HUMAN RESEARCH PROTECTION PROGRAM

iMedRIS Quick Guide

Create an Amendment Request (Form 2)

iMedRIS version: 11.01
Last Revised: 04.15.2020

All changes to your study, even minor ones, must receive IRB approval before you implement them. Implementing changes without IRB approval is a violation of federal regulations and UT policy. Such violations can lead to the suspension of IRB approval and other serious consequences for the investigators, participants, and the university.

Only one amendment can be submitted at a time. After the request is submitted, the amendment package is locked and no further changes can be made unless requested by the IRB reviewer.

> If this submission is related to an issue or event that constitutes reportable new information which has not been submitted to the IRB, submit a **Reportable New Information** form ***before*** submitting an Amendment Request.

Find and Open the Study to be Amended

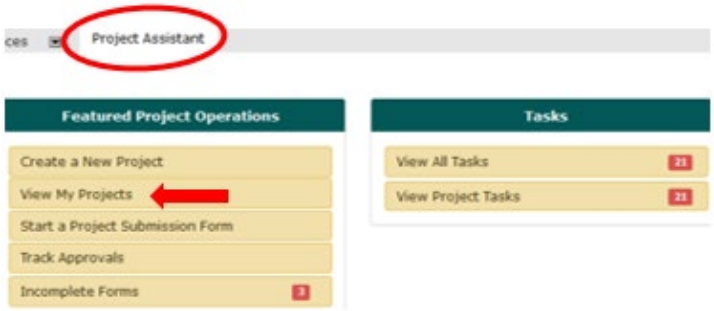
1. Log in to iMedRIS using your **NetID** and **Password**.

NOTE: iMedRIS uses Two-Factor Authentication.

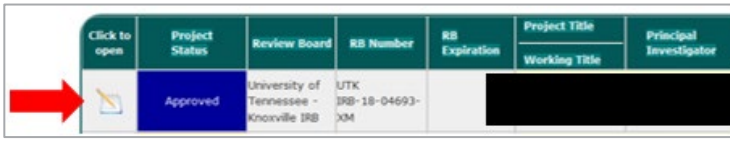
2. If iMedRIS opens to the **Project Assistant** screen (tab circled in red), click **View My Projects**.

If not, hover your mouse pointer over the **My Workspaces** drop-down symbol.

- Click **Project Assistant**.
- Click **View My Projects**.



3. The screen then displays a list of all studies that include you as study personnel. Locate your study. Click the **pad & pencil** icon (red arrow) under the **Click to Open** column. You will then be on the study's Submission screen.

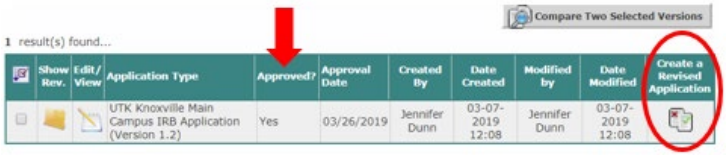


> If study personnel are being added/removed, the IRB application **must be revised to include/remove their information**. See our guidance on which submission components must be revised and attached to your amendment request.

Revise the IRB Application

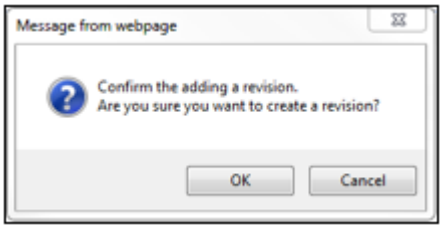
4. Project Application screen

Find the version you want to revise. On the far right, click under **Create a Revised Application**, circled in red. (If your amendment does not require changes to the IRB application, skip this section.)



TIP: Revisions are typically made to the currently approved application. The currently approved version says **Yes** (red arrow) under the **Approved** column. Click the **folder** icon under the **Show Rev.** column to view past versions.

If **prompted by a pop-up window** to confirm creating a revised application, click **OK**.



5. Application Form screen

The editable version of the application form opens to the first screen, **1.0 General Information Screen**.

Navigate through any form screen sections by clicking **either**:

- click Save and Continue to Next Section to save changes and continue to the next screen;

OR

- click the screen section on the navigation bar. Click Save Section to save your changes **before** leaving that screen section.

