UT RESEARCH MANAGEMENT SUITE

IRB Module Frequently Asked Questions

For Researchers & Departmental End Users

1. **When should I start using the new IRB module? And for how long should I still use *IRBaccess*?**

   UT Research Management Suite – IRB (UTRMS-IRB) launched on August 11th, 2020. You may immediately begin using the system to submit your new study applications, including single-site, multi-site, or external IRB studies.

   For existing, active studies, the transition timeline varies by a study's review type:
   - **Full Board studies** will be transferred to the new module on an accelerated schedule based on Continuing Review (CR), assisted by the IRB central office staff. IRB Analysts will reach out to applicable Study Teams to initiate and assist with the transfer process.
   - **Exempt and Expedited Studies** will be transferred on a more gradual schedule based on CR (for example, a study with a CR date of 10/1/20 should prompt initiation and completion of the CR in ***UTRMS-IRB***, likely sometime in September):
     - Through September 30th: all Follow-on Submissions, including Amendments, CR's, and Closures, should continue in *IRBaccess.*
     - In the month of October, Study Teams of Exempt or Expedited studies are encouraged to complete transfer of their studies and documentation at time of CR.
     - Beginning November 1st, studies must be transferred at time of CR.
     - Until a study is transferred, all actions should continue in *IRBaccess*; however, once transferred, all actions should take place in ***UTRMS-IRB***.
     - Exempt and Expedited Studies approved prior to January 21, 2019, will also transition to the New Common Rule at the time of transfer.

IRB Transition Schedule
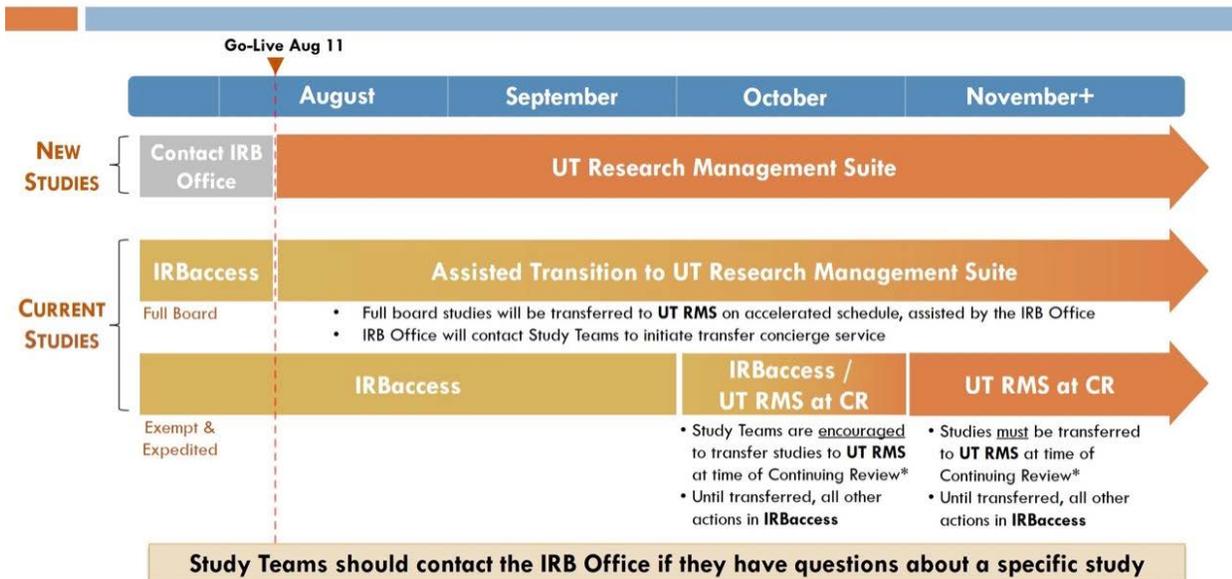
2. How do I transfer my existing study at time of Continuing Review? What information is being transferred from *IRBaccess*, and what will I need to provide?

Not all *IRBaccess* records have been migrated to the new system; only active protocols have been transferred. For those migrated, only the associated data has been ported to *UTRMS-IRB*. The applicable study documents (proposal, consent forms, etc.) have not been extracted, and will need to be identified in *IRBaccess*, downloaded, and then uploaded to the new system's record manually.

IRB staff will be in touch with study teams to initiate and assist with this transfer process. See the IRB website for additional guidance. Study Teams are encouraged to contact the IRB office for questions about a particular transfer.

