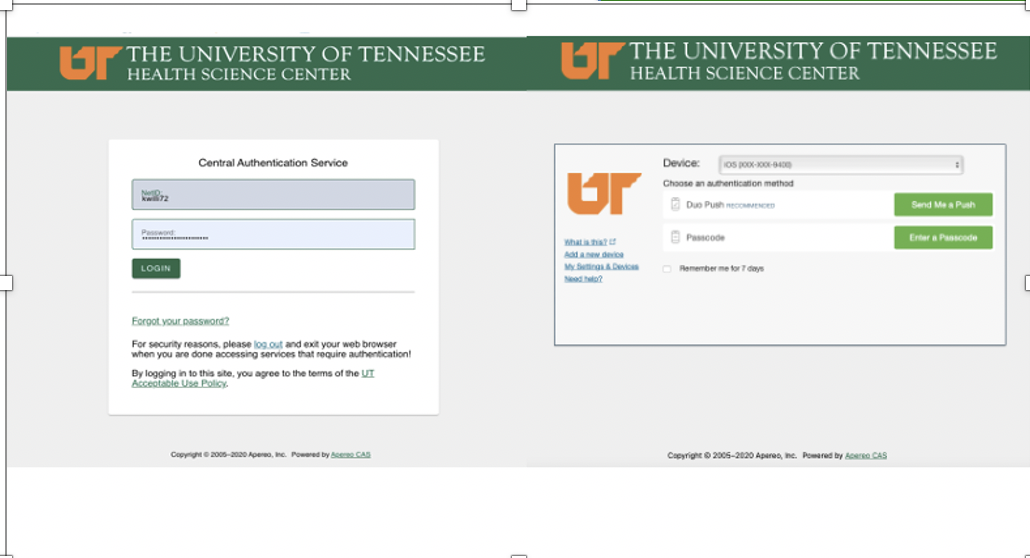
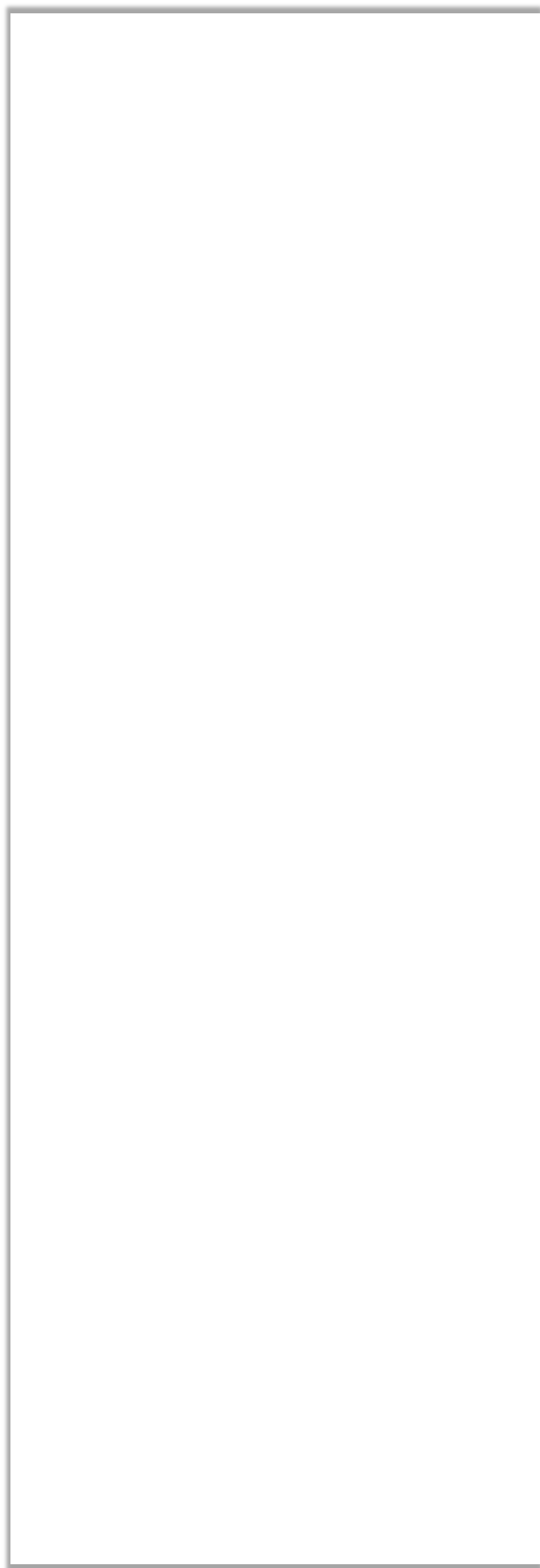
2022