Avoid Delays!

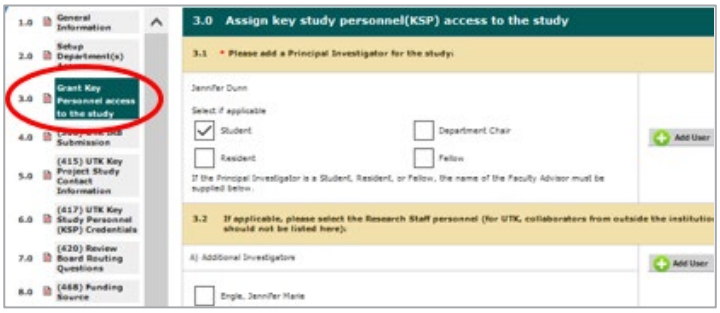
See What to Include in Your Amendment Request

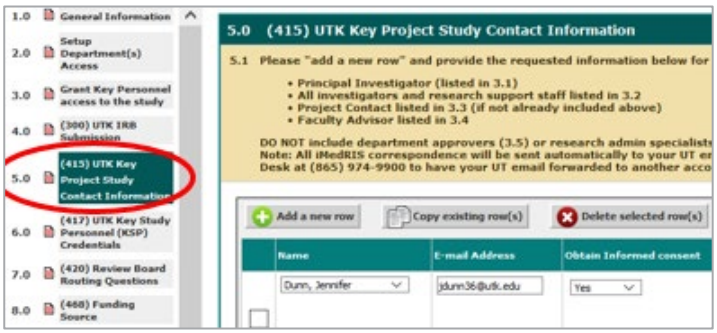
TIP: Adding/Removing UTK personnel?

Revise **ALL** the following screen sections:

- **3.0 Grant key personnel access to the study** (circled in red),
- **(415) UTK Key Project Study Contact Information**, (circled in red), and
- **(417) UTK Key Project Study Personnel Credentials**.

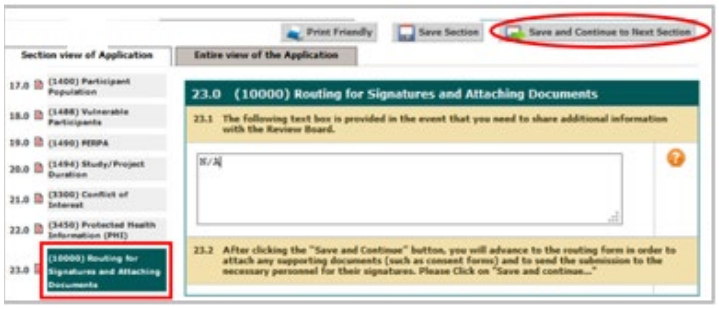
For step-by-step instructions on adding or removing study personnel, see our guidance, Add or Remove ONLY UTK Personnel Request.





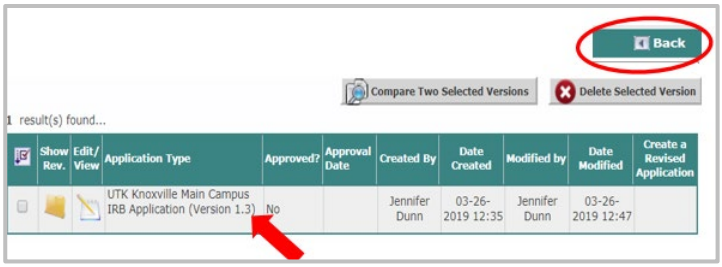
6. **After** completing your changes to the IRB application form:

- Click the last screen section, **(1000) Routing for Signatures and Attaching Documents**, outlined in red.
- Make any needed changes to this screen, when finished, click **Save and Continue to Next Section**, circled in red.
- You will be returned to the **Project Application** screen (as in **Step 4** above).



