How To Guide:
Submit a Protocol Modification in iMedRIS

THE UPDATED PROTOCOL MUST BE ATTACHED TO THE **MODIFICATION.**
THE SYSTEM DOES NOT DO THIS AUTOMATICALLY.

1. Log in to https://irb.ihmc.us/. Select the protocol that requires modification.
2. On the left-hand side of the *Submissions* pane, select "*Study Modification Form*".

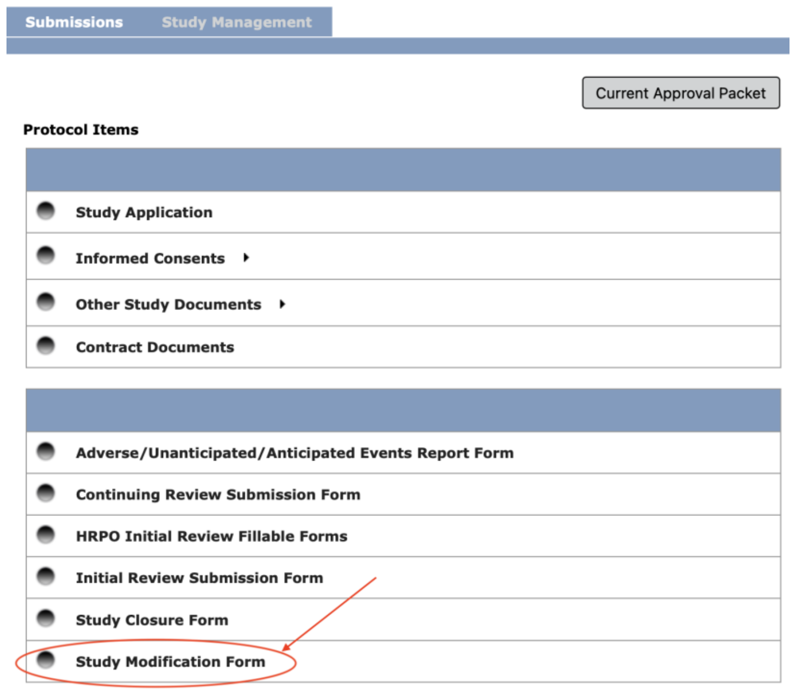

Figure 1: *The submissions pane that appears after selecting the desired protocol.*

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

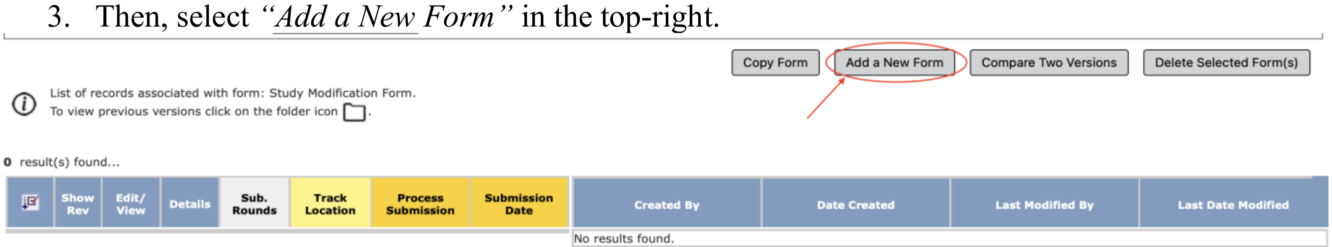

Figure 2: *The modification form menu that tracks all modifications submitted for a protocol.*

Sections 1 & 2: Study Information & Type of Modification

4. Complete all sections in the left-hand side of the *Section view of the Form* starting with the *Study Information* tab.
    - This tab should be self-populated. Confirm that all the information is correct.
    - Select the "*Save and Continue to Next Section*" button at the top of the form.
5. Move on to the *Type of Modification* tab. Complete all fields as they apply to your desired modifications to the protocol.

