

Guidelines for the Development of Undergraduate Classroom Research Projects Involving Human Subjects

A. Introduction

This policy addresses faculty supervising students' research or class projects involving human subjects. The University of Puerto Rico at Mayagüez Assurance of Compliance for the Protection of Human Research Subjects is in harmony with the **Code of Federal Regulations TITLE 45 PUBLIC WELFARE DEPARTMENT OF HEALTH AND HUMAN SERVICES PART 46 PROTECTION OF HUMAN SUBJECTS**.

The Institutional Review Board for the Protection of Human Subjects participating in Research (known in Spanish as *Comité para la Protección de los Seres Humanos en la Investigación, CPSHI*) recognizes the University of Puerto Rico at Mayagüez contribution in the provision of learning experiences that help students develop the skills for appraising and conducting research involving human participants (subjects). The CPSHI definition of research and human subject is sustained on the Common Rule 45 CFR 46. Research is defined as **a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge (45CFR46.102(d))**. Human subject is defined as **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) Identifiable private information (45CFR46.102(f))**.

The CPSHI distinguishes between research conducted as part of a learning experience ("Undergraduate Student Classroom Research Project"), from research conducted to add to generalizable knowledge or a professional body of knowledge (clinical research, thesis, or dissertation work). The purpose of these guidelines is to clarify and provide guidance for when an undergraduate student classroom research project must be reviewed by the CPSHI, or if faculty teaching the course is responsible for its review. Undergraduate classroom research projects that are designed solely with the objective of providing students with training about and experience with research methods are not considered **research**. Undergraduate classroom research projects designed to contribute to generalizable knowledge must follow the submission for review by the CPSHI. If the faculty member teaching the course allows a student to design a research project that involves **vulnerable populations or sensitive information, CPSHI review and approval are required**.

CPSHI will have the authority and responsibility to review, approve or disapprove, or require changes to research protocols involving human subjects (cited in page 3, #6 of the Assurance of Compliance with the Department of Health and Human Services Regulations for the protection of Human Research Subjects of the UPR at Mayagüez) Assurance.

B. Definitions

1. Comité para la Protección de los Seres Humanos en la Investigación (CPSHI): Stands for the University of Puerto Rico at Mayaguez' Institutional Review Board for the Protection of Human Participants (subjects) in research and whose primary purpose is to assure the protection of the rights and well-being of human subjects while participating in a research project or protocol.

2. Undergraduate Classroom Research Project: Entails the development and conduct of a research project developed by a student as part of the undergraduate course student-learning outcomes. This research project may include observations or interventions, conducting an interview or administering survey instruments, but will not lead to generalizable knowledge or publication or dissemination of findings outside of the classroom or the University of Puerto Rico at Mayagüez academic community.

3. Faculty Advisor of Undergraduate Student Research in a classroom setting: Faculty member teaching an undergraduate course in which a student-learning outcome is the development and conduct of a research project. He or she is primarily responsible for training student researchers in the proper conduct of research and ensuring the protection of the rights and well-being of the human subjects.

4. Student researcher: Student enrolled in an undergraduate course at the University of Puerto Rico at Mayagüez, which requires as a student-learning outcome the development and conduct of a research project under the supervision of a faculty member teaching the course.

5. Dissemination: Includes but is not limited to presentation at a scientific meeting or conference, submission to or publication (paper or electronic) in a regional magazine or a scientific journal, and posting on a poster presentation or the Internet.

6. Intervention: Includes both physical procedures by which data are gathered and manipulations of the subject or the subject's environment that are performed for research purposes. Interaction includes communication or interpersonal contact between investigator and subject. *Private information* includes information about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place, and information which has been provided for specific purposes by an individual and which the individual can reasonably expect will not be made public (for example, a medical record). Private information must be individually identifiable (i.e., the identity of the subject is or may be ascertained by the investigator or associated with the information) in order for obtaining the information to constitute research involving human subjects (as cited from 45CFR46.102(f)).

7. Minimal risk: 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 (as cited from 45CFR46.102(i)).

8. Deception: Includes but is not limited to intentionally misleading human subjects about their status; giving false information about the investigators or the research purpose and omitting information about the real purpose of the research. The use of deception in research needs to be justified and may not be reviewed as exempt.

9. Exempt research: The six Human Research categories that are exempt from full CPSHI review are identified in 45CFR46.101(b) (www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html)

10. Expedited research review: Review of research protocol involving human subjects that is evaluated by one or more experienced reviewers of the CPSHI. Procedures are described in 45CFR46.110 (<http://www.hhs.gov/ohrp/policy/expedited98.html>) *Categories of Research That May Be Reviewed by the Institutional Review Board (IRB) through an Expedited Review*.

C. Faculty Responsibilities:

Consistent with UPR at Mayagüez Assurance of Compliance for the Protection of Human Research Subjects, all student classroom research projects involving human subjects must respect the rights and well-being of all individuals involved. Nevertheless, faculty responsible for teaching an undergraduate course in which students have as a student-learning outcome the development and conduct of a research project involving human participants (subjects) must comply with the following:

1. Consider the nature and intent of the research activity. Each classroom research project that involves research methodology with the intent to develop or contribute to generalizable knowledge -- an indication of which the goal is to disseminate data gathered and analyzed -- must be reviewed and approved by the CPSHI before the research is conducted.

