

VERAS Guide - IBC Amendment Manual

ATTENTION: During the transition into VERAS, if you need to submit an amendment and your protocol has not been converted into the VERAS interactive *IBC - Study Application* yet, please contact biosafety@uidaho.edu before you start on your amendment submission.

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.

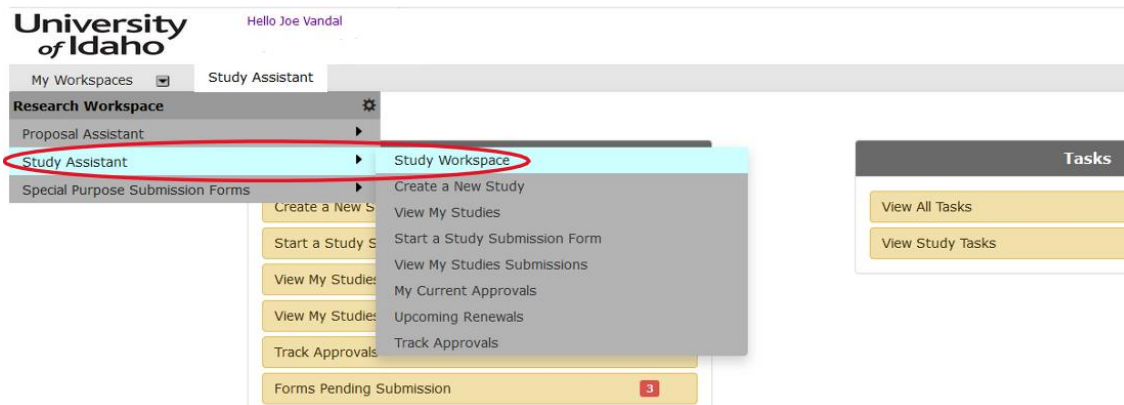
Let's get started!

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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Featured Study Operations

Create a New Study

View My Studies Submission Status

View My Studies


Start a Study Submission Form




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 6/4	Vandal, Joe	
	Pending - Submitted for Initial Review	IBC	IBC-20020	06/10/2023	Test 6/4	Vandal, Joe	
					Test 5/8/2020 BME		
					5/8/2020 - test 9,9		

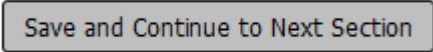
2. Locate the protocol row you want to amend, select  **Forms** under the **Action** column.
3. A pop-up window will appear showing *IBC Renewal, Amendment & Closure Forms*, locate the *IBC – Amendment Form* or if you are making any personnel changes (additions or removals), you must submit an *IBC - 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 for personnel working on or with export controlled items [EAR](#) and [ITAR Category XIV](#) or select agents, 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  , to move forward in the form.

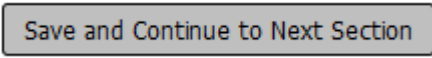
Section 2.0 Modification Request

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

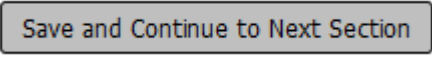
- Protocol Title

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- 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
- 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.

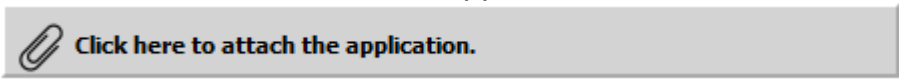
Section 3.0 Description and Justification of Modification Request

