

INSTITUTIONAL REVIEW BOARD (IRB)**IRB GUIDANCE ON CLASS PROJECTS INVOLVING HUMAN PARTICIPANTS**

SCOPE: This guidance applies to all class projects which propose to include human subjects as participants.

BACKGROUND:

The IRB recognizes class projects are conducted to fulfill course requirements and may involve activities which could be considered research. Generally, activities conducted solely to fulfill a course requirement lack the intent to develop or contribute to generalizable knowledge, nor involve public dissemination of findings. Projects in which data will not be used outside of the class context and will be destroyed upon completion, are not considered research, and do not require IRB approval. Projects designed with the objective of providing students with training in and experience with research methods are not considered research, except for doctoral dissertations; master's and honors theses; funded research; research conducted through entities external to UMassD. Therefore, recognizing its role in the protection of human participants, the IRB has determined some class projects may require review and approval by the IRB.

ELEMENTS FOR CONSIDERATION:

The IRB considers class assignments involving human subjects and research activities, to be educational in nature, and not subject to IRB review and approval, *when all the following criteria are true:*

1. The project is considered minimal risk, does not involve deception, is limited to the observation of public behavior or standard educational exercises or inquires related to the topic(s) being studied in an official University course.
2. Surveys/questionnaires/interviews, if used, are non-invasive and do not contain sensitive questions which intend to gather personal or confidential information that could "label" or "stigmatize" an individual.
Examples of Sensitive Information:
 - Information relating to an individual's psychological mental health diagnosis.
 - Information relating to sexual behavior, attitudes, preferences, or practices.
 - Information relating to illegal or incriminating behavior, or the use of alcohol, drugs, or substances.
 - Information relating to individual's academic standing, test scores, or employment.
 - Information relating to medical history, of which disclosure could lead to discrimination, stigmatization, etc.
 - Information, that if released, could place the individual at risk of criminal or civil liability or be damaging to the individual's financial standing, employability, or reputation.
 - Information relating to privacy, where an individual provides information for specific purposes and can reasonably expect the information will not be made public.
 - Identifiable Information, where identity of participant may be readily ascertained or associated with the information.
3. The target population is non-specific or not from a protected or vulnerable population that requires extra protections.
Examples of Vulnerable Populations:
 - Pregnant women and/or their fetus(es);
 - Children, or minors under age 18.
 - Individuals who identify as LGBTQIA+, veteran, or homeless.
 - Individuals who are incarcerated in the criminal justice system.
 - Individuals who lack the capacity to provide consent, are cognitively impaired, or are physically impaired.
4. Recordings, if used, are for the sole purpose of capturing accuracy. If recording, *all the following are true:*
 - Recordings are saved without any direct or indirect (e.g., race, gender, code number) identifier linking the participant to data.
 - No direct identifiers are recorded, and any indirect identifiers could not be combined to identify the participants.
 - The recorded data could not reasonably harm the participant's reputation, employability, financial standing, or place the participant at risk of criminal or civil liability.
5. The data will be destroyed at class completion and results of the class assignment will not leave the class, or, if the project involves gathering data from or about a company, agency, or organization, the data/results are shared only with that company, agency, or organization, and the company will not share the data or results with anyone else.

NOTE: If any one of the foregoing criteria is not true, then the project requires IRB review and approval.

INSTRUCTOR RESPONSIBILITIES:

Instructors are responsible for educating students on the general principles of research ethics prior to the initiation of any class project involving human subjects. In addition, instructors should meet with students proposing to use human subjects in a class project to go over the *UMassD IRB Guidance on Class Projects Involving Human Subjects*, as early as feasible. It is the instructor's responsibility to determine if the project meets the criteria to be classified as a class project. If the project does not meet the criteria to be classified as a class project, then the instructor and student must submit an IRB application with corresponding documents to the IRB for review and approval. Instructors are encouraged to contact the IRB Office via email (irb.research@umassd.edu) if assistance is necessary to determine if IRB oversight is required.

If the class project meets the definition of human subject's research:

- The instructor and student must submit the IRB application, proposal, consent forms(s), and participant facing materials (recruitment flyers/emails, surveys/questionnaires/interview scripts, etc.) to obtain IRB approval to engage in research activities.
- If the proposed project involves an external site, the instructor or student must identify the local point of contact and ensure the necessary letters of support are obtained prior to submitting the application. Please see the *UMassD IRB Guidance on Reliance Agreements* document for additional considerations.

If the Instructor has confirmed the class project does not meet the definition of human subject's research:

- Instructors must ensure planned activities include adequate safeguards to maintain the aforementioned criteria.
- Instructors must ensure students are adequately trained and project is conducted according to the ethical standards.
- Instructors must submit signed class project form, information sheet(s), and participant facing materials (recruitment flyers/emails, surveys/questionnaires/interview scripts, etc.) to obtain IRB confirmation of class project designation.

INFORMED CONSENT VIA INFORMATION SHEETS:

When data is collected from human subjects for a class project that does not meet the definition of research (as defined by the federal regulations) and does not require approval by the IRB, it is still important to protect the rights and welfare of the individuals who act as participants and ensure participants are informed of their rights by:

1. Clarifying the student is performing the class project to fulfill a course requirement, and the course is specifically identified.
2. Clarifying the purpose, procedures, and length of participation for each participant on the project.
3. Identifying the name and contact information of the supervising faculty and student for questions/concerns.
4. Clarifying what the data will be used for and confirming data collected will not include personal or identifiable information and will be destroyed after the class project is completed.
5. Identifying the persons who have access to the individual data and/or summarized results are specified (e.g., instructor only, company/organization/agency).
6. Confirming participation is completely voluntary and no compensation will be offered.
7. For online survey, provide the information sheet on first page of the survey or in the recruitment email.

FREQUENTLY ASKED QUESTION (FAQ):

How long is the review process?

The IRB recognizes the importance of class projects and strives to support the educational process by expediting the class project confirmation process. The IRB reviews class projects submitted by students individually or in groups, in the order in which they are received. At this time, the approximate timeline for the IRB to provide confirmation to faculty and students of the class projects designation's appropriateness varies based on the volume of submissions the IRB receives.

Adapted with gratitude from the following references:

1. Northeastern University. Human Subject Research Protection. [Policy on Classroom Research Involving Human Subjects](#).
2. Yale University. Human Research Protections Program. [Human Subjects Committee Review of Student Projects](#).
3. Northwestern University. Human Research Protections Program. [IRB Policy on Classroom Based Research Projects](#).
4. The University of Maine. Office of Research Compliance. [Guidelines for Class Projects Involving Human Subjects](#).