Managing human subjects research protocols in the newest module of UT Austin’s integrated electronic Research Management system
Agenda

• Project Background
• Changes to IRB Processes
  – Study Transition Schedule
  – Submissions
  – Student Investigators
  – PI Eligibility
  – DRC
• Welcome to the Suite: Demonstration
  – Navigation
  – Submitting and managing a study in the IRB module
• Question & Answer
• Resources for Reference and Help
Q&A Information

- Please submit questions via the Q&A window. Feel free to comment on questions or discuss via chat.
- We will pause periodically throughout the program to discuss questions which have arisen in the previous segment.
- If you would like to ask your question live, let us know via the chat feature, and we will unmute you.

On today’s panel:
- UT Research Management Suite Project Team Members
- ORSC’s IRB Team Representatives
PROJECT BACKGROUND
What is it?

**UT Research Management Suite – IRB** is a software platform for submission, review, monitoring, and documenting all human subjects research conducted at UT Austin.

Why do we need it?

The IRB module will streamline the submission, review, approval, and management of studies in an easy-to-use one-stop system that will integrate fully with the other components of the UT Research Management Suite. Study origination, routing, and approval will become a much more efficient and transparent process for PIs.

When will it be available?

The IRB module will be available to investigators and departmental users on August 11, 2020.
The Office of the Vice President for Research is overseeing the implementation of an enhanced electronic Research Administration system for managing components of the research enterprise at UT.

Known as the **UT Research Management Suite**, the project scope encompasses replacement of our legacy research support applications, including managing Proposal, Award, IRB, IACUC, and FCOI records, with an integrated suite of pre-award and compliance software tools.

A competitive procurement resulted in a vendor selection and phased implementation starting in Fall 2019. The first phase was completed in Spring 2020 with the launch of the Agreements module, followed by the IRB module in Summer 2020.

- Compliance Scope: IRB, IACUC, and FCOI
- IBC and Animal Ordering to remain on eProtocol, and will be reassessed for inclusion after initial implementation
Project Schedule

Phase 1
Planning

Phase 2
Implementation

Phase 3
Support

2018
2019
2020
2021
2022
2023

NON-FUNDED AGREEMENTS
IRB
2021
GRANTS/ AGREEMENTS
COI
IACUC
IRB BUSINESS PROCESS CHANGES
IRB Transition Schedule

**NEW STUDIES**

Contact IRB Office

**CURRENT STUDIES**

IRBaccess

- Full Board studies will be transferred to UT RMS on accelerated schedule, assisted by the IRB Office
- IRB Office will contact Study Teams to initiate transfer concierge service

IRBaccess / UT RMS at CR

- Study Teams are encouraged to transfer studies to UT RMS at time of Continuing Review
- Until transferred, all other actions in IRBaccess

UT RMS at CR

- Studies must be transferred to UT RMS at time of Continuing Review
- Until transferred, all other actions in IRBaccess

Study Teams should contact the IRB Office if they have questions about a specific study
### Submissions

<table>
<thead>
<tr>
<th>IRBaccess</th>
<th>UT Research Management Suite – IRB</th>
</tr>
</thead>
<tbody>
<tr>
<td>&quot;Paper&quot; forms available on ORSC website</td>
<td>Revised &amp; simplified forms, including Standard Submission form:</td>
</tr>
<tr>
<td><strong>Web forms:</strong></td>
<td>• Unlocked for easier collaboration &amp; numbered for clearer reference</td>
</tr>
<tr>
<td>• IRB Application</td>
<td>• Available in document Library within IRB module</td>
</tr>
<tr>
<td>• Amendment request</td>
<td>Personnel &amp; Amendment Summary forms eliminated</td>
</tr>
<tr>
<td>• IRB Continuing Review Request</td>
<td><strong>Streamlined SmartForms:</strong></td>
</tr>
<tr>
<td>• Protocol Closure Report</td>
<td>• Create New Study</td>
</tr>
<tr>
<td>• IRB Problem Report</td>
<td>• Create Modification/CR/Closure</td>
</tr>
<tr>
<td><strong>Submission permissions:</strong></td>
<td>• Report New Information</td>
</tr>
<tr>
<td>• New study: all users</td>
<td><strong>Submission permissions:</strong></td>
</tr>
<tr>
<td>• Problem report: study team members</td>
<td>• New study: users with PI status or assigned PI Proxies</td>
</tr>
<tr>
<td></td>
<td>• Reportable New Information: all users</td>
</tr>
<tr>
<td><strong>Other:</strong></td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Viewable training reports for Study Team members</td>
</tr>
</tbody>
</table>
Student Investigators

- Student-led research, including that by graduate, undergraduate, and postdoctoral researchers, must be overseen by a faculty sponsor.
- The faculty sponsor will be the **PI of Record** for all student-led research.
- The student investigator will be assigned **Student Lead Investigator** role as a Study Team member.
- The student investigator may be assigned PI Proxy for a study, authorizing them to act as the PI for the study.
IRB PI Eligibility

- Faculty and staff with job titles that do not automatically grant PI eligibility will need to request PI eligibility before submitting a study with themselves as a stand-alone PI.
- Faculty and staff without automatic PI eligibility may serve as Co-PIs in studies with an eligible PI without requesting prior approval.