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

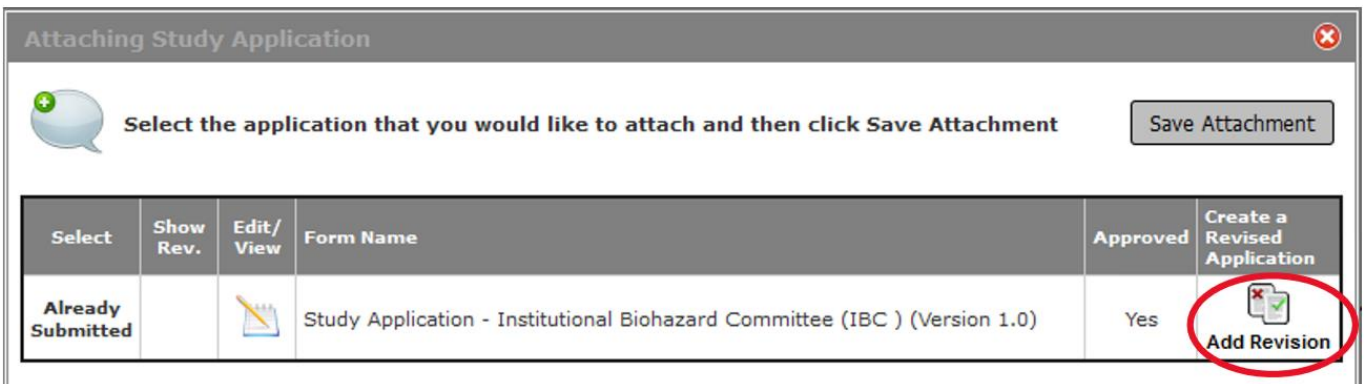
Section 4.0 Revised Study Application

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”



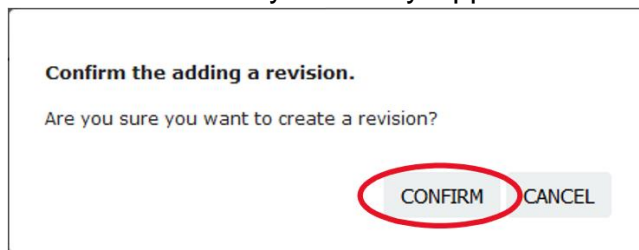
2. Select “Add Revision”.



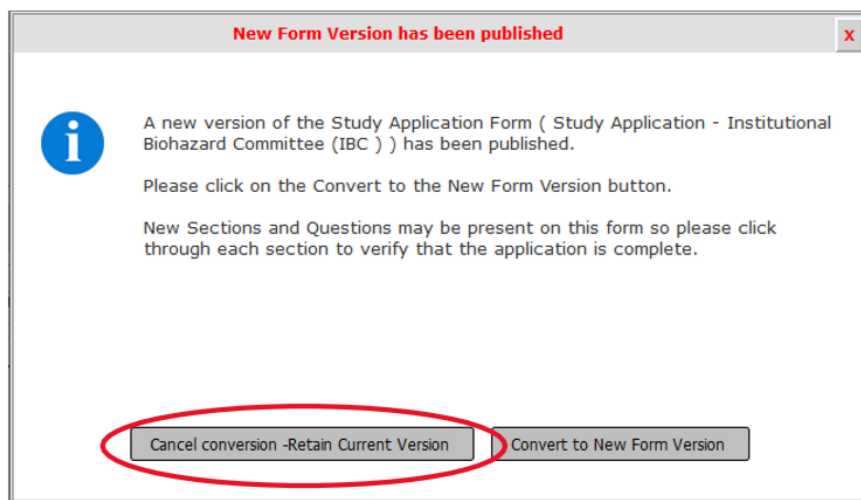
The current version of the Study Application cannot be modified if it has been submitted for review. When you click the pencil/paper icon in the **Edit/View** column, the application will open, but because it has been submitted, you cannot modify it or add it to the Amendment form. You will need to create 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.

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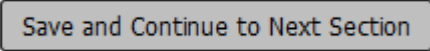
3. Confirm you want to create a revision of your Study Application



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.”





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.

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Section 5.0 Submission

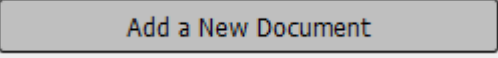
In section 5, you can attach or update additional or other study documents (e.g., permits, SOP's, Maps, etc.)

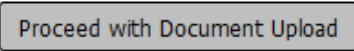
The screenshot shows the '5.0 Submission' section. Below the header is a yellow box with the text '5.1 Attach additional documents (if any) here:'. Underneath are three buttons: 'Select or Revise Existing', 'Add a New Document', and 'Add Multiple Documents'. Below these buttons is a table with columns: 'Detach', 'Version', 'Title', 'Category', and 'Expiration'. The table is currently empty, with a message below it stating 'No Document(s) have been attached to this form.'

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

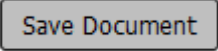
Once all documents are updated and added select .

How to add New Documents

Select .

Select the *Category* for the document, then select .


The screenshot shows a dialog box titled 'Study Document Add Verification'. It contains the text 'What Category is the document you are Adding?' and 'Please select the Category:'. A dropdown menu is open, showing the following options: '--none--', 'Protocol', 'Standard Operating Procedure', 'Permit', 'Inspection Report', 'Other', 'SOPs', 'Biohazard Inventory Form', and 'Biological Agent Addendum'.


