

Use of Human Subjects in Research 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 member, staff, and student or guest investigators. This policy describes the purpose and function of the WCU Institutional Review Board (IRB) and the associated university requirements for submitting protocols to the IRB for review and approval when human participants are used in research.

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 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 (b) is funded internally or externally, or (c) is conducted through 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. Therefore, if a researcher 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, they must submit a regular IRB protocol and have it reviewed accordingly.

Policy Framework

A. Role and Responsibilities of the IRB

The IRB reports directly to Vice Provost for Research and Creative Activity who is the Institutional Official (IO) responsible for research compliance at WCU. The IO reports to the Deputy Vice Provost who reports to the Provost and Executive Vice President for Academic Affairs and to the President.

The IRB must review and monitor human research under the WCU Federalwide Assurance (FWA) and follows the regulations and guidance of the Office of Human Research Protections for all studies conducted under that assurance.

The purpose of the IRB is to ensure that all research and teaching by and for WCU complies with ethical principles and legal requirements pertaining to the rights of human subjects.

The IRB is to provide an independent determination concerning:

1. The safeguarding of the rights and welfare of individual research subjects.
2. Whether these subjects are placed at risk; and, if risk is involved, whether:
 - (a) the risks to the participants are so outweighed by the sum of the benefit to the subject and the importance of the knowledge to be gained as to warrant a decision to allow the subject to accept such risks;

- (b) the rights and welfare of any such subject(s) are protected;
- (c) legally effective informed consent will be obtained by adequate and appropriate means; and
- (d) the conduct of the research activity will be reviewed at timely intervals.

The IRB will meet on a monthly basis to review research questions, policies, and efforts to educate members of the WCU community on the ethical principles and legal requirements pertaining to the rights of human subjects.

The IRB is a recommending body. Recommended decisions made by the IRB can be overturned by the IO in the event that they pose a risk to the WCU from the standpoint of risk management.

B. IRB Membership

Members of the IRB are appointed by the IO upon the recommendation of the Provost. IRB members are appointed for a three-year term and may be reappointed when this initial term expires. There are at least six members of the IRB, with various backgrounds and fields of expertise. The IRB will have a minimum of one member who is a community representative with competence in special areas as a permanent member of the IRB with voting privileges. The committee must be diverse in race, gender, and cultural backgrounds. Consideration shall be given to the inclusion of one or more individuals who have specific knowledge about and experience in working with these subjects. The IRB complement from the various colleges will reflect the applications submitted over the past three years.

Conflicts: When any potential conflicts of interest that arise with IRB applications that are assigned to them, IRB members must notify the IRB co-Chairs, in writing. In order to ensure objectivity and participant safety, the IRB co-Chair will reassign the application to another member of the IRB.

Confidentiality: During IRB meetings, confidential information about application, personnel, or events may be discussed. In order to protect the other members of the IRB, the university and the individuals discussed, IRB members must maintain confidentiality regarding these deliberations.

Commitment: IRB members must be committed to the university's self-imposed assurance to safeguard privacy, the rights and welfare of human subjects, in all research under its sponsorship, and to serve as their protector on behalf of the community of which the university is a part. As members of a diverse board, there may be discordance at times. However, it is important for each member of the IRB to respect the integrity and abilities of their fellow members and strive to advance the purpose and unity of the board. Each member must recognize that the determinations of their fellow members are a reflection of the entire IRB's shared goals and decision-making process and not based on the personal judgements of any one member.

C. Responsibilities of Faculty Members Leading or Supervising Human Subjects Research

Each Faculty Member assumes responsibility for the legal and ethical conduct related to their work including that of all research personnel (staff and student and guest investigators) working on their projects involving human subjects.

Prior to the initiation of any research involving animal subjects, each Faculty Member is responsible for requesting IRB protocol review and approval and for the training of all research personnel (staff and student and guest investigators) who will participate in the research.

A Faculty Member Leading Research must certify the following:

1. That all information provided in their IRB application is complete and correct.

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2. That they have ultimate responsibility for the conduct of the study, the ethical performance this project, the protection of the rights and welfare of human subjects, and strict adherence to any stipulations imposed by the IRB.

3. That all individuals involved with the conduct of the project are qualified to carry out their specified roles and responsibilities and are in compliance with WCU policies regarding the collection and analysis of the research data.

4. That they will comply with all WCU policies and procedures, as well as with all applicable federal, state, and local laws regarding the protection of human subjects, including, but not limited to the following:
 - (a) Conducting the project by qualified research personnel according to the approved protocol
 - (b) Implementing no changes in the approved protocol or consent form without prior approval from the IRB
 - (c) Obtaining the legally effective informed consent from each participant or their legally responsible representative prior to their participation in this project using only the currently approved, stamped consent form
 - (d) Promptly reporting significant adverse events and/or effects to the IRB in writing within 5 working days of the occurrence.