6. Select the "*Save and Continue to Next Section*" button at the top of the form.

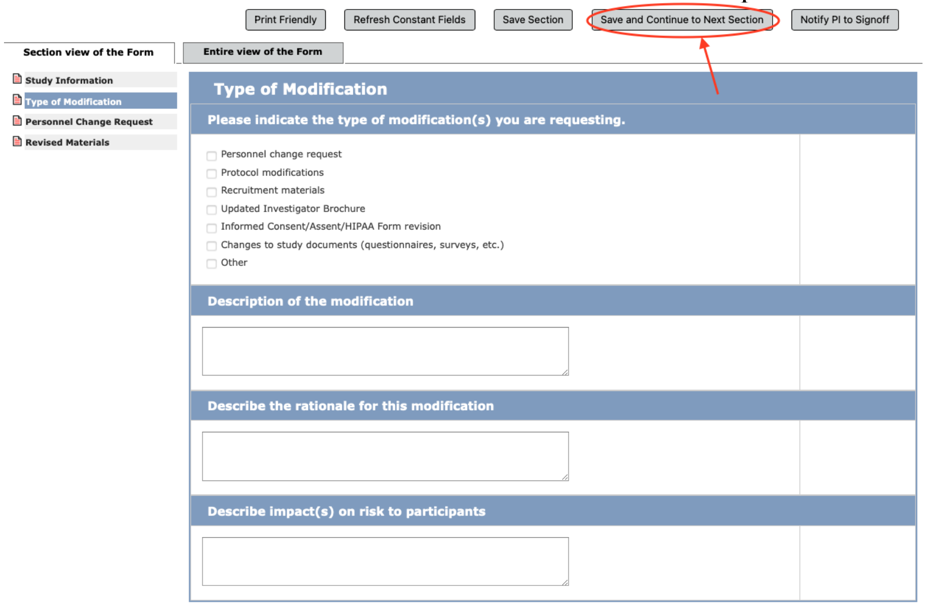

Figure 3: *All fields should be completed with ample detail for the reviewers to have a clear understanding of the changes being requested and the potential impacts on the protocol and participants.*

Section 3: Personnel Change Request

7. Move on to the *Personnel Change Request* tab. Only complete this tab if you are adding or removing personnel to the protocol.
   - To edit personnel, click the "*Setup Key Study Personnel Request*" button.

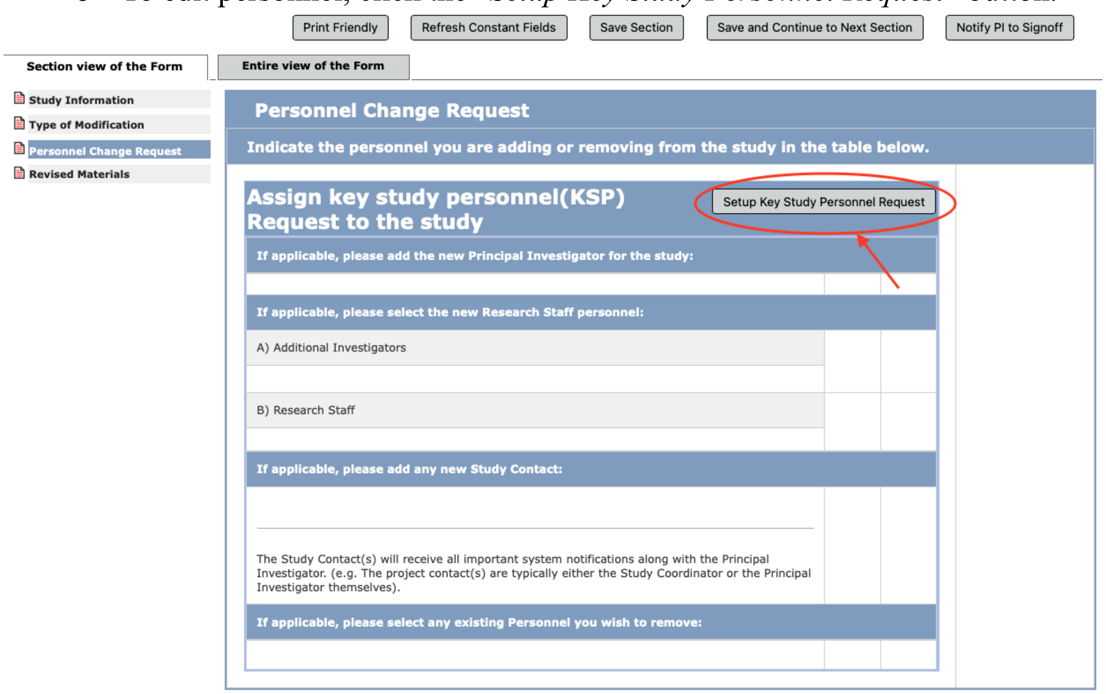

Figure 4: *The personnel change request pane as it appears in the modification manager.*