<table>
<thead>
<tr>
<th>Status/Title</th>
<th>IRB PI Eligibility</th>
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</thead>
<tbody>
<tr>
<td>Tenure-track faculty</td>
<td>Automatic</td>
</tr>
<tr>
<td>Research-Assistant, Associate or Full Professor</td>
<td></td>
</tr>
<tr>
<td>Research Scientists</td>
<td></td>
</tr>
<tr>
<td>Research Associates</td>
<td></td>
</tr>
<tr>
<td>Non-tenure track faculty who are paid UT employees</td>
<td></td>
</tr>
<tr>
<td>Affiliate or Clinical Faculty when all of the research will be conducted in a UT, Dell, or Seton facility</td>
<td></td>
</tr>
<tr>
<td>Emeritus faculty</td>
<td>Stand-alone PI: Eligible with Dept. Chair/Dean Approval</td>
</tr>
<tr>
<td>Adjunct faculty</td>
<td></td>
</tr>
<tr>
<td>Lecturers</td>
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<tr>
<td>Visiting faculty and scholars</td>
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</tr>
<tr>
<td>Full Time Instructors</td>
<td></td>
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<tr>
<td>Librarians</td>
<td></td>
</tr>
<tr>
<td>Affiliate or Clinical faculty who are not paid UT employees conducting research outside of a UT, Dell or Seton facility</td>
<td>May serve as Co-PI</td>
</tr>
<tr>
<td>Postdoctoral fellows</td>
<td>Under the direction of a PI (PI Proxy)</td>
</tr>
<tr>
<td>Research assistants</td>
<td></td>
</tr>
<tr>
<td>Graduate students</td>
<td></td>
</tr>
<tr>
<td>Undergraduate students</td>
<td></td>
</tr>
</tbody>
</table>
Departmental Review Committees (DRC)

- Study Teams should refer to department/CSU policy on DRC reviews
- The IRB module includes ancillary reviews and reports that can be leveraged by departments to support DRCs
- Unlike IRBaccess, new studies are not blocked from submission if they have not gone through DRC review
- Departmental reviewers and staff can contact Kristen Crabtree, Assistant Director, IRB, to discuss specific needs
SUITE WALKTHROUGH
Log In at: irb.research.utexas.edu
### My Inbox

**Filter by**
- **ID**
- Enter text to search for

<table>
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<th>State</th>
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<td>7/17/2020 2:54 PM</td>
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<td>Orlando Max (irbc)</td>
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<td>7/16/2020 1:00 AM</td>
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<td>Pre-Submission</td>
<td>Orlando Max (irbc)</td>
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Shortcut to Create New Study or Report New Information
Introduction

This tour of system navigation will take about 10 minutes. Please be aware that exiting the browser prior to saving will result in changes not being saved.

Let’s start with an overview of the navigation links on the left before we go into each link in detail.

Click Next to begin.

Next →
<table>
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<th>Submission Type</th>
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<td>John</td>
<td>Dow</td>
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<td>Initial Study</td>
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<tr>
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<td>Max (irbc)</td>
<td>Initial Study</td>
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<td>Orlando</td>
<td>Max (irbc)</td>
<td>Initial Study</td>
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<td>Orlando</td>
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<td>Initial Study</td>
</tr>
</tbody>
</table>
Creating New: IRB Submission

Basic Study Information

1. * Title of study:

2. * Short title:

3. * Brief description:
4. **What kind of study is this?**
   - Multi-site or Collaborative study
   - Single-site study
   - Clear

5. **Will an external IRB act as the IRB of record for this study?**
   - Yes
   - No
   - Clear

6. **Local principal investigator:**
   - John Doe

7. **Does the local principal investigator have a financial interest related to this research?**
   - Yes
   - No
   - Clear

8. **Attach the protocol:**
   - ![Update](icon) Test Protocol(0.01)  IRB Protocol  7/21/2020  History
# Study Funding Sources

1. **Identify each organization supplying funding for the study:**

<table>
<thead>
<tr>
<th>Funding Source</th>
<th>Sponsor’s Funding ID</th>
<th>Grants Office ID</th>
<th>Attachments</th>
</tr>
</thead>
<tbody>
<tr>
<td>Health and Human Services - DHHS</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
### Local Study Team Members

**1. Identify each additional person involved in the design, conduct, or reporting of the research:**

<table>
<thead>
<tr>
<th>Name</th>
<th>Roles</th>
<th>Financial Interest</th>
<th>Involved in Consent</th>
<th>E-mail</th>
<th>Phone</th>
</tr>
</thead>
<tbody>
<tr>
<td>Jane Dow</td>
<td>Co-Investigator (Covered Individual) Coordinator (Covered Individual)</td>
<td>no</td>
<td>no</td>
<td><a href="mailto:janedow@huron.com">janedow@huron.com</a></td>
<td></td>
</tr>
</tbody>
</table>

