Investigator Guide

Submitting a New IRB Protocol in eProtocol

PURPOSE:

This guide is designed to assist Principal Investigators (PIs) and their research staff:

- Understand the process for creating a new IRB protocol in eProtocol.
- Initiate and complete a new protocol application.
- Add current research personnel and verify required training.
- Upload study documents for IRB review.
- Review and successfully submit the protocol for IRB review.

KEY DETAILS OF THE NEW PROTOCOL PROCESS

- A new protocol should be created for research that has not previously received UTEP IRB approval.
- Complete all sections that apply to the proposed research activities.
- The protocol application and supporting documents should provide consistent information about how the study will be conducted.
- All study research personnel should be listed with the appropriate study roles.
- Documents to be used with participants must be uploaded for IRB review, as applicable.
- Human subjects research activities must not begin until the required IRB review is complete and approval or another applicable determination has been issued

BEFORE YOU BEGIN

Prepare the following information and documents:

- Study title and a brief description of the proposed research.
- A current list of all co-investigators and other research personnel.
- Information about the study population, recruitment, consent process, and research procedures.
- Study locations and funding information, if applicable.
- Data collection, storage, and confidentiality information.
- Clean versions of all study documents that require IRB review.

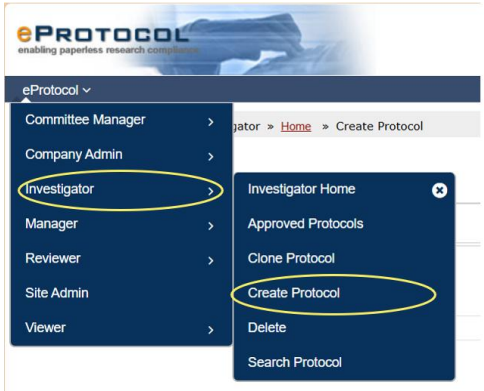
NEW PROTOCOL SUBMISSION PROCESS

Follow the steps below to create, complete, and submit a new IRB protocol in eProtocol.

PART 1 – STARTING A NEW PROTOCOL

1. Open the Investigator Home Page

- Open the **Investigator** menu in eProtocol.
- Select **Investigator Home**.
- Locate the option to **Create Protocol**.



2. Create the New IRB Protocol

- Enter the Study Title.
- Select IRB.
- Select IRB Form to begin the new protocol application.



Before continuing: Confirm that a new protocol is appropriate for the study. If the research already has an existing UTEP IRB record, contact the IRB office before creating a duplicate protocol.

PART 2 – COMPLETING THE INITIAL PROTOCOL INFORMATION

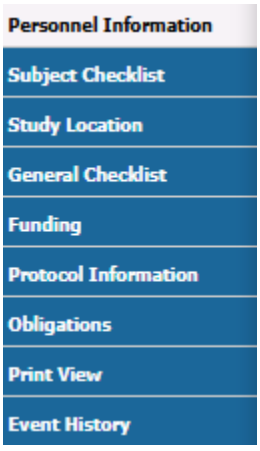
3. Enter the Study Information

Complete the required information for the proposed study, including the study title and other requested protocol details.

Keep the record consistent: Information entered in the protocol should match the procedures described in the supporting study documents.

4. Review of the Protocol Sections

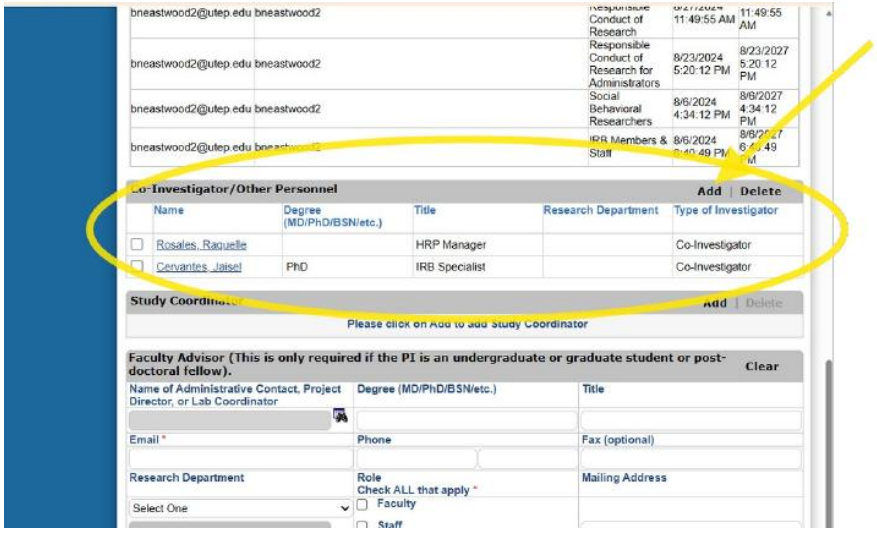
eProtocol will provide sections of the application based on the information entered for the study. Review each applicable section carefully and respond based on how the research will actually be conducted. Save each section as you proceed.



