g., USDA APHIS, CDC, etc.)
- Other, if you select “Other” a text box will appear where you will need to identify what other change you are requesting.

Select  , to move forward in the form.


Section 3.0 *Description and Justification of Modification Request*

In section 3, you will describe the modification you are requesting and justify the request. Once answered, select  , to move forward in the form.

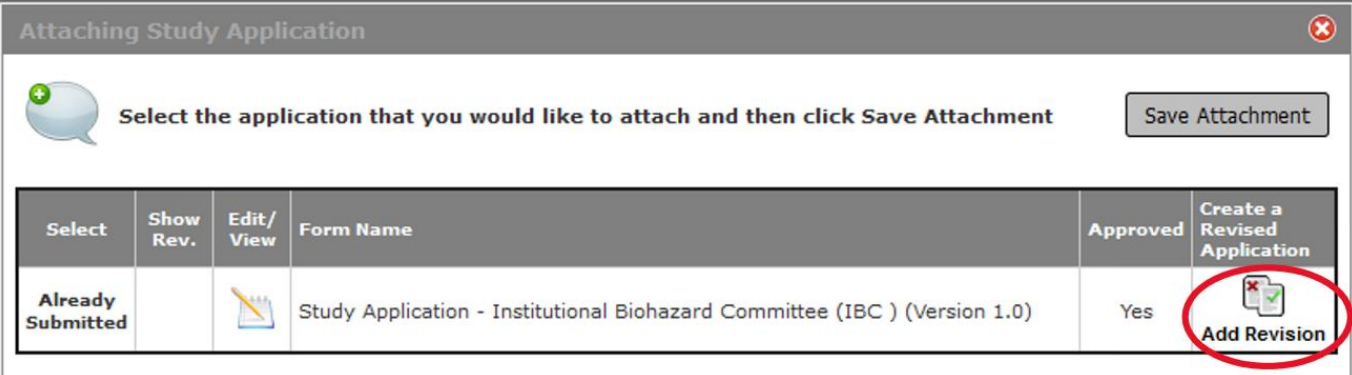
Section 4.0 *Revised Study Application*

In section 4, you will revise the Study Application/protocol, so the newest version incorporates the details of your amendment request and link it to the amendment submission.


1. Select “Click here to attach the application”

 [Click here to attach the application.](#)

2. Select “Add Revision”.

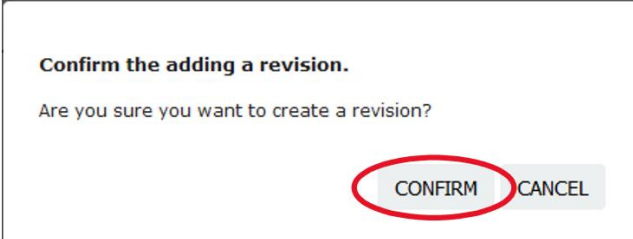


The dialog box titled "Attaching Study Application" contains a message: "Select the application that you would like to attach and then click Save Attachment" with a "Save Attachment" button. Below is a table with columns: Select, Show Rev., Edit/View, Form Name, Approved, and Create a Revised Application. The table has one row for "Study Application - Institutional Biohazard Committee (IBC) (Version 1.0)" which is marked as "Approved" (Yes). The "Create a Revised Application" column for this row contains an icon of a document with a checkmark and the text "Add Revision", which is circled in red.

Select	Show Rev.	Edit/View	Form Name	Approved	Create a Revised Application
Already Submitted			Study Application - Institutional Biohazard Committee (IBC) (Version 1.0)	Yes	 Add Revision

You will need to create a revision and click the icon in the **Create a Revised Application** button. Note: this icon is only available in the most current version of the application.

