**Protocol Certification Checklist for PIs**

As described in the IRB Investigator Responsibilities [policy](https://research.illinoisstate.edu/downloads/102-investigator-responsibilities.pdf), faculty or staff serving as PI on dissertation, thesis, capstone, and other student-led human subjects research projects are responsible for all aspects of the research, including certifying that all the information in the protocol is “true, complete, and accurate.” The intent of this checklist is to assist you in supporting your student and setting them up for success by making sure each section of the protocol is ready for IRB review. There is also information within the Cayuse form to guide you through the completion of the protocol.

General

* The review level selected is appropriate.
* Responses completely address the questions asked.
* Attachments are clearly labeled.
* You should have discussed with your student the study risks (including any risks posed to participants if a breach of confidentiality were to occur) and benefits, all of which are clearly described in the protocol and consent.

Research Team

Requirements for who must be listed in the Research Team section are dependent on the review level of the protocol.

* Exempt:
  + List PI (must be a faculty or staff of ISU)
  + List the student who is conducting the study for their thesis or dissertation.
* Expedited/Full:
  + List PI (must be a faculty or staff of ISU)
  + List the student who is conducting the study for their thesis or dissertation.
  + List any other person who is “engaged” in the research. Engaged means the individual “obtains for the purposes of research:
    1. Data about the subjects of the research through intervention or interaction with them;
    2. Identifiable private information about the subjects of the research; or
    3. The informed consent of human subjects for the research.”

CITI

* Verify CITI trainings are correct and current prior to certifying the protocol. To do this, in the Research Team section of the protocol click “View” all the way to the right of the individual’s name listed in Cayuse.
* Student CITI training:
  + Exempt/Expedited: Students can take the No More than Minimal Risk Research with Human Subjects (aka Students – Class Projects).
  + Full board: Students must complete the same training as PIs (Educational Social and Behavioral Research with Human Subjects – Basic)
* PI CITI training:
  + The Educational Social and Behavioral Research with Human Subjects – Basic or Refresher. More details on required CITI training can be found [here](https://research.illinoisstate.edu/ethics/training/human-subjects/).
* If Cayuse does not display any CITI training history and the training is complete, attach a copy of the up-to-date certificate to the Additional Documents section.

Attachments

Verify all required attachments are complete and attached to the correct sections of the protocol. Requirements vary depending on the study.

* Site Permission:
  + Required when recruiting participants through a school, agency, etc.
  + Required when recruiting participants from a database or listserv not open and available to the public.
  + Required when conducting research at or obtaining data from a location such as a school, agency, etc.
  + Indicate in the protocol when permissions are not yet obtained by all or some of the sites.
* Instruments:
  + Attach any research-specific instruments. For example, interview or survey questions, observation guides, formal questionnaires, etc.
  + Instruments must be attached and not linked.
* Consent Forms:
  + Consent forms for adult participants are complete and customized to the study.
  + We highly encourage you to use our [templates](https://research.illinoisstate.edu/forms/). When using our templates, instructional text must be replaced with the details of the study. When not using our templates, you must include all required information as demonstrated in our templates.
  + If the project is sponsored, indicate that and who the sponsor is.
  + Are written to “you” and not “they”/”the participant”.
  + Are understandable for the targeted population, typically an eighth-grade reading level.
  + Instructions for turning on readability statistics in Microsoft Word can be found [here](https://support.microsoft.com/en-us/office/get-your-document-s-readability-and-level-statistics-85b4969e-e80a-4777-8dd3-f7fc3c8b3fd2#:~:text=Go%20to%20File%20%3E%20Options.,Select%20Show%20readability%20statistics.).
  + Tips on informed consent can be found [here](https://research.illinoisstate.edu/ethics/human-subjects/consent/).
* Permission/Assent Forms:
  + Permission and assent forms for minors or individuals with a legally authorized representative (LAR) are complete and customized to the study.
  + We highly encourage you to use our [templates](https://research.illinoisstate.edu/forms/). When using our templates, instructional text must be replaced with the details of the study. When not using our templates, you must include all required information as demonstrated in our templates.
  + If the project is sponsored, indicate that and who the sponsor is.
  + Permission forms are written to “you and your child/the person you represent” or “your child/the person you represent” and should be understandable, typically an eighth grade reading level.
  + Assent forms are written to “you” and must be understandable for the individual being assented. Note that there are alternative methods of obtaining assent that may not involve forms.
  + Instructions for turning on readability statistics in Microsoft Word can be found [here](https://support.microsoft.com/en-us/office/get-your-document-s-readability-and-level-statistics-85b4969e-e80a-4777-8dd3-f7fc3c8b3fd2#:~:text=Go%20to%20File%20%3E%20Options.,Select%20Show%20readability%20statistics.).

International Research

* Register international research that involves travel with Risk Management via the contact information linked within the International Research section of the protocol.
* Check U.S. State Department Travel [Advisories](https://travel.state.gov/content/travel/en/traveladvisories/traveladvisories.html) to help safeguard your student, the participants, and the data. Describe these details in the International Research section of the protocol.
* Consult the Office for Human Research Protections’ International [Compilation](https://www.hhs.gov/ohrp/international/compilation-human-research-standards/index.html) of Human Research Standards as well as other research entities in the country to determine whether there are country-specific requirements to conduct research such as licensing requirements, data security, etc. Describe these details in the International Research section of the protocol.