PART 3 – ADDING RESEARCH PERSONNEL

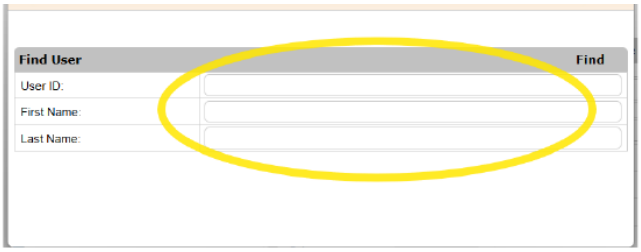
5. Open the Personnel Section

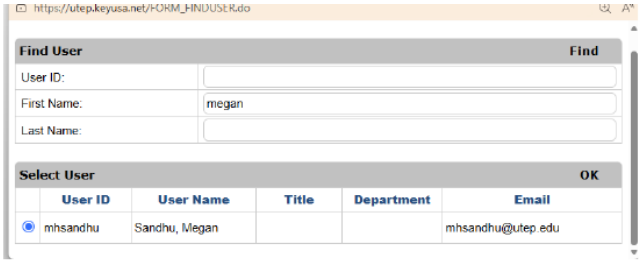
- Open **Personnel Information**.
- Scroll to **Co-Investigator/Other Personnel**.
- Select **Add**. Repeat this process for each person who should be listed on the study.



6. Search for the Person

- Select the **binoculars icon**.
- Search by user ID, first name, or last name.
- Select the correct person.
- Select **OK**.





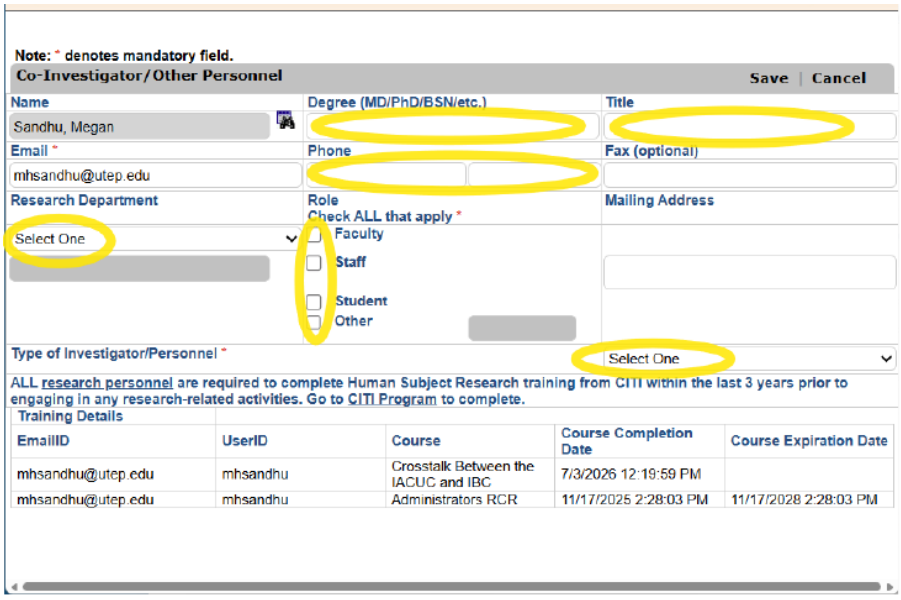
If the person cannot be found: Ask the person to sign in to eProtocol once. After the account is created in the system, search again. Do not substitute another person or enter an unverified identity.

7. Complete Personnel Information

Review the populated information and complete all required fields, including:

- Degree
- Title
- Phone number
- Research department
- Study role
- Type of investigator or personnel

Select every role that applies and save the entry.

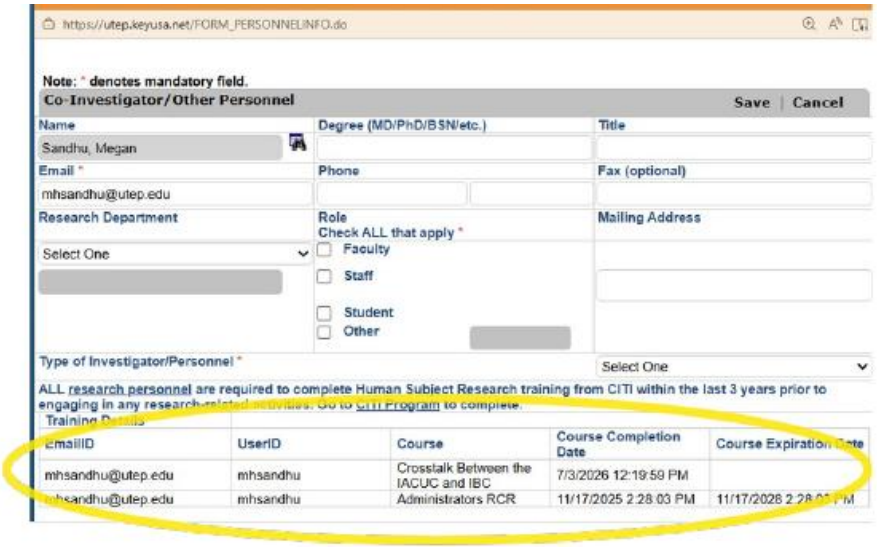


8. Verify Required Training

Review the training information displayed for each person.