5. That they have read the IRB application in its entirety and affirm the content accuracy, clarity, and methodology.

6. That if they are unavailable to direct this research personally, they will arrange for a co-investigator to assume direct responsibility in their absence. That this person will be named as co-investigator in the IRB application, or that the Faculty Member will identify the replacement to the IRB, by letter, in advance of such arrangements.

7. To conduct this study only during the period approved by IRB.

8. To prepare and submit a renewal request and supply all supporting documents to the IRB before the approval period has expired if it is necessary to continue the research project beyond the time period approved by the IRB.
9. To prepare and submit a final report upon completion of the research project.
10. To accept the responsibility for the conduct of this research, the supervision of human subjects, and maintenance of informed consent documentation as required by the IRB.
11. That they should have full access to the data and be able to produce the data in the case of an audit.

A Faculty Member Supervising Research must certify the following:

1. That all information provided by the student or guest investigator in the IRB application is complete and correct.
2. That any student or guest investigator is knowledgeable about the regulations and policies governing research with human subjects and has sufficient training and experience to conduct this particular study in accord with the approved protocol.
3. That the project will be performed by qualified research personnel according to the approved protocol using conventional or experimental methodology.
4. To meet with any student or guest investigator on a regular basis to monitor study progress.
5. To be available personally, to supervise the student or guest investigator in solving them any problems that arise during the course of the study.

6. That the student or guest investigator will promptly report significant adverse events and/or effects to the IRB in writing within 5 working days of the occurrence.

7. If unavailable, they will arrange for a qualified, alternate Faculty Member to assume responsibility during the absence, and will advise the IRB by letter of such arrangements.

8. To assume that responsibility, if the student or guest investigator is unable to fulfill requirements for submission of renewals, modifications or the final report.

D. Faculty Member and Research Personnel Conflict of Interest

All Faculty members and research personnel (staff and student and guest investigators) must disclose any financial or management interest in an outside company or other entity as it relates to their employment. This ensures that both the individual who discloses the information and the university are compliant with the federal and state regulations designed to safeguard objectivity in research.

E. Special Instructions for Course-based Research

Federal Regulation 45 CFR 46 [45 CFR 46](#) Part 46101.b. (1) and (2) recognizes that some student projects 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. The **WCU Policy for the Use of Human Subjects for Course-Based Research Projects** provides instructions for IO review of course-based research projects.

F. Noncompliance

Human subject use for research in the absence of IRB approval is a serious violation of this policy, and in some cases, a violation of federal law.

Human subject use for research conducted under the guise of an approved IRB protocol but which are not specifically outlined in that protocol are considered a violation of this policy, and in some cases, a violation of federal law.

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

WCU is dedicated to assuring that ethical principles and legal requirements pertaining to the rights of human subjects are applied to research on our campuses. The IRB will monitor the following university procedures, which have been established so that that activities of Faculty Members and research personnel (staff and student and guest investigators) will be consistent in ethical and scientifically sound conduct of human participant research while remaining in compliance with applicable laws, regulations, and WCU policy.

A. Training

IRB Members: The committee members will complete online training for IRB provided through CITI. CITI training must be renewed every three years.

IRB co-Chairs. Every three years (or whenever a new IRB co-Chair is appointed), (a) the remaining co-Chair will be asked to continue for at least one year in order to acclimate the new person to the position; (b) every effort will be made to appoint someone from a different college than that of the remaining co-Chair so that a variety of expertise will be represented in the make-up of the IRB leadership team; and (c) every effort will be made to appoint a co-Chair who has participated as an IRB member for the past three years. The IO will earmark funds to support the new

Co-Chair's attendance at a workshop for IRB administration. Additionally, both co-Chairs will be required to complete online training for IRB provided through CITI. CITI training must be renewed every three years.

Faculty Members, Staff, and Student or Guest Investigators. All faculty members, staff, and student or guest investigators who will participate in research involving human subjects will complete online training provided through CITI before those activities begin. CITI training must be renewed every three years.

B. IRB Review Categories

The IRB will use the following guidelines for completing each of the three types of human subject research review.

Exempt Reviews will be completed by new IRB members as a method for training and assuring it qualifies for exemption. The reviewer will ask question to their senior review team or IRB chair if they have any questions regarding the application.

Expedited Reviews will be completed by **experienced IRB members only**. These reviewers have a minimum of 1 year experience and have demonstrated proficiency by an IRB chair and during their annual reviews.