7. On the **Project Application** screen:

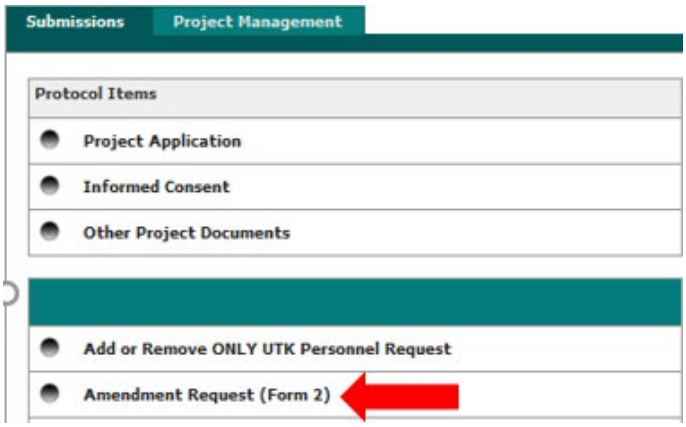
- **Confirm** the version displayed indicates **a new version number** (red arrow) and **Approved?** column should say **No**.
- Click **Back**, circled in red, to return to the **Submissions** screen.



Create an Amendment Form

8. **Submissions** screen

- Click **Amendment Request (Form 2)**, red arrow.
- Any changes made to the study components **MUST ALSO BE REFLECTED** in the Amendment Request form.

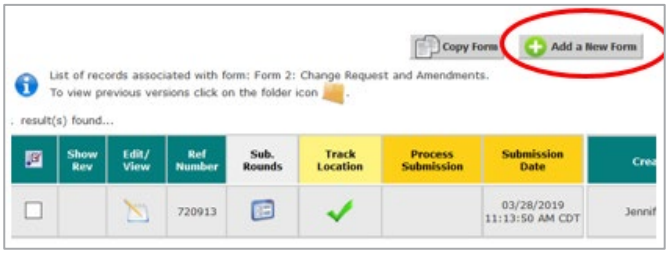


If the amendment is limited to **ONLY** adding or removing UT study personnel, and changes to study materials are limited to their addition/removal, consider using the **Add or Remove ONLY UTK Personnel Request**.

9. **Amendment Request** screen

Click **Add a New Form** to create a new amendment.

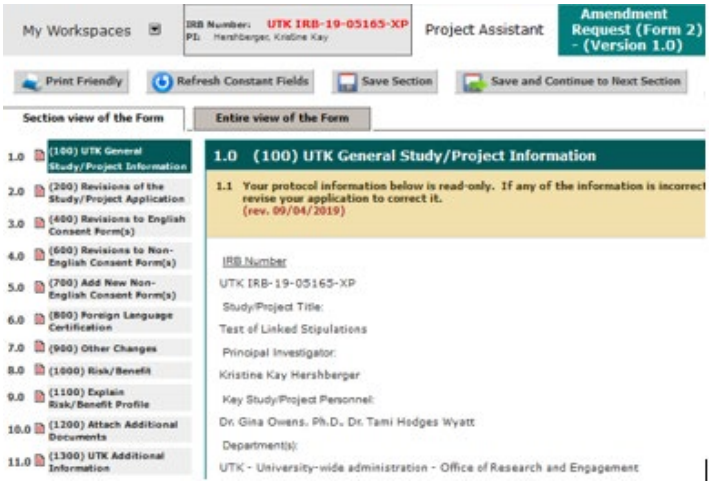
TIP: If previous requests were created using this form, those are displayed on this screen.



10. (800) UTK General Study/Project Information

- **Item 1.1**: Basic study information (e.g., IRB number, title, PI name) is displayed. No changes need to be made in this section.
- **Item 1.2**: Change to Study Title
- **Item 1.3**: Changes to IRB application, consent forms and other materials
- Click **Save and Continue to Next Section**.

TIP: This form is dynamic and branches to different screen sections based on your responses.



