

How To Guide: Submit a Continuing Review in iMedRIS

! THE PROTOCOL DOCUMENTS (E.G., APPLICATION, CONSENTS, ETC.) MUST BE ATTACHED TO THE CONTINUING REVIEW.

THE SYSTEM DOES NOT DO THIS AUTOMATICALLY.

1. Log into <https://irb.ihmc.us/>. Select the protocol requiring a Continuing Review.
2. On the left-hand side of the *Submissions* pane, select “*Continuing Review Submission Form*”.

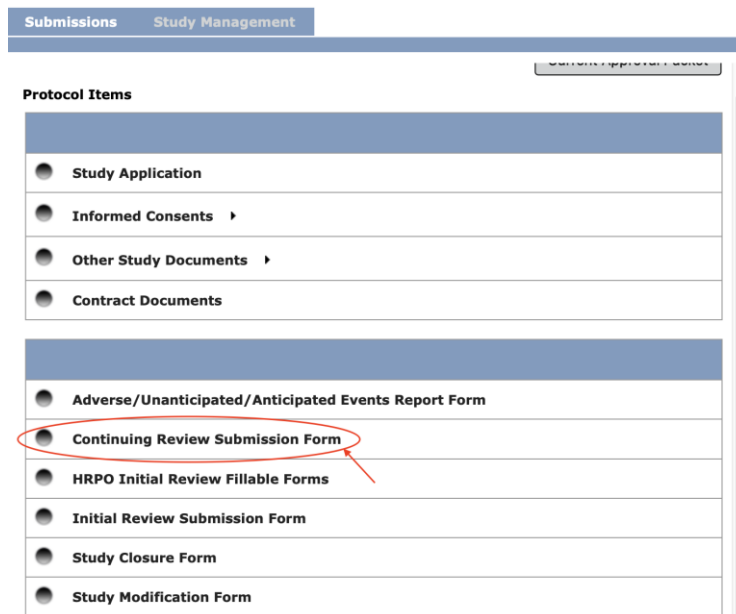


Figure 1: The submissions pane that appears after selecting the desired protocol.

3. Then, select “*Add a New Form*” in the top-right.

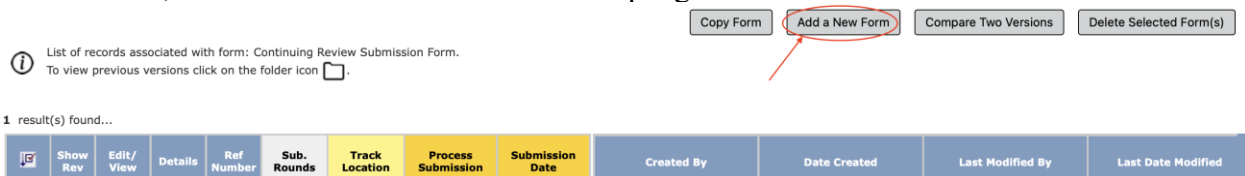


Figure 2: The continuing review form menu that tracks all continuing reviews submitted for a protocol.

Section 1: Continuing Review Submission Form

4. The *Continuing Review Submission Form* populates. Some fields auto-fill (IRB Number, Protocol Title, Principal Investigator), but others require user entry:
 - o Date (of Continuing Review)
 - o Status of Project (Continuing, Completed [Closure], Terminated)
 - If the project is Completed, **stop**. Close the *Continuing Review Form* and start a *Study Closure Form* instead.
 - o Changes in Research Staff

The screenshot shows a form with several sections. The 'Date' field has a red arrow pointing to the date input. The 'Status of project' section has three radio button options: 'Continuing', 'Completed (Closure) - STOP - Submit Closure Form', and 'Terminated'. A red arrow points to the 'Completed' option. The 'Do you wish to make any changes in research staff at this Continuing Review?' section has two radio button options: 'Yes' and 'No'. A red arrow points to the 'Yes' option. A note at the bottom states: 'NOTE: If an individual obtains informed consent independently of an investigator, they must have completed an approved training program, and documentation of this kept on file by the investigator'.

