HUMAN RESEARCH PROTECTION PROGRAM

iMedRIS Quick Guide

Continuing Review Request (Renewal – Form 3)

iMedRIS version: 11.01
Last Revised: 04.15.2020

Continuing review (CR) occurs when the principle investigator (PI) reports what has happened since the IRB's last review and approval. The IRB ensures that the study still meets all of the regulatory criteria for approval. CR of research must be substantive and meaningful.

Although iMedRIS sends a continuing review reminder to the PI, **the PI is responsible for submitting the CR request at least four (4) weeks before the expiration date** to avoid lapses in approval. After receipt of the request, the IRB conducts its review within the thirty-day period prior to the study's expiration date.

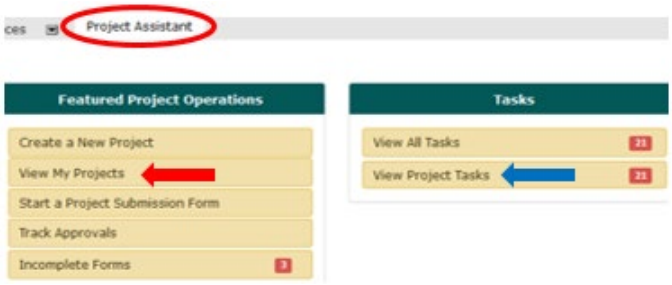
Find and Open a Study Requiring Continuing Review

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

NOTE: iMedRIS uses Two-Factor Authentication.

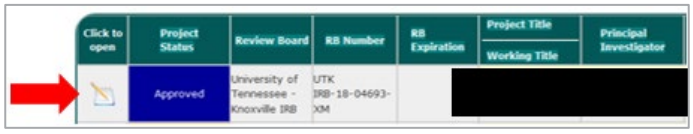
iMedRIS should open to your **Project Assistant** workspace (tab circled in red). If not, hover your mouse pointer over the **My Workspaces** drop-down symbol and click **Project Assistant**.

- Click **View My Projects** (red arrow) to see all the studies on which you are listed as study personnel, or
- Click **View Project Tasks** (blue arrow) to see your pending **Study Tasks** if responding to notification from the IRB.



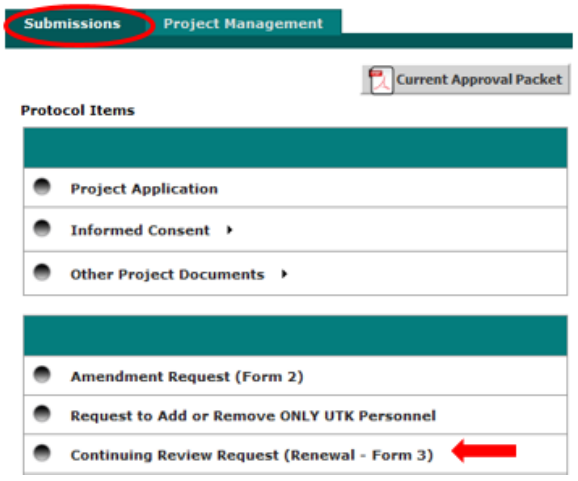
The screen displays a list of all studies that include you as study personnel.

- Locate your study.
- Click icon under the **Click to Open** column.



Submissions screen

Click **Continuing Review Request (Renewal – Form 3)** (red arrow).

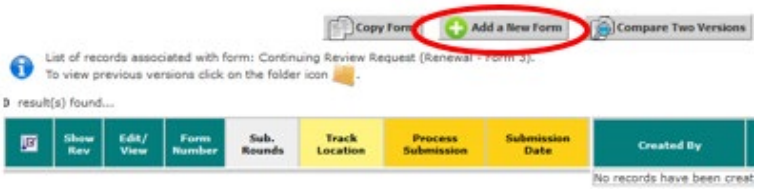


Create a Continuing Review Request

2. Continuing Review Request screen

Click **Add a New Form** (circled in red).

TIP: If the study received continuing review in the past, those forms will be listed here. Open those forms to view information reported about the study in previous years.



