

Use of Human Subjects for
Course-based Research Projects Policy

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Purpose and Scope

West Chester University (WCU) is dedicated to the protection of human subjects who participate in research conducted by our faculty members, staff, and students. This policy describes the WCU requirements for involving human subjects in course-based research projects in accordance with federal and state regulations.

Policy Statement

The United States Department of Health and Human Services (DHHS) Office of Human Research Protections requires the university to follow Federal Regulation 45 CFR 46. This regulation states that all activities meeting any one of the definitions of human subjects' research **(even if the investigator(s) believe that there is no risk to the human subjects)** and carried out at the university must be reviewed and approved by the Institutional Review Board (IRB) prior to the start of the research activity.

Any research using human subjects that (a) will develop or contribute to generalizable knowledge/be disseminated publicly including doctoral dissertations/capstone projects, Master's theses/projects, and WCU Research and Creativity Day oral or poster presentations and/or (b) is funded internally or externally, and/or (c) is conducted with collaborations external to WCU must be reviewed and approved by the IRB before the research may begin.

NOTE: The WCU IRB does not provide approval for projects after the research has been completed (retroactive approval). Therefore, if a student believes that the results of the research will be presented (e.g., poster, oral or written) at WCU, local, state, national or international conferences, published, or used for a

thesis/dissertation at any time in the future, the student must submit a regular IRB protocol and have it reviewed accordingly.

Policy Framework

A. Course-based Research Projects

IRB Review is not required. Federal Regulation 45 CFR 46 Part 46101.b. (1) and (2) recognizes that some student projects or assignments conducted to fulfill course requirements involve activities that, in a different context, might meet the definition of human subjects research but do not, in this context, require IRB review. **At WCU, course-based projects or assignments involving human subjects that are conducted for educational purposes or training solely to fulfill a course requirement and are not intended to develop or contribute to generalizable knowledge/be disseminated publicly** do not meet the regulatory definition of research. Therefore, these classroom projects or assignments can be excluded from the requirement to submit an IRB application for review and approval; however, there are specific parameters listed below that must be reviewed and followed to confirm exclusion from review.

WCU does not require IRB review of student research conducted within an academic course provided the following criteria are met:

1. the student research is categorized as a course assignment,
2. the student research is supervised by a WCU faculty member,
3. the data collection and interpretation is for pedagogical purposes only,
4. the research is contained wholly within the course environment,
5. all conditions described in Course-based Research Conditions Checklist below are followed, and **there is no plan for the results of the student research to be disseminated to any audience beyond the course.**

IRB review is required. Unless all of the criteria above are met, IRB review will be required prior to the commencement of research. In addition, Federal Regulation 45

CRF 46 Part 46101.b (3) states that course-base projects do require IRB review if “the human subjects are elected or appointed public officials or candidates for public office or if federal statute(s) require(s) without exception that the confidentiality of the personally identifiable information will be maintained throughout the research and thereafter.”

B. Role and Responsibilities of the Faculty Member Supervising the Research

WCU Faculty who require students to do course-based research projects are responsible for the conduct of those projects and assure that the conditions described above are adhered to. If research falls outside of the conditions described above, the project must be submitted to the IRB for a regular review.

1. It is the responsibility of faculty to determine whether an assigned project involving humans can be classified as a course-related student project under the criteria above. Faculty can contact the IRB office for assistance if needed in making this determination.

2. Faculty teaching research methods and overseeing student research projects are expected to understand the philosophy, ethics, and practice of protecting human subjects in research; to ensure students adhere to these principles during the conduct of classroom research projects; and to teach these practices and principles to students.

3. Faculty are responsible for discussing ethical conduct in research with the students prior to the initiation of the project. In addition, the faculty must ensure that all surveys/questionnaires/interviews are preceded by a disclosure of the following points to the subjects. If an information sheet or any recruitment materials are used, these points must be in that document:
 - (a) The student identifies him/herself as a WCU student who is performing the activity to fulfill a course requirement, and the course is specifically identified.