Figure 3: The three user-entry dependent fields are noted with red arrows in the example above.

5. If you do wish to make changes to the research staff, the *Assign Key Study Personnel (KSP) Request* pane populates.
 - o To edit personnel, click the “*Setup Key Study Personnel Request*” button.

The screenshot shows a pane titled 'Assign key study personnel(KSP) Request to the study'. At the top right, there is a button labeled 'Setup Key Study Personnel Request' which is circled in red with a red arrow pointing to it. Below the title, there are several sections: 'If applicable, please add the new Principal Investigator for the study:', 'If applicable, please select the new Research Staff personnel:' (with sub-sections A) Additional Investigators and B) Research Staff), 'If applicable, please add any new Study Contact:', and 'If applicable, please select any existing Personnel you wish to remove:'. A note at the bottom states: 'NOTE: If an individual obtains informed consent independently of an investigator, they must have completed an approved training program, and documentation of this kept on file by the investigator'.

Figure 4: The personnel change request pane as it appears in the continuing review form manager.

6. Several options appear, including adding or removing personnel.

- o To add personnel, use the *User Search* and select “*Find User/Search Directory*”.

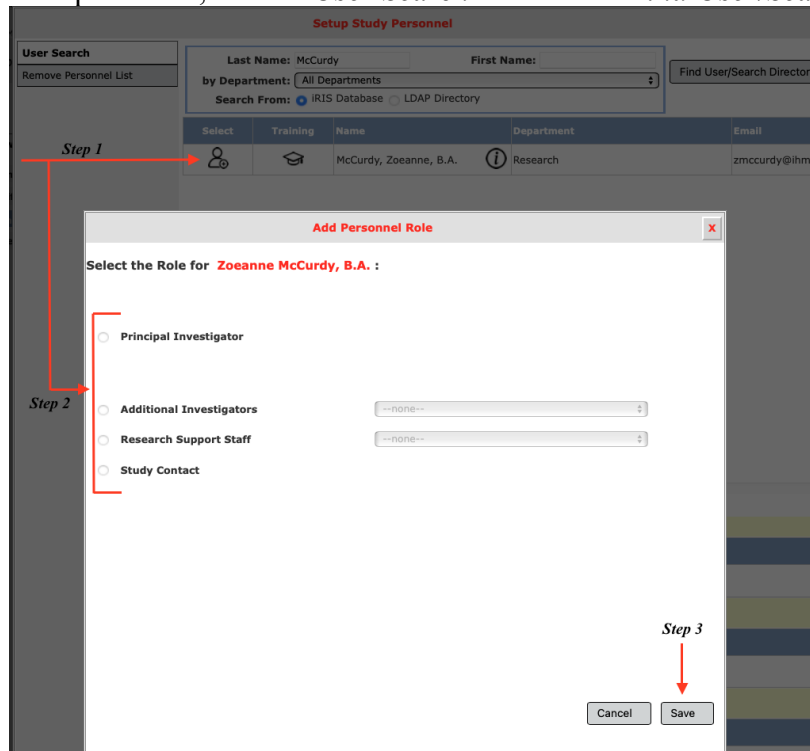


Figure 5: Step-by-step instructions on how to find and add a user. You can search from the iRIS database or the LDAP directory. Users newly assigned to roles (e.g., PI, Contact, etc.) will appear in the lower categories.

- o To remove personnel, use the *Remove Personnel List* and select the users you wish to remove from the protocol. Then, *Save Selections*.