Revised: March 15, 2022

Form 2: Change Request & Amendments

**How to Submit a Form 2: Change Request/Amendment via iMedRIS**

1. Open your web Open your web browser. Make sure you are using a version of an Internet browser that is supported by iMedRIS.

* Chrome
* Edge
* Firefox
* Safari

1. Type in the iMedRIS home page web address <https://imedris.uthsc.edu> (bookmark this page) and you will be directed to the DUO login screen. Please note, prior to accessing iMedRIS, you will need to install the “DUO Mobile App” [**https://www.uthsc.edu/its/cybersecurity/duo/**](https://www.uthsc.edu/its/cybersecurity/duo/)**. The University requires this two-factor authentication to protect against cyber-attacks.**

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1. The will take you to your iMedRIS homepage. On the top left side of your screen, under the **My Workspaces** tab, hover over/highlight  **Study** then click on **View and Manage My Studies.** Note that if you are already in the Study tab, you can also click **View and Manage My Studies** under the **Featured Project Operations** section at the top of the page.

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# OR

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1. Scroll to the bottom of the home screen and will see your list of studies/projects. Click to openthe study you wish to change/revise.

Graphical user interface

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1. On the **Submissions** screen, click Form 2: Change Request and Amendments.

Graphical user interface

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1. Click **Add a New Form** to open a new Form 2: Change Request/Amendment.

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The first section of the Form 2 (Section 1.0, Question 1.1) provides general information about your study. In Section 1.2 of the Form 2, indicate the number of subjects that are approved for your study and currently enrolled in your project (if any). You must provide a response to each question. Once you have answered each question, click **Save and Continue to Next Section**

Graphical user interface, text, application, email

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1. If you forget to respond to a question, you will receive an error message. Click **Ok** and make the appropriate correction. Click **Save and Continue** when you are done.

Graphical user interface, text, application, email

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1. In Section 2.0, Question 2.1, choose the status of the study from the list of options provided.

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1. In Section 3.0, choose which study documents are being revised.

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1. On the next screen, select **Click here to add another entry** to describe the changes/revisions that will be made to the electronic study application, if applicable. You should add a new entry for each section of the application that is revised. Note that if you have not selected any changes to the application on the previous page, you will not receive this section of the Form 2.

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1. Describe each revision and click the gray bar to revise and attach the new version of your study application.

Graphical user interface, text, application, email

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1. You will see each version of your study application that has been reviewed and approved by the UTHSC IRB. Click **Add Revision** to incorporate your changes/revisions to study application.

Graphical user interface, application

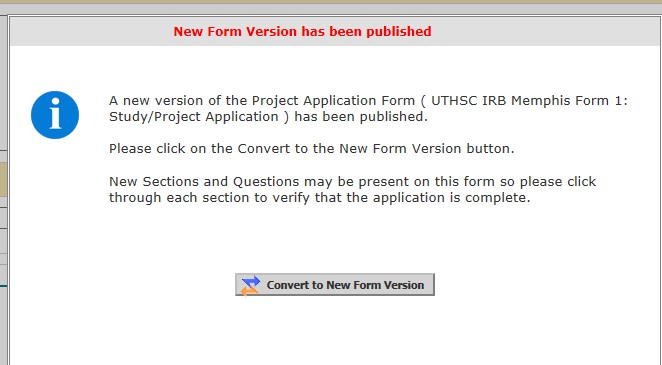
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1. You will be asked to confirm that you want to create a revision to your study application. Select **Ok**.