- (b) The name of the supervising faculty member to contact for questions is provided.
- (c) The persons who have access to the individual data and/or summarized results are specified.
- (d) Subjects are informed that their participation is completely voluntary and confidential.
- (e) Subjects are informed that data collected from the course assignment will be used in the completion of the assignment and shared only with the course instructor and/or students in the same course

4. Faculty must ensure that care is taken to protect the rights and welfare of the individuals who act as subjects. Standard research practices such as obtaining consent, ensuring confidentiality, responsible fieldwork, and providing subjects with a contact name must be employed.

C. Noncompliance

Failure to comply with federal and state regulations, policies, and guidelines for the ethical treatment of human subjects might result in prosecution by the federal government and the imposition of federal, civil, criminal, and/or administrative penalties or sanctions, denial of research privileges, and loss of reputation. It might also result in disciplinary action in accordance with the appropriate Collective Bargaining Agreement (APSCUF CBA articles 12, 14, 15, 42, *et. al.*).

Procedures

A. Course-based Research Conditions Checklist

— UNIVERSITY POLICY —

For a course-based research assignment to be excused from IRB approval, the faculty member supervising the research must ensure the following conditions are met:

| # | CONDITION | ✓ |
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| 1 | The primary purpose of the assignment is to develop student's research skills. | |
| 2 | The risk level of the project is no more than minimal risk (no more than would be encountered in routine daily activities). | |
| 3 | The project does not include any persons as research subjects who are classified as protected populations or vulnerable subjects according to Federal regulations [e.g., pregnant women, children, prisoners, human fetuses, neonates, individuals with physical disabilities, individuals with cognitive impairments, economically disadvantaged, socially disadvantaged, terminally ill or very sick, racial or ethnic minorities and institutionalized persons (persons in correctional facilities, nursing homes, mental health facilities, etc.)] | |
| 4 | No subjects will be under the age of 18 | |
| 5 | No identifiers will be collected. | |
| 6 | The project is limited to surveys/questionnaires/interview procedures, observation of public behavior, or standard educational exercises directly related to the topic(s) being studied. | |
| 7 | The content of interviews, surveys, or questionnaires are anonymous. | |
| 8 | The content of interviews, surveys, or questionnaires does not involve sensitive, personal, or incriminating topics. | |
| 9 | No WCU faculty, staff, or student is receiving monetary compensation or any type of support from an external company/organization/agency for collecting, analyzing, or reporting the results of this project. | |
| 10 | Subjects will be recruited in a voluntary manner. | |

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| 11 | The data will not be archived or saved in any way to be used in the future. | |
| 12 | The student researcher(s) and the instructor understand that the results of this work may be presented in the classroom to peers, but they cannot be disseminated outside of the classroom in any form. | |

Expectations

Faculty: All faculty who supervise course-based research activities are responsible for (a) reading and understanding this Policy and (b) having an up-to-date online training for Human Subjects Research and any other appropriate complementary training provided through CITI.

Students: All students who carry out course-based research activities are responsible for (a) reading and understanding this Policy and (b) completing the online training for Human Subjects Research and any other appropriate complementary training provided through CITI.

Definitions

Research. The DHHS defines research as a systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge.

Human Subject. According to [45 CFR 46](#), a human subject is a living individual about whom an investigator (whether professional or student) conducting research

- (a) Obtains information or biospecimens through intervention or interaction with the individual, and uses, studies, or analyzes the information or biospecimens;
- or
- (b) Obtains, uses, studies, analyzes, or generates identifiable private information or identifiable biospecimens."

Intervention means both physical procedures by which data are gathered (for example, venipuncture) and manipulations of the subject or the subject's environment that are performed for research purposes. [45 CFR 46.102(f)]

Interaction means communication or interpersonal contact between investigator and subject. [45 CFR 46.102(f)]

Private information means 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). [45 CFR 46.102(f)]

Identifiable information means information that is individually identifiable (i.e., the identity of the subject is or may readily be ascertained by the investigator or associated with the information).

