

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](#).

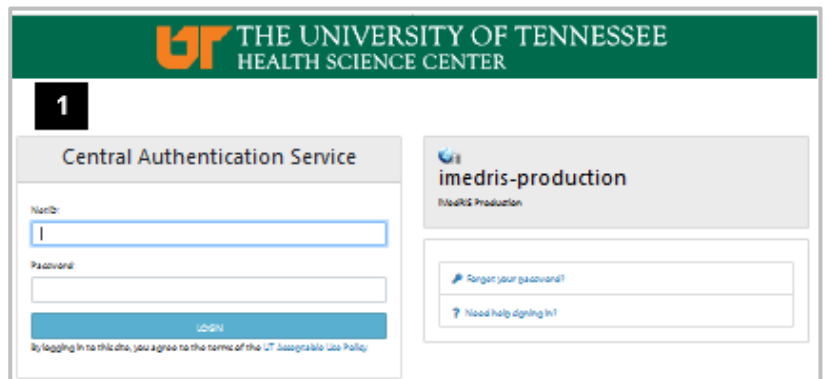
- Principle Investigator (PI)
- Co-Principal Investigator (co-PI)
- Co/Sub-Investigator (co/sub-I)
- Faculty Advisor (if student PI)
- Department Head
- Department Review Chair

## Respond to a Submission Correction Notification

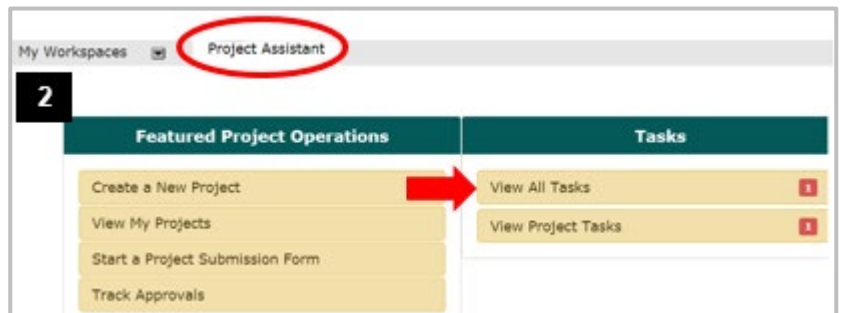
Follow the steps below to ensure the routing and signoff procedure includes all required individuals.

1. Log in to [iMedRIS](#) using your **NetID** and **Password**.

**NOTE:** iMedRIS uses Two-Factor Authentication.

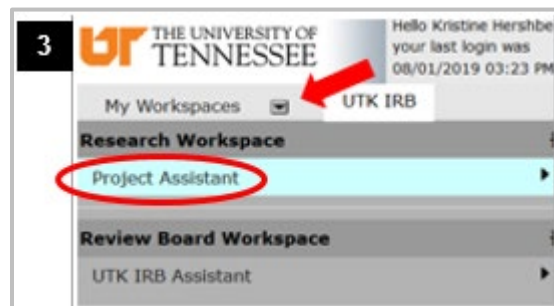


2. If iMedRIS opens to the **Project Assistant** screen (tab circled in red) click **View All Tasks**. If not, go to **Step 3**.



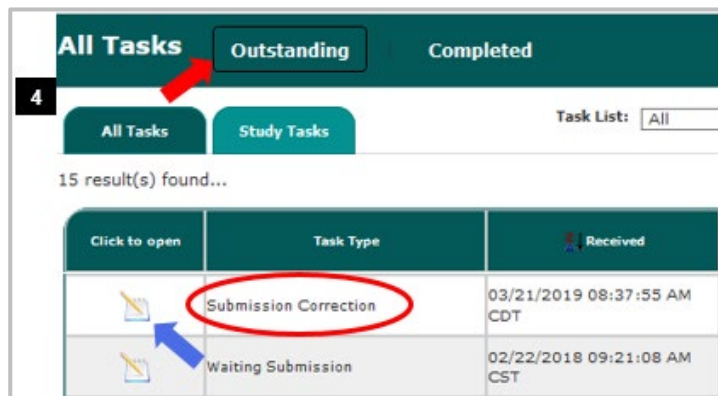
3. Hover your mouse pointer over the **My Workspaces** drop-down symbol.