Graphical user interface, application, Teams

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1. If you receive the following message, click **Convert to New Form Version.**



1. A new version of the application will open for you to modify. Be sure to click **Save and Continue to Next Section** after each change is made.

Graphical user interface, application, table

Description automatically generated

1. When you have completed the revisions to the study application, the revised study application will be attached to your Form 2. If you need to make additional changes to the application, click **Edit/View** to open and revise the application.

Graphical user interface, text, application, email

Description automatically generated

1. Once the revisions to the study application are complete, Click **Save and Continue to Next Section.**



1. If you need to make changes to your consent form, you will need to describe each of the changes/revisions, just as you did with the study application. Select **Click here to add another entry** to describe each change.

Graphical user interface, text, application, email

Description automatically generated

1. To revise and attach your updated consent form, click **Select or Revise Existing**.

Graphical user interface, text, application, email

Description automatically generated

1. Next, you will create a revised version of your currently approved consent form so that you can make the appropriate changes. Click the icon under **Create Revision**.

Graphical user interface

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1. Next, you will want to check out the consent form to make appropriate changes. Select **Checkout-out Document**.

Graphical user interface, application

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1. The window will pop up to ask if you are sure you want to check out the document. Click **Confirm.**

Graphical user interface, application

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1. Your consent form will open in Word (or will be downloaded if you are using a Mac) so that you can make the appropriate changes. Once you have completed your changes to the consent form and updated the preparation date in the footer, save a copy to your computer.
2. Next, you will receive a prompt asking if you would like to check the document back into iMedRIS. Click **Check-in Document**.

Graphical user interface, text, application

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Locate the revised consent form on your computer by clicking **Choose File.** .

Graphical user interface, text, application, email

Description automatically generated

1. Locate the document on your computer, select it, and click **Open**.

Graphical user interface, application, table

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1. Next, select **Save selected file** and the document will be uploaded into iMedRIS.

Graphical user interface, text, application, email

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1. Make sure that the consent title, version number, and version date are correct and click

# Save Consent.

Graphical user interface, text, application

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1. The revised version of the consent form is now attached to the Form 2.

Graphical user interface, application, table

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1. Once you have outlined each of the change(s) to the consent form and attached the revised consent form, click **Save and Continue to Next Section** to move to the next screen.

Graphical user interface, text, application, email

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1. Address whether the changes affect the risk/benefit ratio and click **Save and Continue to Next Section**.

Graphical user interface, text, application

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1. Next, indicate whether you have any additional study documents to attach. If you do, click the appropriate gray button and follow the same steps for attaching study documents as outlined above. If you have no additional study documents to attach, indicate this and click **Save and Continue to Next Section**.

Graphical user interface, application

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1. Next, click **Sign and Submit** to route the Form for appropriate signature(s).

Graphical user interface, application

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1. To verify who will receive the Form 2 for signatures, click **Save Selection and Continue the Signoff Process**.

Graphical user interface, text, application

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1. Select the appropriate key study personnel for signatures. **Note**: If a new investigator(s) is being added to the study, the application will need to be routed to each new investigator for signature(s).

Graphical user interface, text, application

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1. Once you click **Save-Signoff Routing List**, you will be asked to verify that the list above represents the finalize Personnel for review and sign-off. If the list is correct, click **Yes** and then click **Save-Start Signoff Routing**. If not, click **No** and select **Cancel-Finalize Late**r or **Go Back to Make Changes**.

Graphical user interface, text, application, email

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1. You will then see the screen below. You may click **OK** or wait until the 10-second countdown ends, which will then take you to the PI Responsibilities screen

Graphical user interface, text, application

Description automatically generated

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Graphical user interface, application

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1. You may verify the electronic signatures in the Workflow Tracking of iMedRIS.

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1. For more instructions regarding routing and signoff, download the iMedRIS Guide ***Routing, Workflow Tracking & Signoff*** from the IRB website at [http://www.uthsc.edu/research/research\_compliance/IRB/guides.php.](http://www.uthsc.edu/research/research_compliance/IRB/guides.php) In addition, do not hesitate to contact the IRB office at **901.448.4824** for assistance.