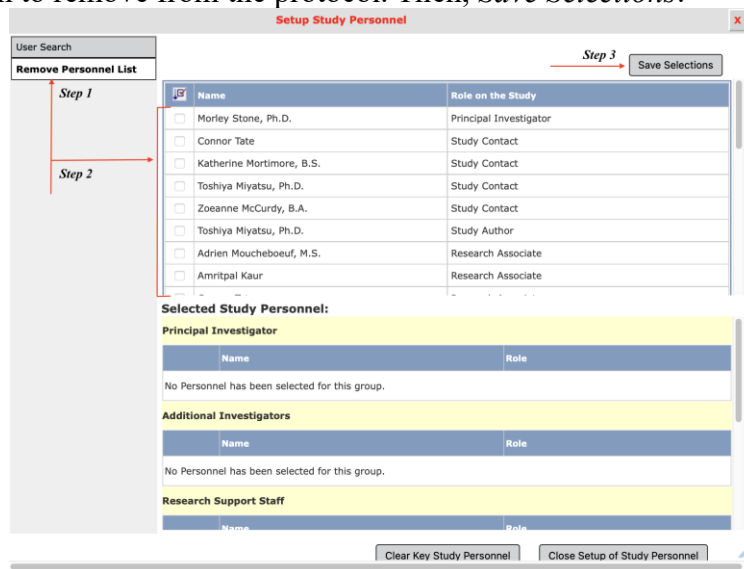


Figure 6: Step-by-step instructions on how to remove a user. You can select a user from the study personnel list.

7. Once done, select “*Close Setup of Study Personnel*”.
8. In the top-right corner, select “*Save and Continue to Next Section*” to move on.

Section 2: Modifications

9. The *Modifications* Section populates automatically. Select the designation of any modifications you wish to make for the present continuing review.
 - o If the answer is **yes**, list all any modifications approved since your initial submission.

Figure 7: An open-text window populates when the “Yes” option is selected.

! If you have new modifications to submit, enter them below the current approved modifications (in the same box) and identify these are the new modifications with this continuing review.

10. Select “*Save and Continue to Next Section*”.

Section 3: Deviations

11. The *Deviations* section populates automatically. Select the designation of any deviations occurring since the last protocol review.
 - o If the answer is **yes**, summarize all protocol deviations in the automatically populating free-response box.

Figure 8: If the user selects “Yes”, an open-text window populates for a summary of all protocol deviations.

12. Select “*Save and Continue to Next Section*”.

Section 4: Advertising & Recruitment


13. The *Advertising/Recruitment* section populates automatically. Select the option that best applies if there have been any changes to the existing approved advertising or recruitment methods since the last review.
 - o If the answer is **yes**, summarize all changes that occurred in the automatically populating free-response box.

Figure 9: A “Yes” populates an open text window. No window appears if “No” or “N/A” is selected.

14. Select “*Save and Continue to Next Section*”.

Section 5: Attaching Application Revisions

15. The *Attach Application Revisions* section populates automatically.

- o To attach the application, select the button prompt or  icon (**required**).