3. How can I learn to use the IRB module?

Within *UTRMS-IRB*, you can access self-guided walk-throughs by clicking on the *Get Help* button at the center top of the screen:

At launch, these include *System Navigation* (basic orientation) and *Create a New Study* (not only trains but assists in completion of a new submission). Additional on-demand guidance appears throughout the system in help text and pop-up tips.

Two tabs within the IRB module also offer helpful reference materials:
- The Library hosts the Investigator Manual (HRP-103) under the General tab.
- The Help Center offers the IRB Researcher's Guide under the Guides tab.

If needed, you may also request additional training.

4. How can I schedule additional IRB module training for myself, my students, colleagues and/or others?

Visit our booking service to schedule training with a member of our project team.

5. What new terms should I familiarize myself with?

Some key new terms include:
- *IRB Coordinator*: the system role assigned to IRB Analysts within the system. The terms are roughly synonymous, though Analyst refers to an IRB staffer's official job title, while Coordinator implies certain system permissions.
- *Modification*: new term for an Amendment
- *Reportable New Information*: new term for Unanticipated Problem(s) or Adverse Event(s)
- *Modification Required*: equivalent to Explicit Conditions determination

These and others are collected in the IRB Glossary of Terms available on the project website.

6. How is my role assigned in the system? And what actions can I take in the system based on my role?

UT Research Management Suite integrates with the UT Enterprise Directory, Workday HR, and the DEFINE Department System to create profiles for all UT employees that will grant access to users. The IRB account manager defines their roles within the system as either PI, departmental coordinator, or study staff.

A PI or study creator may add Study Team members, who will receive the study staff designation. A PI may also assign PI Proxies who may submit studies and follow-on submissions, respond to clarification requests, and otherwise act on behalf of the PI.

Your role in the system and affiliation with a submission will determine the information you may access as well as the level of activities you may perform:
- *Guests*: may view the study
- *Primary Contact*: may view the study and receive notifications related to the study and follow-on submissions
- *Study Team Members*: may create a new study submission, edit the submission, and attach documents. May also create follow-on submissions for approved studies.

- *PI Proxies*: may submit studies and follow-on submissions, and respond to clarification requests on behalf of the principal investigator
- *Principal Investigator*: may submit a submission to the IRB office for processing and respond to any requests for clarifications or modifications.

Only users with PI or PI Proxy roles may submit a study (see questions below for more on PI eligibility and how to designate a PI Proxy).

7. I don't see myself or my colleague in the PI list; why not? And how do I request PI status?

The list of names appearing in the PI picklist is limited to those with granted PI status. If your name or that of a colleague does not appear in the list, it is likely due to a lack of automatically granted status.

The below titles/statuses are automatically granted IRB PI status:
- *Tenure-track faculty*
- *Research-Assistant, Associate or Full Professor*
- *Research Scientists*
- *Research Associates*
- *Non-tenure track faculty who are paid UT employees*
- *Affiliate or Clinical Faculty when all the research will be conducted in a UT, Dell, or Seton facility*

The below titles/statuses may serve as Co-PI, and are eligible for stand-alone IRB PI status with Department Chair/Dean approval:
- *Emeritus faculty*
- *Adjunct faculty*
- *Lecturers*
- *Visiting faculty and scholars*
- *Full Time Instructors*
- *Librarians*
- *Affiliate or Clinical faculty conducting research outside of a UT, Dell or Seton facility who are not paid UT employees*

While student researchers are no longer eligible to be PI of record on new studies within the **UTRMS-IRB**, the below titles/statuses may act on behalf of and under the direction of a PI, with assignment of the PI Proxy role:
- *Postdoctoral fellows*
- *Research assistants*
- *Graduate students*

To request PI status for yourself or another researcher not eligible per the above criteria, email the IRB office. PI eligibility remains the decision of the IRB and exceptions to the policy are rare.

8. Can I assign a proxy to submit a study or follow-on submission on my behalf?

Eligible PI end users may delegate proxy status to another user to access and submit a study on their behalf. Click **Assign PI Proxies** in the activity section of the Study Record Workspace. This will open a space where you can select another study staff user to complete the submission. The proxy must be identified in the first question of the Local Study Team Members page of your study submission.

9. I am a faculty supervisor for student research; how can my students apply to the IRB?

Student-led research must be overseen by a faculty sponsor. In **UTRMS-IRB**, a faculty sponsor will be the PI of record for all studies conducted by a student researcher not eligible for PI status (see question above for more on PI eligibility).

To submit a new study, a student should complete the study and relevant documents, name their faculty supervisor as the Local Principal Investigator in the Basic Study Information page of their submission, and list themselves as Student Lead Investigator in the first question of the Local Study Team Members page.

