

Advisor’s Guide: Helpful Hints for Advising Students Through an IRB New Protocol Submission

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

Please go to the “Things to Think About” section on the [ETSU IRB Getting Started page](#) to download the most recent version of the Student Check List. Changes are made whenever necessary.

In working with student investigators, the campus board and IRB staff have noticed common areas that tend to delay progress when moving protocols through the IRB review process. Based on these observations, we have outlined a list of questions to ask yourself and the student throughout the IRB submission process. The goal is to assist you in ensuring the submission is complete and facilitate a smooth IRB process for the student. Please note that students have a companion guide that they should use.

A. Research Determination:

1. If there is any doubt as to whether the project qualifies as Human Subjects Research, recommend that the student complete a [Form 129](#). Once this form is submitted and reviewed, the student will receive a determination letter to let them know whether their project needs IRB Approval. This will save a lot of effort if the IRB determines that the project is not Human Subjects Research

B. It’s Human Subject’s Research—what next?

1. Advise your student to wait for final project approval by you or the student’s committee before working on their IRB submission.
2. Once the project is approved by you or the student’s committee, let the student know that it is time to work on their xForm.
3. Make sure the student understands the [time necessary to get through the IRB process](#) and advise them to start early.
4. Ensure that you, the student, and every study staff member is up to date on [CITI training](#).
5. Do both you and the student have [OneAegis logins \(formerly IRBManager\)](#)? Investigators use this program to submit their protocol, and as an advisor, you will need to review the form and sign off on it.
6. Recruitment:
 - a) Does the student have access to the proposed participant group?
 - b) Is there a clear method of recruiting participants?

- c) Has the student developed materials to contact people and introduce them to the study, including any emails, online posts, etc.? Even if participants are being invited verbally, the IRB will need to see a copy of the verbal script.
 - d) You may want to recommend that the student review our [Recruitment Letter Template](#)
7. Are external sites involved in this project?
- a) If so, has the student obtained site permission?
 - b) Does that site have an IRB?
 - c) While the student can submit a study for review prior to receiving permissions, final approval will not be granted until all site permissions have been submitted.
8. Consent:
- a) Does the student have a solid plan for consenting participants including how the participants acquire and return the consent form?
 - b) Who is consenting participants? Unless they are simply handing out or providing a link to the consent form (without providing any other details or answering questions), anyone engaged in the consent process is considered study staff (and therefore is expected to complete CITI training.)
 - c) Are consent forms being signed? If not, the student needs to request a Waiver of Documentation. (If the study is exempt, waivers are not needed.)
 - d) Provide guidance on the consent form. Encourage the student to use one of the IRB consent templates: <http://www.etsu.edu/irb/forms.php>
9. [Does the study involve minors?](#)
- a) Parental permission and child assent are required unless asking for a waiver.
 - b) It may be possible to ask for a waiver of parental permission with strong rationale indicating the study is minimal risk and that it is impracticable (and not just challenging) to obtain permission from all parents.
10. Ensure that the student understands the different [types of IRB review](#):
- a) Exempt (please emphasize that this does not mean the project is exempt from the IRB process)
 - b) Expedited (please emphasize that this does not mean it is a faster process)
 - c) Full (rarely used in behavioral/social research but does occur occasionally)
11. Is there a clear path from [recruitment](#) to [consent](#) to study procedure, and is [privacy and confidentiality](#) maintained throughout all phases? The student should be able to step through the process so everyone involved in reviewing the project has a clear understanding of the entire procedure.
12. Confirm that the student has the necessary 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. Templates can be found at <https://www.etsu.edu/irb/forms.php>
- 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) Final versions of survey or interview questions
- j) Data collection sheet (if downloading and analyzing data) When collecting data from existing records, this allows the IRB to determine exactly what data is being collected.
- k) Grant application (if applicable)*
- l) [Potential Conflict of Interest Forms](#) for all study staff**
 - *While the student can submit their xForm without these attachments, the IRB cannot grant final approval and research cannot begin until these forms are submitted and approved.
 - **As Faculty advisor, you also need to complete one of these. The student will maintain the forms in the event of an audit