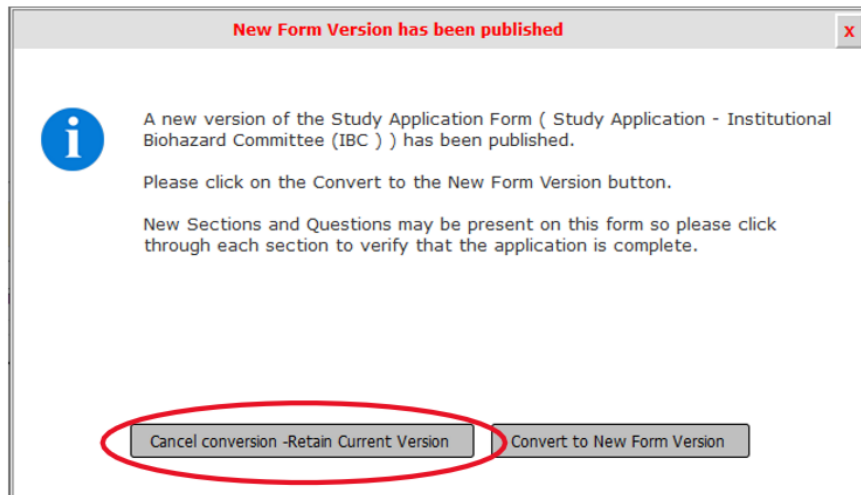
3. Confirm you want to create a revision of your Study Application

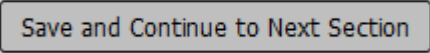




The dialog box contains the text: "Confirm the adding a revision." followed by "Are you sure you want to create a revision?". At the bottom, there are two buttons: "CONFIRM" and "CANCEL". The "CONFIRM" button is circled in red.

4. If a pop-up appears informing you that a “New Form Version has been Published” make sure you select “Cancel Conversion – Retain Current Version.”

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5. A version of the study application allowing edits will open. You will need to make the applicable updates to your study application, which you have indicated in your amendment form.
 - a. Make sure you save your section or  when you are making changes.
 - b. Once updated, select the **Back** button, in the top right corner of your web browser, to return to the Amendment form.
6. When you return to the amendment form, the revised study application will be listed in the Application Attachment table.
 - a. If the study application needs additional editing, select the pencil/paper icon in the **Edit/View** column, to reopen the study application and continue to update it accordingly.

Unattach	Revise/ Attach	Edit/ View	Title
			Study Application - Institutional Biohazard Committee (IBC) (Version 1.1)

- b. If you need to detach the application, click the icon in the **Unattach** column. This will not delete this version of the application; it will simply remove the version from the amendment form.

Section 5.0 Submission

In section 5, you can attach or update additional or other study documents (e.g., permits, SOP's, Maps, etc.)

5.0 Submission

5.1 Attach additional documents (if any) here:

Select or Revise Existing

Add a New Document

Add Multiple Documents

Detach	Version	Title	Category	Expires
No Document(s) have been attached to this form.				

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You can choose to add or revise any existing document on your study, or you can add a brand-new document.