Studies Involving Collaborations with Non-UTK Researchers

If your study involves a **reliance agreement or an investigator agreement** to cover non-UTK researchers collaborating on the study, and UT, Knoxville IRB is the IRB of record, the **PI <u>must</u> report information pertaining to those study sites in the Continuing Review Request**. This includes the number of participants enrolled, participant complains, problems, etc.

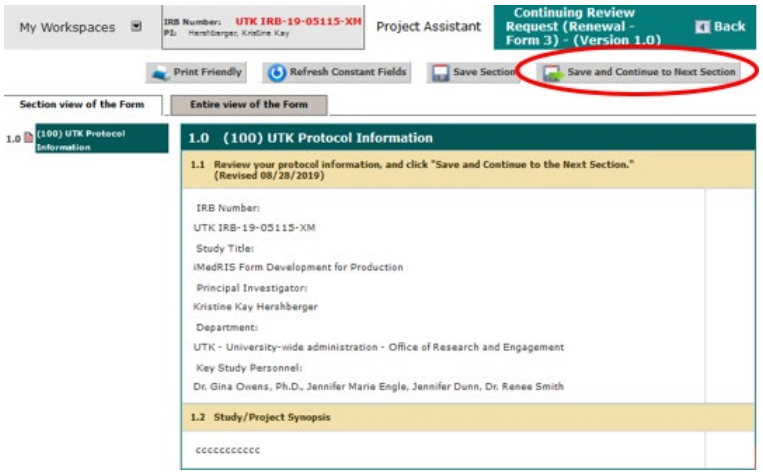
3. (100) UTK Protocol Information.

- Displays basic study information (IRB number, title, PI name, etc.) and includes the Study Synopsis. No changes need to be made in this section.
- Click **Save and Continue to Next Screen**.

TIP: The navigation bar on the left displays each screen section. The form builds as you complete each section and branches based on your responses.

Navigate through screen sections by clicking either

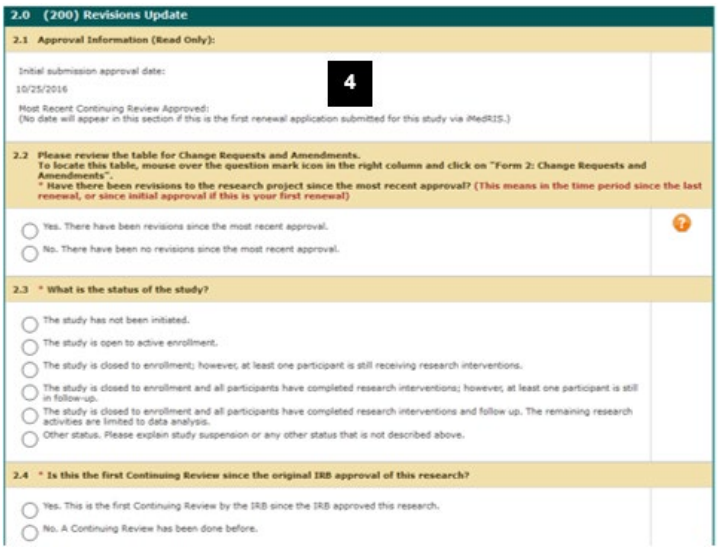
- Save and Continue to Next Section , or
- the desired screen section from the navigation bar. Always click Save Section **before** leaving that screen section after making changes.



4. (200) Revisions Update

- **Item 1**: Approval Information (read only).
- **Item 2**: Amendments
  - A **Yes** response requires amendments approved during the last approval period be summarized.
- **Item 3**: Study status.
- **Item 4**: Past reviews
- Click **Save and Continue to Next Screen**.

TIP: View your previously submitted amendments by returning to the **Submissions** screen and clicking the amendment form.

