

Student's Guide: Helpful Hints when Preparing for and Completing an IRB New Protocol Submission

By reviewing this form online, you will have access to links that provide additional information

Please go to https://www.etsu.edu/irb/documents/student_pi_check_list.pdf to download the most recent version of this form. Changes are made whenever necessary.

In working with investigators, the campus board and IRB staff have noticed common areas that tend to delay progress when moving protocols throughout the IRB process. Based on these observations, we have outlined a list of questions for you to consider while working your way through the IRB submission process. The goal is to assist you in ensuring the submission is complete and facilitate a smooth IRB process. Keep in mind that no recruitment or research can begin until you receive your IRB approval letter.

A. Research Determination:

1. If you have any doubt as to whether your research qualifies as Human Subjects Research, please complete a [Form 129](#). Once this form is submitted and reviewed, you will receive a determination letter to let you know whether you need IRB Approval. This will save a lot of effort if your project is not determined to be Human Subjects Research.

B. It's Research—what next?

1. Have you contacted your Faculty Advisor?
 - a) Has the proposal been approved by your advisor and/or committee?
 - b) Did your Faculty Advisor deem that the project is ready for IRB submission?
2. How much time do you have? [Please start early!](#)
3. Have you completed [CITI training](#)? This online program consists of ethics training modules for research with human subjects.
4. Has everyone on your study team completed CITI training? Prior to final IRB approval, all study staff, including your faculty advisor, must be up-to-date on their Human Subjects Training.
5. Do you have an [IRB manager account and login](#)? You will use this program to submit your IRB protocol.
6. Recruitment:
 - a) Do you have access to a participant group?
 - b) Is there a clear process for recruiting participants?
 - c) Have you created materials to contact people and introduce them to this study?
7. Are external sites involved in this project?
 - a) If so, have you obtained site permission?
 - b) Does that site have an IRB?
 - c) While you can submit a study for review prior to receiving permissions, you cannot get final approval until all submissions have been submitted.

8. Are you familiar with the difference between the [three types of IRB review](#):
 - a) Exempt (doesn't mean exempt from the process of IRB)
 - b) Expedited (doesn't mean it is a faster process)
 - c) Full (rarely used in behavioral/social research)

9. Do you have your consent form? There are templates on the IRB website at <http://www.etsu.edu/irb/forms.aspx>

10. [Do you have minors in your study?](#) If so, be sure to work on a parental permission and child assent (both are typically required unless a waiver can be justified)

11. Have you thought about the entire procedure from [recruitment](#) to [consent](#) to study procedure, being sure to maintain [privacy and confidentiality](#) throughout all phases?

12. Do you have all your attachments?
 - a) Training certificates for study staff that did not complete CITI through ETSU*
 - b) Site Permissions*
 - c) Pertinent Literature (may be typed into the xForm or added as an attachment)
 - d) CV
 - e) Informed Consent Document
 - f) Child Assent (if involving minors)
 - g) Parental Permission (if involving minors)
 - h) Recruitment materials (ads, flyers, letters, phone scripts, emails, online posts, verbal script, etc.)
 - i) Survey or interview questions
 - j) Data collection sheet (if downloading and analyzing data)
 - k) Grant application (if applicable)*
 - l) [Potential Conflict of Interest Forms](#) for all study staff**

*While you may begin the review process by submitting your xForm prior to receiving these files, the IRB cannot grant final approval and research cannot begin until these forms are submitted and approved.

**You will not attach these to the xForm. Please keep these forms, as they would be necessary if an audit is ever needed.

C. When completing the xForm

1. Have you completed all the steps in Section B of this guide?

2. Add your faculty advisor as a [collaborator to the xForm](#) AND as a Faculty Advisor in the study staff section.

3. Study Staff: Information for the PI is already recorded. Within this table, enter all other study staff. **Be sure to select Save at the end of each row.**

4. Recruitment:
 - a) How do you have access to the list of participants? Provide an explanation of where you are obtaining participant lists and/or who is giving you access to this information.

