The individuals listed below must sign off on a new application before the IRB will accept it for review. Studies missing a signoff from a required individual **will be returned to the PI without review**. Signoff requirements vary by submission type (new application, amendment, etc.). See Signoff Requirements by Submission Type.

- Principle Investigator (PI)
- Co-Principal Investigator (co-PI)
- Co/Sub-Investigator (co/sub-I)
- Faculty Advisor (if student PI)
- Department Head
- Department Review Chair
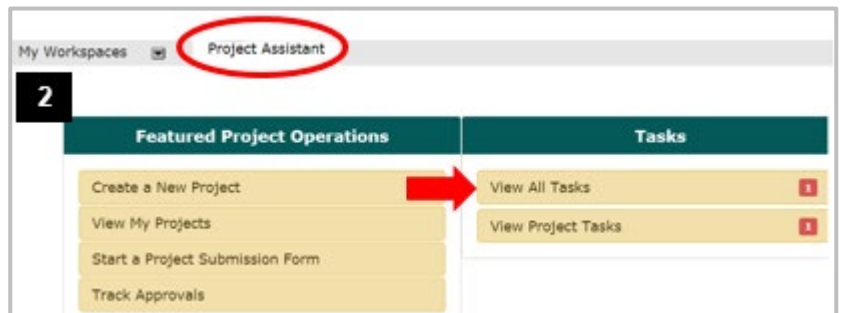
Respond to a Submission Correction Notification

Follow the steps below to ensure the routing and signoff procedure includes all required individuals.

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

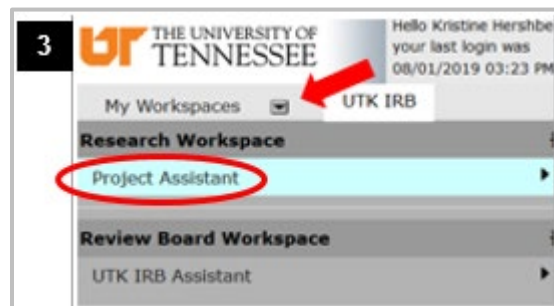**NOTE:** iMedRIS uses Two-Factor Authentication.
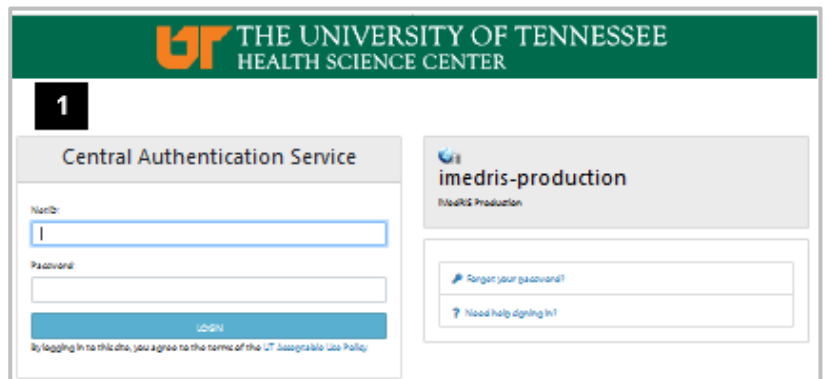
2. If iMedRIS opens to the **Project Assistant** screen (tab circled in red) click **View All Tasks**. If not, go to **Step 3**.


3. Hover your mouse pointer over the **My Workspaces** drop-down symbol.

- Click **Project Assistant** (circled in red).

- Click **View All Tasks**.

4. Project Assistant screen

- Click **Outstanding** (red arrow) to show all tasks requested by the IRB that are incomplete.

- Find **Submission Correction** (circled in red) under the Task Type column.

- Click the **pad & pencil icon** (blue arrow) under the **Click to Open** column.
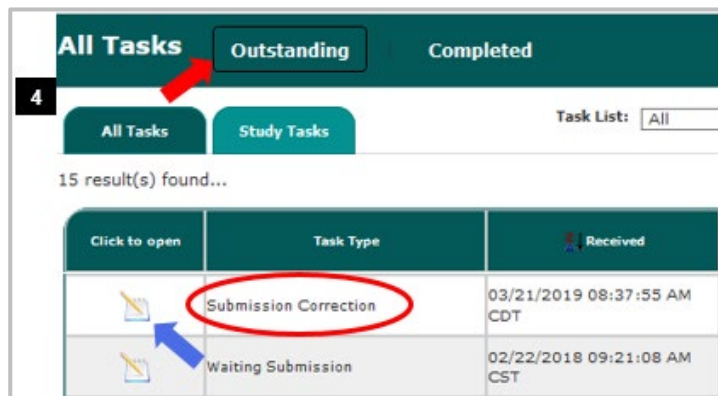

5. Pre-Review Correction Form screen – Find IRB Request

- Use scroll bar on the far right to scroll down to section **1.3 Issues Requiring a Response** (outlined in red). This section will display the IRB's requested changes

- Individuals that are highlighted must be placed in the routing and signoff process for the application package.