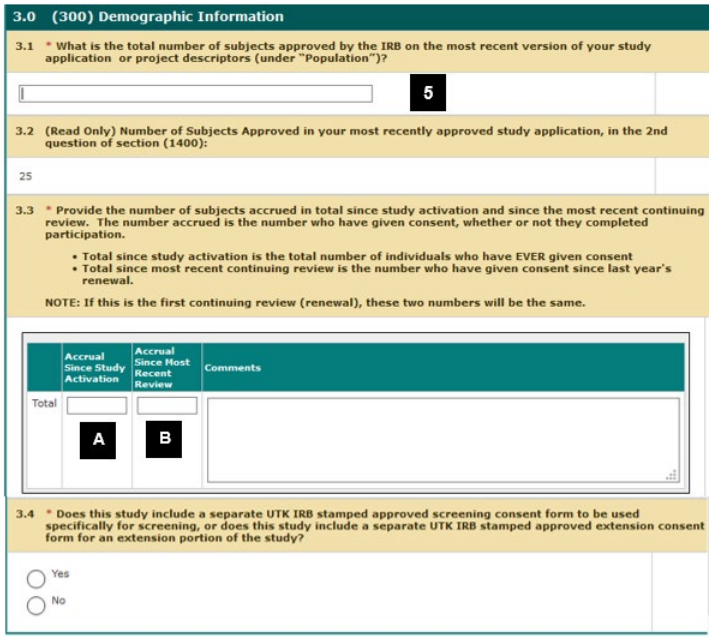


5. (300) Demographic Information

- Answer **Items 1 – 4** number of participants enrolled in the study (see **Enrollment** definition below).
- **Item 3** – Must include the following information:
  - **A** – Number of participants enrolled since the study's initial approval (when the study first began).
  - **B** – Number of participants enrolled since the last time the study was approved (i.e., last continuing review, or if a new study, the date of its initial approval).
- Click **Save and Continue to Next Screen**.

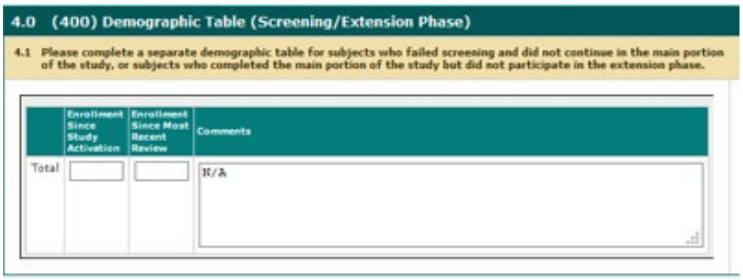
Enrollment occurs when an individual goes through the informed consent process and voluntarily agrees to participate in a research study.

* Participants who do not provide complete data or withdraw before completing all study procedures **are still considered to be enrolled and count towards participant accrual**.



(400) Demographic Table (Screening/Extension Phase)

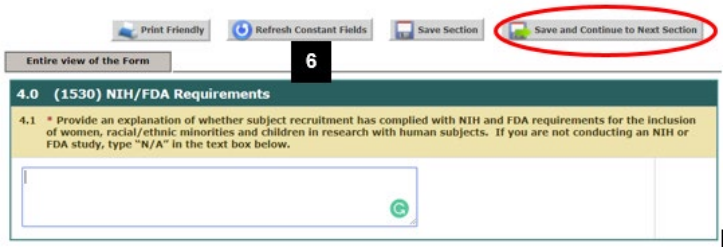
- Answer **Item 1** – Participants who failed screening. If not applicable to your study, enter N/A into the **Comments** text box.
- Click **Save and Continue to Next Screen**.



6. (1530) NIH/FDA Requirements

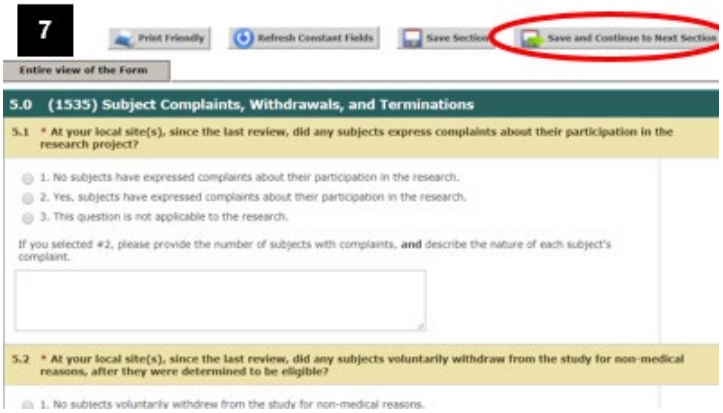
If subject to NIH requirements (due to funding) **or FDA regulations**.