Once all documents are updated and added select

Save and Continue to Next Section

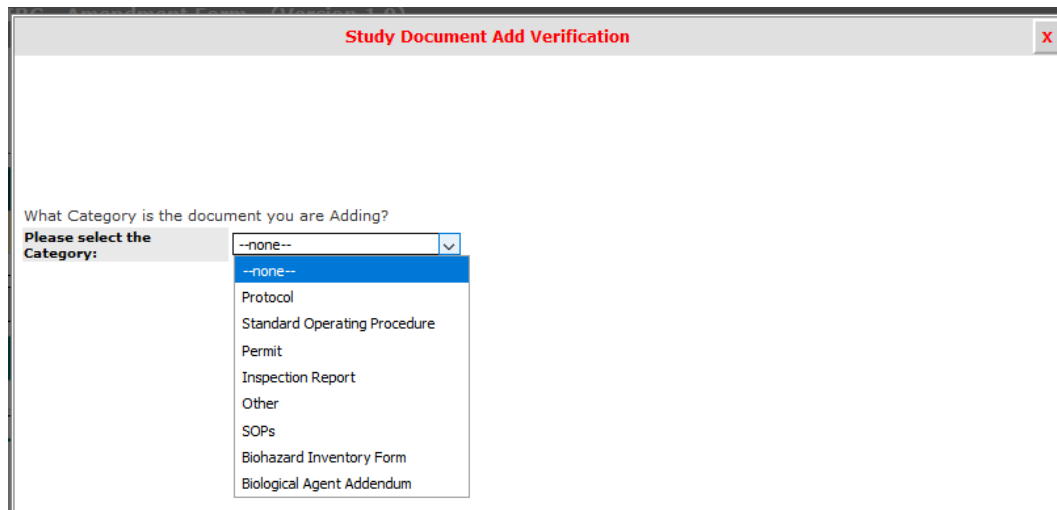
How to add New Documents

Select

Add a New Document

Select the *Category* for the document, then select

Proceed with Document Upload



Complete the addition by “drop file” or upload the documents and entering in the applicable information,


Save Document


How to update an “Other Study Document”

To revise an existing document, click the

Select or Revise Existing

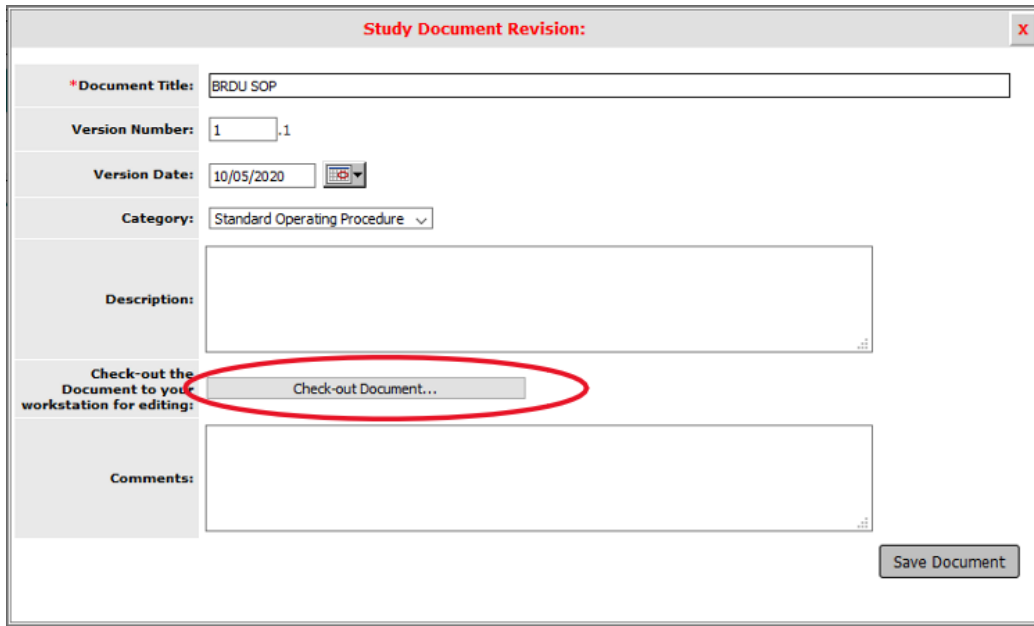
button.

A window will open within the browser that lists existing documents for this protocol. If you have already made changes, you can choose a document to attach by clicking the  in the **Select** column.

If you have not yet modified the document, you will click the  in the **Create Revision** column.

The window will refresh and populate with details of the document you are revising, allowing you to change details and checkout the revised document. Click the **Check-out Document** button.

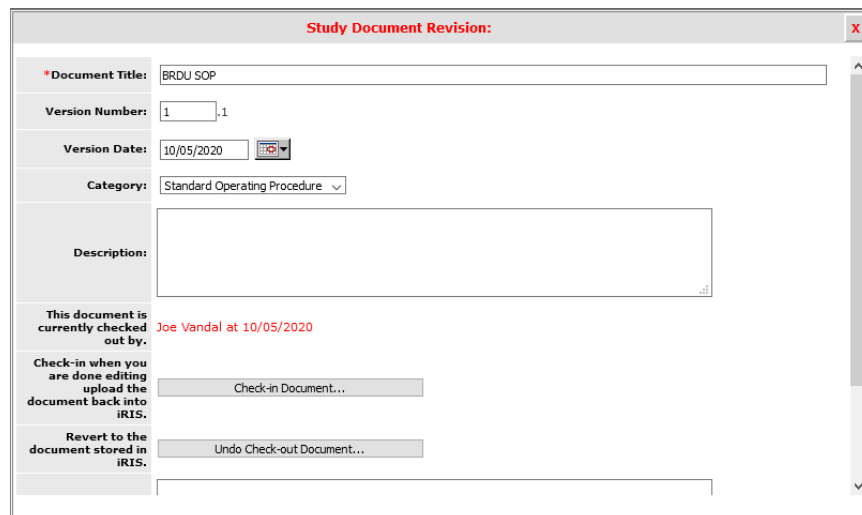
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A window will open, confirming that you want to check-out the document. Click **Confirm**. The document should automatically download. Note: different internet browsers might function differently in the way they process downloaded files.

