

# 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.

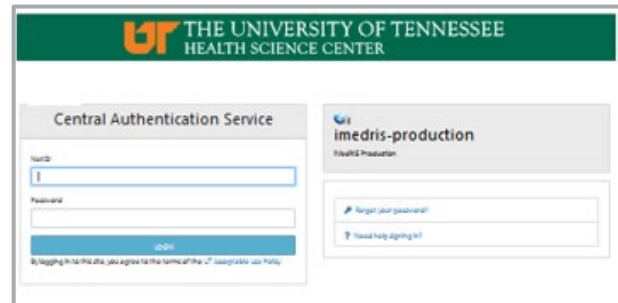


Although iMedRIS sends a continuing review reminder to the PI, **the PI is responsible for submitting the CR request at least four (4) weeks before the expiration date** to avoid lapses in approval. After receipt of the request, the IRB conducts its review within the thirty-day period prior to the study's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

## Find and Open a Study Requiring Continuing Review

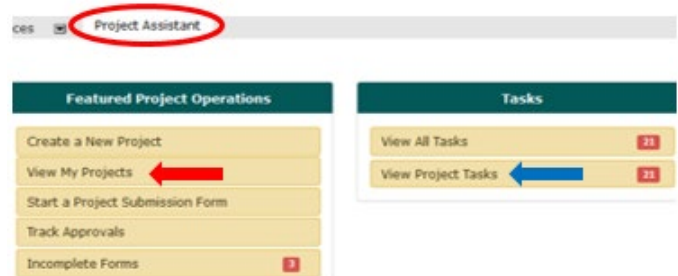
1. Log in to [iMedRIS](#) using your **NetID** and **Password**.

**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.



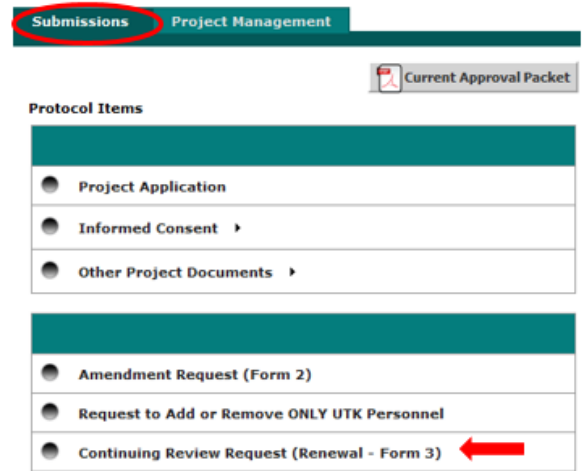
The screen displays a list of all studies that include you as study personnel.

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

Click to open	Project Status	Review Board	RB Number	RB Expiration	Project Title	Principal Investigator
	Approved	University of Tennessee - Knoxville IRB	UTK IRB-18-04693-XM			

Submissions screen

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

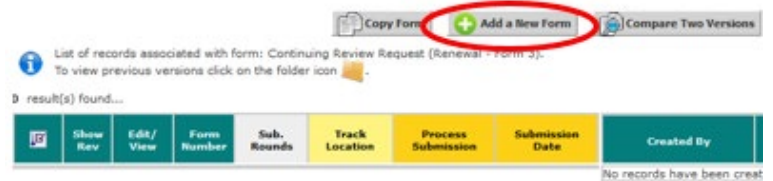


## Create a Continuing Review Request

### 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 must report information pertaining to those study sites in the Continuing Review Request**. This includes the number of participants enrolled, participant complains, problems, etc.

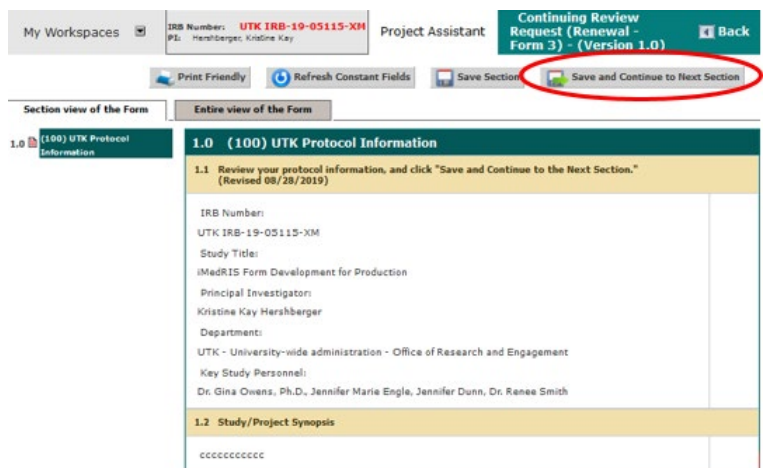
### 3. (100) UTK Protocol Information.