- Describe how your study complies with these requirements.
- Otherwise, enter **N/A**.
- Click **Save and Continue to Next Screen**.



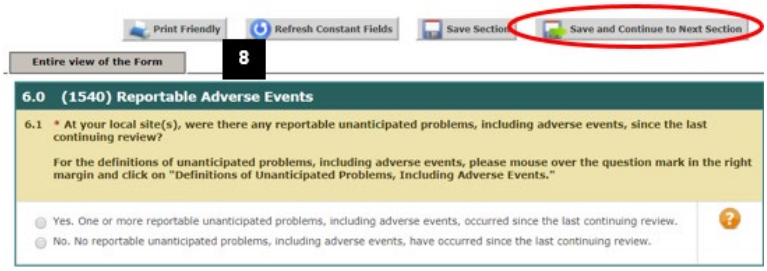
7. (1535) Subject Complaints, Withdrawals, and Terminations

- Answer **Items 1 – 4**.
- **Local site** refers to all studies approved by UT, Knoxville IRB. Any issues related to these studies should be reported in this Continuing Review Request.
- Click **Save and Continue to Next Screen**.



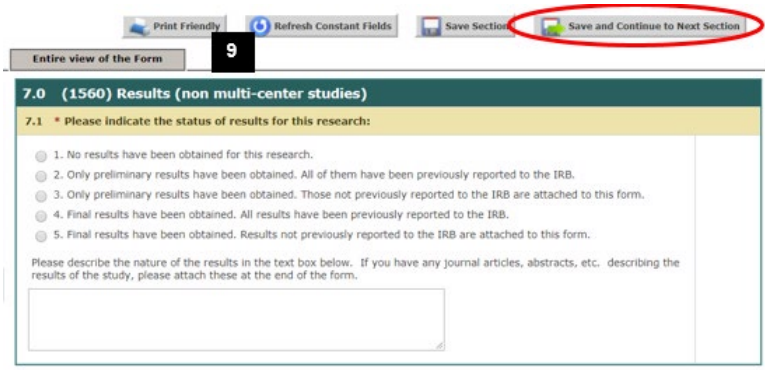
8. (1540) Reportable Adverse Event

- Answer **Item 1**.
- Click **Save and Continue to Next Screen**.



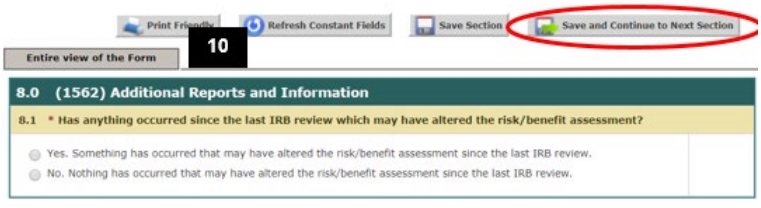
9. (1560) Results (non multi-center studies)

- Answer **Item 1**.
- Click **Save and Continue to Next Screen**.



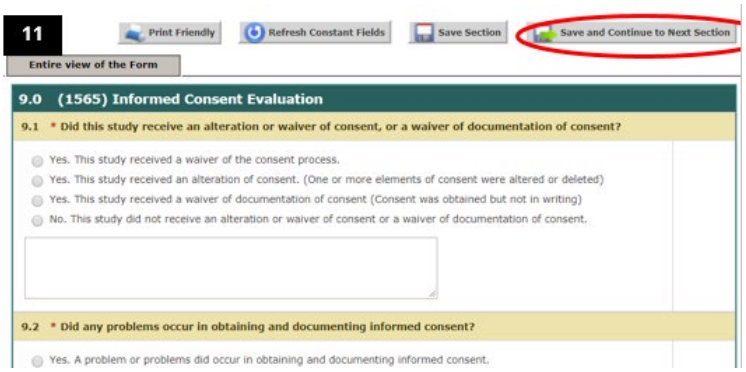
10. (1562) Additional Reports and Information

- Answer **Item 1**.
- Click **Save and Continue to Next Screen**.



