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*".

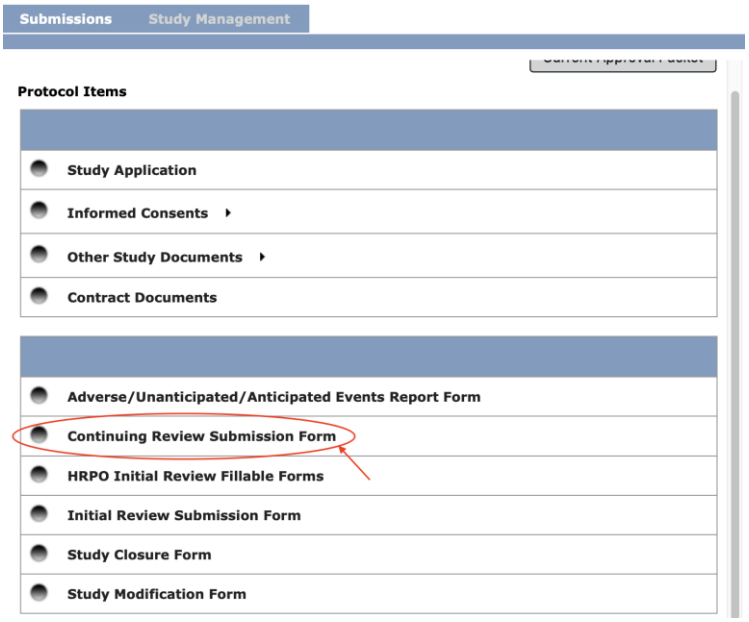

Figure 1: *The submissions pane that appears after selecting the desired protocol.*

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

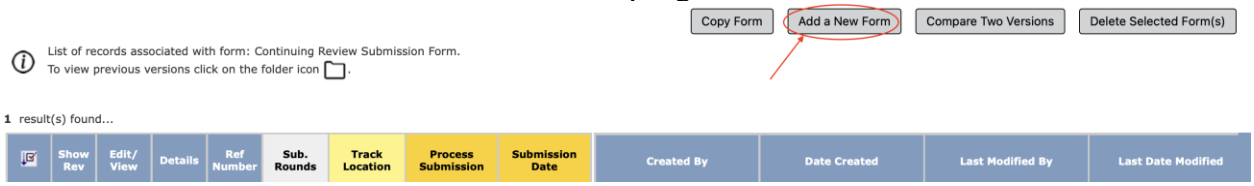

Figure 2: *The continuing review form menu that tracks all continuing reviews submitted for a protocol.*

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:
    - Date (of Continuing Review)
    - 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.
    - Changes in Research Staff

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.
    - To edit personnel, click the "*Setup Key Study Personnel Request*" button.

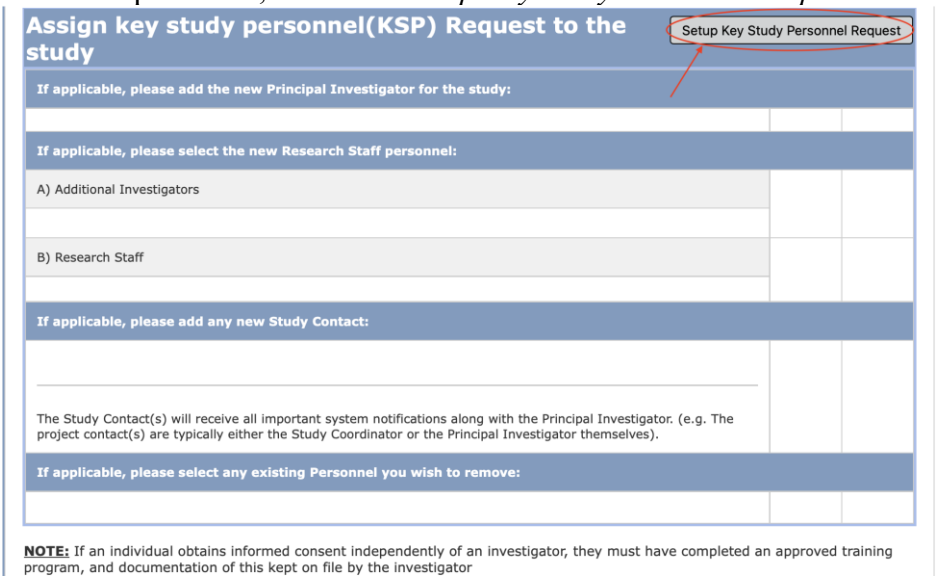

Figure 4: *The personnel change request pane as it appears in the continuing review form manager.*

