

UTHSC RSC Submission Response



Central Authentication Service

NetID:

Password:

LOGIN

By logging in to this site, you agree to the terms of the [UT Acceptable Use Policy](#).



imedris-production

iMedRIS Production

[Forget your password?](#)

[? Need help signing in?](#)

For security reasons, please log out and exit your web browser when you are done accessing services that require

Table of Contents

Getting Started	3
Navigational Tips	4
Responding to Recommendations or Provisos	7

Getting Started

1. Open your web browser. Make sure that you are using a version of an internet browser that is supported by iMedRIS.
 - Firefox
 - Safari
 - Google Chrome
2. Type in the iMedRIS home page web address (<https://imedris.uthsc.edu>) and the iMedRIS log-in screen will appear.

A screenshot of the iMedRIS login interface. On the left is the 'Central Authentication Service' box with fields for 'NetID:' and 'Password:', a blue 'LOGIN' button, and a link to the 'UT Acceptable Use Policy'. On the right is the 'imedris-production' box with a globe icon and two links: 'Forget your password?' and 'Need help signing in?'.

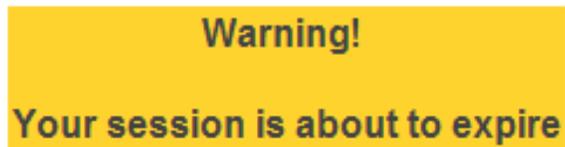
3. Log in using your UT Net ID and password. If you need to obtain a UT Net ID, go to the University of Tennessee's Office of Information Technology website at <https://oit.utk.edu/accounts/forms/Pages/default.aspx>. If you are having trouble with your password, you may need to contact the Help Desk at 901.448.2222.

Navigational Tips

1. For security reasons, iMedRIS will log you out after 30 minutes of inactivity. There is a 25-minute warning that will ask you if you would like to continue working. If you are not available to click the button, you will lose any unsaved information when the system logs you out. Before leaving the computer, make sure you have clicked

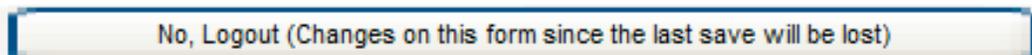
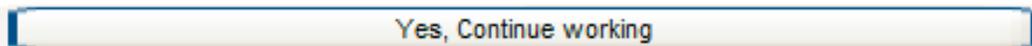


located in the top right corner of the screen before stepping away from your work.

