

Am I qualified to supervise human subjects research?

This questionnaire is intended to help you to determine the following:

- Am I qualified to supervise this project?
- Is the student qualified to take on this research?
- Do I have professional capacity to supervise this student's project?

Responsibilities always include:

- Guidance with research design
- Support with the development of an informed consent process
- Creation of a data storage plan
- Review of multiple drafts of IRB protocol
- Assuming responsibility for the ethical and responsible conduct of research
- Ongoing check-ins regarding data collection, analysis, and presentation
- Completion of CITI training

Responsibilities may include:

- Securing local contacts and approval letters
- Assistance with translations

Before responding to the prompts below, please be sure to take the time to read these definitions culled from the Federal Policy on Human Research Protections, also known as the Common Rule.

“Research” is defined as “a systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge.” (§46.102(l)).

“Human subject” is defined (§46.102(e)(1)) as: a living individual about whom an investigator (whether professional or student) conducting research:

- (i) Obtains information or biospecimens through intervention or interaction with the individual, and uses, studies, or analyzes the information or biospecimens; or
- (ii) Obtains, uses, studies, analyzes, or generates identifiable private information or identifiable biospecimens.

Note that *some* scholarly and journalistic activities (e.g., oral history, journalism, biography, literary criticism, legal research, and historical scholarship) are not counted as research, namely when they “focus directly on the specific individuals about whom the information is collected.” (§46.102(l)(1)). When the scholarly or journalistic activity collects and uses information about specific individuals but does not generalize to other individuals, it does not count as human subjects research.

Please consult Bowdoin’s [IRB website](#) for information about CITI training, links to country-specific regulations, consent form templates, guidance on class projects, ethnographies, and documentaries, and more.

Have you read the definitions above before responding to the prompts?

- Do I conduct human subjects research? (please be sure you have read the definitions above) Y / N
- If no, have I been trained (defined as supervised by a professional in the field) in human subjects research as a graduate student, professor, or in another professional capacity? (NOTE: CITI training alone does not constitute training) Y / N
- Following training, have I garnered experience conducting human subjects research? Y / N
- If no, is a Bowdoin colleague who trained and qualified to conduct human subjects research willing and able to serve as a co-advisor and to serve as the Principal Investigator of record? Y / N
- Have I written successful IRB protocols within the last 5 years? Y / N
- Do I have the time to review multiple versions of this student's protocol to facilitate timely and efficient review by the IRB? Y / N
- Will this student work need to be categorized as research (as defined by the OHRP)?
E.g., the project will be made public as an Honors Project, poster, or presentation outside of class;
or, the student intends to use the data in graduate school Y / N
- Could this study be an independent study/class project that will *never* be made public, and the data will *never* be used for any future purposes? (Note: [Responsible and Ethical Conduct of Research](#) still applies.) Y / N
- Is the scope and topic appropriate for research at an undergraduate institution? Y / N
- Does the study involve subject populations identified by the OHRP as vulnerable (pregnant women and fetuses, minors, prisoners, persons with diminished mental capacity, and those who are educationally or economically disadvantaged)? Y / N
- Does the student have the expertise to engage ethically in this investigation? Y / N
- Does the student have the capacity to conduct the research without harm to the participants? Y / N
- Does the research proposed require substantial mentoring due to collecting data from international participants, speakers of languages other than English and/or populations deemed vulnerable by the IRB, such as Native peoples? Y / N
- Can the student demonstrate local contacts and proficiency in the required languages? Y / N
- Will I need to assist the student in acquiring agreements to engage in this research at a particular site? Y / N
- Will this research require a reciprocity agreement at another institution? Y / N
- Have I taken CITI training that will enable me to serve as the Principal Investigator of record?
CITI training is a 2-3 hour commitment and certificates need to be updated every three years. Y / N

We hope that this questionnaire has helped you to determine your eligibility to supervise student research. If you are not sure whether to supervise this research, we recommend that you consult with your department/program chair. If you would like to have a conversation with a formally non-evaluative person, contact the Associate Dean for Faculty Development and Inclusion.