- 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.**

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

Entire view of the Form

### 5.0 (1535) Subject Complaints, Withdrawals, and Terminations

5.1 \* At your local site(s), since the last review, did any subjects express complaints about their participation in the research project?

1. No subjects have expressed complaints about their participation in the research.  
 2. Yes, subjects have expressed complaints about their participation in the research.  
 3. This question is not applicable to the research.

If you selected #2, please provide the number of subjects with complaints, and describe the nature of each subject's complaint.

5.2 \* At your local site(s), since the last review, did any subjects voluntarily withdraw from the study for non-medical reasons, after they were determined to be eligible?

1. No subjects voluntarily withdrew from the study for non-medical reasons.

## 8. (1540) Reportable Adverse Event

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

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

Entire view of the Form

### 6.0 (1540) Reportable Adverse Events

6.1 \* At your local site(s), were there any reportable unanticipated problems, including adverse events, since the last continuing review?

For the definitions of unanticipated problems, including adverse events, please mouse over the question mark in the right margin and click on "Definitions of Unanticipated Problems, Including Adverse Events."

Yes. One or more reportable unanticipated problems, including adverse events, occurred since the last continuing review.  
 No. No reportable unanticipated problems, including adverse events, have occurred since the last continuing review.

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

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

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

Entire view of the Form

### 7.0 (1560) Results (non multi-center studies)

7.1 \* Please indicate the status of results for this research:

1. No results have been obtained for this research.  
 2. Only preliminary results have been obtained. All of them have been previously reported to the IRB.  
 3. Only preliminary results have been obtained. Those not previously reported to the IRB are attached to this form.  
 4. Final results have been obtained. All results have been previously reported to the IRB.  
 5. Final results have been obtained. Results not previously reported to the IRB are attached to this form.

Please describe the nature of the results in the text box below. If you have any journal articles, abstracts, etc. describing the results of the study, please attach these at the end of the form.

## 10. (1562) Additional Reports and Information

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

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

Entire view of the Form

### 8.0 (1562) Additional Reports and Information

8.1 \* Has anything occurred since the last IRB review which may have altered the risk/benefit assessment?

Yes. Something has occurred that may have altered the risk/benefit assessment since the last IRB review.  
 No. Nothing has occurred that may have altered the risk/benefit assessment since the last IRB review.



### 11. (1565) Informed Consent Evaluation

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

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

Entire view of the Form

**9.0 (1565) Informed Consent Evaluation**

9.1 \* Did this study receive an alteration or waiver of consent, or a waiver of documentation of consent?

- Yes. This study received a waiver of the consent process.
- Yes. This study received an alteration of consent. (One or more elements of consent were altered or deleted)
- Yes. This study received a waiver of documentation of consent (Consent was obtained but not in writing)
- No. This study did not receive an alteration or waiver of consent or a waiver of documentation of consent.

9.2 \* Did any problems occur in obtaining and documenting informed consent?

- Yes. A problem or problems did occur in obtaining and documenting informed consent.

### 12. (1570) Investigator/Institution Issues

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

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

Entire view of the Form

**10.0 (1570) Investigator / Institution Issues**

10.1 \* Has a new conflict of interest (as defined in the current University of Tennessee Conflict of Interests Policy) developed for the principal investigator or other key study personnel since the most recent IRB continuing review approval? Assessment should include anyone listed as an investigator or key study personnel in the IRB application.

- Yes. A new conflict of interest has developed for at least one person listed as key research personnel on the initial study application.
- No. No new conflicts of interest have developed for any persons listed as key research personnel on the initial study application.

10.2 \* Have there been any changes in the investigator's situation or qualifications (e.g., suspension of hospital privileges, change in medical license/status, or increase in number of research studies conducted by the investigator)?

- Yes, there has been a change in the investigator's situation or qualifications.