**2. External team member information:**

<table>
<thead>
<tr>
<th>Name</th>
<th>Description</th>
</tr>
</thead>
<tbody>
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</tbody>
</table>

There are no items to display
Study Scope

1. * Does the study specify the use of an approved drug or biologic, use an unapproved drug or biologic, or use a food or dietary supplement to diagnose, cure, treat, or mitigate a disease or condition?  
   - Yes  
   - No  

2. * Does the study evaluate the safety or effectiveness of a device or use a humanitarian use device (HUD)?  
   - Yes  
   - No
**Locally Research Locations**

1. Identify research locations where research activities will be conducted or overseen by the local investigator:

<table>
<thead>
<tr>
<th>Location</th>
<th>Contact</th>
<th>Phone</th>
<th>Email</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dell Medical School</td>
<td></td>
<td></td>
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</tr>
</tbody>
</table>

**You Are Here:** IRB Webinar Demonstration

**Editing:** STUDY00000151
### Local Site Documents

1. **Consent forms:**
   - There are no items to display

2. **Recruitment materials:** (add all material to be seen or heard by subjects, including ads)
   - There are no items to display

3. **Other attachments:**
   - There are no items to display
Final Page

You have reached the end of the IRB submission form. Read the next steps carefully.

1. Click **Finish** to exit the form.

2. **Important!** To send the submission for review, click **Submit** on the next page.

Before submitting, please confirm the following steps were completed:

1. Ensure that all documents are the most current versions.

2. If applicable, complete any required Department Ancillary Reviews before submission.

3. If applicable, add PI Proxies to your record (note: the Proxy must be added as a study team member first, only the PI may execute the Add Proxy activity).
Workspace Overview

1. User Information
2. Current State
3. Metadata
4. Workflow Diagram
5. Associated Data
6. User Activities
STUDY00000151: IRB Webinar Demonstration

Principal investigator: John Dow
Submission type: Initial Study
Primary contact: John Dow
PI proxies:

IRB office: UT Austin IRB
IRB coordinator:

Next Steps
- Edit Study
- Printer Version
- Submit
- Assign Primary Contact
- Assign PI Proxy
- Manage Ancillary Reviews

Pre-Submission

Pre-Submission → Pre-Review → IRB Review → Post-Review → Review Complete

Clarification Requested → Clarification Requested → Modifications Required

Study Staff Training Report

History
- Activity Created
  - Study Created
  - Dow, John
  - 7/21/2020 12:52 PM
By signing below you are verifying that:

- You have obtained the financial interest status ("yes" or "no") of each research staff.
- You have obtained the agreement of each research staff to his/her role in the research.
- You will conduct this Human Research in accordance with requirements in the HRP-103 - Investigator Manual.

Submit
STUDY00000151: IRB Webinar Demonstration

Principal investigator: John Dow
Submission type: Initial Study
Primary contact: John Dow
IRB office: UT Austin IRB
IRB coordinator:

Next Steps
View Study
Printer Version

Assign Primary Contact
Assign PI Proxy
Manage Ancillary Reviews
Manage Guest List
Add Related Grant
Add Comment
Copy Submission
Withdraw
Discard

History

Filter by: Activity
Enter text to search for
Activity | Author | Activity Date
--- | --- | ---
Submitted | Dow, John | 7/22/2020 12:06 PM
Study Created | Dow, John | 7/21/2020 12:52 PM

Study Staff Training Report

Pre-Submission → Pre-Review → IRB Review
Clarification Requested → Clarification Requested → Post-Review
Modifications Required → Review Complete
Notifications

Generated at the following points:

• Analyst (Coordinator) assigned
• Designated Reviewer assigned
• Determination Letter sent
• Clarification Requested
• Comment added
• Ancillary Review requested
  and others
Q&A
Questions?

Please submit your question via the available Q&A window.
A FEW LAST REMARKS
Resources

Within UT Research Management Suite – IRB

- Investigator Manual
- Worksheets & Checklists
- Protocol & Consent Templates
- Walk-throughs:
  - System Navigation
  - Submitting a New Study
- Help Text

On Project Website
- research.utexas.edu/eraproject/

Get Help Now
- Live Chat staffed by project team
- IRB resources

FAQ’s Organized by Role
- Researcher
- Departmental End User
- Central Office Staff
Get In Touch

- Please leverage our project website’s Get In Touch web form to:
  - Provide feedback on this webinar, the IRB module, or the project
  - Ask further questions that may occur to you after we conclude today
  - Submit a request to be added to our newsletter mailing list

- Would you like to contribute to ongoing improvement of the **UT Research Management Suite – IRB**?
  - Please reach out to our project team to volunteer for a forthcoming IRB Working Group, launching later this fall. We welcome both researcher and administrative staff participation.
Additional Webinar Dates

- **Aug. 13**
  - Thursday, 1:00 pm - 2:00 pm
  - [Registration](#)

- **Aug. 17**
  - Monday, 1:00 pm - 2:00 pm
  - [Registration](#)

- **Aug. 27**
  - Thursday, 10:00 am - 11:00 am
  - [Registration](#)
THANK YOU