

Study Closure Request (Form 7)

iMedRIS version: 11.01
Last Revised: 04.15.2020

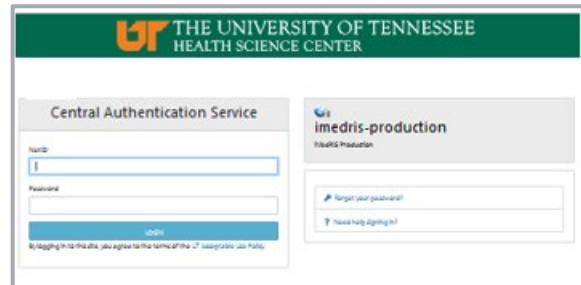
You must submit a Study Closeout Request for ALL study types. This submission updates the IRB on the conduct and outcomes of the study, including any risks or problems that may have arisen since the last review and may need to be disclosed to the study participants or others.

- !** **Do NOT close out a study if any of the following conditions apply.** Studies meeting any of the conditions listed below must remain active and receive ongoing IRB review and approval.
- Any of the following activities are ongoing:
 - Enrollment of study participants,
 - Research-related interventions or interactions
 - Participant follow-up procedures.
 - Data analysis or manuscript preparation that involves use or access to individually identifiable information (this **includes** coded data for which a code key exists).
 - Biological specimens containing individually identifiable information are being maintained in a repository that has been approved as part of this study or upon which analysis or research continues. If specimens were transferred to a separate repository that has ongoing IRB approval, then the study may be closed.
 - If there is a study sponsor, and you have not received permission from the study sponsor to close the study with the IRB.

Find and Open the Study to be Closed

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

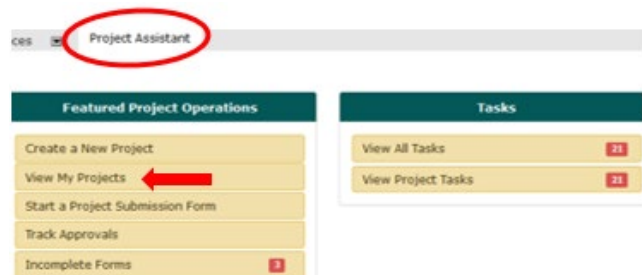
NOTE: iMedRIS uses Two-Factor Authentication.



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

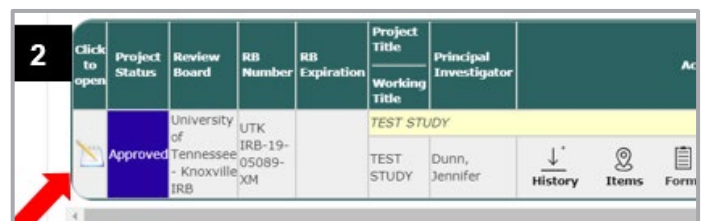
If not, hover your mouse pointer over the **My Workspaces** drop-down symbol.

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



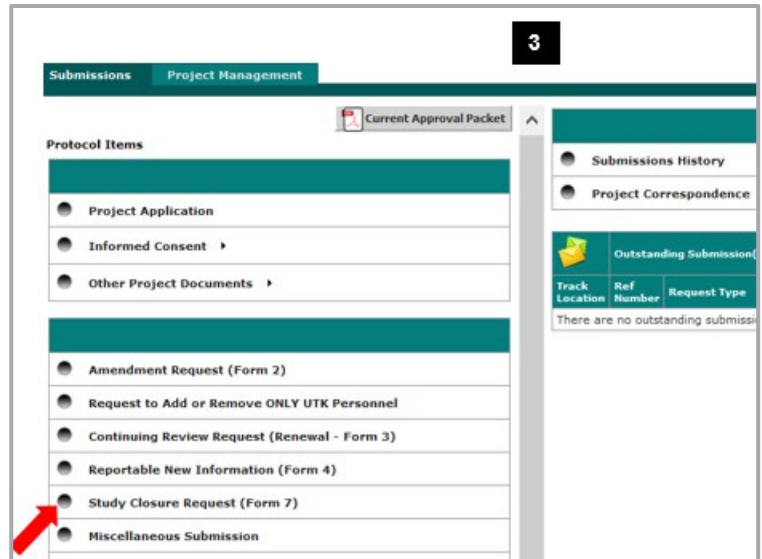
2. The screen then displays a list of all your studies (those which include you as study personnel). The most recently accessed study is displayed at the top of the list.

Locate your study. Click the **pad & pencil** icon (red arrow) under the **Click to Open** column.