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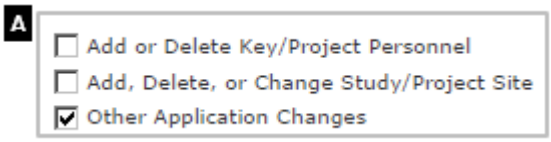
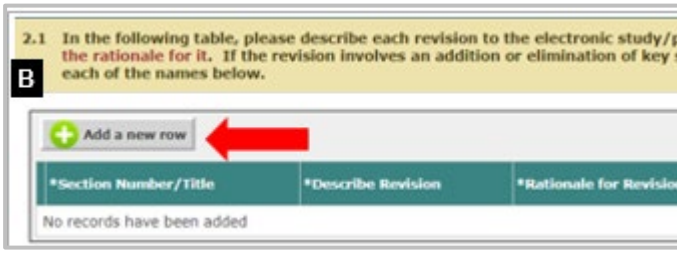
11. (810) Revisions of Study Application – This section appears only if one of the first three options is checked in **Step 10** (**picture A**).

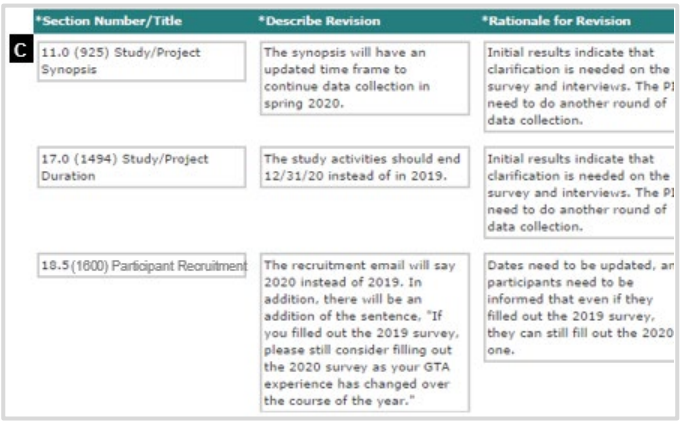


Item 2.1: Click **Add a new row** (red arrow) for each change being made to the IRB Application (**picture B**).



In each row, include the following information for that change (**picture C** on right).

- Section Number/Title
- Describe Revision
- Rationale for Revision



Item 2.2: Click the **Click here to attach the application** button (red arrow).

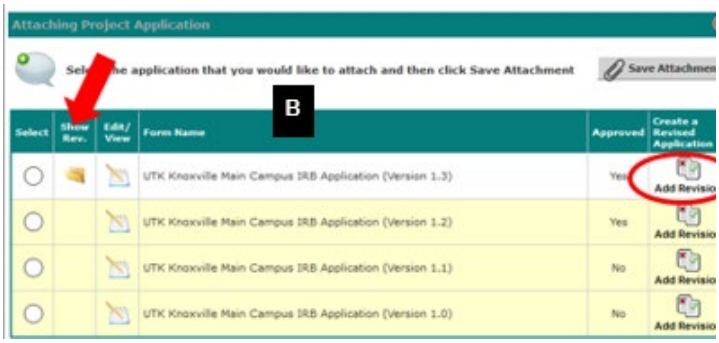
12. Attaching Project Application

A. In the new window, the most recent version of the IRB application will be displayed (**picture A** on right).

- Click the button under the **Select** column for the version that includes the changes reflected in this Amendment Request form. That version will say **No** (red arrow) under the **Approved?** column.
- Click **Save Attachment**. You will then be returned to the **Amendment Request** form.

B. If the application **was not already revised**, the first version listed will say **Yes** under the **Approved?** column **(picture B** on right).

- Click  under the **Create a Revised Application** column, circled in red.
- Follow **Steps 4 – 6** in the previous section of this document.
- When you return to this **Attaching Project Application** window (**picture A** above right), **confirm** the version has a **new version number** (**picture A** above right, red arrow). That version will say **No** under the **Approved?** column.
- Follow the bullets under **12A** above.



TIP: View past versions by clicking the **folder** icon (red arrow) under the Show Rev. column

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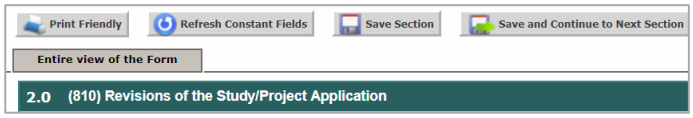
13. On (810) Revisions of Study Application, after the revised IRB application is attached.

- Click **Save and Continue to Next Section**.