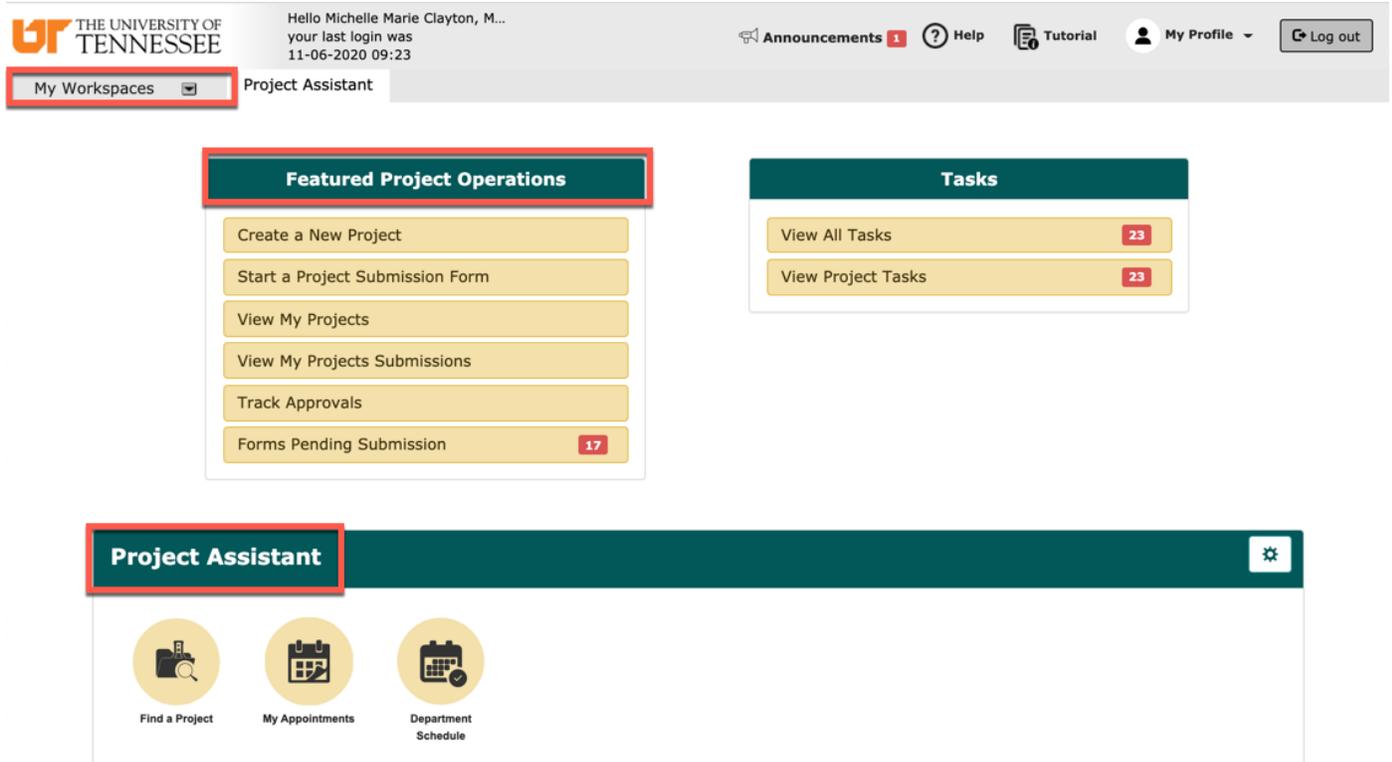


Would you like to continue?

There has been no interaction with the system in 25 minutes. Session login is calculated on requests to the system.



2. The home screen will appear as:



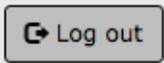
3. Under **Featured Project Operations**, you have the option to:

- Create a New Project
- Start a Project Submission Form
- View My Projects
- View My Projects Submissions
- Track Approvals
- Forms Pending Submission

4. Your menu selections are also available from a drop-down menu on the top left side of the home screen (**My Workspaces**). Your tasks are listed under 'All Tasks' and 'All Projects.' From any screen in iMedRIS, you can use the 'My Workspaces' drop-down menu to navigate to other areas.

5. The **Project Assistant** section will display several widgets where you are able to search your projects, create calendar appointments (this does not sync with outlook), and view your departmental schedule.

6. Key Icons:

- The  logo in the top left corner of the screen allows you to return to the iMedRIS home page.
- The  button in the top right corner of the screen allows you to exit the iMedRIS system. The system will NOT automatically save any changes you have made.
- The  button in the top right corner of the screen provides links to the iMedRIS Guides & Tips, as well as links to RSC policies and procedures.
- The  button in the top right corner of the screen provides a section by section guide to the homepage. The tutorial will appear automatically each time the user accesses iMedRIS, until it is turned off, in which case the user can select the tutorial button if needed.
- The  button in the top right hand corner of the screen will take you to the previous page. DO NOT USE the back button on your internet browser when you are in iMedRIS. To navigate back through the application, click on the links through 'My Workspaces' on the top left side of the screen. The 'Back' button will NOT take you back one page (to the previous section), when you are working on an application.
- The iMedRIS banner (the bar at the top of the screen) contains several navigation links to assist you as you work in iMedRIS. The Path section allows you to move between pages in iMedRIS.



Account: Michelle Marie Clayton, MPH
Department: UTHSC - COM - Peds - General Pediatrics
Path: Home > project mgmt.