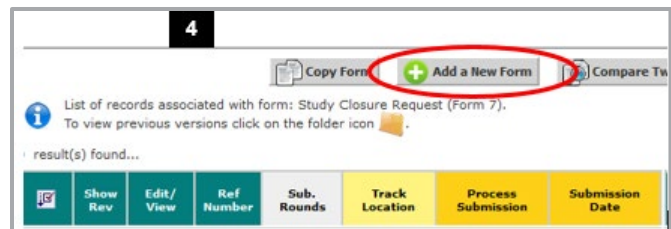


Create a Study Closure Request

3. Click **Study Closure Request (Form 7)** on the **Submissions** screen (red arrow).



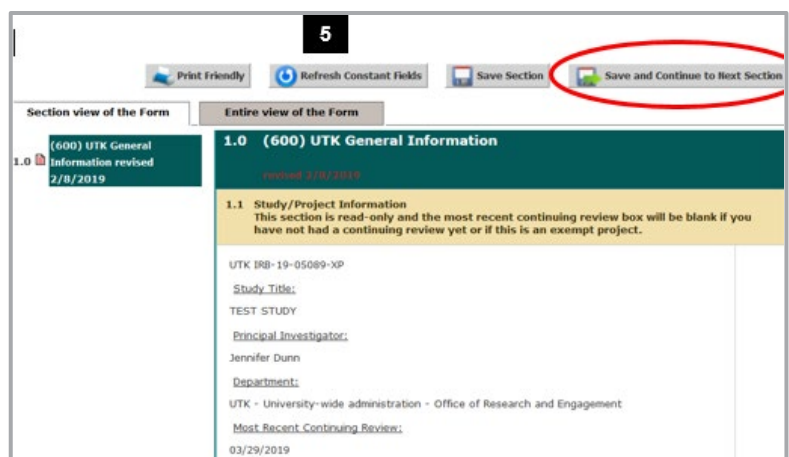
4. The **Study Closure** form screen opens. Click **Add a New Form** (circled in red).



5. **Section (600) UTK General Information.**

- Displays basic information about the study (e.g., IRB number, title, PI name).
- To advance to the next screen section, click **Save and Continue to Next Screen** (circled in red).

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



6. Section (620) Study/Project Termination

- **Item 1:** Date the study ended.
- **Item 2:** Total number of participants who enrolled in the study. Depending on your procedures, this number may refer to
 - number of individuals who signed the consent form; or
 - number of individuals who returned completed surveys or provided data; or
 - number of individuals about whom records/data/biospecimens were obtained.
- **Item 3:** Did any incidents occur requiring the submission of reportable new information?

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Print Friendly Refresh Constant Fields Save Section Save and Continue to Next Section

Section view of the Form Entire view of the Form

1.0 (600) UTK General Information revised 2/8/2019

2.0 (620) Study/Project Termination

2.0 (620) Study/Project Termination

2.1 * Date of Project Termination:

09/01/2019

2.2 * Subjects Enrolled:

50

2.3 * Did any subjects experience any reportable adverse events?

No subjects experienced reportable adverse events.

At least one subject experienced a reportable adverse event.

7. Section (640) Results

- **Item 1:** Displays the study description from the approved study application screen (925) Project Synopsis. Do not make changes to this description.
- **Item 2:** Enter a brief summary of the study results in the text box (red arrow).

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Print Friendly Refresh Constant Fields Save Section Save and Continue to Next Section

Section view of the Form Entire view of the Form

1.0 (600) UTK General Information revised 5/9/2018

2.0 (620) Study/Project Termination

3.0 (640) Results

3.0 (640) Results

3.1 Below is the study/project synopsis in read-only format, as presented in the most recent review:

Click here to access the text editor.

1) The purpose of this study is to discover if an advance directive form for persons

3.2 * Provide a brief narrative of overall results with respect to efficacy and safety with special attention to the purpose of the project as stated above.

8. Section (670) Study Closure Form

- Attach any documentation related to the closure of the study. Studies required to obtain a participant's signed consent must submit a **consent audit**.
- Click the **Add a New Document** button and follow the instructions in **Step 9**. Provide any additional information for the IRB in text box.
- A consent audit is not required for exempt studies or those studies granted a waiver of consent or waiver of signed consent. Users can skip to **Step 11** for such studies.

Consent Audits, Information, or Other Documentation

Section view of the Form Entire view of the Form

1.0 (600) UTK General Information revised 2/8/2019

2.0 (620) Study/Project Termination

3.0 (640) Results

4.0 (670) UTK Study Closure Form

4.1 If you have separate documentation regarding closure of this project, for example, correspondence regarding project closure, please attach here. Also, if you have enrolled any participants a scanned copy of one of your signed, dated Informed Consent forms from the past 12 months. Audit in the Other study documents section.

Select or Revise Existing Add a New Document Add New Document

Detach	Version	Title	Category	Expiration Date	Document Outcome
No Document(s) have been attached to this form.					

The following text box is provided in the event that you need to share any additional information with the Review Board.

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9. How to add a Consent Audit.

- Upload a scanned copy of consent or assent form signed and dated by a participant (or their legally authorized representative) enrolled in the study.
- The participant's **signature should be blocked or obscured** so that the participant cannot be identified.
- Select **Consent Audit** from the Project Document Category drop-down menu.
- Click **Save Document**.
- Submit one audit document for each population that gave signed consent or assent.

Many studies use only one consent document, but **some studies use multiple consent forms** because they involve:



- different participant populations (e.g., students and their advisors);
- multiple procedures which some completed by some participants, while other participants complete different procedures, or
- some or all participants cannot consent for themselves such as child participants who give assent while their parent gives their permission or an adult who is unable to give legally affective informed consent so surrogate consent from a legally authorized representative is required.

In cases such as these, a consent audit is required for each form type.

10. After uploading all the consent audit documents, click **Save and Continue to Next Screen** (circled in red).

Detach	Version	Title	Category	Expiration Date	Document Outcome	Checked Out	View Document
✖	1.0	Teacher Consent Form	Consent Audit				25.08 KB
✖	1.0	Student Consent Form	Consent Audit				25.08 KB

11. 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

12. Setup Signoff Submission Routing

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

13. 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.

Document History

Date	Summary of Changes
09.06.2019	Original Approval
03.26.2020	Added login information, updated some procedures information, and reformatted some sections.
04.15.2020	Updated instructions and formatting to be consistent with other guidance documents and added routing.