### 13. (1580) Recommendations/Provisos

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

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

Entire view of the Form

**11.0 (1580) Recommendations / Provisos**

11.1 Do not change the response below unless instructed to do so by the IRB Staff.

- No
- Yes

### 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**.

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

Entire view of the Form

**12.0 (1590) Attachments**

12.1

1. If your research is open to enrollment, include a **CLEAN COPY** of your most-recently approved version of your **CONSENT FORM(S)** so that we may apply the approval stamp with a new expiration date for your study. Be sure that if you are obtaining identifiable data, you have added the section on Future Research required by the Revised Common Rule; this is the only way the form may differ from what is already approved. If you wish additional changes, you must submit a Form 2 Change Request. Please also be sure consent forms are uploaded in the Consent Forms section.
2. Attach one used copy of any consent forms signed since the last renewal of this study. You may mark out the participant's name but not the date of the signature on the consent form. The signed consent forms should be added to the submission using the "Add a New Document" button below and the category "Consent Audit." If you used more than one consent form (e.g., enrolled participants in more than one category), please submit a Consent Audit for each form used.
3. For devices administered under a treatment IDE, please submit the most recent semi-annual report submitted by the sponsor to the FDA under 21 CFR 812.36(f) and the most recent annual report submitted by the sponsor to the FDA under 21 CFR 812.150(b)(5).
4. Please attach any additional supporting documentation for this annual renewal submission, including any clinical or laboratory results, or any published articles or presentations related to the preliminary results of the study.

If your research is still open to enrollment, attach consent form(s) to be stamped below. Please follow the instructions in #1 above.

**Add a New Consent**

Detach	Version	Title	Category	Language	Expiration Date	Consent Outcome	Checked Out	View Document
No Consent(s) have been attached to this form.								

### 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.

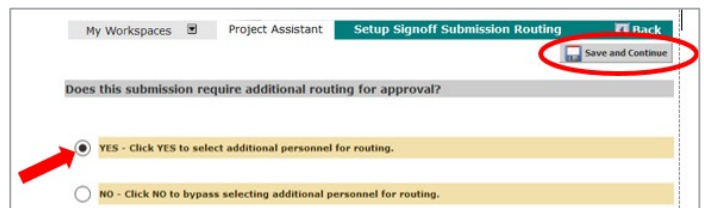
**TIP:** If study personnel other than an investigator completes the form, only the **Exit Form** button appears. The PI then must open the form and click **Signoff and Submit**.



## 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

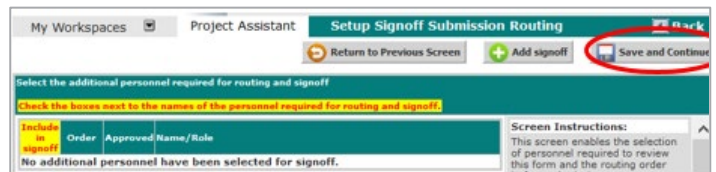
- Check the boxes (red arrow) for either the PI or another investigator (co/sub or co-PI).
- Click **Save and Continue**.



### 18. Setup Signoff Submission Routing – Additional Personnel

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

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

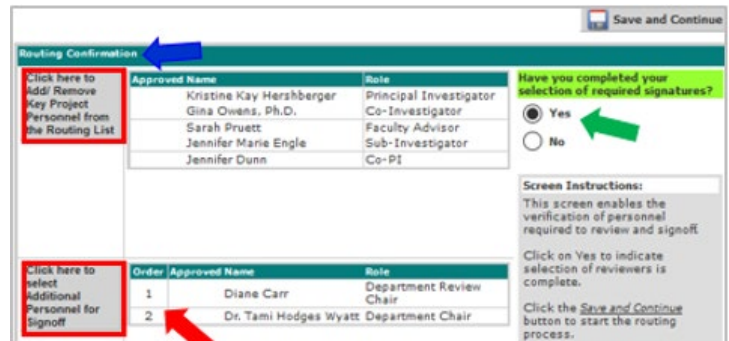


### 19. Routing Confirmation

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.

My Workspaces | Project Assistant | Submission Routing Signoff | Back

Save Signoff

Project Title: iMedRIS Form Development for Production  
Submission Reference Number: 18471

Printable Version

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

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

Copy Form | Add a New Form | Compare Two Versions

List of records associated with form: Form 2: Change Request and Amendments.  
To view previous versions click on the folder icon.

1 result(s) found...

Show Rev	Edit/View	Ref Number	Sub. Rounds	Track Location	Process Submission	Submission Date	Created By
		720913		In Process	Retract	03/28/2019 11:13:50 AM CDT	Jennifer Dunn

## 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