2. Consider getting involved in an education activity: Faculty involved in teaching an undergraduate course in which students are engaged in the development or conduct of a research project involving human subjects must complete an on-line training module on ethical principles for the protection of human subjects in research. (<http://phrp.nihtraining.com/users/login.php>) and (<https://www.citiprogram.org/>); or CPSHI

3. Consider that IRB approval cannot be made retroactive. If there is any likelihood that the results of the classroom research project might later be used for research that might lead to generalizable knowledge (for example, a presentation to a group other than the classroom setting or the academic community at the University of Puerto Rico at Mayagüez), CPSHI approval must be sought prior to conducting the research. CPSHI approval cannot be granted retroactively.

4. Minimize risks whenever possible. Faculty members should help students understand that they are obliged to minimize risks for human subjects with whom they interact during the development, conduct and completion of their classroom research project.

5. Require an informed consent form and, if required, parental permission or a child assent form:

The voluntary consent of the human subject is absolutely essential. Basic elements of informed consent shall be provided to students (45 CFR 46, §46.116 *General requirements for informed consent*, §46.117 *Documentation of informed consent* and §46.408 *Requirements for permission by parents or guardians and for assent by children*.

<http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html>.

6. Minimize the gathering of sensitive information and the inclusion of a vulnerable population. If the research project does not intend to produce generalizable knowledge, but its methodology requires participation of subjects considered vulnerable or data collection of a sensitive topic, the classroom research project does not qualify for a waiver and therefore needs the CPSHI approval.

Sensitive information includes:

- Sexual attitudes, preferences or practices
- Use of alcohol, drugs or other addictive products
- Illegal conduct
- Information that, if released, may cause damage to subject's financial standing, employability, or reputation within a community
- Recorded in a patient's medical record, if disclosure could lead to social stigmatization or discrimination
- Individual's psychological well-being or mental health
- Genetic information
- Institutionalized elderly people

Populations considered vulnerable

- Pregnant women (Studies that may influence their health)
- Embryos, fetuses, or fetal tissue
- Children (under eighteen years of age)
- Mentally disabled persons or with emotional incapacities
- Persons with illnesses or major physical incapacities
- Persons with terminal illnesses
- Institutionalized persons: Prisoners; persons in detention centers.
- Dependent or impoverished individuals
- Educationally disadvantaged persons
- Employees, students of researcher
- Minorities

7. Assess that the waiver does not affect the rights and well-being of the subjects: Any decision taken on whether a research project needs CPSHI review or not may not jeopardize the rights and well-being of human subjects. The Waiver Requirement Checklist helps to determine whether the **Request for Waiver of IRB Application** is applicable.

8. Encourage undergraduate classroom research projects that are exempt or require no more than an expedited review by the CPSHI. All human subjects research conducted at or sponsored by the University of Puerto Rico at Mayagüez, whether exempt or not, must be conducted in accordance with the Guidelines set forth in this document and the Assurance of Compliance with the Department of Health and Human Services Regulations for the Protection of Human Research Subjects, the Code of Federal Regulations (45 CFR 46) of the U.S. Department of Health and Human Services, and the ethical principles set forth in the Belmont Report. All classroom research projects must meet all the criteria as defined in the Federal Regulations 45 CFR 46 (<http://www.hhs.gov/ohrp/policy/expedited98.html>). Faculty should be well acquainted with these regulations. If the faculty member has concerns or doubts about their interpretation, check and consult with the CPSHI.

9. Consider data destruction: At the end of the semester request students to hand in research project data and any other copy in their possession and have it destroyed.

10. Ask the Office of the CPSHI for guidance: Whenever in doubt concerning how to fill out the Waiver Requests: Undergraduate Classroom Research Project Waiver of IRB

Application, or the Undergraduate Course Waiver Form, please call the CPSHI at 787.832.4040, ext. 6277, visit the CPSHI office located in Celis 108, or send a message to cpshi@uprm.edu.

References:

Assurance of Compliance with the Department of Health and Human Services Regulations for the Protection of Human Research Subjects. University of Puerto Rico at Mayagüez.

Belmont Report, Office of the Secretary, Ethical Principles and Guidelines for the Protection of Human Subjects of Research, The National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, April 18, 1979.
<http://www.hhs.gov/ohrp/humansubjects/guidance/belmont.html>

Code of Federal Regulations TITLE 45 PUBLIC WELFARE DEPARTMENT OF HEALTH AND HUMAN SERVICES PART 46 PROTECTION OF HUMAN SUBJECTS Revised January 15, 2009 Effective July 14, 2009
<http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html>

Office for Human Research Protections (OHRP) - Categories of Research
Categories of Research That May Be Reviewed by the Institutional Review Board (IRB) through an Expedited Review Procedure
<http://www.hhs.gov/ohrp/policy/expedited98.html>