8. Several options appear. To add personnel, use the *User Search* and select "*Find User/Search Directory*".

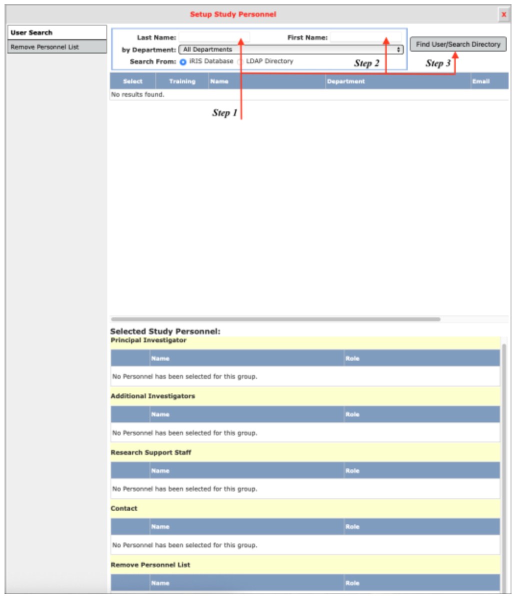

Figure 5: *Step-by-step instructions on how to find a user. You can search from the iRIS database or the LDAP directory. Users newly assigned to roles (e.g., PI, Contact, etc.) will appear in the lower categories.*

9. Once a user is searched through the desired database or directory, click the "*Select*" icon to select the desired personnel.
10. Once the user is selected, select the *Role* that they will fulfill in the protocol.
    - A) Principal Investigator B) Additional Investigator
      C) Research Support Staff D) Study Contact
    - For Additional Investigators and Research Support Staff, make sure to fill the associated drop-down menu to the right.
    - Once complete, select the "*Save"* option at the bottom right.

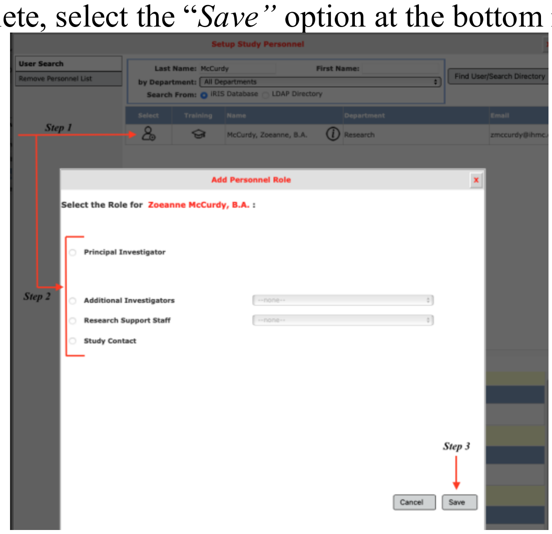

Figure 6: *Step-by-set instruction example on how to select personnel, assign a study role, and save changes. These steps will be repeated for every person that needs to be added to the study personnel list.*

11. Close the *Setup Study Personnel* pane by clicking the "*Close Setup of Study Personnel"* button in the bottom right corner.
    - Do not close the pane with the X, as this will not save any changes made.
12. Select the "*Save and Continue to Next Section*" button at the top of the form.

13. Move on to the *Revised Materials* tab. Here you attach the revised protocol application and all revised consents and documents.

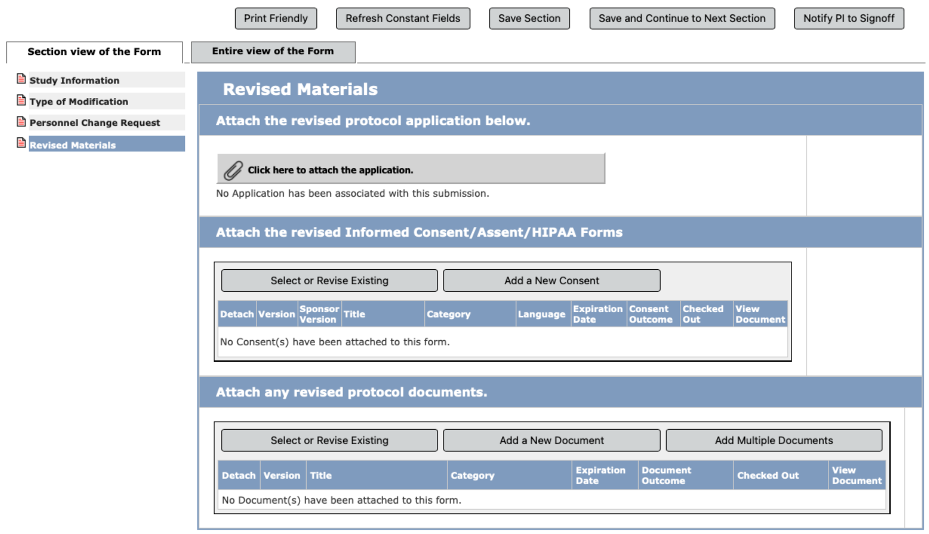

Figure 7: *The Revised Materials tab. The protocol should always be attached no matter the changes being made.*

14. In Subsection 1, make changes to the protocol application. This is **required** to submit the modification and have it reviewed by the IHMC IRB. The protocol must include all proposed changes mentioned in the modification and should be consistent in its entirety.
    - When you select the "*Click here to attach the application"* button, the *Attaching Study Application* pop-up appears.