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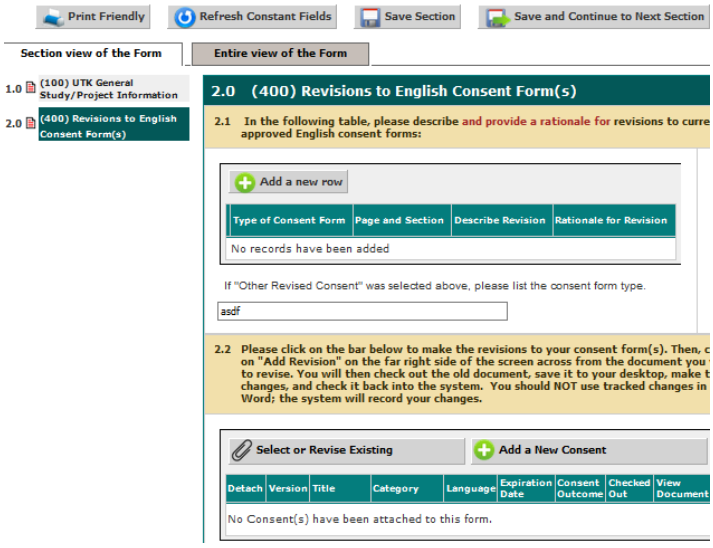
14. (400 - 800) Changes to Consent Form(s)

- Describe the changes made to each consent form applicable to this amendment request.
- Upload the revised consent forms.
- When finished, click **Save and Continue to Next Section**.



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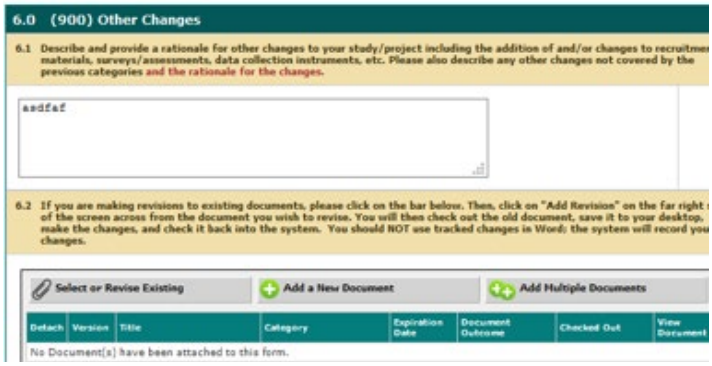
15. (900) Other Changes

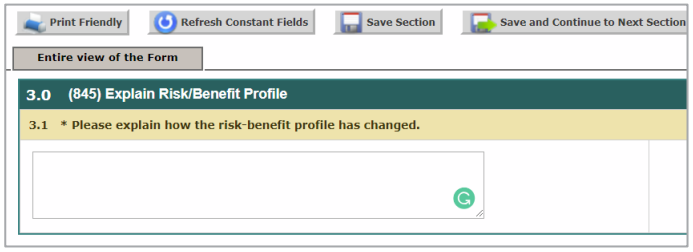
Include changes made to other study materials such as recruitment, screening, interview scripts, data collection sheets/instruments, etc.

- Describe the changes made.
- Upload the revised documents.
- When finished, click **Save and Continue to Next Section**.



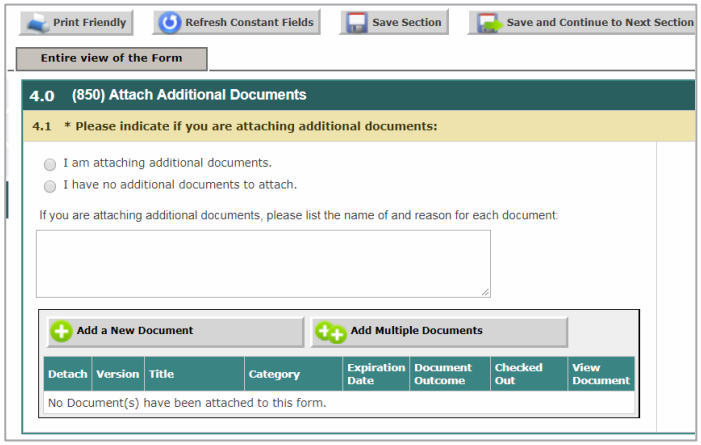
16. (845) Explain Risk/Benefit Profile

- Describe how the changes impact the study's risk/benefit assessment. If there is no change, that should be stated.
- When finished, click **Save and Continue to Next Section**.