Save the document in a safe and known location so that you can check it back into the system when complete.

You will return to the Study Document Revision page. The page will indicate the document is checked out and you will have the ability to **Check-in Document** or **Undo Check-out Document**.



After you have made changes to the document in Microsoft Word, you can check it back in by clicking the **Check-in Document...** button.

A window will open, allowing you to browse your computer for the updated document you would like to upload. Click the **Save selected file** button once you specify the document location.

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1.

Document Location: **Browse...** BRDU SOP (2).docx

Instruction: Uploading a document into iRIS™ requires locating the document on the computer. Once you have located the document click on the 'Save selected file' button. The buttons will become disabled. If the document is a large document the window will stay in place until the upload operation has completed.

2.

Save selected file Cancel

You will then be returned to the Study Document Revision window with the document successfully checked in and associated to the study. Click the **Save Document** to apply the changes.

Study Document Revision:

*Document Title: BRDU SOP

Version Number: 1 .1

Version Date: 10/05/2020

Category: Standard Operating Procedure

Description:

Check-out the Document to your workstation for editing: Check-out Document...

Comments: Updated contact information

Save Document

You will return to the form, and any document you selected will display in the table.

Select or Revise Existing			Add a New Document		Add Multiple Documents		
Detach	Version	Title	Category	Expiration Date	Document Outcome	Checked Out	View Document
	1.1	BRDU SOP	Standard Operating Procedure				11.43 KB

Final Step - Signoff and Submit

- A summary of the submission will be displayed.
- For your personal record, you can save the form into a single pdf document:
 - Check the boxes under the 'Include in PDF Packet' column for each document you want to be included in the single pdf.
 - Create a single pdf by selecting the 'Printable Version' icon.
- Under the *IBC Principal Investigator Agreement*, select 'Approve' and submit your form by clicking on the 'Save Signoff' button

1.

Joe Vandal as Principal Investigator
do you Approve or Deny this submission? ☒ Approve ☐ Deny

Comments: Click here to add comments.

2.

Save Signoff

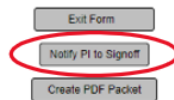
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- Once submitted, the PI and Study Contact will receive an auto-generated confirmation email of the submission.

Note: Other study roles may author any of the IBC forms. Instead of seeing the approve and signoff as above, other study roles besides the PI will need to select “Notify PI to Signoff.” The PI will receive an email and home screen task notification to review and signoff on the submission. The PI must signoff on the submission before it is sent to the IBC for review and approval.

Form has been Completed!

Please select the Signoff button below to submit your application/form. ** Note: you must still proceed to the next page to complete your signoff and start the routing process.



IBC - Personnel Change Only Form Components

If you need to request personnel changes (adding or removing study personnel), you will need to complete the *IBC- Personnel Change Only* form. This form will look similar to Section 2.0, *Key Personnel*, of the Study Application, where you add personnel to the study. Any user added to the study will have the ability to access the study in VERAS but not until the submission receives approval of the change in personnel.

Once the committee approves the personnel change, a new version of the application will be created to reflect the newly updated personnel.

Please Note: If you need to add personnel AND submit an amendment to your protocol, you must submit an IBC - Personnel Change Only form and receive approval for the personnel change before submitting an IBC - Amendment Form.