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

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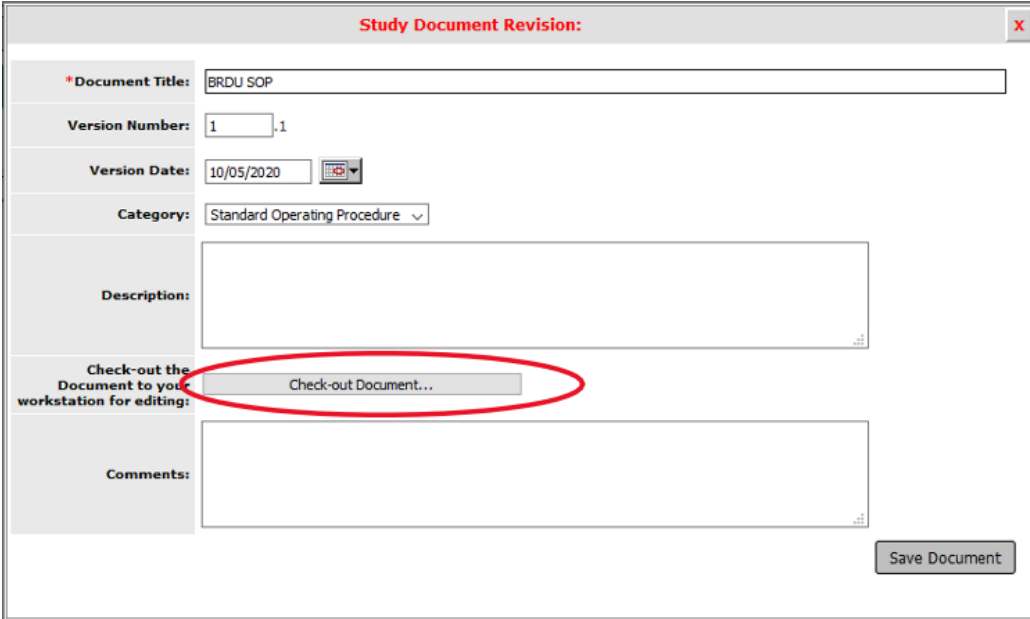
How to update an “Other Study Document”

To revise an existing document, click the  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.



The screenshot shows a web-based form titled "Study Document Revision:". The form includes the following fields and controls:

- * Document Title:** Text input field containing "BRDU SOP".
- Version Number:** Text input field containing "1" followed by ".1".
- Version Date:** Text input field containing "10/05/2020" with a calendar icon to its right.
- Category:** Dropdown menu currently showing "Standard Operating Procedure".
- Description:** Large text area for entering details.
- Check-out the Document to your workstation for editing:** A button labeled "Check-out Document..." is circled in red.
- Comments:** Large text area for entering notes.
- Save Document:** Button located at the bottom right of the form.

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**.

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Study Document Revision:

*Document Title: BRDU SOP

Version Number: 1 .1

Version Date: 10/05/2020

Category: Standard Operating Procedure

Description:

This document is currently checked out by: Joe Vandal at 10/05/2020

Check-in when you are done editing upload the document back into iRIS.

Revert to the document stored in iRIS.

After you have made changes to the document in Microsoft Word, you can check it back in by clicking the 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.

1.

Document Location: 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.

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:

Comments: Updated contact information

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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

- 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.

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Please note, anyone working on or with export controlled items EAR and ITAR Category XIV, 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.

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.