- Click **Project Assistant** (circled in red).
- Click **View All Tasks**.



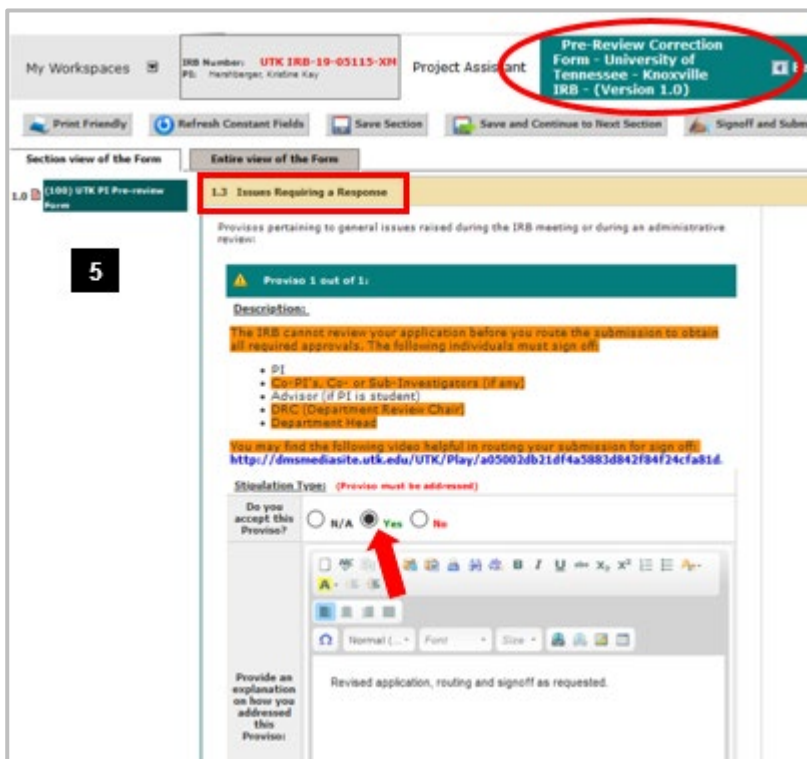
#### 4. Project Assistant screen

- 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.



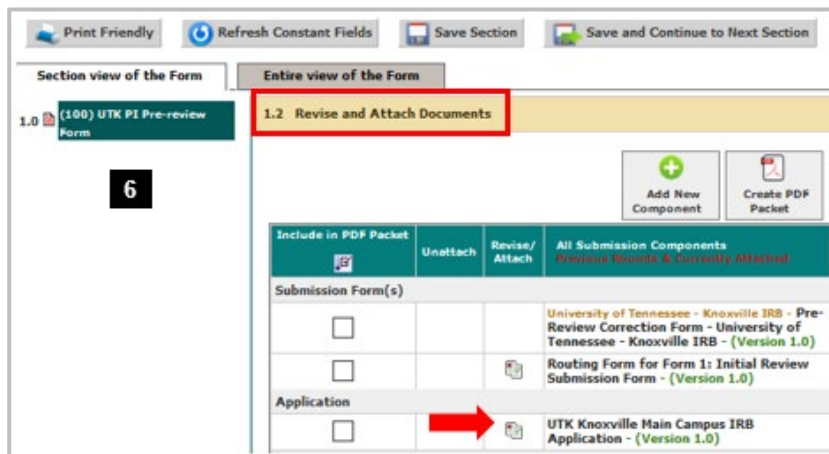
#### 5. Pre-Review Correction Form screen – Find IRB Request

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

The screenshot shows the 'Section view of Application' on the left navigation pane, with '3.0 Grant Key Personnel access to the study' highlighted. The main content area shows '3.0 Assign key study personnel(KSP) access to the study'. Under '3.1 \* Please add a Principal Investigator for the study', the name 'Kristine Kay Hershberger' is listed. Below the name, there are checkboxes for 'Student' (checked and circled in red), 'Department Chair', 'Resident', and 'Fellow'. An 'Add Us' button is visible to the right.