Announcements 

 Help

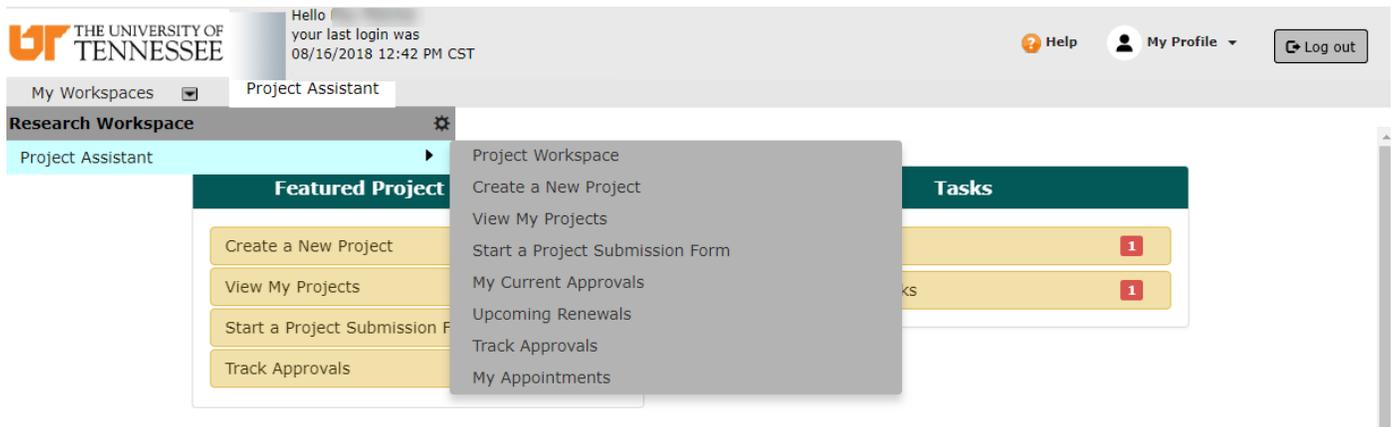
 My Profile ▾

 Log out



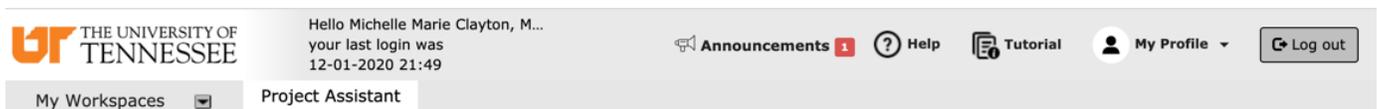
- The  drop-down menu selection (located on the top right side of the home screen) contains account information, announcements, the help menu, a list of completed tasks, and correspondence.

- The Project Assistant tab in the 'Research Workspace' menu (located on the left side of the home screen) contains the options to add a new project (study protocol) as an investigator, view current project information, find a project, and to edit, view, or add appointments.



Responding to Recommendations and Provisos

1. When the RSC sends you recommendations or provisos (i.e., instructions or questions regarding your protocol), you will receive one of two response forms.
2. Under your 'Study Tasks' tab on your iMedRIS home page, you will see items under the Task Type column: 'Submission Response' (initial Pre-Reviewed protocols) or 'Submission Correction' (subsequent protocols that have already been through the initial pre-review process, and have been reviewed by members of the pre-review committee).