- You can either take the following actions now or during **Step 12**.

  o Click **Yes** to accept the requested changes (red arrow).

  o **Enter your response** in the text box (below the arrow) to describe the changes made.
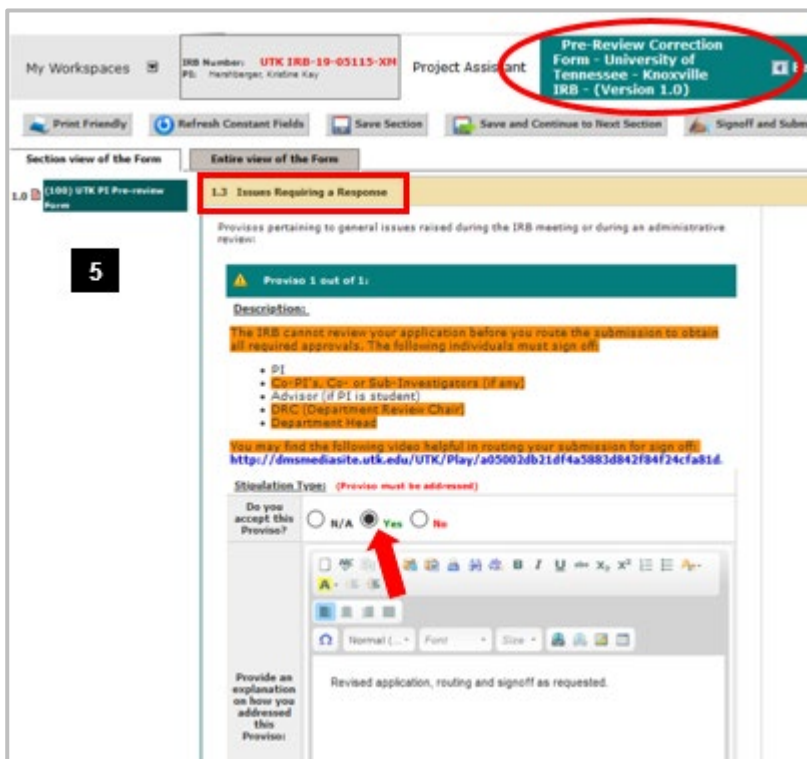
6. Pre-Review Correction Form screen – Revise Application

- Scroll back up to section **1.2 Revise and Attach Documents**.

- Find the **UTK Knoxville Main Campus IRB Application**

- Click the **Document icon** (red arrow) under the **Revise/Attach** column to add the required individuals to the routing and signoff process.

- Click **OK** on pop-up asking if you want to revise the application.
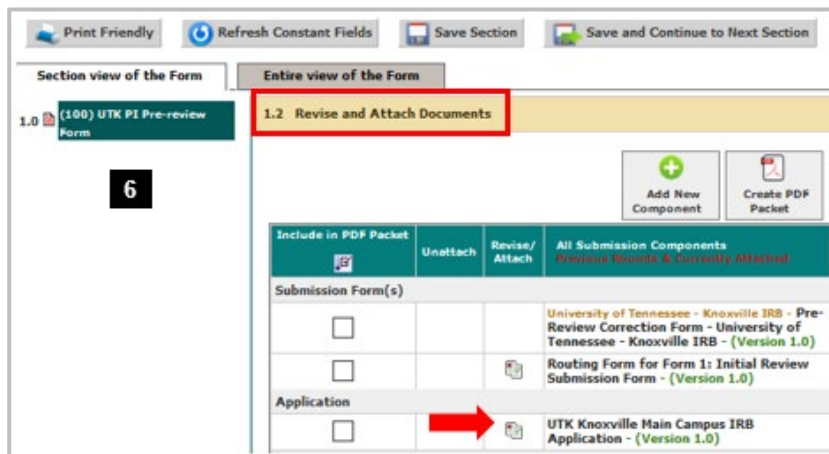
Revise the IRB Application

7. Application Form screen.

- Click section **3.0 Grant Key Personnel access to the study** on navigation pane (outlined in red).

- If the **PI is a student**, confirm **Student** is checked under item **3.1** (Principal Investigator)

8. Find items **3.2 to 3.6**.

- Click **Add User** (circled in red) in the applicable section to add any individuals requested by the IRB in the Submission Correction Form.

- Confirm all of the following individuals are listed (as applicable to the study).
  - Co-PI
  - Co/Sub-Investigators
  - Research Support Staff
  - Study Contact
  - Faculty Advisor (if student PI)
  - PI's Department Review Chair
  - PI's Department Chair/Head
  - Research Administrative Specialist, if any

9. Search User Directory screen. The Search function defaults to the **iMedRIS Database**.

- Enter the person's last name
- Click **Find**

10. In the search results:

- Click the **check box** (circled in red) left of person to be added.
- Click **Save Selected User(s)** (circled in red).
- If the individual you seek is not in the results, click the **LDAP Directory** option and try the search again.

11. In the **Application Form** screen after all changes are made:

- Scroll down the navigation pane
- Click last section, **(1000) Routing for Signatures and Attaching Documents**
- Click **Save and Continue to Next Section**

12. Pre-Review Correction Form screen

- Scroll down to section **1.2 Revise and Attach Documents**. If the application was revised, confirm new version is attached (circled in red).
- To resubmit, click **Signoff and Submit** (and skip to item 14 below) *or* click **Save and Continue to Next Section** (then follow item 13 below).