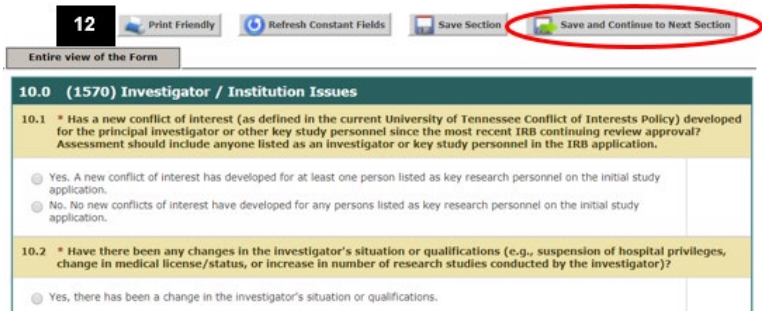
11. (1565) Informed Consent Evaluation

- Answer **Items 1 – 5**.
- Click **Save and Continue to Next Screen**.



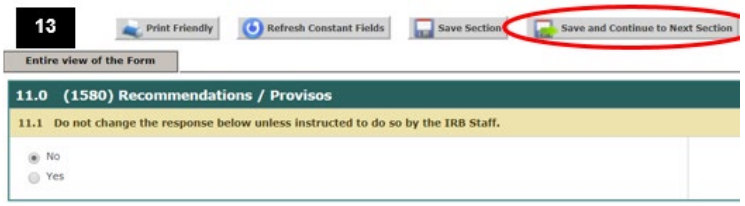
12. (1570) Investigator/Institution Issues

- Answer **Items 1 – 3**.
- Click **Save and Continue to Next Screen**.



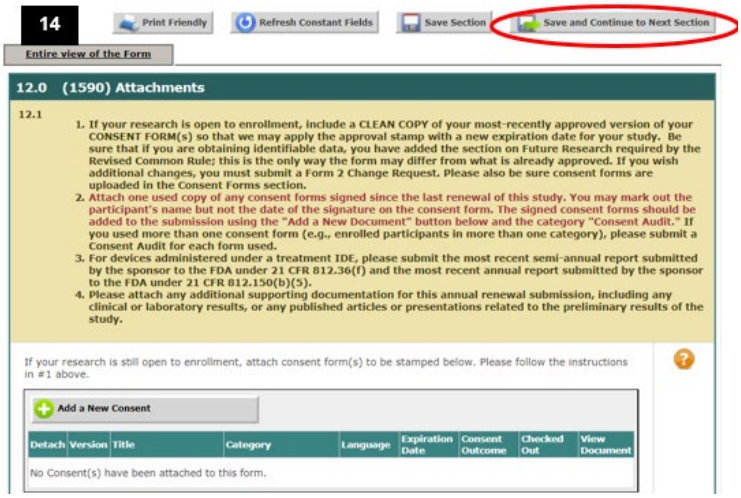
13. (1580) Recommendations/Provisos

- **Item 1** – No action is necessary.
- Click **Save and Continue to Next Screen**.



14. (1590) Attachments

- Answer **Item 1**.
- Include all requested documents applicable to your study.
- If participants enrolled by **signing a consent form since the last time the study was approved** (i.e., the last continuing review, or its initial approval date), attach a Consent Audit. Follow the instructions on this screen.
- Failure to submit the required consent audit will result in the return of the submission without review and may result in expiration of the study's approval.
- Click **Save and Continue to Next Screen**.