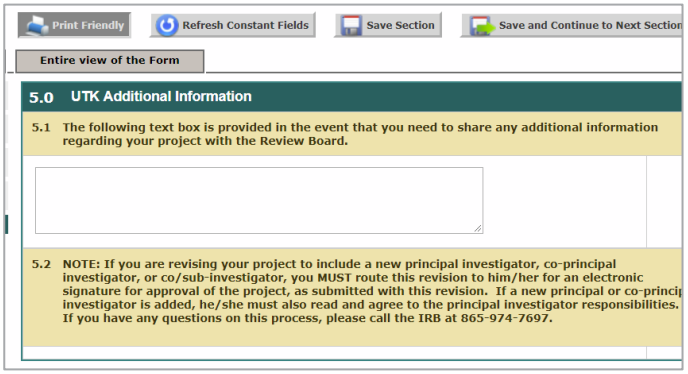
17. Section 850 Attach Additional Documents

- Describe any other documents you may include such as site authorization letters, letters of support, etc.
- Upload any applicable documents.
- When finished, click **Save and Continue to Next Section**.



18. Section 5.0 UTK Additional Information

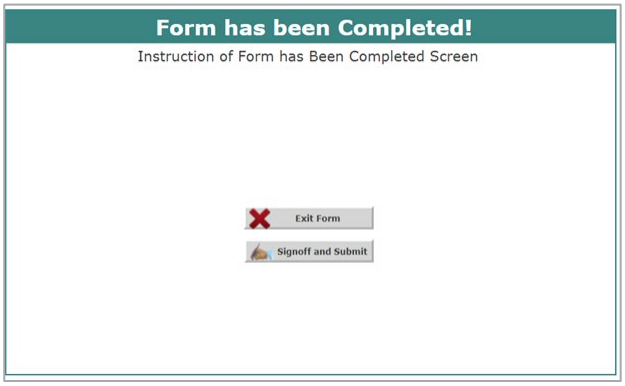
- Identify any additional information related to the submission that you want the IRB to know.
- When finished, click **Save and Continue to Next Section**.



19. Form Completed screen

- Either the PI **or** another investigator (co/sub or co-PI) must click **Signoff and Submit**.
- Then users are routed to the **Setup Signoff Submission Routing** screen.

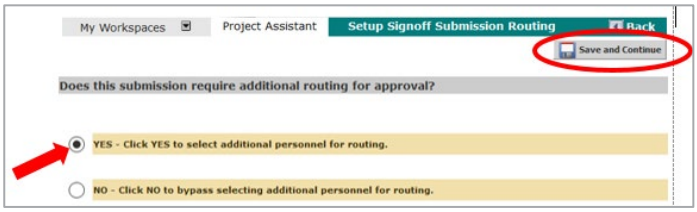
TIP: If study personnel other than an investigator completes the form, only the **Exit Form** button appears. The PI then must open the form and click **Signoff and Submit**.



Required Routing and Submission Signoffs

20. Setup Signoff Submission Routing

- Click **Yes IF**:
  - an investigator (co/sub or co-PI) **is added**;
  - a Faculty Advisor **is added**; or
  - a **new** PI is replacing the existing PI.
- Otherwise, click **No**.
- Click **Save and Continue** (circled in red).



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21. Select Key Personnel for Routing and Signoff

- Check the boxes (red arrow) for:
  - Either the PI **or** other investigator (co/sub or co-PI) who will sign off on the submission;
  - **All newly added** investigators (co/sub or co-PI), if any;
  - **Newly added** Faculty Advisor, if any, and
  - **Newly added** PI, if any.
- Click **Save and Continue** (circled in red).

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22. Setup Signoff Submission Routing – Additional Personnel

- No additional study personnel are required for amendment submissions.
- Click **Save and Continue** (circled in red).

