

Low-Risk, Non-Publishable Classroom Research *Excluded* from IRB Review

All faculty requiring research (defined in §45 CFR 46.102[d])* as part of an undergraduate or graduate course assignment accepts responsibility for protection of human subjects (defined in §45 CFR 46.101[f])* in student research projects. The classroom instructor of record determines that the student research assignments/projects meet criteria for protection of human subjects and that the projects can be excluded from IRB review. Projects in this category are confined to the specific class and end at the termination of the class. Student classroom research activities must be supervised by a Fontbonne University faculty member. Faculty members are expected to inform students regarding standards for protecting human subjects in research projects. These standards can be found at the following link: <https://www.hhs.gov/ohrp/international/compilation-human-research-standards/index.html>.

Faculty instructing courses with a requirement for student research must complete training for the protection of human subjects (RECT). The certification is valid for a three-year period and protects both the faculty member and the institution. Before assigning or approving student research assignments/projects, faculty must file the Research Ethics Training Curriculum (RETC) or the another equivalent training certificate of completion documenting that the faculty member has passed the ethics training assessment. This site is located at: <https://www.fhi360.org/sites/all/libraries/webpages/fhi-retc2/index.html>. Ethics training certificates are valid for three years at Fontbonne University.

The instructor determines that the student research project adequately protects human subjects by reviewing and documenting (complete the Excluded Student Research Faculty Declaration below) and that the student project meets **ALL** of the following criteria:

- 1) **The project is conducted under the auspices of the instructor of record.** The project is conducted with the faculty's instruction, supervision, and assessment.
- 2) **The project does not involve a vulnerable population*.** The project does not involve vulnerable populations, which include children and minors, prisoners, and pregnant women. See §45 CFR 46.201-207, 300-306, 401-409. If students propose projects that involve vulnerable populations, faculty could ask them to conduct the research on a non-vulnerable population.
- 3) **The project does not involve a sensitive subject*.** Sensitive subjects include any research procedures that might prompt emotional distress or cause embarrassment if data was not kept confidential. Examples of sensitive topics might include illegal or punishable conduct such as use of alcohol or drugs; information that could damage an individual's financial standing, employability, or reputation; physical, sexual, or emotional maltreatment; mental health; sexual orientation, attitudes, preferences; religious orientation or views; and political orientation or views. These are examples only and not an exhaustive list.
- 4) **The project contains no more than minimal risk.*** The threshold for risk is probability of harm or discomfort from the research is not greater than ordinarily encountered in daily life or during the performance of routine physical or psychological examinations. See §45 CFR 46. Risk includes, but is not limited to, threats to privacy, confidentiality, and intense physical exercise.
- 5) **The project does not involve invasive procedures or deception of any kind.** An example of an invasive procedure is a blood draw; an example of deception is misrepresenting the protocol.
- 6) **The project includes voluntary participation by individuals.** The individuals involved in the research must participate voluntarily without any coercion or pressure being placed upon them by the researcher. Participants are informed regarding voluntary participation; opting out does not carry any penalty.
- 7) **Project data are recorded anonymously by students.** Respecting confidentiality*, the data does not contain subject names or any other information or codes that can link subjects to a list of names and/or does not identify subjects through their behavior.
- 8) **The project involves learning research techniques and is not intended for generalization*.** The overriding and primary purpose of the assignment/project is as a learning experience in the methods and procedures of research. The assignment/project will not be published or presented beyond the classroom.

*Glossary

RETC Training: refers to the Human Subjects Research course provided by the Family Health International (FHI) foundation. The training is free and is completed online.

Confidentiality: pertains to the treatment of information an individual has disclosed in a relationship of trust and with the expectation that it will not, without permission, be divulged to others in ways that are inconsistent with the understanding of the original disclosure. Reference: Trochim, W. M. K., & Donnelly, J. P. (2008). *Research methods knowledge base* (3rd ed.). ~~Florence, KY: Cengage Learning/Atomic Dog.~~

Generalizability: “the degree to which study conclusions are valid for members of the population not included in the study sample.” Reference: Trochim, W. M. K., & Donnelly, J. P. (2008). *Research methods knowledge base* (3rd ed.). ~~Florence, KY: Cengage Learning/Atomic Dog.~~

Human Subjects §45 CFR 46.101[f]: “living individual(s) about whom an investigator conducting research obtains: (1) data through intervention or interaction with the individual; or (2) identifiable private information.”