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

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

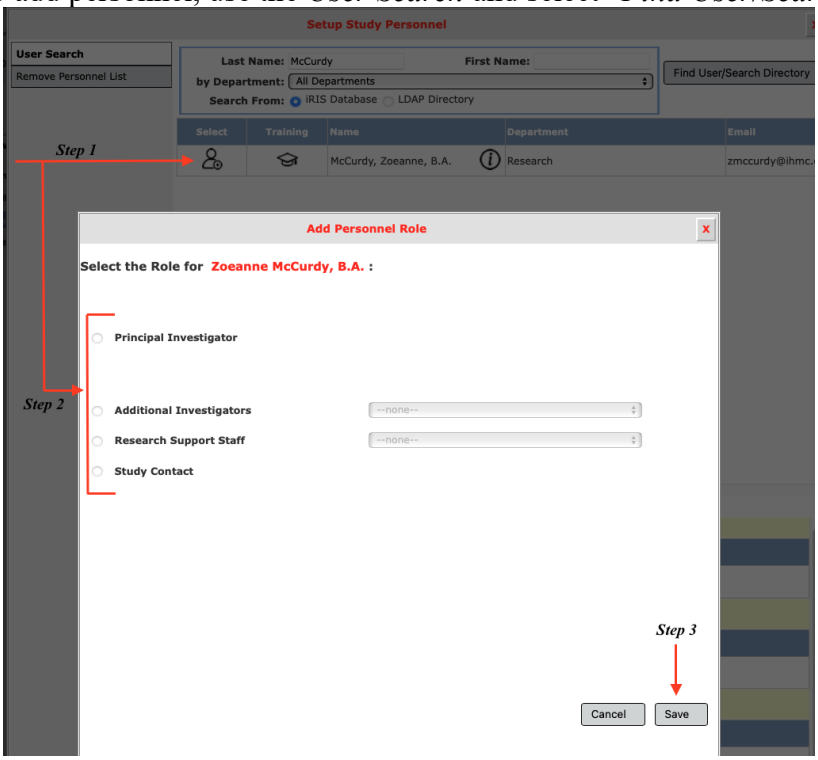

Figure 5: *Step-by-step instructions on how to find and add a user. You can search from the iRIS database or the LDAP directory. Users newly assigned to roles (e.g., PI, Contact, etc.) will appear in the lower categories.*

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

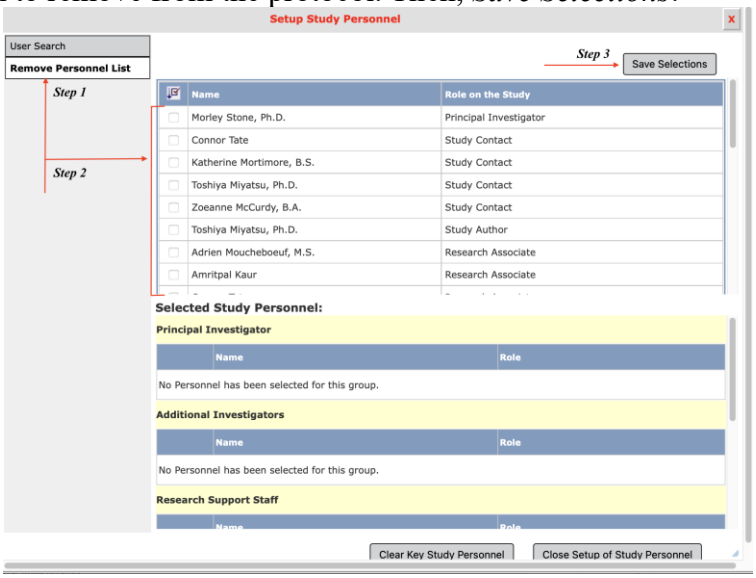

Figure 6: *Step-by-step instructions on how to remove a user. You can select a user from the study personnel list.*

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.
    - If the answer is **yes**, list all any modifications approved since your initial submission.