All Tasks				
Outstanding		Completed		
All Tasks		Project Tasks		
Task List: All				
27 result(s) found... 1 - 10				
	Click to open	Task Type	Received	Description
<input type="checkbox"/>		Submission Response	12/01/2020 11:01:14 PM CST	RSC returned the submission with the outcome of Review Complete - Edits Required
<input type="checkbox"/>		Submission Routing Signoff	12/01/2020 10:36:12 PM CST	Michelle Marie Clayton, MPH as Principal Investigator review and apply signoff
<input type="checkbox"/>		Reviewer Assignment	11/23/2020 01:27:22 PM CST	Michelle Marie Clayton, MPH has been assigned as the Biostatistician for an Administrative Review on the Submission Response for Routing Form: Initial Review Submission Form
<input type="checkbox"/>		Analyst Assignment	10/26/2020 08:46:24 AM CDT	Michelle Marie Clayton, MPH has been assigned as the analyst
<input type="checkbox"/>		Waiting Submission	10/22/2020 11:32:45 AM CDT	Routing Form: Initial Review Submission Form is waiting to be submitted

3. Select the pencil and notepad icon under the 'Click to Open' column for the study requiring a response.

The screenshot shows the top navigation bar of the Project Assistant interface. It includes the University of Tennessee logo, the user's name (Michelle Marie Clayton, M...), the last login time (12-01-2020 21:49), and navigation links for Announcements, Help, Tutorial, My Profile, and Log out. Below the navigation bar, there are tabs for 'All Tasks', 'Outstanding', and 'Completed'. The 'Outstanding' tab is selected. A 'Task List' dropdown menu is set to 'All'. Below the tabs, it says '27 result(s) found...' and '1 - 10'. A table with the following columns is displayed: 'Click to open', 'Task Type', 'Received', and 'Description'. The first row has a red box around the pencil and notepad icon in the 'Click to open' column. The second row has a pencil and notepad icon in the 'Click to open' column.

Click to open	Task Type	Received	Description
<input type="checkbox"/>	Submission Response	12/01/2020 11:01:14 PM CST	RSC returned the submission with the outcome of Review Complete - Edits Required
<input type="checkbox"/>	Submission Routing Signoff	12/01/2020 10:36:12 PM CST	Michelle Marie Clayton, MPH as Principal Investigator review and apply signoff

4. If you have an old version of the response form, or if you have the new version that needs an update, you will get a pop-up window asking you to convert to the new form. If you do not receive the pop-up window, then you already have the most updated version of the response form.

The screenshot shows a pop-up window with a red title bar that says 'New Form Version has been published'. The window contains an information icon (i) and the following text: 'A new version of the Form (PI Response to Review) has been published. Please click on the Convert to the New Form Version button. New Sections and Questions may be present on this form so please click through each section to verify that the form is complete.' At the bottom of the window, there is a button labeled 'Convert to New Form Version' with a blue arrow icon. A red arrow points to this button.

5. Scroll down past the protocol information, to view the provisos provided by the UTHSC RSC. The first time you receive comments will be from the pre-review process. These provisos must be addressed before the full committee meeting. The second time you will receive comments will be after the full committee meeting. To ensure approval of the protocol, all the provisos must be addressed and resubmitted to the RSC.
 - a. For each proviso, there is a description that will include the name of the section, as well as what change is requested.
 - b. Below the description, you will be asked to confirm your acceptance of each proviso.
 - c. After confirming your acceptance, you will be asked to provide details of how the proviso was addressed. These steps must be completed for each proviso.

Section view of the Form | Entire view of the Form

1.0 Protocol Information revised 10/22/2020

Proviso/Modification 1 out of 2:

Description:
TEST PROVISO 1

Stipulation Type: (Proviso/Modification must be addressed)

Operation	Action Status	Component Name	Action
Modify Existing Attachment	Action Not Complete	UTHSC Radiation Safety (Version 1.1) Section: Irradiation of Materials Question: *Identify the type of irradiator.	Revise Existing

Do you accept this Proviso/Modification? N/A Yes No

Provide an explanation on how you addressed this Proviso/Modification:

6. In addition to explaining how you addressed each of your provisos in the response form, you will also need to create a revision of the study application. The new revision of the application will need to include any changes requested by the RSC.
 - a. There are two ways that may be available to create your revision. For each response form you submit, you should only create one revision.
 - i. If RSC reviewers have linked your proviso to the initial application, you will see the option to create a revision beside each linked proviso.
 - ii. Additionally, you can view the initial protocol previously submitted to the RSC by selecting the 'UTHSC RSC Safety' with the appropriate version number.