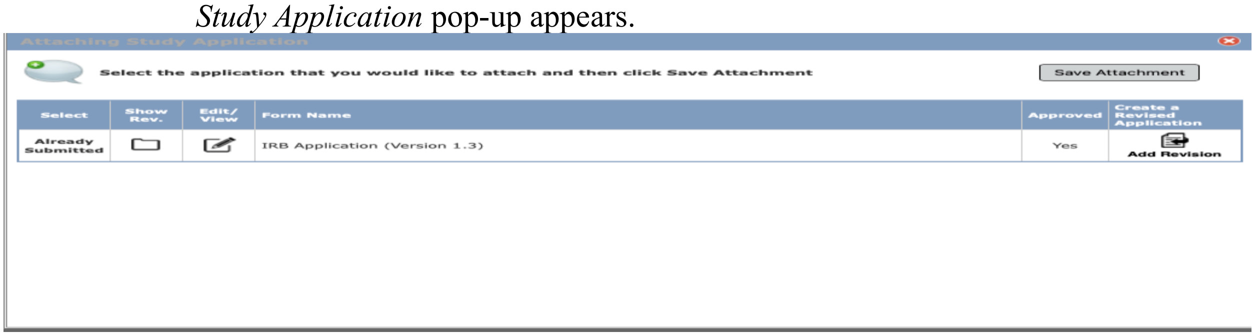

Figure 8: *Here you can show the status of the submission, see the revision history, edit and view the form, and create a revised application.*

    - Select "*Add Revision"* to create a revised application. The revised application should include all proposed changes mentioned in the modification and should be consistent throughout the entirety of the protocol.
        - If you added any personnel, verify these changes are reflected in the **KSP Section** and **Section 12**. Make sure to update the current CITI training links in section 12. The link **<u>must</u>** be to the completion report, **<u>not</u>** the certificate.
    - Once done with revisions, select "*Save Attachment"* and close the pop-up.

15. In Subsection 2, attach any revised Informed Consent/Assent/HIPAA Forms.
    - You can *Select or Revise Existing* consent documents, which is preferred if you are planning on making changes to an already existing or approved consent document.

    - You can also *Add a New Consent*, which is useful if you have a population-specific consent form you need to add in compliment to another existing consent document (e.g., one consent is meant for IHMC employees only, and another is intended only for community members).
    - Select "*Save and Continue*".

Any consent uploaded or revised **must** be a clean version, **unstamped**.

16. In Subsection 3, attach any revised protocol documents (e.g., recruitment materials, command letter of support, FDA information about supplements, etc.).
    - Make sure to complete the following fields for each protocol document for tracking purposes:
        - *Version number*
        - *Date*
        - *Category*

Any document uploaded or revised **must** be a clean version, **unstamped**.

    - For each document, make sure to select "*Save and Continue*" once done editing.
    - When all of the documents have been uploaded, save the documents.
17. Select the "*Save and Continue to Next Section*" button at the top of the form.

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18. The *Instruction of Form has Been Completed Screen* will appear. Select the "*Notify PI to Signoff"* button.

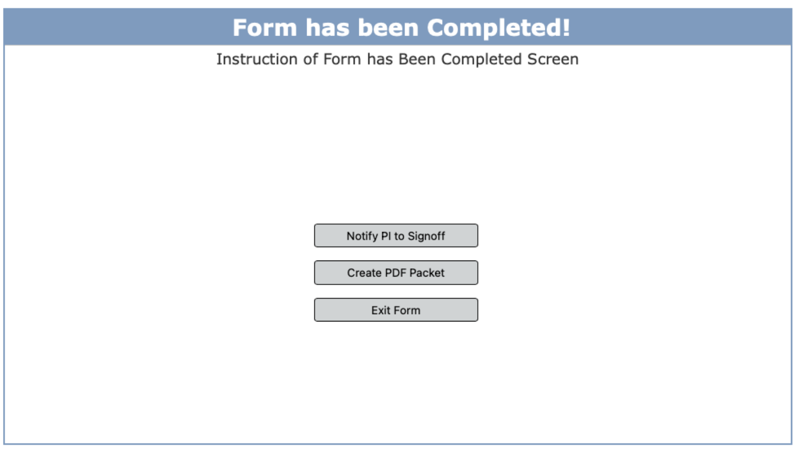

Figure 9: *The form completion screen auto-populates after moving off to the next section. You can create a PDF packet, notify the PI to sign off, and/or exit the form here.*

    - If you are the PI, move to sign and submit the changes.
    - If you are not the PI, the rest of the process is entirely left to the PI.
19. For PIs: Sign off and submit.
    - Select "*Approve*".
    - Select "*Save Sign Off*".