- b) Inclusion/Exclusion – Is your study restricted to adult participants? If so, be sure to add “Age 18 & over” to your inclusion criteria and explain your methods for determining how all eligibility requirements are met.
 - c) Payments/incentives may be provided to offset the time commitment of the participant and should not be coercive. If using ETSU money or process, be sure you are following the [ETSU policy for participant payments](#)
5. Consent
- a) Types of Consent: Depending on your study, you may need to select multiple types of consent.
 - 1) If you check more than one option, you will need to explain how these methods apply. For example, you may be using online consent without a signature to participants completing a survey and then signed consent for those being interviewed.
 - 2) The answers to these questions allow us to determine if you need a consent waiver. If your answers indicate that you need a waiver, questions will appear later in the form requesting clarification on why the waiver is needed.
 - b) Consent Process: When/how are you consenting your participants? Clearly state all the steps from initial recruitment to consent to research procedures. Remember, the IRB reviewers are not as familiar with your study as you are, so the answers on this xForm need to be informative and understandable.
 - c) Is someone besides you involved in attaining consent? If so, they are considered study staff and typically have to complete CITI training.
 - d) Do you (or the person who is consenting the participants) have a relationship with participants who will be in your study? If so, how will you prevent coercion?
6. Risks: What are the risks of your study?
- a) Be consistent with the risks throughout the xForm and consent form. No Foreseeable Risks ≠ Minimal Risks.
 - b) Many studies include a possible risk of loss of confidentiality. If that applies to your study, be sure to list it.
7. Benefits: Are there any direct benefits to the participant?
- a) It is often the case that there are no direct benefits to the participant, and the only benefit is towards future knowledge in the content areas. If that is the case, this information should be clear in both the xForm and Informed Consent Document.
 - b) Payment and/or extra credit are not considered benefits.
8. [Privacy & Confidentiality](#): Do you know the difference between privacy and confidentiality?
- a) Privacy regards the actual participant in the study (this includes the consent and research settings)
 - b) Confidentiality deals with safeguards for the data you are collecting.
 - c) How are you ensuring privacy and confidentiality throughout the entire research process?
 - d) Identifiable Data: If using identifiable data, be prepared to answer why this data is necessary, how it will be protected, and how it will eventually be destroyed.
9. Transferring data: Are you moving your data from one location to another? Unless all data is being collected and analyzed in the exact location of where it will be stored, then you are electronically or physically sending the data to another location. (This includes downloading data from a server to another drive.) How are you safely transporting this data?

10. Are you collecting data from existing records? If so, you need to include a data collection sheet that shows exactly what data you are collecting.

D. Informed Consent Documents (ICDs):

1. Have you included all the required elements of consent? Visit https://www.etsu.edu/irb/documents/Checklist_For_Informed_Consent.pdf for a complete list
2. Is the reading level appropriate?
 - a) This is not a scholarly article but a document used to clearly provide the participant with all the information necessary to make an educated decision.
 - b) Make sure the reading level of your consent matches your audience.
 - c) The reading level for the general public is 8th grade.
 - d) If you are working with an educationally disadvantaged group, the level should be lower than 8th grade.
 - e) Children's Assent should be written for the age of the child.
3. Are you using our template?
 - a) We have several consent templates that will help you with the consent process. <http://www.etsu.edu/irb/forms.aspx>
 - b) The first page of the template is instructional text—be sure to remove it
 - c) Always update the date in the footer any time you edit your consent form. This provides clarity if there are multiple versions of your ICD.
 - d) Replace any red text with information specific to your study.
4. Consistency: Does everything on your ICD match what you wrote in the xForm?
 - a) This xForm may include a section just above the consent attachment box displaying your previous answers regarding consent. Use these answers as a guide as they must be consistent with the text in your consent form.
 - 1) If your xForm says, "No foreseeable risks," but the consent form states, "Risks associated with this study are minimal," then it is not consistent.
 - 2) If you say "minimal risks," state what the risks are and how you are protecting the participants from these risks.
5. Did you write the ICD in the second person? Refer to the participants as "you" not "participant(s)"
6. Did you include (or remove) the appropriate signature lines? For example, if you are using an online survey, you will most likely omit signature lines.
7. Is participant agreement clearly stated? The last statement (often before the signature lines) should clearly state what the participant is agreeing to. For online ICDs that do not include signatures, one method to provide an attestation is to include text at the bottom, such as:

Clicking the AGREE button below indicates

- I have read the above information
- I agree to volunteer
- I am at least 18 years old

- I AGREE
- I DO NOT AGREE

For a template specific to online data collection, go to <http://www.etsu.edu/irb/forms.aspx>