

NPS IRB Policy Statement

Classroom and Course Projects: Are They Considered Human Subjects Research?

March 20, 2019

This policy statement addresses classroom and course projects and their status with respect to NPS human subjects research policy. The policy is presented in the first section. The second section cites relevant sections of DOD policies. The third section presents information gleaned from other academic institutions that address generalizability of classroom projects.

Section 1: NPS Institutional Review Board (IRB) policy for classroom projects and course projects that involve interaction with a living individual about whom a student obtains information through intervention or interaction with the individual or identifiable private information.

Based on the policies cited in Section 2 of this policy statement, a review of numerous academic institutions' human research protection program websites (some of which are provided in Section 3), and discussions with faculty members and at IRB meetings, the NPS IRB does not consider classroom and course projects to be human subjects research if they meet all of the following criteria:

- (1) The classroom or course project must be completed to meet published course or program requirements.
- (2) The classroom or course project is submitted for evaluation to an NPS faculty member serving as a course instructor or a project advisor.
- (3) There is no intent on the part of the instructor or advisor to use the paper and/or any data that may have been collected as part of the project beyond assigning a grade to that project.
- (4) There is no intent on the part of the student(s) to use the paper and/or any data that may have been collected as part of the project beyond submitting the project for a grade, except as specified in (5) below.
- (5) In the case where the classroom or course project involves an external customer or client, all of the following criteria must be met:
 - (a) The classroom or course project is designed to examine an activity, process, or policy within the customer's or client's organization.
 - (b) The classroom or course project report contains no language that suggests the findings could be generalized to other activities, processes, or policies, or to other organizations.

- (c) There is no intent on the part of the instructor, advisor, students, client, or customer to distribute the classroom or course project report beyond the organization for which the work was performed.

If any of the above criteria are not met, the activity may be generalizable and, therefore, could meet the DOD definition of human subjects research. In such cases, the instructor or project advisor must submit a determination request form to the IRB and obtain a ruling from the IRB before allowing students to proceed with the classroom or course project.

Section 2: DOD Policy Definitions

The following excerpt from DODI 3216.02 defines research and identifies activities not considered research:

Any activity or systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge. Activities that meet this definition constitute research for purposes of this instruction, whether or not they are conducted or supported under a program that is considered research for other purposes. For example, some demonstration and service programs may include research activities. The following activities are deemed not to be research:

- (1) Scholarly and journalistic activities (e.g., oral history, journalism, biography, literary criticism, legal research, and historical scholarship), including the collection and use of information, that focus directly on the specific individuals about whom the information is collected.
- (2) Public health surveillance activities, including the collection and testing of information or biospecimens, conducted, supported, requested, ordered, required, or authorized by a public health authority. Such activities are limited to those necessary to allow a public health authority to identify, monitor, assess, or investigate potential public health signals, onsets of disease outbreaks, or conditions of public health importance (including trends, signals, risk factors, patterns in diseases, or increases in injuries from using consumer products). Such activities include those associated with providing timely situational awareness and priority setting during the course of an event or crisis that threatens public health (including natural or man-made disasters).
- (3) Collection and analysis of information, biospecimens, or records by or for a criminal justice agency for activities authorized by law or court order solely for criminal justice or criminal investigative purposes.

(4) Authorized operational activities, as defined by the Defense? Office for Human Research Protections (DOHRP), in support of intelligence, homeland security, defense, or other national security missions. ¹

DODI 3216.02 defines human subjects research as:

Activities that include both a systematic investigation designed to develop or contribute to generalizable knowledge and involve a living individual about whom an investigator conducting research obtains information or biospecimens through intervention or interaction with the individual, or identifiable private information or biospecimens.²

Section 3: How Other Academic Institutions View Generalizability

32 CFR 219³ and DODI 3216.02 do not provide any additional clarity on generalizability. However, other academic institutions have attempted to define the term.

University of California, Irvine:

<http://www.research.uci.edu/ora/hrpp/definition.htm>

Investigations designed to develop or contribute to generalizable knowledge are those designed to draw general conclusions, inform policy, or generalize findings beyond a single individual or an internal program (e.g., publications or presentations). However, research results do not have to be published or presented to qualify the experiment or data gathering as research. The intent to contribute to ‘generalizable (scholarly) knowledge’ makes an experiment or data collection research, regardless of publication. Research that never is published is still research. Participants in research studies deserve protection whether or not the research is published. Note Thesis or dissertation projects involving human subjects conducted to meet the requirement of a graduate degree are usually considered generalizable, and require IRB review and approval.⁴

Notre Dame De Namur University

<https://www.ndnu.edu/academics/research/is-my-project-research/>

Generalizable Knowledge: Data gathered with the intent to draw conclusions from the research which will develop or contribute to a general body of knowledge.

Please note: Results that remain in the classroom or are presented within the

¹ Department of Defense, *Protection of Human Subjects and Adherence to Ethical Standards in DOD-Support Research* (Washington, DC: Department of Defense, 2019, page 27.

² Department of Defense, *Protection of Human Subjects and Adherence to Ethical Standards in DOD-Support Research*, 2019, page 27.

³ “*Protection of Human Subjects*,” 32 CFR 219, January 21, 2019.

⁴ “Activities that Require IRB Review,” University of California, Irvine, 2019, <http://www.research.uci.edu/ora/hrpp/definition.htm>.

confines of the institution (i.e., at NDNU's Undergraduate Research Conference) are not considered generalizable. However, if the results will be published, presented at a conference off-campus, or generalized in some other way, the project will be considered generalizable and will thus be considered research.⁵

Oregon State University

<https://research.oregonstate.edu/irb/does-your-study-require-irb-review>

The intent or purpose of the systematic investigation is dissemination of findings (publication or presentation) outside of OSU.

Intended to have an impact (theoretical or practical) on others within one's discipline.

Dissemination with the intent to influence behavior, practice, theory, future research designs, etc. are contributing to generalizable knowledge.

CONSIDER: Would this project be conducted as proposed if the PI knew that he or she would never receive any form of academic recognition for the project, including publication of results or presentation of the project at an academic meeting?⁶

Skidmore College

<https://www.skidmore.edu/irb/images/SkidmoreIRBGuideforInvestigators.pdf>

Class project[s] that involve human participants and systematic research methods, but present no more than minimal risk and do not result in generalizable research. Frequently, faculty develop course-related activities or students propose independent research projects that are designed to provide opportunities to practice research methods (e.g., interview, observation and survey techniques; data analysis; research design). If such projects are limited in scope, present no more than minimal risk to participants, and do not lead to generalizable results, they do not require human subjects review.⁷

⁵ "Institutional Review Board," Notre Dame de Namur University, 2019, <https://www.ndnu.edu/academics/research/is-my-project-research/>.

⁶ "Does Your Study Require IRB Review?," Oregon State University, 2019, <https://research.oregonstate.edu/irb/does-your-study-require-irb-review>.

⁷ "Is Your Project Human Subjects Research? A Guide for Investigators," Skidmore College, accessed March 6, 2019, <https://www.skidmore.edu/irb/images/SkidmoreIRBGuideforInvestigators.pdf>.