15. Form Completed screen

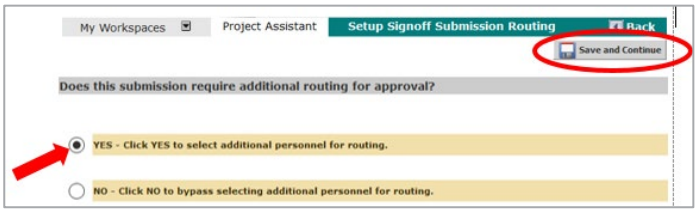
- Either the PI **or** another investigator (co/sub or co-PI) must click **Signoff and Submit**.
- Then users are routed to the **Setup Signoff Submission Routing** screen.

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 Signoff

16. Setup Signoff Submission Routing

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



17. Select Key Personnel Routing and Signoff

- Check the boxes (red arrow) for either the PI **or** another investigator (co/sub or co-PI).
- Click **Save and Continue**.

18. Setup Signoff Submission Routing – Additional Personnel

- No additional study personnel are required for continuing review submissions.

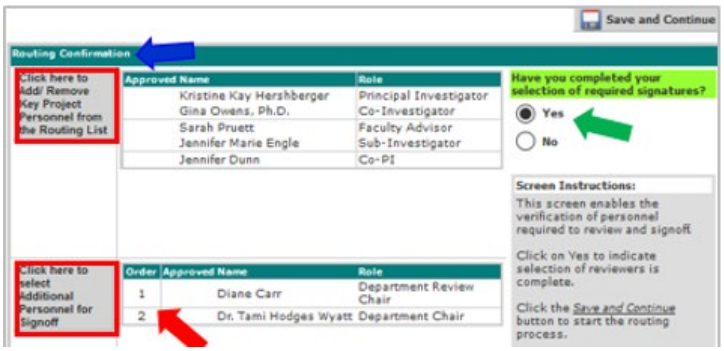
Click **Save and Continue** (circled in red).

19. Routing Confirmation

If all required individuals are listed:

- 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.



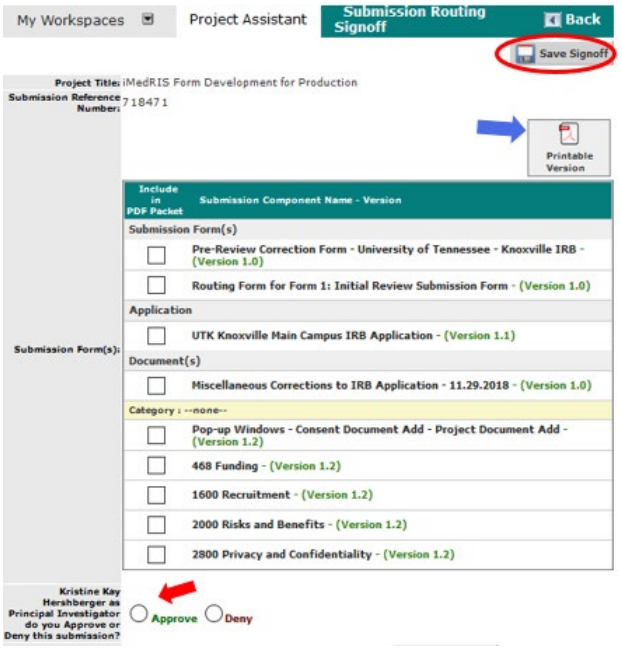
20. Submission Routing Signoff

- **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).

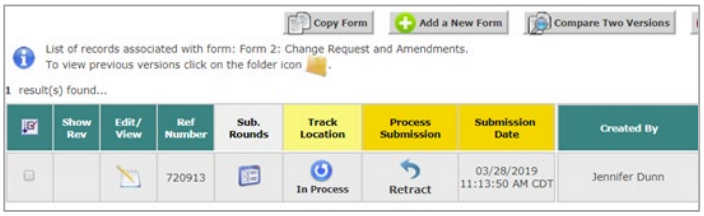
If everything is in order:

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

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



21. After the submission package is sent to the IRB, you can track its progress on the Continuing Review Request screen (**Step 2**).



Document History

Date	Summary of Changes
10.28.2019	Original Approval
04.15.2020	Updated to add login information, some procedures, and reformatted some sections