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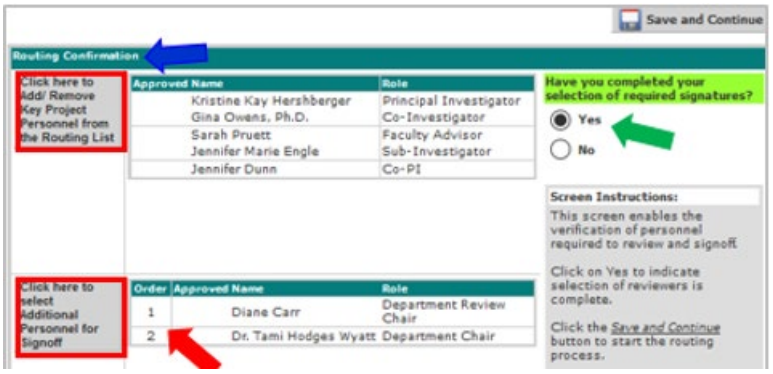
23. Routing Confirmation

If all required individuals are listed, and the routing order, if needed, is correct:

- Click **Yes** in far right column (green arrow).
- Click **Save and Continue**.

TIP: Failure to obtain the required signoffs will result in the submission being returned to the PI without review.



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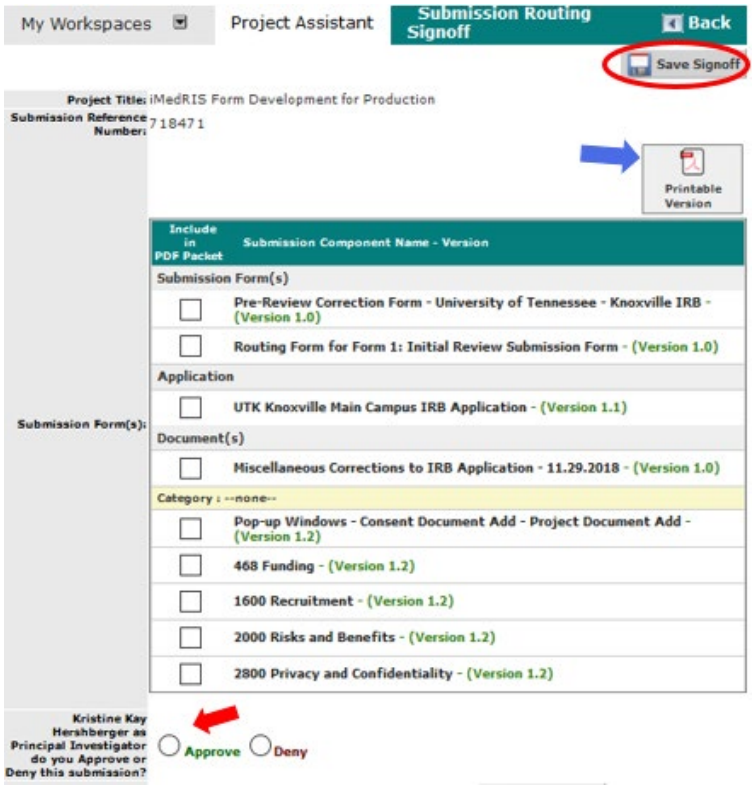
24. Submission Routing Signoff

- **View a document** by clicking on it.
- If you want to **print documents** as a PDF
  - Check the box next to each document you want to print.
  - Click **Printable Version** PDF button (blue arrow).

If everything is in order:

- Click **Approve** (red arrow).
- Click **Save Signoff** (circled in red).

The packet is routed to the IRB after all required personnel have signed off.