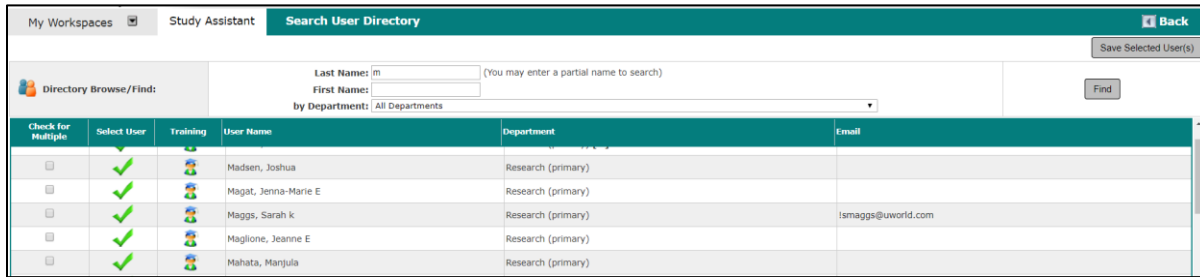
If applicable, please add the new Principal Investigator for the Study:	
<input type="text"/>	<input type="button" value="Add"/>
If applicable, please select the new Research Staff personnel:	
A) Additional Investigators	<input type="button" value="Add"/>
B) Research Staff	<input type="button" value="Add"/>
If applicable, please add any new Study Contact:	
<input type="text"/>	<input type="button" value="Add"/>
<small>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).</small>	
If applicable, please select any existing Personnel you wish to remove:	
	<input type="button" value="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.

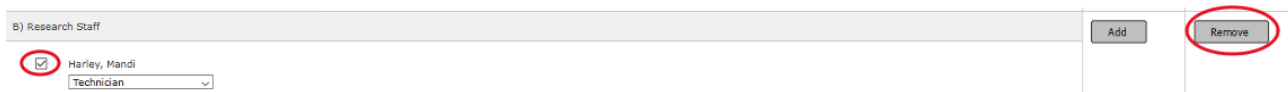
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Note: If you cannot find the personnel in the VERAS User Directory, please let them know they will need to try to log into [VERAS](#) with their UI Network ID and Password. If they don't have an account, the system will direct them to create one. Once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

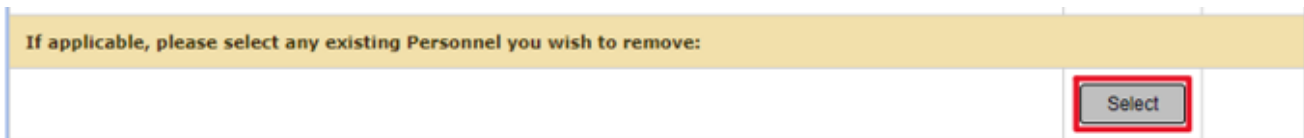


If you added a user to the data value by mistake, you can remove the request by selecting the checkbox next to their name and then clicking the **Remove** button in that same group.

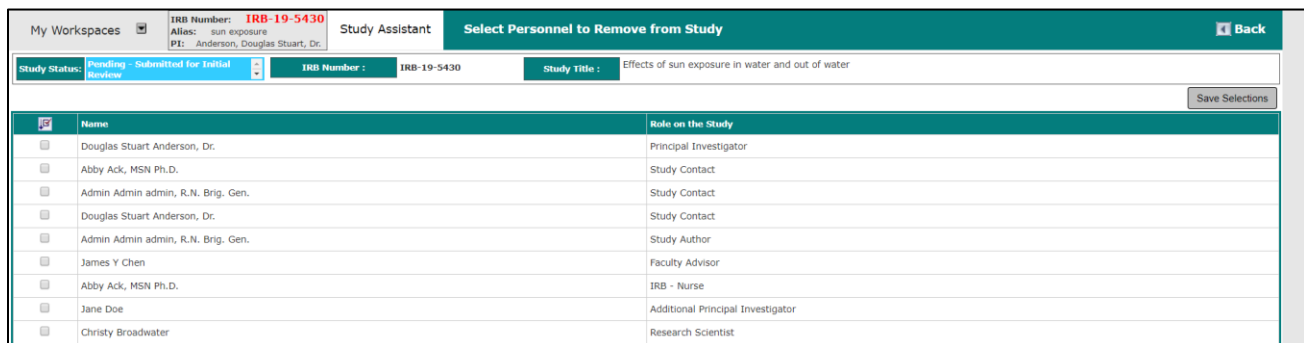


To Remove a User

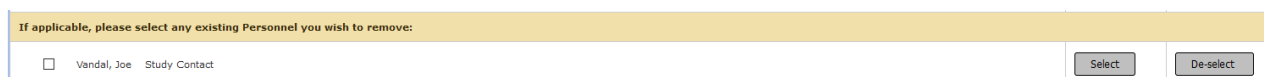
At the bottom of the Personnel Change Request is an area where you can request the removal of personnel from the study. Click the **Select** button in this group highlighted in red.



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.



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.



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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.