Full Board Reviews will be completed by two primary experienced reviewers and then completed by the entire IRB committee. The application will be shared by the primary review team with the entire IRB committee for review and notes. The lead reviewer will notify IRB chair about the need.

C. IRB Review

Individuals who submit applications to the IRB must follow the instructions described in the **West Chester University of Pennsylvania Guidelines for Submitting Protocols to the Institutional Review Board**, posted on the IRB website.

The IRB must follow the **IRB Application Reviewer Instructions for New or Revised Applications**, posted on the IRB website.

D. Ceding IRB Review

The WCU Office of Research and Sponsored Programs supports the use of single IRB review models to streamline the IRB review and approval process for multisite and collaborative research. All decisions regarding whether IRB oversight can be ceded to an external IRB are made by the IO on a case-by-case basis. Study teams are encouraged to consult with the WCU IRB and the IO and Creative Activity about whether ceding IRB review is appropriate for their study. Once the protocol has been approved by the external IRB, the WCU researcher must submit submitting the protocol and the approval letter to the IO.

While the IO will make every effort to ensure IRB review for eligible studies can be ceded to an external IRB when such a request is made, if a reliance arrangement cannot be reached with the external IRB, the study must be reviewed the WCU IRB.

The following types of projects will not be considered for external IRB review:

1. Projects that are supported by internal WCU funds.
2. Collaborations with entities that with which the WCU researcher has a potential financial conflict of interest.

E. IRB Policy Review and Approval

Review of Current IRB Policies. Every three years the IO and IRB will review the **Use of Human Subjects in Research Policy** and all other policies related to the ethical principles and legal requirements pertaining to the rights of human subjects, regardless of the date on which the policy was implemented. Such review will include an assessment of the accuracy and relevancy of the policies, a

determination as to whether the policies are in-line with institutional policies, and whether there is a need for new policies to be developed.

All IRB policies must have approval dates to ensure regular review. Review dates must be added to each policy to ensure regular review.

Approval of IRB Policies. Significant changes to the **Use of Human Subjects in Research Policy** and all other policies related to the ethical principles and legal requirements pertaining to the rights of human subjects must be approved at a meeting of the fully convened IRB. The changes must then be reviewed by the WCU General Counsel and the WCU representatives of the Association of Pennsylvania State College and University Faculty, followed by approval from the IO, the Deputy Vice Provost, the Provost and Executive Vice President for Academic Affairs, and the President.

All revised IRB policies must have revision approval dates to ensure regular review.

Development and Approval of New IRB Policies. New policies related to the ethical principles and legal requirements pertaining to the rights of human subjects will be developed by members of the IRB in collaboration with the IO and in consultation with university stakeholders who will be impacted by the policies at the discretion of the IO. After development, new policies must be approved at a meeting of the fully convened IRB. New policies must then be reviewed by the WCU General Counsel and the WCU representatives of the Association of Pennsylvania State College and University Faculty, followed by approval from the IO, the Deputy Vice Provost, the Provost and Executive Vice President for Academic Affairs, and the President.

F. IRB Forms Review and Approval

Forms are essential tools for use by the research community, OSRP staff, and IRB members to ensure that applicable regulatory requirements are considered during the drafting and reviewing of research applications. Forms include the IRB

application, informed forms, technical review checklists, and templates and are maintained on the IRB website and other appropriate online systems.

Decisions regarding the implementation of new forms or revisions of previously approved forms are made by the IRB Administration/Chairs/committee. Depending on the nature of the form, approval by the IRB Committee may also be required. Updates to the IRB application will be made by the IRB chairs/committee. Updates to the IRB informed consent generator will be made by IS&T and web team specialists.

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.

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- **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. [West Chester University, Charter of the Institutional Review Board](#)
2. [Indiana University of Pennsylvania, Institutional Review Board for the Protection of Human Subjects](#)
3. [University of Wisconsin-Madison, IRB Guidance: Ceding IRB](#)
4. [University of Central Arkansas, Ceding Oversight to a Non-UCA IRB](#)
5. [Agreement Between Association of Pennsylvania State College and University Faculties and the Pennsylvania System of Higher Education, Articles 12, 14, 15, and 42.](#)
6. [45 CFR 46.](#)

Reviewed by: Office of Research and Sponsored Programs, Academic Deans, APSCUF Representative, APSCUF Meet & Discuss, University Legal Counsel, and WCU IRB

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9.19.22

Effective Date: September 19, 2022

Next Review Date: September 19, 2026

History

Initial Approval: September 19, 2022

Review Date:

Amended Date: