

IRB Oversight of Student Projects Involving Human Participants

Background

In accordance with federal regulations, Iowa State University requires that all research involving human participants be prospectively approved by ISU's Institutional Review Board (IRB). This includes research conducted by graduate and undergraduate students. However, some student-led projects that involve humans do not require IRB approval because they do not meet the definition of IRB-regulated human subjects research.¹

This policy outlines the situations under which IRB approval is or is not required for common student-led projects. It is intended to clarify how student projects fit within the definition of IRB-regulated human subjects research. Student-led projects that do not meet the definition of IRB-regulated human subjects research are not subject to IRB oversight.

Student Class Assignments Involving Human Participants

For purposes of this policy, student class assignments involving human participants include activities that are:

- Conducted in fulfillment of course requirements by students enrolled in an official course;
- Typically initiated and completed within a single term/semester;
- Involve collection of information by students from or about individuals not enrolled in the course for purposes of helping students understand concepts covered by the course;
- Not intended to create new knowledge or lead to scholarly publication

Some class assignments involve activities that, in other contexts, could be considered to be human subjects research (e.g., assignments that involve administering surveys, questionnaires, interviews, or other interactions with human participants). As a general rule, when activities are conducted solely to fulfill a course requirement, elements of the regulatory definition of research are lacking. Class assignments typically are not systematic data collection efforts designed to develop or contribute to generalizable knowledge; instead, they are designed for educational purposes.

¹ IRB regulated human subjects research is defined as follows:

Research is "A systematic investigation, including research development, testing, and evaluation, designed to develop to contribute to generalizable knowledge" (45 CFR 46.102(d)). A Human Subject is "A living individual about whom an investigator (whether professional or student) conducting research obtains (1) data through intervention or interaction with the individual, or (2) private and identifiable information (45 CFR 46.102(f)). OR

Any experiment that involves an FDA-regulated test article (drugs, medical devices, food additives) and one or more human subjects (21 CFR 50.3).

Iowa State University considers class assignments involving human participants to be educational in nature and not subject to IRB review when the results of the class assignment, including any audio/video recordings, photographs, etc., are **ONLY** used and shared as follows:

1. In the classroom; and/or,
2. 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/or
3. If the project involves collection of oral histories, the interview transcripts/recordings are shared with an established oral history archive with established procedures for obtaining participant permission (such as ISU Library Special Collections); and/or
4. Project results are presented at departmental or interdepartmental seminars designed to exhibit coursework or to continue the learning process related to presentations.

If data will be shared beyond the circumstances described above (e.g., for publication, presentation at academic conferences, in a thesis/dissertation, etc.), then the project must receive IRB approval prior to initiation.

Undergraduate Capstone Projects and Honors Capstone Projects

Departmental expectations and requirements vary for undergraduate capstone projects and honor's projects. In some cases, these projects are educational in nature and like class assignments, elements of the regulatory definition of research are lacking.

Undergraduate capstone projects that involve human participants are considered to be educational in nature and do not require IRB review if the results are used and shared **ONLY** as follows:

1. With the undergraduate capstone instructor or committee, and/or
2. 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/or
3. If the project involves collection of oral histories, the interview transcripts/recordings are shared with an established oral history archive with established procedures for obtaining participant permission (such as ISU Library Special Collections); and/or
4. Project results are presented at departmental or interdepartmental seminars designed to exhibit coursework or to continue the learning process related to presentations.

Similarly, honors capstone projects that involve human participants do not require review if results will be used and shared **ONLY** as follows:

1. With the honors project advisor(s),
2. 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/or
3. If the project involves collection of oral histories, the interview transcripts/recordings are shared with an established oral history archive with established procedures for obtaining participant permission (such as ISU Library Special Collections); and/or

4. Project results are presented at departmental or interdepartmental seminars designed to exhibit coursework or to continue the learning process related to presentations; and/or
5. Honors Program poster presentations, Undergraduate Research and Create Expression seminars, or at the State Capitol. Presentations given in these settings are considered to be a continuation of the education process or professional training (e.g., experience in public speaking).

If data will be shared beyond the circumstances described above (e.g., for publication, presentation at academic conferences, in a thesis/dissertation, etc.), then the project must receive IRB approval prior to initiation.