22. Form Completed screen

- The PI must click **Signoff and Submit** for new applications.
- Then users are routed to the **Setup Signoff Submission Routing** screen.
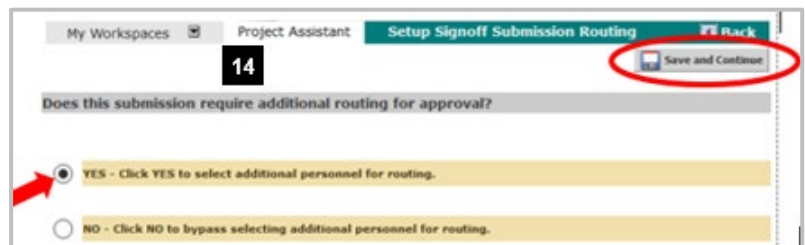
TIP: If study personnel other than an investigator completes the form, only the **Exit Form** button appears. The PI then must open the form and click **Signoff and Submit**.

Assign Required Individuals for Routing and Signoff

14. Setup Signoff Submission Routing Screen

- Click **Yes** (red arrow).
- Click **Save and Continue** (circled in red).

15. Select Key Personnel for Routing and Signoff section (blue arrow)

- Click check boxes under **Include in signoff** column (red arrow) for:
  - o PI
  - o All Co-PIs
  - o All Co/Sub-Investigators
  - o Faculty advisor (if student PI)
- Click **Save and Continue** (circled in red).

16. Additional Personnel Required for Routing and Signoff section (blue arrow)

- Click check boxes under **Include in signoff** column (red arrow) for:
  - o PI's Department Review Chair
  - o PI's Department Chair
- **Order column** is the order these individuals receive the application package after key personnel signoff (**Step 13** above).
  - o Enter **1** for Dept. Review Chair
  - o Enter **2** for Dept. Chair/Head
- Click **Save and Continue**.
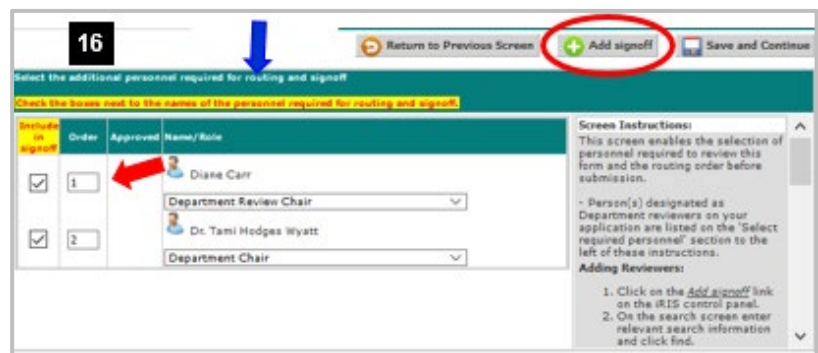
If an individual who is required for this screen is missing, click the **Add Signoff** button circled in red

17. Routing Confirmation section header (blue arrow).

All the individuals required to signoff should be listed here. If not, add those missing individuals via the **Click here** buttons (outlined in red).

If all required individuals are listed, and the routing order (red arrow) is correct:

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

18. Submission Routing Signoff

If you are an investigator on the study, this screen will appear and show all documents included in the submission package.

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

19. Click **Approve** (red arrow)

20. Click **Save Signoff** (circled in red)

The submission package will now be routed to all individuals required for routing and signoff. After all signoffs are completed, the submission package will be routed to the IRB.

Click <u>here</u> to return to beginning of document.

Signoff Requirements by Submission Type

	New Study Application[1]	Response to IRB Request	Amendment Request (Form2)/ Add or Remove UTK Personnel	Cont. Review (Renewal-Form 3)	All Others
Individuals Required to Signoff	• principal investigator • co-principal investigator • co/sub-investigators • faculty advisor (if PI is a student) • PI's dept. review chair (DRC) • PI's dept. chair/head	PI **or** other investigator (co/sub-I or co-PI)	• PI **or** other investigator (co/sub-I or co-PI) already on the approved IRB application • **All newly added** investigators (co/sub-Is and co-PI), if any • **Newly added** faculty advisor, if any • **Newly added** PI, if any	PI **or** other investigator (co/sub-I or co-PI)	PI **or** other investigator (co/sub-I or co-PI)

Click here to return to beginning of document.

Document History

Date	Summary of Changes
08.18.2019	Document approved and posted
09.17.2019	Updated numbering and updated Individuals Required to Signoff
03.19.2020	Added login information, reordered sections, combined some sections, and deleted Tracking and Finding Study sections.
04.15.2020	Updated routing instructions to be consistent with other guidance documents.

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[1] **Only when a *new* study application is submitted for the very first time** are all the individuals identified in the New Study Application column required to sign off on the study. If the IRB requests changes or additional information during the review process, only the PI or other investigator (co/sub-I or co-PI) must signoff on the response submission.