Once drafted with the faculty supervisor named PI of record, the new study should appear in the supervisor's My Inbox. However, the student may also wish to contact their supervisor to request review. The **Add Comment** activity can be leveraged to do so within the system: select the *PI/PI Proxy/Primary Contact* checkbox for question 3 to issue an email notification to the named faculty sponsor.

The faculty sponsor should review the submission and can make the student investigator a PI Proxy on their study by clicking the **Assign PI Proxies** activity and selecting the Student Lead Investigator. Now the student researcher may submit their new study and act as PI through subsequent reviews, follow-on submissions, etc.

10. Where do I find the proposal template and other revised forms for IRB applications? And which forms are no longer applicable?

You may download the revised *Study Proposal Templates* (one of which must be attached to your submission) and applicable supplemental forms from either the IRB website or the IRB **Library** within **UTRMS-IRB**.

The *Personnel* and *Amendment Summary Forms* are no longer applicable, as a study's Local Study Team Member page and the **Create Modification/CR/Closure** action capture the relevant information directly within the system.

11. I have completed my application's SmartForm in the system. How do I submit it for central office review?

Once you complete the last SmartForm page and click **Finish**, your record will remain in the Pre-Submission state until you submit it. At this point it is awaiting further action by you, the Study Creator and PI. You may hold it in this state if you are waiting for additional information to add to the SmartForm or a more suitable date in your calendar to forward it on to central office staff to conduct the internal review.

To launch the review workflow, click **Submit** in the activity section on the left-side navigation area of the Study Record Workspace. The system will run a validation check and you will be asked to attest that you have obtained the financial interest status and agreement to role of each research staff, and will conduct the research in accordance with *HRP-103 – Investigator Manual*. Click *OK*. Your record has now moved forward to the central office and will be in an *Unassigned* state until it is assigned to a reviewer (IRB Coordinator).

12. How do I route a new study to my Departmental Review Committee (DRC)?

Unlike in *IRBaccess*, new studies are not blocked from submission to the IRB office if they have not undergone DRC review. However, the IRB module does include a range of options to support DRCs and their workflows, including the **Manage Ancillary Review** activity and reports. Departmental reviewers and staff should contact Kristen Crabtree, Assistant Director, IRB, to discuss specific needs. Ultimately, Study Team Members should refer to their department/CSU policy on DRC review.

13. How do I submit a follow-on submission (an Amendment, a Continuing Review, or a Closure) for a study in the IRB module?

To launch a follow-on submission, click **Create Modification/CR/Closure** in the activity section of the Study Record Workspace and indicate the purpose of the submission (note: once you click *Continue* on the Modification/Continuing Review page, the selection made cannot be changed):

- To close a study or submit a Continuing Review, select *Continuing Review/Study Closure*:
  - Complete the Continuing Review/Study Closure Information page. Click **Continue and Finish**.
- To submit what was previously termed an Amendment, select *Modification/Update*:
  - Select the applicable *Modification scope* elements; if uncertain, select both checkboxes to open all portions of the study. Note: a change in PI requires choosing *Other parts of the study*. Click *Continue*.
  - Complete the Modification Summary page, summarizing the changes. Click Continue to enter into the Modification Details for editing.
  - This opens the study portions for application of changes. Make the applicable edits, click Continue, and click **Finish**.
  - Note: only one study modification can be under review at a time.
- To submit changes to a study simultaneous with a Continuing Review, take care to select the third, combined option. (You will also need to select *Modification and Continuing Review* when transferring an existing study at CR.) Issues may arise when otherwise simultaneously routing separate Modification and CR submissions.

Click **Submit** in the activity section of the Study Record Workspace to launch the routing workflow. Remember, the Submit activity is only available to those with PI or PI Proxy roles.

14. How do I report an unanticipated problem or adverse event for a study transferred to or created in the IRB module?

Any user may utilize the **Report New Information** activity, which can be launch either via the Dashboard and IRB Workspace shortcut buttons or from within a specific study record. If launched from within a record, the

study question appears under Related studies and modifications. The Reportable Information page has only three other required questions of the seven which appear: date you became aware of the new information, brief description, and submitter's opinion on whether this reflects an added risk or safety issue or a need for revision of the study or consent document. Complete, click *Continue*, and select **Submit RNI** to complete report.

15. How can I track the progress of my study or submission once I have submitted it for review?
The Study Record Workspace offers two visual cues regarding the progress of your submission in the review workflow. The orange-colored State Indicator is in the top left quadrant of the record. This provides a quick visual key to let you know precisely where your request is in the review workflow. Directly to the right of the State Indicator, the Workflow Map offers a high-level overview of the routing workflow, providing a visual key that shows where the request is at any given point.