## 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

The screenshot shows sections 3.2 through 3.6 of the IRB application form. Section 3.2 is titled 'If applicable, please select the Research Staff personnel (for UTK, collaborators from outside the institution should not be listed here):'. It contains two sub-sections: 'A) Additional Investigators' and 'B) Research Support Staff'. Section 3.3 is titled 'Please add a Study Contact: Students must include their advisor as well as themselves in this section.' and lists 'Hershberger, Kristine Kay' and 'Pruett, Sarah'. Section 3.4 is titled 'Students must add a Faculty Advisor' and lists 'Sarah Pruett'. Section 3.5 is titled 'Select the Department Review Chair (DRC) and Department Head.' and lists 'Carr, Diane' and 'Wyatt, Tami Hodges'. The 'Add User' button for 'Carr, Diane' is circled in red. Section 3.6 is titled 'If applicable, please select the Research Administrative Specialist(s):'.

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.

| Check for Multiple                  | Select User                         | Training | User Name                 | Department                            | Email                 |
|-------------------------------------|-------------------------------------|----------|---------------------------|---------------------------------------|-----------------------|
| <input checked="" type="checkbox"/> | <input checked="" type="checkbox"/> |          | Hershberger, Kristine Kay | Research Administration (primary) [+] | khershbe@utk.edu      |
| <input type="checkbox"/>            | <input checked="" type="checkbox"/> |          | Hershberger, Mainan Bryn  | Inactive (primary)                    | mherahb1@vols.utk.edu |

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).

| Include in PDF Packet    | Unattach | Revise/Attach | Revisions | All Submission Components   |
|--------------------------|----------|---------------|-----------|---|
| <input type="checkbox"/> |          |               |           | University of Tennessee - Knoxville IRB - Pre-Review Correction Form - University of Tennessee - Knoxville IRB - (Version 1.0) (Incomplete) |
| <input type="checkbox"/> |          |               |           | Routing Form for Form 1: Initial Review Submission Form - (Version 1.0)   |
| <input type="checkbox"/> |          |               |           | UTK Knoxville Main Campus IRB Application - (Version 1.1)   |

## 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.

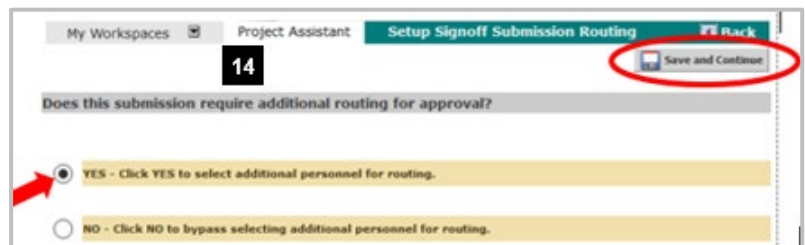
**TIP:** If study personnel other than an investigator completes the form, only the **Exit Form** button appears. The PI then must open the form and click **Signoff and Submit**.



## Assign Required Individuals for Routing and Signoff

### 14. Setup Signoff Submission Routing Screen

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



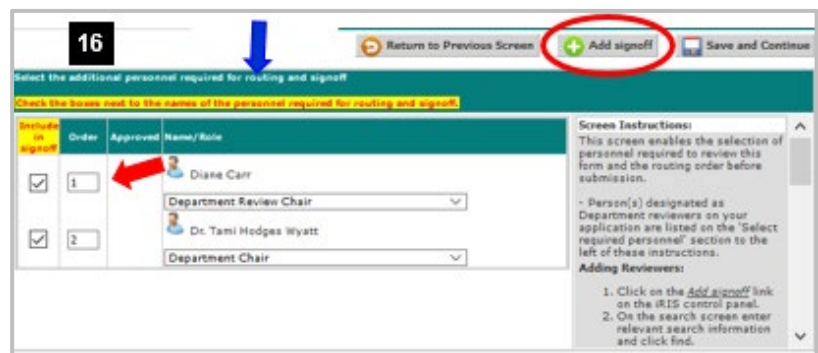
### 15. Select Key Personnel for Routing and Signoff section (blue arrow)