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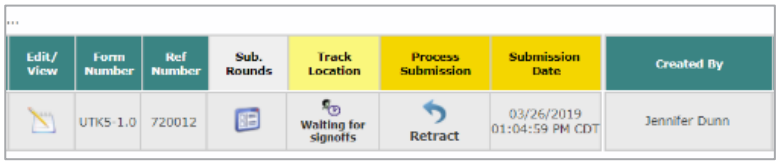
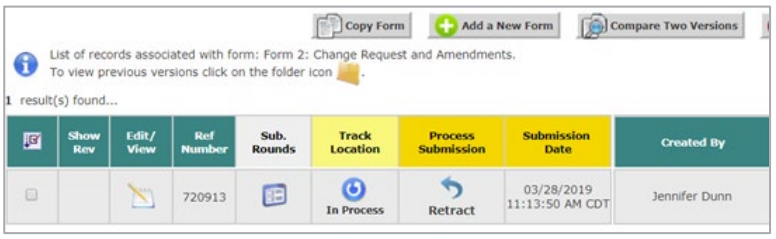
25. After the submission package is sent to the IRB, users can check the status of their submission on the **Amendment Request** screen.





Revise Existing Documents vs Adding New Documents

Changes to Existing Documents

If you need to **replace existing documents** with revised versions, always use the (add/create revision icon) or Create a new version (button) when making those changes.

Examples of these changes include revising study procedures in consent forms, revise recruitment material, updating surveys to remove or add questions, etc.

Benefits include:

- When used with Word documents, an iMedRIS comparison tool automatically displays differences between multiple versions of the same documents.
- The IRB can quickly identify differences between the previous and revised versions of your document which can speed up the review process.
- New version numbers are automatically assigned to the revised documents (e.g., 1.0 to 1.1).
- Quickly identify the current version of your documents.
- Document version control allows researchers to see what was approved at any particular time during the life of the study.

New Documents

If you need to **add documents** that were not previously included in a submission, always use the (add icon) or Add a New Document (button).

Example 1: Study was previously approved for only adult participants. The amendment adds teenagers as study participants and an adolescent consent form that includes required elements for parental permission is being added.

Example 2: Study involving participants who do not speak English was previously approved with both Spanish and English versions of the consent document and other materials. Now an amendment is adding a population who speak Mandarin, so materials translated into Mandarin are submitted.

What to Include in Your Amendment Request

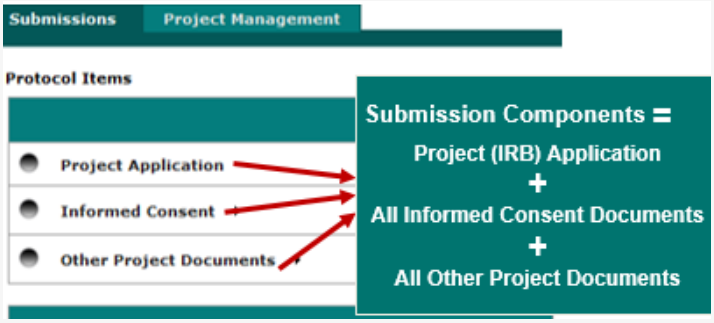
Submission Components Requiring Revision

Study changes must be identified in **BOTH**

1. **Amendment Request form**

AND

2. **All related submission components**



Examples:

IRB Application – adding, removing or changing:

- Study title
- Targeted participant population
- Participant eligibility (inclusion/exclusion criteria)
- Recruitment and screening procedures
- Consent procedures
- Study design or procedures (data collection, interventions, analyses, etc.)
- Privacy or confidentiality procedures (data and research document security and storage
- Number of participants to be enrolled
- Participant compensation
- Funding/Sponsor
- Study Sites
- Study personnel or non-UTK collaborators
- Agreements/contracts

Informed Consent Documents – if enrollment is ongoing:

- Adding consent documents for a new population
- Revising consent documents for existing population to add/change study procedures or changing number of study visits or data collection points, etc.
- Change in listed study personnel

Other Project Documents – adding or changing:

- Recruitment materials, SONA posting, etc.
- Data collection instruments, interview scripts, etc.
- Materials used for interventions
- Data use agreements and other contracts
- Grant or other funding applications
- Site authorization/Letters of support for new study sites
- Non-UTK IRB approvals – for collaborating researchers or study sites having IRBs

Submissions Screen

- Click **A. Project Application** to revise the IRB Application.
- Click **B. Informed Consent** to revise/add consent documents.
- Click **C. Other Project Documents** to revise/add other study related materials.

Document History

Date	Summary of Changes
08.12.2019	Original Document Approved.
04.15.2020	Updated Title, added login information, updated some procedures, and reformatted some sections.