Section view of the Form | Entire view of the Form

1.0 Protocol Information revised 10/22/2020

Proviso/Modification 1 out of 2:

Description:
TEST PROVISO 1

Stipulation Type: (Proviso/Modification must be addressed)

Operation	Action Status	Component Name	Action
Modify Existing Attachment	Action Not Complete	UTHSC Radiation Safety (Version 1.1) Section: Irradiation of Materials Question: *Identify the type of irradiator.	Revise Existing

7. Click the pencil and notepad icon on the left of the revised application to continue editing.

Section view of the Form | Entire view of the Form

1.0 Protocol Information revised 12/01/2020

UTHSC - COM - Peds - General Pediatrics

1.2 Respond to requested changes listed below:

Proviso/Modification 1 out of 2:

Description:
TEST PROVISIO 1

Stipulation Type: (Proviso/Modification must be addressed)

Operation	Action Status	Component Name	Action
Modify Existing Attachment	Action Not Complete	UTHSC Radiation Safety (Version 1.2)	<input type="button" value="Compare Application Version"/> <input type="radio"/> Complete Action <input checked="" type="radio"/> Incomplete Action

Links to Components (These are the items that are linked to this proviso/modification)

Do you accept this Proviso/Modification? N/A Yes No

8. Click the 'Revise Existing' button on the right to create a new version of the study application (if you have NOT created a revision yet).

Confirm the adding a revision.
Are you sure you want to create a revision?

- i. Afterwards, you will need to edit the new application as needed and save through the entire application by clicking . When you have saved through the entire application, you will automatically return to the review response form.
- ii. For each linked proviso, you will be taken to the appropriate section, and the modifications required will be shown in blue.

Account: Michelle Marie Clayton, MPH
Department: UTHSC - COM - Peds - General Pediatrics
Path: Home > form data

Announcements My Profile

My Workspaces Working Title: changing branching RSC 10/29/20
PI: Clayton, Michelle Marie, MPH Project Assistant UTHSC Radiation Safety (Version 1.2)

Section view of Application | Entire view of the Application

1.0 General Information
2.0 Setup Department(s) Access
3.0 Grant Key Personnel access to the study
4.0 Protocol Information REVISED 10/30/2020
5.0 Protocol Type (Check all that apply)
6.0 Qualifications
7.0 Experimental Procedure
8.0 Irradiation of Materials
9.0 Certification

8.0 Irradiation of Materials

8.1 *Does the research involve the irradiation of materials (e.g. animal subject, cellular materials, etc.)?
 Yes No

8.3 *Does the research involve the use of any recombinant DNA, synthetic nucleic acids, human materials or biological agents that must be handled at BSL-2 or above?
 Yes No

8.4 *Does this research involve the irradiation of laboratory animals?
 Yes No

Modifications Required:
TEST PROVISIO 2
 Yes No

- iii. When you return to the review response form, the links to components for each linked proviso will include the option to 'Compare Application Version.' Selecting this button will allow you to compare the versions listed under 'Component Name.'

The screenshot shows the 'Review Response Form - RSC - (Version 1.0)' interface. At the top, there is a header with the University of Tennessee logo, user information (Michelle Marie Clayton, MPH), and navigation links. Below the header, there are tabs for 'Section view of the Form' and 'Entire view of the Form'. The main content area is titled '1.2 Respond to requested changes listed below:' and contains a table of components. The table has columns for 'Operation', 'Action Status', 'Component Name', and 'Action'. The 'Action Status' column shows 'Action Not Complete' in red. The 'Action' column contains a 'Compare Application Version' button, which is highlighted with a red box. Below the table, there are radio buttons for 'Do you accept this Proviso/Modification?' with options 'N/A', 'Yes', and 'No'.

