

UTHSC RSC UPDATE OR AMENDMENT FORM



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

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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, the text 'imedris-production' and 'iMedRIS Production', and two links: 'Forget your password?' and 'Need help signing in?'.

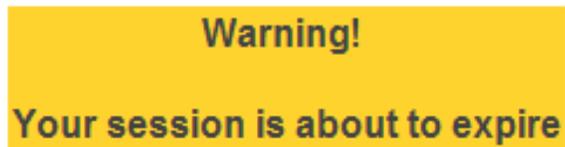
3. Log in using your UT NetID and password. Additionally, you will need to authenticate using DUO. If you need to obtain a UT NetID, go to the University of Tennessee's Office of Information Technology website at <https://oit.utk.edu/accounts/forms/Pages/default.aspx>. If you are having trouble with 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 out. Before leaving the computer, make sure you have clicked

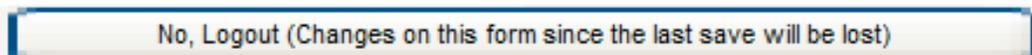
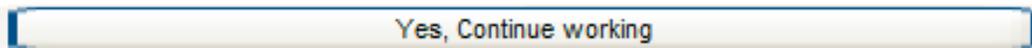


located in the top right corner of the screen before stepping away from your work.

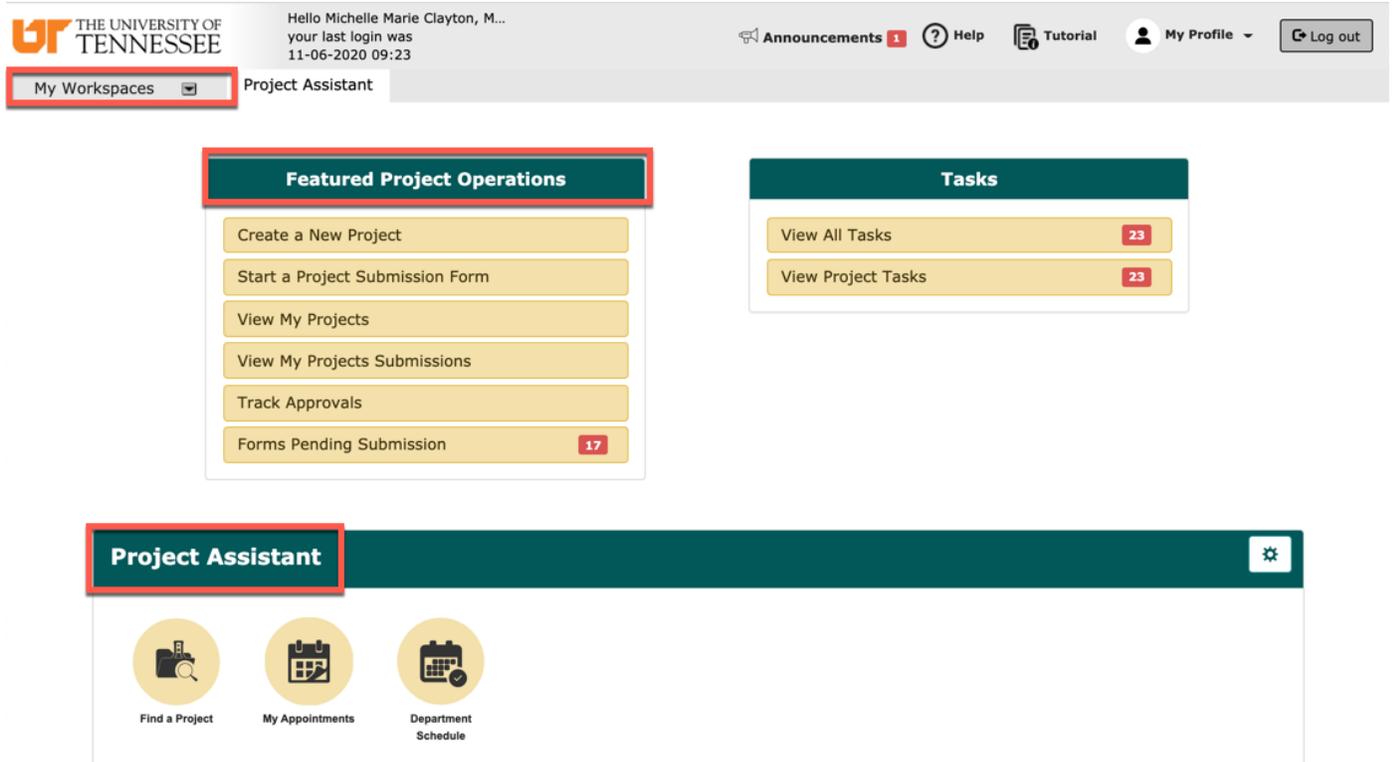


Would you like to continue?