Minimal Risk §45 CFR 46: 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.

Privacy: having control over extent, timing, and circumstances of sharing oneself with others. Reference: Trochim, W. M. K., & Donnelly, J. P. (2008). *Research methods knowledge base* (3rd ed.). ~~Florence, KY: Cengage Learning/Atomic Dog.~~

Research §45 CFR 46.102[d]: “a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge” (<http://www.hhs.gov/ohrp/>). A project or study is research if it: (a) is conducted with the intention of drawing conclusions that have some general applicability, and (b) uses a commonly accepted qualitative or quantitative method. Research involving human subjects must have IRB review regardless of whether it is intended to present or publish (except for low risk, non-publishable excluded classroom research).

Risk: the magnitude of the potential harm or discomfort and the probability of the harm or discomfort occurring. For purposes of protecting human subjects in research projects, risk includes: (a) violation of privacy; (b) violation of confidentiality; (c) questions that the participant may consider sensitive; (d) possible emotional distress or physical injury; and (e) invasive procedures.

Sensitive Topics: any research protocol that involves solicitation of information from human subjects that could reasonably cause harm to the participant if the data were not kept confidential. Causing embarrassment is the minimum threshold for determining whether research harm is foreseeable and thus sensitive. Examples besides those identified in #3 above include, but are not limited to, information (usually in medical records) that could lead to social stigmatization or discrimination; psychological well-being or mental health, including physical or mental abuse; incest, rape, date rape, or sexual molestation; genetic information; veteran or wartime experiences; topics relevant to diversity and possible discrimination such as race/ethnicity, age, disability, gender and socio-economic status; and immigration status. Again, these are examples only and not an exhaustive list. If you have a question about the sensitivity of a topic, please check with the IRB prior to using the Excluded Classroom Research policy.

Vulnerable Population: research that involves fetuses, pregnant women, prisoners, or groups who may have diminished capacity to provide consent or who may be high risk. At <http://www.hhs.gov/ohrp/>, see §45 CFR 46.201-207 (pregnant women), §45 CFR 46.300-306 (prisoners), and §45 CFR 46.401-409 (children and minors).

Excluded Student Research Faculty Declaration

Instructions: A Fontbonne University faculty member/instructor of record who requires students in her/his course to complete a research assignment/ project to satisfy course requirements must complete and file an *Excluded Student Research Faculty Declaration* with the Fontbonne University Institutional Review Board. Faculty members can email the Excluded Student Research Faculty Declaration to Dr. Joanne Fish, IRB Chair at jfish@fontbonne.edu prior to the students undertaking the research assignment/project. One (1) Faculty Declaration submission is required for each research assignment/project, per instructor, per course (not section), each semester or academic year, as appropriate. It is not necessary to submit a declaration for each student/research group in the class.

Faculty Member's Name: Enter name here

E-mail and Telephone Extension: Enter e-mail and telephone extension here

School/Department: Enter name here

Academic Program: Enter name here

Course Number/Name: Enter number/name here

Semester/Year: Enter semester/year here

Number of Students in Class Completing Project: Enter number here

Briefly describe the required, course-based student research assignment/project (type of research, purpose, subjects, sampling methods, research methods, etc.): Enter description here (detailed assignment directions including these components are acceptable)

As the course instructor of record, I certify that all the basic conditions governing low risk, non-publishable *excluded student research* listed below accurately depict the required student research in the identified course. I additionally certify that I am fully aware of all aspects of the research project and will take responsibility for overseeing the project and assuring that ethical principles are adhered to in the conduct of those activities.

- 1) The project is conducted under the auspices of the instructor of record.
- 2) The project does not involve a vulnerable population.
- 3) The project does not involve a sensitive subject.
- 4) The project contains no more than minimal risk.
- 5) The project does not involve invasive procedures or deception of any kind.
- 6) The project includes voluntary participation by individuals.
- 7) Project data are recorded anonymously by students.
- 8) The project involves learning research techniques and is not intended for generalization.

Signature (your typed signature is sufficient): Type signature here

Date: Enter date here

- Save a completed copy of this form on your computer and then e-mail a copy to Fontbonne University IRB Chair, Dr. Joanne Fish at jfish@fontbonne.edu.
- An IRB Chair reviews the form, confirms completion, and maintains in applicable IRB documentation files.