Operation	Action Status	Component Name	Action
Modify Existing Attachment	Action Not Complete	UTHSC Radiation Safety (Version 1.2)	Compare Application Version
		UTHSC Radiation Safety (Version 1.1) Section: Irradiation of Materials Question: *Identify the type of irradiator.	<input type="radio"/> Complete Action <input checked="" type="radio"/> Incomplete Action

- iv. Before submitting your form, and if your proviso has been addressed in your application, mark each action as complete.

This screenshot shows the same table as the previous one, but with the 'Action Status' column now showing 'Action Complete' in green. The 'Compare Application Version' button is still present, and the 'Complete Action' radio button is selected, indicated by a red arrow pointing to it.

Operation	Action Status	Component Name	Action
Modify Existing Attachment	Action Complete	UTHSC Radiation Safety (Version 1.2)	Compare Application Version
		UTHSC Radiation Safety (Version 1.1) Section: Irradiation of Materials Question: *Identify the type of irradiator.	<input checked="" type="radio"/> Complete Action <input type="radio"/> Incomplete Action

- v. If you do not have provisos linked to the initial application, you will need to create a revision of the application at the bottom of the form.
 1. Select the checkbox next to the UTHSC RSC PROTOCOL application.
 2. After selecting the application, select revise submission.

1.3 Use table below to make corrections:

Compare	Include in PDF Packet	Compare to Last Approved	View in Separate Window	Unattach	Revise/ Attach	Revisions	All Submission Components Previous Rounds & Currently Attached
<div style="display: flex; justify-content: space-around;"> <div style="border: 1px solid gray; padding: 5px; text-align: center;">+ Add New Component</div> <div style="border: 1px solid gray; padding: 5px; text-align: center;">Compare Item(s)</div> <div style="border: 1px solid gray; padding: 5px; text-align: center;">Create PDF Packet</div> </div>							
Submission Form(s)							
<input type="checkbox"/>	<input type="checkbox"/>						RSC - Review Response Form - RSC - (Version 1.0 (Incomplete))
<input type="checkbox"/>	<input type="checkbox"/>						UTHSC RSC Update or Amendment Form - (Version 1.0)
Application							
<input type="checkbox"/>	<input type="checkbox"/>						UTHSC Radiation Safety - (Version 1.2)

3. Select 'OK' if you have not yet created a revision.

Confirm the adding a revision.
Are you sure you want to create a revision?

Cancel
OK

4. After selecting OK, you will receive a notification box stating the new version number.

A new version has been created. The document you are editing is version 1.1

Close

9. After addressing the provisos, both in the review form and as part of the revised application, select the

Save and Continue to Next Section

or

Signoff and Submit

10. The next page shown will be the Submission Routing Signoff Sheet. Beside the UTHSC Radiation Safety Form, the version number shown should match the revision number previously displayed on the pop-up window. If you have addressed all provisos, select 'Approve' and save the signoff.

Account: Michelle Marie Clayton, MPH
Department: UTHSC - COM - Peds - General Pediatrics
Path: Home

Announcements 1 ? Help My Profile Log out

My Workspaces Project Assistant **Submission Routing Signoff** Back

Save Signoff

Project Title: changing branching RSC 10/29/20
Submission Reference Number: 710011

Printable Version

	Include in PDF Packet	Unattach	Revise/Attach	Compare to Last Approved	View in Separate Window	Revisions	Submission Component Name - Version
Submission Form(s)							
Submission Form(s):	<input type="checkbox"/>	<input checked="" type="checkbox"/>					Review Response Form - RSC - (Version 1.0)
	<input type="checkbox"/>						UTHSC RSC Update or Amendment Form - (Version 1.0)
Application							
	<input type="checkbox"/>	<input checked="" type="checkbox"/>					UTHSC Radiation Safety - (Version 1.2)

Michelle Marie Clayton, MPH as Principal Investigator do you Approve or Deny this submission?

Approve Deny

Save Signoff