How to Submit a New Study

Training Requirements

- Have you completed CITI training for human research within the last 3 years?

> **If you are not up to date on your CITI Training:**
>
> - *Go to: http://www.citiprogram.org*
> - *Follow instructions and complete CITI Training.*

- Have you received IRBManager training and been assigned a username and password? *If not, see instructions on page 2.*

- Tips for a successful submission: *See Page 4.*

- What you should be prepared for ahead of time: *See pages 5 & 6.*

- Ready to start your xForm? *See page 7.*

How to Submit a New Study

Getting Set Up in IRBManager

IRBManager is a web-based system designed specifically for the IRB review process, all the way from submission to approval letters.

> With IBRManager you can:
> - Submit new studies online (ETSU researchers)
> - Track the progress of your studies
> - Manage existing studies

Before you can use IRBManager, you must:

1. **Submit a Request for Login form**:
   - Either download the "Request for Login form" from the website or email zerbyl@etsu.edu to request one.

   - When you have completed your form, you may either:
     - Scan it and email it to zerbyl@etsu.edu
     - Fax it to 439-6060
     - Deliver it to the IRB Office in Ross Hall, Room 423

How to Submit a New Study

2. **<u>Complete Training by Phone</u>**:

   o Once the IRB department receives your Request for Login Form, they will contact you to set up a training date and time.

   - Training takes approximately 20 minutes
   - You will need to be at a computer with internet access

   o You will receive your Login and Password during this session.

Version 2_8.5.15

How to Submit a New Study

Tips for a Successful Submission

- **Contact the IRB office for help:** We will be glad to help you and this will speed up IRB turn-around time.

- **Plan ahead:** The review process could take 4-6 weeks from the time all documents are submitted correctly.

- **External site permission/approval:** You must have permissions and/or approvals from all external sites.

- **Provide complete & consistent submissions:** Info in submission should match the info in consent, etc.

Version 2_8.5.15

How to Submit a New Study

Information You Should Be Prepared to Provide

- Resources (population, time, staff & facilities)
- Study staff info
- Review Type: Exempt, Expedited, Full (**See Page 11**)
- Study Details & Objectives
- Procedures for Recruitment & Enrollment of Participants
- Informed Consent documentation (**See Page 12**)
- Roles, Risks, Benefits, Payments, and Costs to Participants
- Privacy (about the person) & Confidentiality (about the data)
- Conflict of Interest
- Ensure all study staff have completed their CITI training

How to Submit a New Study

Attachments You May Need

- Informed Consent Document

- Survey/Interview Questions

- Letters, Ads, Flyers

- Email/Phone Script

- CV/Resume

- References/Bibliography

- Approval Letter or email from any external sites (not required for submission but is required before final approval can be issued)

How to Submit a New Study

Access the IRBManager Login Screen

You can either go directly to the website: https://etsu.my.irbmanager.com

Or, you can access it through the ETSU IRB web page:

Go to http://www.etsu.edu/irb/

On **HOME** page, under "**Quick Links**", select "**IRBManager**"

Quick Links:

- IRBManager - Online system for submitting New Protocols and changes to existing studies.
- CITI Training - Courses required before you can work on studies involving human research subjects
- IRB Board Meeting Schedules & Deadlines

You will see the IBRManager Login Screen

EAST TENNESSEE STATE UNIVERSITY

Login

User Name	
Password	
Client	etsu

☑ Remember Client

Login   Forgot Password?

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Enter your Username & Password

*Client is **etsu***

Check the "Remember Client" box

Select the Login button

How to Submit a New Study

Starting Your New Protocol xForm

Any form created in IRBManager is called an xForm

Once you are logged into IRBManager, select the **Home** tab, and under the **Actions** column, **select Start xForms**

Choose the appropriate New Protocol Submission according to the location of the research:

Version 2_8.5.15

How to Submit a New Study

Complete and submit the xForm; include attachments where applicable.

Collaborators: You can allow other IRBManager users to edit your xForms. We recommend that students add their Faculty Advisor as a collaborator on their

Version 2_8.5.15

How to Submit a New Study

New Protocol Submissions. [Click here for additional information on the collaborator feature.](#)

Page Jumping: Use this feature to move to specific pages in the New Protocol Submission; it allows you to skip past incomplete pages yet prohibits you from submitting the form until all required fields are complete. Click here for additional information. [Click here for information on using the Page Jumping feature.](#)

Throughout IRB Manger:

- Use "Next" to move to the next page
- If you need to take a break and work on it later, select "Save for Later"

Version 2_8.5.15

How to Submit a New Study

Review Type: Exempt, Expedited, or Full Review

There are 3 types of review:

1. Exempt
   a. Chair review
   b. No formal consent doc
   c. No expiration date

What type of review are you requesting? *(Requir...)*

- ⦿ Full Review (more than minimal risk)
- ⦿ Expedited Review (minimal risk as determined by federal guidelines)
- ⦿ Exempt

2. Expedited
   a. Minimal risk as determined by federal guidelines
   b. Chair and/or expedited reviewers
   c. Requires a Consent unless waived
   d. Requires Continuing Review

> *Minimal Risk* *means that the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.*
>
> *For detailed information on the three types of review, go to:*
> *http://www.etsu.edu/irb/review_process/basics.aspx*

3. Full Review
   a. More than minimal risk
   b. Goes to Full Board for review

How to Submit a New Study

Informed Consent Document (ICD)

- Expedited Submissions: Require an ICD with all required elements unless a waiver of informed consent has been requested.

- Exempt Submissions: If your study involves interaction with people, it requires a consent paragraph with these 4 elements:

    o The activity involves research

    o A description of the procedures

    o That participation is voluntary

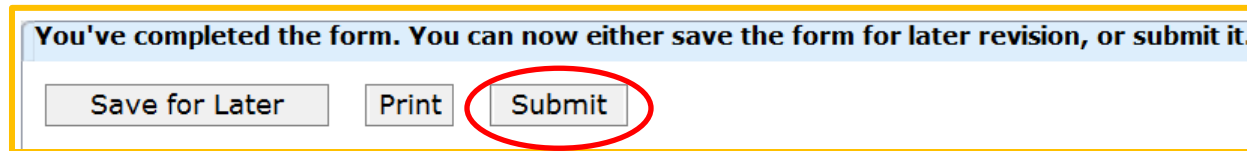   o The name and contact info of investigator

> *You can create your informed consent document from the ICD template on the IRB website: http://www.etsu.edu/irb/forms.aspx*

Version 2_8.5.15

How to Submit a New Study

Submitting and What Happens Next

When you have completed the entire form, select "Submit"

Once submitted, your Protocol will go through the following review stages:

- IRB Pre-Review
- Faculty Attestation (for students)
- Dept. Chair/Head Signs xForm (for non-students)
- IRB Initial/Coordinator Review
- IRB Chair Review
- If approved, Approval Letter!

We can send your form back to you with notes for corrections at any stage

(Note: There are additional review stages for VA and MSHA studies.)

Version 2_8.5.15

How to Submit a New Study

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