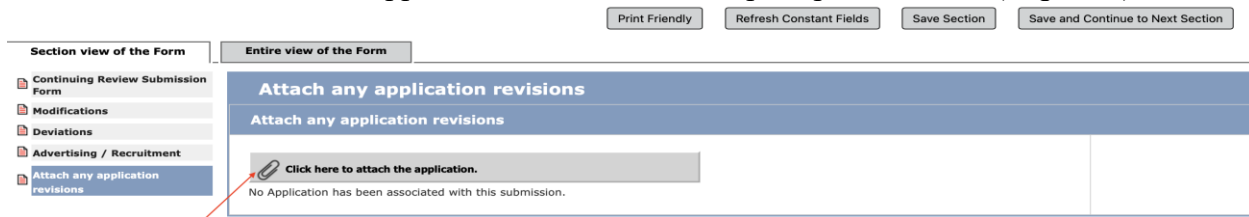
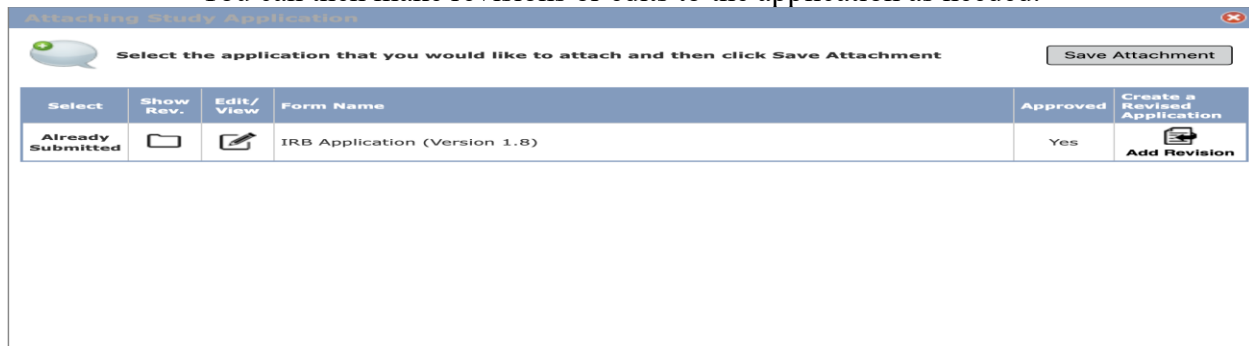


Figure 10: *The Attach Application Revisions pane.*

- o Then, from the options that appear, select the application you would like to attach. You can then make revisions or edits to the application as needed.






Select	Show Rev.	Edit/View	Form Name	Approved	Create a Revised Application
Already Submitted			IRB Application (Version 1.8)	Yes	 Add Revision

Figure 11: *An example of what the Attaching Study Application window would look like.*

- ! If there are personnel changes, the changes must be reflected in the Key Study Personnel section as well as Section 12 of the application. Personnel must be listed in both sections of the application.
- ! The attached protocol application requires all CITI links to be current and valid in *Section 12* of the application. The link must be to the Completion Report, not the Certificate.
- ! The application must reflect all current and approved modifications, as well as all new proposed modifications.

16. Once done, select “*Save and Continue to Next Section*”.

Section 6: Study Document(s)

17. The *Study Document(s)* section populates automatically.
18. To attach any study documents, which are required for a continuing review, you can choose from three options:
 - o Select or Revise Existing – for already existing documents in the application.
 - o Add a New Document – for a document that does not exist yet.
 - o Add Multiple Documents – for documents that do not exist yet (up to 5).

Print Friendly

Refresh Constant Fields

Save Section

Save and Continue to Next Section

Entire view of the Form

Study Document(s)

Attach Study Document(s)

Select or Revise ExistingAdd a New DocumentAdd Multiple Documents

Detach	Version	Title	Category	Expiration Date	Document Outcome	Checked Out	View Document
No Document(s) have been attached to this form.							

Figure 12: The Attach Study Document options appear automatically. Attaching documents is required for a continuing review.

- ! For any intended changes to documents, choose the “*Select or Revise Existing*” option and follow the prompts.

Make sure any attached documents are the clean, unstamped versions.

19. Once done, select “*Save and Continue to Next Section*”.

Section 7: Informed Consent(s), Assent(s), or HIPAA Forms

20. The *Informed Consent(s), Assent(s), or HIPAA Forms* section populates automatically.
21. To attach any consents, assents, or HIPAA forms—which are required for a continuing review—you can choose from two options:
 - o Select or Revise Existing – for already existing forms in the application.
 - o Add a New Consent – for consents that do not yet exist.

- ! For any intended changes to consents, assents, or HIPAA forms, choose the “*Select or Revise Existing*” option and follow the prompts.

Make sure any attached forms are the clean, unstamped versions.

22. Once done, select “*Save and Continue to Next Section*”.

23. The screen will then display “*Form has been Completed*”.
 - o Select “*Notify PI to Sign Off*” to prompt PI signature and send-off to IHMC IRB.