- Click check boxes under **Include in signoff** column (red arrow) for:
  - PI
  - All Co-PIs
  - All Co/Sub-Investigators
  - 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:
  - PI's Department Review Chair
  - PI's Department Chair
- **Order** column is the order these individuals receive the application package after key personnel signoff (**Step 13** above).
  - Enter **1** for Dept. Review Chair
  - 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**.

| Approved Name            | Role                   |
|--------------------------|------------------------|
| Kristine Kay Hershberger | Principal Investigator |
| Gina Owens, Ph.D.        | Co-Investigator        |
| Sarah Pruett             | Faculty Advisor        |
| Jennifer Marie Engle     | Sub-Investigator       |
| Jennifer Dunn            | Co-PI                  |

| Order | Approved Name         | Role                    |
|-------|-----------------------|-------------------------|
| 1     | Diane Carr            | Department Review Chair |
| 2     | Dr. Tami Hodges Wyatt | Department Chair        |

**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.

Project Title: iMedRIS Form Development for Production  
Submission Reference Number: 718471

| Include in PDF Packet     | Submission Component Name - Version  |
|---------------------------|--|
| <input type="checkbox"/>  | Pre-Review Correction Form - University of Tennessee - Knoxville IRB - (Version 1.0) |
| <input type="checkbox"/>  | Routing Form for Form 1: Initial Review Submission Form - (Version 1.0)              |
| <b>Application</b>        |  |
| <input type="checkbox"/>  | UTK Knoxville Main Campus IRB Application - (Version 1.1)                            |
| <b>Document(s)</b>        |  |
| <input type="checkbox"/>  | Miscellaneous Corrections to IRB Application - 11.29.2018 - (Version 1.0)            |
| <b>Category: --none--</b> |  |
| <input type="checkbox"/>  | Pop-up Windows - Consent Document Add - Project Document Add - (Version 1.2)         |
| <input type="checkbox"/>  | 468 Funding - (Version 1.2)  |
| <input type="checkbox"/>  | 1600 Recruitment - (Version 1.2)   |
| <input type="checkbox"/>  | 2000 Risks and Benefits - (Version 1.2)  |
| <input type="checkbox"/>  | 2800 Privacy and Confidentiality - (Version 1.2)                                     |

Kristine Kay Hershberger as Principal Investigator do you Approve or Deny this submission?  
 Approve  Deny

Click [here](#) to return to beginning of document.

## Signoff Requirements by Submission Type

| Individuals Required to Signoff | New Study Application <sup>1</sup>  | Response to IRB Request                      | Amendment Request (Form2)/ Add or Remove UTK Personnel   | Cont. Review (Renewal-Form 3)                | All Others                                   |
|---------------------------------|---|--|--|--|--|
|                                 | <ul style="list-style-type: none"> <li>principal investigator</li> <li>co-principal investigator</li> <li>co/sub-investigators</li> <li>faculty advisor (if PI is a student)</li> <li>PI's dept. review chair (DRC)</li> <li>PI's dept. chair/head</li> </ul> | PI or other investigator (co/sub-I or co-PI) | <ul style="list-style-type: none"> <li>PI or other investigator (co/sub-I or co-PI) already on the approved IRB application</li> <li><b>All newly added</b> investigators (co/sub-I's and co-PI), if any</li> <li><b>Newly added</b> faculty advisor, if any</li> <li><b>Newly added</b> PI, if any</li> </ul> | 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.  |

<sup>1</sup> 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.