Anyone working on or with export-controlled items EAR and ITAR Category XIV or select agents, will need to be added as study personnel to the protocol. You must submit an *IBC - Personnel Change Only* form and receive approval for the personnel change before submitting an *IBC - Amendment Form* updating their roles and materials they will be handling.

To Add a User

To add a user, select the **Add** button next to the corresponding role:

Principal Investigator – You can only have one Principal Investigator listed on the study. If you are requesting a change in PIs, select the first **Add** button, highlighted in green, add the desired PI to the form, and when the review board approves the change, the system will change the PI.

Additional Investigators – Any new investigator user for the study, aside from the Principal Investigator, can be listed here, by selecting the second **Add** button, highlighted in green. You may have any number of Additional Investigator's, and after you add a user to this group, you will be able to specify their role title.

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Research Support Staff – This section is for any non-investigator users (e.g., Post Docs, Grad Student, Undergrad, Technician, Lab Manager...) that needs to be added to the study, select the third **Add** button, highlighted in green. You may have any number of research support staff listed here, and after you add a user to this group, you will be able to specify which role title they have.

Study Contact – You may add additional Study Contacts as needed, select the fourth **Add** button, highlighted in yellow/orange. A Study Contact is a user on the study who will receive study related notifications from the system (e.g., Submission Correction notifications, Review Response notifications, Submission Outcome Letters...). The PI should be listed as the Study Contact. Examples of additional Study Contacts would include the Lab Manager or Co-PI.

If applicable, please add the new Principal Investigator for the Study:		
	Add	
If applicable, please select the new Research Staff personnel:		
A) Additional Investigators	Add	
B) Research Staff	Add	
If applicable, please add any new Study Contact:		
	Add	
The Project Contact(s) will receive all important system notifications along with the Principal Investigator. (e.g. The project contact(s) are typically either the Study Coordinator or the Principal Investigator themselves).		
If applicable, please select any existing Personnel you wish to remove:		
	Select	

Once the **Add** button is selected, the system will direct you to the VERAS User Directory, where you will search by First name, Last name, or Department, then click the **Find** button.

Note: If you cannot find the personnel in the VERAS User Directory, please let them know they will need to try to log into [VERAS](#) with their UI Network ID and Password. If they don't have an account, the system will direct them to create one. Once they have an account, you will be able to find them in the VERAS User Directory to add to the submission request.

To select a user to add, click the **Select User** icon. This selects the user and brings you back to the *IBC- Personnel Change Only* form. You can select more than one user by checking the boxes next to the users and then click the **Save Selected User(s)** button.

My Workspaces

Study Assistant

Search User Directory

Back

Save Selected User(s)

Directory Browse/Find:

Last Name: m (You may enter a partial name to search)

First Name:

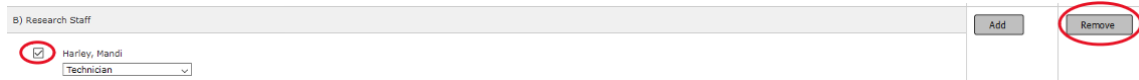
by Department: All Departments

Find

Check for Multiple	Select User	Training	User Name	Department	Email
<input type="checkbox"/>	<input checked="" type="checkbox"/>		Madsen, Joshua	Research (primary)	
<input type="checkbox"/>	<input checked="" type="checkbox"/>		Magat, Jenna-Marie E	Research (primary)	
<input type="checkbox"/>	<input checked="" type="checkbox"/>		Maggs, Sarah k	Research (primary)	ismaggs@uworld.com
<input type="checkbox"/>	<input checked="" type="checkbox"/>		Maglione, Jeanne E	Research (primary)	
<input type="checkbox"/>	<input checked="" type="checkbox"/>		Mahata, Mangula	Research (primary)	

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If you added a user to the data value by mistake, you can remove the request by selecting the checkbox next to their name and then clicking the **Remove** button in that same group.