C. When reviewing the xForm

1. Has everything in the preceding section (Section B) been discussed with the student?
2. The student should have added you as a [collaborator to the xForm](#); this gives you access to the xForm during the student's data entry stage.
3. Study Staff: Has the student added you as Faculty Advisor on the study staff table? Has everyone involved in recruiting, consenting, collecting data, or analyzing identifiable data been added?
4. Recruitment: Do all the questions regarding recruitment match the discussion you had with the student?
 - a) How does the student have access to the list of participants?
 - b) How are participants introduced to the study, and has the student indicated that recruitment materials are being used. These materials include flyers, emails, online posts, phone scripts, or verbiage the student or someone else plans to say in front of a group. (This information is added in the Attachment section towards the end of this xForm.)
 - c) Inclusion/Exclusion – If no minors are involved, make sure the student indicated “Age 18 & over” and explained how they will determine whether participants meet this eligibility requirement. If there are multiple populations, this information must be included for each of them.
 - d) Payments/Incentives: Payments/incentives may be provided to offset the time commitment of the participant and should not be coercive. If using ETSU money or process, confirm that the [ETSU policy for participant payments](#) is being followed.
 - e)
5. Consent Process: Verify the answers that were discussed in Section B:

- a) Did the student need multiple types of consent? (For example, they may need consent without a signature for online surveys and also a signed consent for interviews.) Be sure they selected all that apply and that they have explained how each type of consent will be used.
 - b) When/how are participants being consented? Does the submission clearly state all the steps from initial recruitment to receiving the consent form consent to consenting and to research procedures. Remember, the IRB reviewers are not as familiar with this study as you and your student are, so the answers on this xForm need to be informative and understandable
 - c) Is someone besides the student involved in attaining consent? If so, they are considered study staff and typically have to complete CITI training.
 - d) If the person consenting is familiar with the participants, how will coercion be prevented?
6. Risks: Have all risks been clearly stated, and is this consistent throughout the xForm and the Informed Consent Document.
- a) No Foreseeable Risks ≠ Minimal Risks.
 - b) If there is a possibility for loss of confidentiality, has that been addressed? If at any time any study staff member has the ability to match the data with the participant, it is considered identifiable data.
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**: Make sure the student understands the difference between privacy and confidentiality and answers these questions appropriately.
- a) Privacy regards the actual participant in the study (this includes the settings for consent and research procedures)
 - b) Confidentiality deals with the data being collecting.
 - c) Have privacy and confidentiality been addressed throughout the entire research process?
 - d) Identifiable Data: If using identifiable data, has the student adequately answered why it is necessary, how it will be protected, and how it will eventually be destroyed?
9. Transferring data: Is the student moving data, including the consent forms, from one location to another? Unless all data is being collected and analyzed in the exact location of where it will be stored, then the student is electronically or physically sending the data to another location. (This includes downloading data from a server to another drive.) Did the student include a safe method for transporting this data?
10. Data Storage & Backup:
- a) Ensure that the student's plans comply with ETSU's Data Storage and Backup Policy. This policy can be found at <https://www.etsu.edu/policies/info-tech/digitaldata.php>
 - b) Student research data is owned by ETSU. Ensure that the student has plans to provide you with a copy of the data that can be accessed after the student leaves ETSU. .

11. Is the student collecting data from existing records? If so, a data collection sheet must be attached so the IRB can determine exactly what data is being collecting.

D. Informed Consent Documents (ICDs):

1. Make sure the student includes all the required elements of consent. Visit <https://www.etsu.edu/irb/forms.php> for a guidance for writing Informed Consent Documents and the most consent templates.
2. Is the reading level appropriate?
 - a) Make sure the reading level of the ICD matches the intended audience.
 - b) The reading level for the general public is 8th grade.
 - c) If working with an educationally disadvantaged group, the level should be lower than 8th grade.
 - d) Children’s Assent should be written for the age of the child.
3. Did the student use an ETSU IRB template? (Recommended but not required)
 - a) The first page of the template is instructional text—ensure it was removed
 - b) The footer should reference the current date. While this might seem minor, if additional edits are required, the dated footer is used to identify each version.
 - c) Make sure all template text was replaced with information specific to the study.
4. Consistency: Does everything on the ICD match the answers in the xForm?
 - a) If the xForm says, “No foreseeable risks,” but the consent form states, “Risks associated with this study are minimal,” then it is not consistent.
 - b) If the term “minimal risks” is used, the risk(s) are and method(s) for protecting the participants from these risks must be included.
5. Is the ICD written in the second person? Participants should be referred to as “you” not “participant(s)”
6. Did the student include (or remove) the appropriate signature lines? For example, if it is an online survey, most likely signature lines should be removed.
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 am physically present in the United States

- I AGREE
 I DO NOT AGREE

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