

# How to Submit a New Study

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## 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.*

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## 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 IRBManager 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](mailto:zerbyl@etsu.edu) to request one.
- When you have completed your form, you may either:
  - Scan it and email it to [zerbyl@etsu.edu](mailto:zerbyl@etsu.edu)
  - Fax it to 439-6060
  - Deliver it to the IRB Office in Ross Hall, Room 423

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## 2. Complete Training by Phone:

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

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## 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.

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## 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

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## 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)

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## 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

*Enter your Username & Password*

*Client is **etsu***

*Check the “Remember Client” box*

*Select the Login button*

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## 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:

Start xForm			Wednesday Feb 04 09:26 AM	
			Filter: <input type="text"/>	
Action	Form (Click to start)	Description		
	Form 200 Humanitarian Use Device (HUD) initial submission	Submit this form to request initial approval for a HUD. Note: If the HUD is the subject of a clinical investigation (one in which safety and effectiveness data is being collected to support a PMA), this form may not be used. Instead, you must submit the new protocol submission form.		
	New Protocol Submission V6	ETSU or MSHA researchers, submit this form for a NEW protocol submission. NEW: page jumping capability! Use drop down menu at top of page to move around within the xform!		
	Request to Rely on an External IRB v 2	THIS FORM IS ONLY TO ASK IF AN EXTERNAL IRB MAY BE UTILIZED. PLEASE CONTACT THE IRB OFFICE TO DISCUSS BEFORE USING THIS FORM.		
	VA INVESTIGATORS ONLY New Protocol Submissi_V7	VA Investigators Only - Use this form to submit a New Protocol Submission NEW: page jumping capability, and ability to add a collaborator to the xform!		



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Complete and submit the xForm; include attachments where applicable.

The screenshot shows the '1. Submitter Information' form in IRBManager. At the top, the 'Collaborators' icon and the '1. Submitter Information' dropdown menu are circled in red. The form includes a 'Submitted by' section with a text field containing 'Test\*, Test', an 'Email' field with 'testtestirb@gmail.com', and a 'Business' field with '423-439-6002'. The 'Add Note' link is also circled in red. Below this is a section for 'Enter your Project Title' with a text area and a note: 'If funded or submitted for funding, the title must match your grant application. VA Proposals must not exceed 142 characters.' The next section is 'Enter the email address of the Principal Investigator (PI)' with a text field and a note: 'If you are the PI, enter your own email address. If you are not the PI, enter the PI's email address. If you are not certain of the email address, save the form for later, obtain the email address, and return to the form to complete.' The final section is 'Please choose the most appropriate category describing the affiliation of the PI to ETSU' with five radio button options: 'ETSU paid employee', 'ETSU clinical appointment only', 'ETSU student', 'ETSU resident', and 'No affiliation with ETSU'. At the bottom, the 'Next' button is circled in red, along with the 'Save for Later' and 'PDF' buttons.

Throughout IRBManager, use "Add Note" to add additional information to any field

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

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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”

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## 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

### 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

### 3. Full Review

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

What type of review are you requesting? (Required)

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

**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](http://www.etsu.edu/irb/review_process/basics.aspx)

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## 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:
  - The activity involves research
  - A description of the procedures
  - That participation is voluntary
  - The name and contact info of investigator

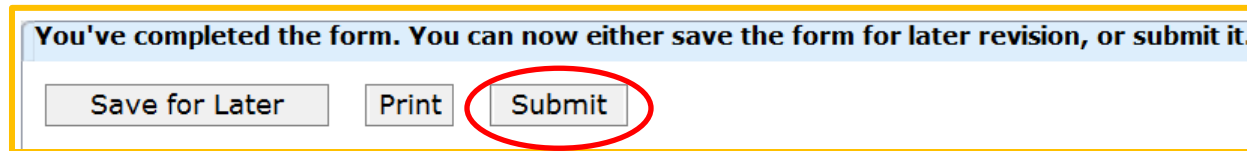
*You can create your informed consent document from the ICD template on the IRB website: <http://www.etsu.edu/irb/forms.aspx>*

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## Submitting and What Happens Next

When you have completed the entire form, select “Submit”



A screenshot of a web form completion screen. At the top, a light blue banner contains the text: "You've completed the form. You can now either save the form for later revision, or submit it." Below this banner are three buttons: "Save for Later", "Print", and "Submit". The "Submit" button is circled with a red oval, indicating it is the action to be taken.

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.)

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## Institutional Review Board (IRB) Staff

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