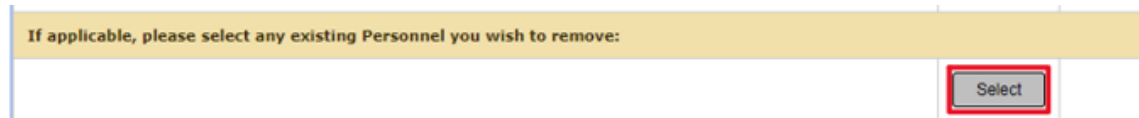
B) Research Staff

<input checked="" type="checkbox"/>	Harley, Mandi Technician
-------------------------------------	-----------------------------

Add Remove

To Remove a User

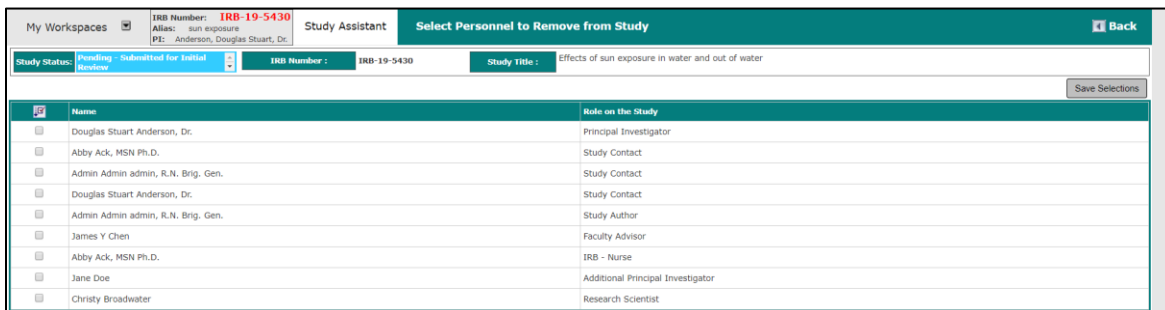
At the bottom of the Personnel Change Request is an area where you can request the removal of personnel from the study. Click the **Select** button in this group highlighted in red.



If applicable, please select any existing Personnel you wish to remove:

Select

A new page will open that lists the current personnel on the study. Select the user(s) you would like to remove from the study, then click the **Save Selection** button.

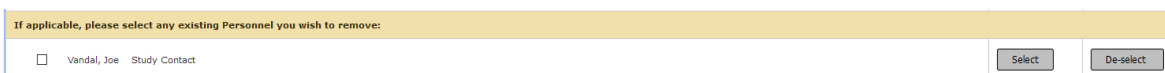


My Workspaces IRB Number: IRB-19-5430 Study Assistant Select Personnel to Remove from Study Back

Study Status: Pending - Submitted for Initial Review IRB Number: IRB-19-5430 Study Title: Effects of sun exposure in water and out of water Save Selections

Name	Role on the Study
<input type="checkbox"/> Douglas Stuart Anderson, Dr.	Principal Investigator
<input type="checkbox"/> Abby Ack, MSN Ph.D.	Study Contact
<input type="checkbox"/> Admin Admin admin, R.N. Brig. Gen.	Study Contact
<input type="checkbox"/> Douglas Stuart Anderson, Dr.	Study Contact
<input type="checkbox"/> Admin Admin admin, R.N. Brig. Gen.	Study Author
<input type="checkbox"/> James Y Chen	Faculty Advisor
<input type="checkbox"/> Abby Ack, MSN Ph.D.	IRB - Nurse
<input type="checkbox"/> Jane Doe	Additional Principal Investigator
<input type="checkbox"/> Christy Broadwater	Research Scientist

Any user you selected to be removed will be listed in this group. If you selected a user to remove in error, select the checkbox next to their name and click the **De-select** button.



If applicable, please select any existing Personnel you wish to remove:

☐ Vandal, Joe Study Contact

Select De-select

Signoff and Submit

Signoff and Submit the *IBC- Personnel Change Only* form following the steps previously detailed. Any change in personnel will not take effect on the study until the review board approves the request. This means that any user requested in the study will not have access to the study until the review board approves their role.

Once the committee approves the personnel change, a new version of the application will be created to reflect the newly updated personnel.

Please contact the IBC ((208)-885-7258 or ibc@uidaho.edu) if you have any questions.