16. How can I check the training status of my Study Team Members?
Navigate to a Study Record to view a summary of its study staff's training records. The Study Record Workspace also offers access to a Study Staff Training Report, linked directly below the Study Metadata and above the Workflow Map. Click the link to open a listing of members' CITI and other training completion dates in a new tab.

17. How do I communicate with central office reviewers (IRB Analysts) about my submission?
You may now contact the IRB Analyst assigned to processing your submission directly through the system by using the **Add Comment** activity. Include your question, information, or request in the first field; if necessary, attach any supporting items, including emails for context; if you'd like to generate an email, select the *IRB Coordinator* checkbox under *Who should receive an email notification?* This comment will appear in the History tab.

18. Will the system notify me when I need to take action?
When your submission is assigned a central office reviewer you will be notified by email. Additionally, when a reviewer or IRB Committee Member requests clarification about or modification to your submission, you will receive email notifications with links directing you to take action. Lastly, when a finalized Determination Letter is issued, you will receive a notification with a letter PDF attached.

19. I received an email requesting clarification on my submission. What do I do?
Click on the link in the email notification which takes you directly to the submission record. Select the History tab directly beneath the Workflow Map. Click on **Clarification Requested** at the top of the History Activity Column. Read the instructions provided here by your central office reviewer and open any associated attachments. Return to the Study Record Workspace and click the **Edit Study** button on the left-hand side of the page to make the requested changes to your submission. Click on **Submit Changes** in the activity section of the Study Record Workspace to return your submission to the reviewer.

20. How do I update the documents associated with my study?
Wherever you use the **Add** button to upload a new document, use the **Update** button (or **Upload revision** option in the ellipsis dropdown) to replace the current document with an updated version. Using the **Update** button to replace an older version allows all users accessing a record to leverage the **Compare** function to easily track and verify document revisions.

21. I received a determination letter requiring a modification to my submission. What do I do?
Follow the link embedded in the notification email, or log into **UTRMS-IRB** and navigate, to the Study Record Workspace of the study in question. View the details of the modification(s) required in the determination letter which can be found both attached the notification email and in the **History** tab or Summary area of the Study Record Workspace.

Click the **Edit Study** button on the left-hand side of the page to make the requested changes to your submission. Remember to use the **Update** button when uploading revised versions of previously submitted documents. Click **Submit Response** to launch IRB review of the modifications.

22. I'm having trouble locating my approved study documents; where can I find them in the system?
From a given record's Study Record Workspace, click the **Documents** tab. Final, approved (and watermarked, as applicable) versions of study documents are listed under the Final heading.

23. I no longer need an application that I started or submitted. How do I pull it from the review workflow?

At any point up until the study or foll0w-on submission is approved (reviewed, documents finalized and letter sent), you make click **Discard** in the activity section of the Study Record Workspace to remove the submission from the review workflow. Your request to discard prevents you from submitting that particular request again. However, it will always continue to exist as a discarded record in the **Archive** tab of the IRB Workspace where it can be referenced and copied for future action.

24. Can I clone a submission, so I don't have to begin the process anew each time?

UT Research Management Suite acts as a document repository for all approved submissions, preserving active, modified, and expired protocols in perpetuity. You can clone a study by clicking **Copy Submission** in the activity section in the Study Record Workspace. Rename your copy as prompted and then wait for the new submission to load in the Workspace; once loaded, a direct link to the new copy's Record Workspace is available in the **History** tab. Make any necessary changes using the **Edit Study** function and submit for review when you are ready to begin the review workflow.

25. Where can I find a list of all my studies?

In the IRB Submissions Workspace, you can easily keep track all your studies and follow-on submissions—that is, submissions for which you are a PI or Study Team Member, Primary Contact, or Guest, and so have permission to view. They are sorted into the following categories: **In-Review** (under review by central office staff), **Active** (all Approved studies, with Date Modified updated with each submission), **New Information Reports** (all reports of unanticipated problems or adverse events, regardless of state), **External IRB** (all studies relying upon another IRB), **Relying Sites** (all sites relying upon UT), **All Submissions** (every submission regardless of state), and **Archived** (discarded and expired).

You can easily search for a protocol by selecting *Filter by category* and entering % before your key search term in the search bar. For example, if you want to search for a study with the Short Title "Investigating Adverse Childhood Events (ACEs)", you can *Filter by Name* and enter "%ACE" in the search bar and every record with the text string "ACE" somewhere in its Short Title will display in your search results.