Graduate-Level Creative Components/Capstone Projects for Masters Degree with Non-Thesis Option

Departmental expectations and requirements vary for graduate-level non-thesis projects (creative components or capstone projects). In some cases, these projects are intended to be a “non-research” culminating project toward a graduate degree. In other instances, creative component or capstone projects may involve independent student-led research for purposes of developing or contributing to generalizable knowledge (i.e., contributing to a body of scientific knowledge, drawing broadly-applicable conclusions, testing theories or hypotheses, etc.).

A graduate-level creative component or capstone project that involve human subjects requires prospective IRB approval when it is *a systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge*. IRB approval is not required for creative components or capstone projects that:

1. are not systematic investigations, or
2. are not designed to contribute to generalizable knowledge, or
3. do not involve human subjects.

Guidance and self-tests for determining [whether a project requires IRB oversight](#) are available on the [IRB website](#).

Thesis or Dissertation Research

In general, a thesis or dissertation involves independent research led by students for the purposes of contributing to generalizable knowledge. Thus, thesis or dissertation research that involves human participants must receive IRB approval prior to initiation.

The IRB recognizes that for some disciplines, thesis or dissertation work may involve human participants, without an intent to contribute to generalizable knowledge. For example, human participants may be needed to create a work of art, write a biography, record oral history, or other similar types of activities. Those efforts are typically not designed to contribute to generalizable knowledge and thus, do not meet the regulatory definition of research that requires IRB oversight. Students and their faculty advisors should contact the IRB office for guidance on these types of projects.

Retroactive IRB Approval WILL NOT be granted

Careful consideration must be given to the possibility of an eventual desire to publish, present the material, or use any collected data in future research (such as a thesis or dissertation), etc. Additionally, students may wish to conduct these projects as the beginning stages of their thesis or dissertation research. **Retroactive approval will not be given for studies conducted without IRB approval.** For example, if a class assignment or honor's project was conducted without IRB approval and resulted in unexpected but important findings or data, those findings or data may not be presented at a national meeting or used in a future research study, including a students' thesis or dissertation.

Instructor/Advisor Oversight Responsibilities

The course instructor or faculty advisor is responsible for determining whether or not an assigned project requires IRB review in accordance with this policy. Faculty should contact IRB staff if assistance in making this determination is needed. Instructors/advisors must convey to students the circumstances under which data may be used/shared in accordance with this policy.

The course instructor or project advisor is also responsible for ensuring that the rights and welfare of participants in student projects are protected. This responsibility includes discussing the principles of ethical research with human subjects with the student(s) prior to the initiation of the project. It also includes reviewing project plans and adequately monitoring project activities to ensure that human participants are protected. If the project will be conducted outside of ISU, appropriate permissions from the external sites must be obtained. Any assurances made to project participants and/or external sites regarding confidentiality and use of results must be honored.

In addition, the following practices are strongly recommended:

- Require students to complete human subjects protection training prior to designing their projects or interacting with participants.
- Do not require certain levels of enrollment in student projects (i.e., assigning points or grades based on the number of participants enrolled). Doing so encourages coercive enrollment practices.
- Discuss special care that must be taken when interacting with vulnerable subjects (e.g., parental permission prior to interaction with children, etc.).
- Limit collection of sensitive information to only that necessary to achieve the learning objectives.
- Require, whenever possible, that data be collected/recorded without identifiers.
- If identifying information must be obtained, require separation of identifying information from responses immediately. Instruct students on how to develop coding systems that protect confidentiality.
- Provide mechanisms for confidential data security, such as storage space on departmental servers, CyBox folders, locking office space to store completed questionnaires, etc. along with instructions on how to appropriately use these systems.
- Require destruction of participant information at the end of the course.

Disclosure to Participants

All student projects involving human participants conducted under this policy *must* be preceded by a disclosure of the following information to the participant. If an informed consent document or letter is used, these points must be included in that document:

1. The student identifies him/herself as an ISU student who is performing the activity to fulfill a course or educational requirement, and the course or educational requirement is specifically identified.
2. The name and contact information for the supervising faculty member to contact for questions is provided.
3. The persons/entities who have access to the individual data and/or summarized results are specified (e.g., instructor only, company/organization/agency, ISU Digital Repository).
4. Participants are informed that their participation is completely voluntary, that they can skip any questions they do not wish to answer (e.g., for surveys, interviews, focus groups, etc.), and that they can stop participating at any time.
5. Participants are informed of the extent to which their identities will be kept confidential.
6. The disclosure should *not* state that the project has been approved by the ISU IRB.

Document History

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