Categories of risk: In human subject research, research is categorized into in two categories:

- (a) Minimal risk; or
- (b) Greater than minimal risk

Research is considered **minimal risk** when the risks of the research are not greater than those experienced in regular daily life. Researchers are responsible for identifying any possible risks of the research and minimizing risks to subjects whenever possible. Some common types of risks are:

- Economic risks: Payment by subjects for procedures not otherwise required, loss of wages or other income and any other financial costs, such as damage to a subject's employability, as a consequence of participation in the research.
- Loss of Confidentiality: In all research involving human subjects, confidentiality of identifiable information is presumed and must be maintained unless the

investigator obtains the express permission of the subject to do otherwise. Subjects have the right to be protected against injury or illegal invasions of their privacy and to preservation of their personal dignity. The more sensitive the research material, the greater the care that must be exercised in obtaining, handling, and storing data. In order to minimize the risk for loss of confidentiality, investigators should only collect personal information that is absolutely essential to the research activity. If personal data must be collected, it should be coded as early in the activity as possible and securely stored so that only the investigator and authorized staff may access it. Identities of individual subjects must never be released without the express consent of the subject. In addition, if an investigator wishes to use data for a purpose other than the one for which it was originally collected and the data are still identifiable (e.g. a code list for the data still exists), the investigator may need to obtain consent from the subjects for the new use of the data.

- Legal risks: Legal risks exist when the research methods are such that the subject or others will be liable for a violation of the law, either by revealing that the subject or others have or will engage in conduct for which the subject or others may be criminally or civilly liable, or by requiring activities for which the subject or others may be criminally or civilly liable.
- Physical risks: Physical risks include physical discomfort, pain, injury, illness or disease brought about by the methods and procedures of the research. A physical risk may result from the involvement of physical stimuli such as noise, electric shock, heat, cold, electric magnetic or gravitational fields, etc. Engaging a subject in a social situation which could involve violence may also create a physical risk.
- Psychological risks: The potential for negative affective states such as anxiety, depression, guilt, shock and loss of self-esteem and altered behavior. Sensory deprivation, sleep deprivation, use of hypnosis, deception or mental stresses are examples of psychological risks.
- Social risks: The potential for alterations in relationships with others that are to the disadvantage of the subject, including embarrassment, loss of respect of

others, labeling a subject in a way that will have negative consequences, or in some way diminishing those opportunities and powers a person has by virtue of relationships with others.

Types of human subject research review: Human subject research may undergo three different types of review by the IRB.

- **Exempt Review.** For research where there is no risk to the subject an exempt determination will be made.
- **Expedited Review.** For research where there is minimal risk to the subject and therefore can be reviewed by only one member of the IRB.
- **Full Review.** Research for which there is more than minimal risk to the subject and the research does not fall into the Expedited Review category.

Conflict of Interest: Any social, professional, or economic relationship with individuals leading or participating in human subject research or with the content of a research protocol that could affect the judgement of or be perceived to affect the judgement of a Faculty Member, research personnel (staff and student or guest investigators), or a member of the IRB. A conflict of interest may also result in an outcome that might not reflect the best interest of the Faculty Member, research personnel (staff and student or guest investigators), or a member of the IRB.

References

1. Adapted/drafted from:

- [IUP Classroom Policy.](#)
- [University of Michigan's Classroom Research.](#)
- [Kennesaw State University Student Class Project Guidelines and Procedures.](#)

2. [PASSHE Procedures and Standards for University Operations, #2012-14-A, Compliance with United States Export Control Laws.](#)

3. [45 CFR 46](#).

Reviewed by: Office of Research and Sponsored Programs, Academic Deans, APSCUF Representative, WCU IRB, HR

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