- Nursing, Pharmacy, & Allied Health Researchers Training, or
- Social Behavioral Research Training

If the information is missing or incorrect, ask the person to confirm that their CITI Program account uses their UTEP institutional email address.



Training troubleshooting: Signing into eProtocol creates the user record. Using the UTEP institutional email in CITI helps the systems match the training record to the correct person. Contact the IRB office if the record remains incorrect after both items are confirmed.

PART 4 – COMPLETING THE PROTOCOL RECORD

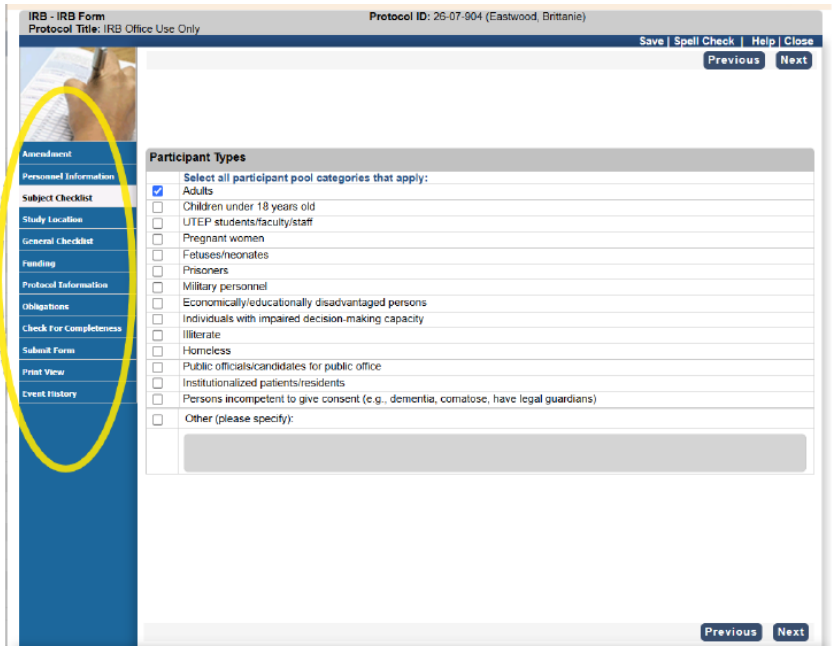
9. Review Every Protocol Tab

Complete every section that applies to the proposed study.

Review the following areas, as applicable:

- Personnel Information
- Subject Checklist
- Study Location
- General Checklist
- Funding
- Protocol Information
- Obligations

Save each section as you proceed.



Keep the record consistent: The participant population, recruitment procedures, consent process, study activities, and data-management practices should align throughout the protocol and supporting documents.

PART 5 – UPLOADING SUPPORTING DOCUMENTS

10. Identify Documents that Require IRB Review

Determine which documents will be used to recruit participants, obtain consent, collect data, or otherwise conduct the research.

11. Upload Study Documents

Upload clean versions of each document that requires IRB review. Examples include:

- Consent, parental permission, and assent documents
- Recruitment materials, advertisements, emails, scripts, and flyers
- Surveys, questionnaires, interview guides, and data-collection instruments
- Information sheets or participant instructions
- Any other document used to conduct the study

Use final working versions: Upload documents that accurately reflect how the study is proposed to be conducted. Remove duplicate or outdated drafts before submission.

PART 6 – REVIEWING AND SUBMITTING THE PROTOCOL

12. Final Quality Check

Confirm that:

- The protocol is being submitted as the correct type of application.
- The study title and protocol information are accurate.
- All current research personnel are listed.
- Personnel roles and required information are complete.
- CITI training information is visible, or any mismatch has been addressed.
- Every applicable protocol section is complete.
- Study procedures are described clearly and consistently.
- Recruitment and consent procedures are accurately described.
- Data collection, storage, and confidentiality information is complete.
- All applicable study documents are attached.
- Information in the protocol matches the supporting documents.

13. Submit the Protocol

- Select **Check for Completeness**.
- Resolve any missing required fields or errors.
- Review and save the completed protocol.
- Select **Submit Form**.

Saving the protocol does not submit it for IRB review.

> **After submission:** Monitor eProtocol and your UTEP email for IRB questions, requested revisions, or requests for clarification. Do not begin human subjects research activities until the appropriate IRB review has been completed and the required approval or determination has been issued.

QUESTIONS? WE ARE HERE TO HELP!

If you have questions about creating a new protocol, completing the application, adding research personnel, or uploading study documents, please contact the UTEP IRB office for assistance at irb@utep.edu.