Guide for Submission of IRB Amendments

1. Log in to iRIS.
2. From the main dashboard, access "**Featured Study Operations.**" At this point, there are two options, click on "**Start a Submission Form" or "View My Studies.**" Both will take you to the list of studies
3. Find the study that you want to create the form for
4. On the right hand side, under Actions, select "Forms" and select the "**IRB Study Amendment Form**." Follow the steps indicated below starting with #7
5. You may also access the form using the previous format by clicking on the "**Open**" button
4. Under the "**Submissions**" tab, in "IRB Submission Forms," click on "**IRB Study Amendment Form**."
5. Click "**Add New Form**" located on the right hand side of the page.
7. The first section, "Study Information," is pre-populated.
8. Click "**Save and Continue"** to go to the next section, "General Information."
9. Complete the fields and click "**Save and Continue**."
10. If adding or removing personnel:
    - Click the "**Add**" button next to the appropriate role. The PI section does not need to be revised unless making a change to the PI.
    - Enter the user's last name in the "Last Name" field and click "**Find**."
    - Verify that the person's educational training is up-to-date by clicking on the graduate icon.
    - Select the check mark box next to the person you wish to add and click "**Save Selected User(s)**."
    - Assign a role from the drop-down list for each person added.
    - Repeat steps above until all study personnel have been listed.
    - To remove personnel, click on "**Remove**" at the bottom of the section.
    - Select the check mark box next to the person(s) you wish to remove and click "**Save Selections**."
    - All personnel changes are now displayed. Click "**Save and Continue**."
11. Enter your reason for the modification in the text box; include a summary of changes, and whether the changes require revision of the currently approved documents. If so, indicate which documents are being changed.
12. For a personnel change, indicate the name of the person being added; whether they are an employee, faculty, resident, student or volunteer; their role in the study; when they completed the required training and submitted a financial disclosure form; and what they will be doing for the study.
13. Click "**Save and Continue.**"
14. Select the check box beside the item that you are attaching to the submission.
15. Click the gray bar for the appropriate attachment.

    a. Applications

    i. A revised application needs to be created prior to being able to attach it. Go to the study application.
    ii. Click on "**Create a Revised Application.**" It will then indicate "Confirm the adding of a revision. Are you sure you want to create a revision?"
    iii. Click "**OK.**" If it indicates "*A new version of the application form has been published*." If it indicates that you need to convert, please click on the button to convert. Click **"OK"** to convert.
    iv. Click "**Save and Continue to Next Section**" to move through the application making any necessary changes as you go.
    v. Highlight all changes made that allow highlighting.
    vi. When finished with the last section of the application, go back to the study amendment form and click on "**Click here to attach the application.**" You will see the revised application available for selection.
    vii. Click "**Save and Continue to Next Section.**"

    b. Study Documents

    i. For new documents:

    - Click "**Add New Document.**"

        - Click "Select the document to upload."
        - Click "Browse" and locate the appropriate file and click "Open."
        - Enter version number one, version date, and category in the appropriate fields.
        - Select a category from the drop down menu.
        - Click "Save Document."
    - Repeat steps above for any other new documents that need uploading.

ii. For documents previously submitted:

- Click "Select or Revise Existing" and you will see a list of all existing documents.
- Do not click "Edit."
- Click "Create Revision" on the right for the row that the document needing revision is in.
- A new version will be created with a new version number.
- Change the version date to the date you revised the document or the current date.
- Select a category from the drop-down menu.
- Click "Check-out Document."
- You will see a box open up that indicates "Open, Save, Cancel."
- Click "Open" and the document will open up for editing in Word.
- Highlight all changes made to the document.
- When editing is complete, save the document to your desktop and close it.
- In iRIS Click "Complete Checkout."
- Click "Check In Document" to upload the new version of the document.
- Select "Browse" and locate the file on your computer and select "Open."
- Click "Save selected file."
- Click "Save Document."
- The revised document is attached to the form. You are now able to select other documents for revision. If no other documents need to be revised, click on the red **X** to close the box. If no other forms need to be attached, click "Save and Continue" in the upper right-hand corner, sign off and submit.

c. Informed Consent

i. Click on "Select or Revise Existing."

- You will see the existing consent form listed.
- DO NOT CLICK "Edit/View."
- Click "Create a Revision," on the last column on the right, for the row that the consent needing revision is in.
- A new version will be created.
- Change the version date to the date you revised the document or the current date.
- Click "Check Out Document."
- You will see a box open up that indicates "Are you sure?" select "yes".
- Click "Open" and the document will open up for editing in Word.
- Click "Enable Editing."
- Change the version date in the footer of the consent form to the date you revised the document or the current date (must match with date above).
- Highlight all changes made to the document.
- When editing is complete, save the document to your desktop and close it.
- In iRIS, click "Complete Checkout."
- Click "Check In Document" to upload the new version of the document.
- Select "Browse" and locate the file on your computer and select "Open."
- Click "Save selected file."
- Click "Save Document" on the bottom right-hand corner.
- The updated version should now be the only version visible. The previous version will now be saved inside of the yellow folder and remains part of the record.

    - Click on the red **X** to close the box.
    - Click on “**Select or Revise Existing**.”
    - Click the green select option with the plus sign to select the revised version.
- The revised consent is attached to the form. You are now able to select other documents for revision. If no other documents need to be attached, click “**Save and Continue**” in the upper right-hand corner, sign off and submit.