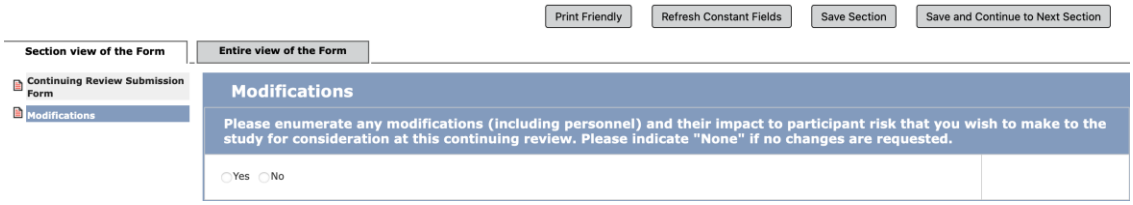

Figure 7: *An open-text window populates when the "Yes" option is selected.*

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

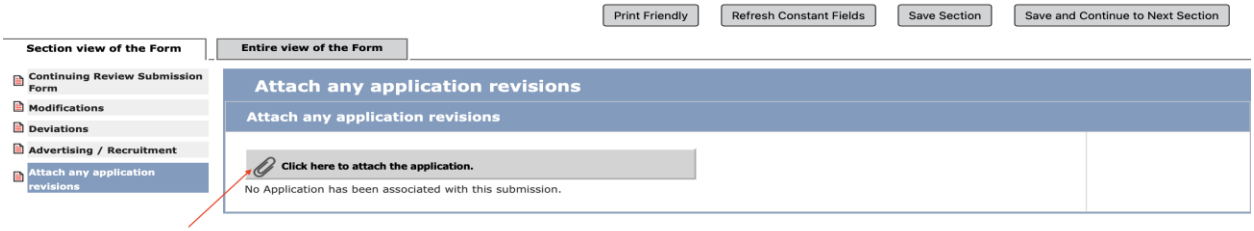

Figure 10: *The Attach Application Revisions pane.*

    - 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.

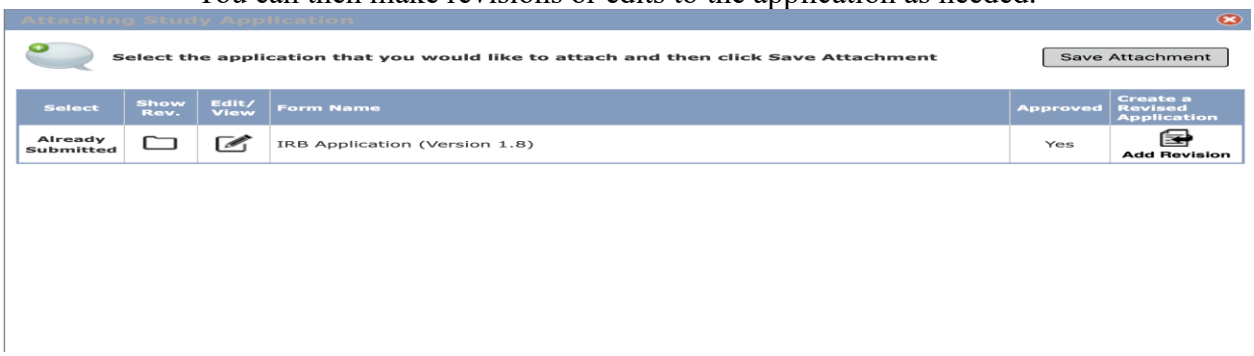

Figure 11: *An example of what the Attaching Study Application window would look like.*

- 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 <u>both</u> 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:
    - Select or Revise Existing – for already existing documents in the application.
    - Add a New Document – for a document that does not exist yet.
    - Add Multiple Documents – for documents that do not exist yet (up to 5).

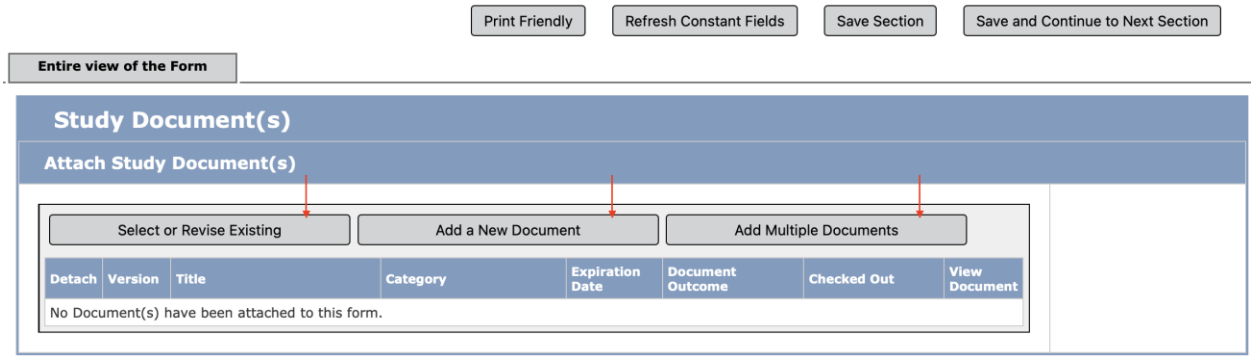

Figure 12: *The Attach Study Document options appear automatically. Attaching documents is required for a continuing review.*

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:
    - Select or Revise Existing – for already existing forms in the application.
    - 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*".
    - Select "*Notify PI to Sign Off*" to prompt PI signature and send-off to IHMC IRB.