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

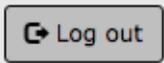


2. The home screen will appear as:



- 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
- 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.
- 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.

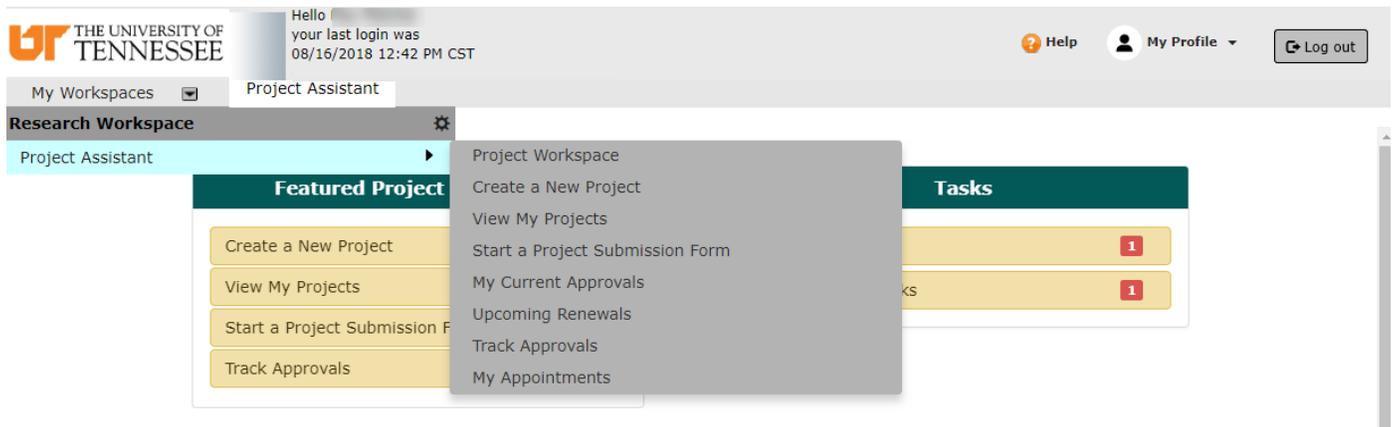
6. Key Icons:

- 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.



- 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.

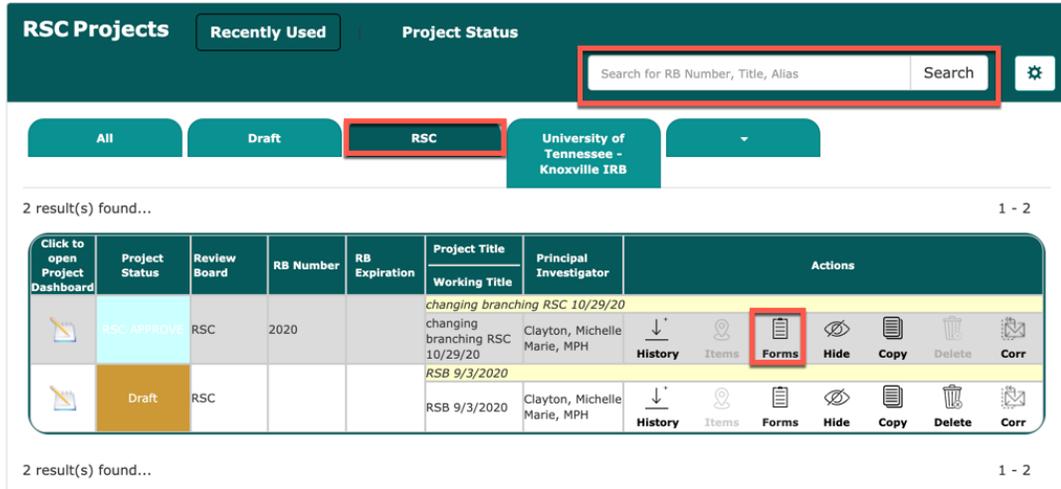


Submitting an Update/Amendment

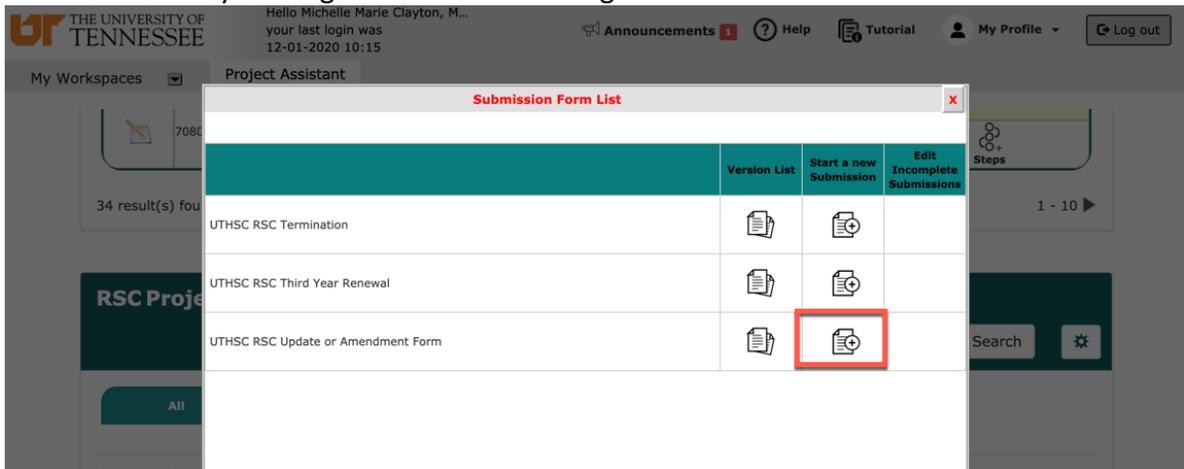
1. This form should be used to make changes to an active RSC protocol, addition of materials or devices (radioisotopes, radiation producing machines, nonionizing devices, etc.), changes in the location of research, and/or description of new experimental procedures. It can be used to make changes to the protocol that alter the radiation safety and/or biosafety considerations of the project (e.g. adding in vivo studies to a protocol that was approved only for in vitro work, rDNA, synthetic nucleic acids, infectious agents, human derived materials, etc.). Changes that do not alter radiation safety and/or biosafety are considered updates (e.g. adding research staff), and changes that do alter radiation safety and/or biosafety are considered amendments.
2. From the home screen, select the 'Start a Project Submission Form' option under 'Featured Project Operations.'



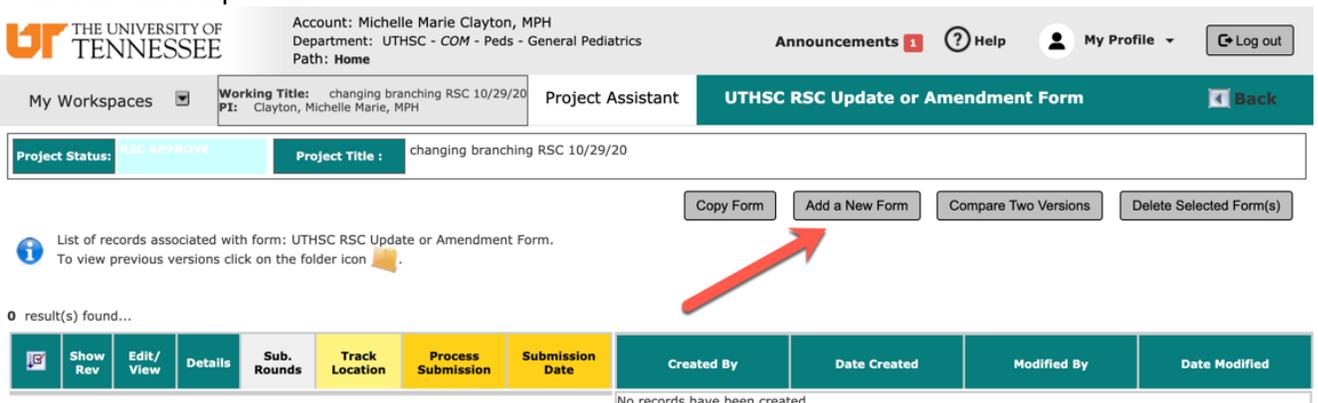
- You will be directed to select the study for which you need to submit the form. You will need to select the appropriate review board tab (if you have multiple). To find the study you need to update, you can use the title search bar. Once you have identified the study, select the 'Forms' icon.



- After selecting the 'Forms' icon, you will see a list of submission options. Select the UTHSC RSC Update or Amendment form by clicking the icon with a '+' sign on it.



- If you select the icon without the plus sign, the next screen will give you the option to add a new form, copy forms, compare form versions, or delete selected forms. Information on drafts and unsubmitted forms will be listed, including when the form was created, the last person to modify it, and where it is in the submission process.



6. The first part of the form will display the PI's name and Project Title. Click the 'Save and Continue to Next Section' button.

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

Announcements 1 ? Help My Profile Log out

My Workspaces Working Title: changing branching RSC 10/29/20
PI: Clayton, Michelle Marie, MPH Project Assistant UTHSC RSC Update or Amendment Form - (Version 1.0) Back

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 Protocol Information revised 12/01/2020

1.0 Protocol Information revised 12/01/2020

1.1 (Read Only)

PI's Name:
Michelle Marie Clayton, MPH

Project Title:
changing branching RSC 10/29/20

7. The next section of the form provides 2 options for the form's use. The subsequent questions depend on your selection.

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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 Protocol Information revised 12/01/2020

2.0 Details for Use

2.0 Details for Use

2.1 * Please indicate which definition applies:

1. Update - an update should be submitted if there are changes to the work that DO NOT alter the risk assessment of the work

- a change in location of the work
- a change in personnel
- addition of radioisotope/s that will be used in the studies (unless the type of isotope was not already approved - this would require an amendment [see below])

2. Amendment - an amended protocol must be submitted when changes to the research that DO alter the radiation safety and/or biosafety considerations of the work

- a significant change in the experimental procedure that does alter the radiation safety considerations of the work (e.g. addition new source of radiation, isotopes, assay procedure, detection/measurement devices etc.)
- a change in the experimental protocol that does alter the radioactive materials (isotopes, compound, quantity), waste (liquid and solid)
- Addition of infectious agents, cells/tissue/fluids that changes the containment level from BSL-1 to BSL-2).
- addition of in vivo studies (if the latest approved protocol did not provide approval of any in vivo studies), or
- addition of in vivo studies that change the containment level (ABSLs)

Update - changes that DO NOT ALTER biosafety/radiation safety considerations (see above)

Amendment - changes that DO ALTER biosafety/radiation safety considerations (see above)

8. To complete the form, you must create a revision of the application. To do so, select the grey bar labeled 'Click here to attach the application.'

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Announcements 1 ? Help My Profile Log out

My Workspaces Working Title: changing branching RSC 10/29/20
 PI: Clayton, Michelle Marie, MPH Project Assistant UTHSC RSC Update or Amendment Form - (Version 1.0) Back

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 Protocol Information revised 12/01/2020
 2.0 Details for Use
 3.0 Change Summary: Update

3.0 Change Summary: Update

3.1 * Please select all protocol changes requested.

Study Address or Lab Room Number
 Personnel
 Radioisotope/s

* Attach your modified study application.

Click here to attach the application.
 No Application has been associated with this submission.

9. You will then see a pop-up window appear that will allow you to attach a revised study application. To create a revision, select the 'Add Revision' icon. You will then be asked to save through a new version of the original protocol application, where you will be able to make changes, and returned to section 2.0. Save and continue through the entire application. If you already have a revised application that you would like to attach, select the revision by expanding the 'Show Rev.' folder, and select the 'Save Attachment' button.

Attaching Project Application

Select the application that you would like to attach and then click Save Attachment Save Attachment

Select	Show Rev.	Edit/View	Form Name	Approved	Create a Revised Application
<input type="radio"/>			UTHSC Radiation Safety (Version 1.0)	No	Add Revision

10. The next screen will show the version of the application that has been attached. Select 'Save and Continue to Next Section.'

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

Announcements 1 ? Help My Profile Log out

My Workspaces Working Title: changing branching RSC 10/29/20
 PI: Clayton, Michelle Marie, MPH Project Assistant UTHSC RSC Update or Amendment Form - (Version 1.0) Back

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 Protocol Information revised 12/01/2020
 2.0 Details for Use
 3.0 Change Summary: Update

3.0 Change Summary: Update

3.1 * Please select all protocol changes requested.

Study Address or Lab Room Number
 Personnel
 Radioisotope/s

* Attach your modified study application.

Unattach	Revise/Attach	Edit/View	Title
			UTHSC Radiation Safety (Version 1.1)

11. The next page will show that the form has been completed.

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

Announcements 1 ? Help My Profile Log out

My Workspaces Working Title: changing branching RSC 10/29/20
 PI: Clayton, Michelle Marie, MPH Project Assistant UTHSC RSC Update or Amendment Form - (Version 1.0) Back

Print Friendly Signoff and Submit

Section view of the Form Entire view of the Form

1.0 Protocol Information revised 12/01/2020
 2.0 Details for Use
 3.0 Change Summary: Update

Form has been Completed!

Select exit form to save the form and return to the home screen. This will not send your form to the review board, but will allow you to send it at a later date. Select signoff to submit the form to the review board.

Exit Form
 Signoff and Submit

12. To complete the form, select 'Approve,' enter in your NetID and password, and select 'Save 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

Include in PDF Packet	Compare to Last Approved	View in Separate Window	Submission Component Name - Version
<input type="checkbox"/>			UTHSC RSC Update or Amendment Form - (Version 1.0)
Application			
<input type="checkbox"/>			UTHSC Radiation Safety - (Version 1.1)

Printable Version

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

Save Signoff