Policy on Human Subject Research at William Paterson University

Introduction to the WP IRB Educational Module

This module has two purposes:

The first is to provide the final module for completion of the CITI Program Course on the Protection of Human Subjects in Research. If you are involved in the CITI Program Course, you will have the automatic opportunity to complete a knowledge test at the end of the module.

The second is to provide a stand-alone module for individuals who have previously obtained Certification in the Use of Human Subjects in Research at another institution and need to obtain training on William Paterson's policy and procedures. If you are completing the stand-alone module, the knowledge test will be sent to you separately by the IRB only after you provided a copy of your most recent certification report.

Everyone completing this module should begin by familiarizing themselves with WP's policy and forms, then read the module, and then complete the knowledge test. The IRB policy and related forms can be found on the IRB's webpage: www.wpunj.edu/osp/irb.dot.

Educational Module

William Paterson University (WPU) embraces the ethical position that integrity, objectivity, honesty and the avoidance of self-dealing are essential elements in the ethical conduct of sponsored projects and research. This is critical for defining excellence and is foundational for obtaining and maintaining public trust. WPU and its employees are committed to conducting themselves and their activities in accordance with the highest standards of integrity and ethics. For research involving the use of human subjects, this ethical foundation is based on The Belmont Report.

What Research Is Reviewed by the IRB

The IRB is only concerned only with biomedical and social-behavioral research that is a systematic investigation designed to develop or contribute to generalizable knowledge without regard to the location or reason for factors motivating the research, AND that involves living human subjects about whom an investigator conducting research obtains either (a) personal and individually identifiable data through intervention or interaction with the individual, or (b) identifiable personal information.

Conflicts of Interest

Federal and State regulations require that WPU employees embrace the ethical position that integrity, objectivity, honesty and the avoidance of self-dealing are essential elements in ethical conduct and critical for excellence as well as public trust. This policy requires all investigators using human subjects to be acting in accordance with the State of New Jersey Uniform Ethics Code and the Plain Language Guide to New Jersey Executive Branch Ethical Standards. When an investigator submits a protocol, he/she must indicate that they have read the WPU Sponsored Projects and Research Conflict of Interest and Commitment Disclosure Policy and, if there is a conflict that must be disclosed, to attach the Conflict of Interest and Commitment Disclosure Statement to their protocol.

Studies That Are Not Submitted For Review

The following types of research should not be submitted to the IRB for review. However, the IRB expects that the investigators have provided documentation of training in the use of human subjects in research to the IRB, that subjects are treated in the same manner as subjects in studies that are reviewed by the IRB, and that subjects have an opportunity to provide informed consent or assent concerning their participation.

Institutional, Departmental and Program Assessment: Research conducted by the administration, faculty and staff on the operation of the University in accomplishing its mission, goals and objectives. Examples of what is included in this type of research are the general assessment activities Office of Institutional Research and Assessment and Program Assessment conducted by an academic unit. An example or what is not included in this type of research is research on secondary concerns of the University will require review, such as alcohol abuse by students.

Pedagogical Assessment: The assessment or evaluation of the effectiveness or efficacy of curriculum materials, resources and educational techniques by faculty, staff and WPU students when that research does not offer substantially different learning outcomes. This includes situations where the students might otherwise be considered a vulnerable population requiring specific safeguards. Instructors defined broadly as any teacher of record.

Examples of pedagogical research that are included are the comparison of one teaching technique against another technique when the alternative enables students to potentially learn as much or more as the original technique, the review or analysis of completed and graded assignments or coursework, especially following the term in which the materials were generated, and research conducted by a reading resource teacher with students that are assigned to her/him. Examples of what is not included in this type of research are the collection of data that would not normally be collected for the course, the collection of data primarily for reporting in a publication or conference presentation, the identification of students in the reporting of results (whether in writing, audio/video recording, or photography), and the long-term tracking of students.

Oral History Projects: Oral history interviews conducted to create an historical record. An example of research that is included in this type of research is interviews of participants in a strike. This type of research does not include medical, psychological, sociological or behavioral background/demographic information of subjects.

Library and Archival Research: These resources have already been published or are available to the general public. Any personal information included in published resources has already been disclosed, and archival repositories have processes and agreements that they supervise should there be protected personal information in their collection. An example of library material would a biography of living individual while an example of archival material would be the personal papers of recent President of the United States.

Publicly Available Databases: These databases have either already been anonymized or information in them has been disclosed to the general or academic public. Examples of what is included in this would be common data sets used by marketing professionals, sociologists or public health specialists. Examples of what is not included are datasets collected and protected by a government agency or private agency for which special protections or non-disclosure agreements are required for use as well as proprietary databases developed by companies to track customer activity.

Studies That Are Submitted to the IRB for Review

All other social, behavioral and biomedical research involving living human subjects or human materials (tissues, cells, fluids, etc.) that will be conducted by faculty, staff, students or outside investigators must be reviewed and approved by the IRB before the research may commence. This is regardless of the source of funding, the location of the study, whether or not the research has been reviewed and approved by another IRB, and whether or not the investigator is on sabbatical when the research will be conducted.

The IRB will determine if the proposed research should be described categorized as “Exempted,” “Expedited,” or “Full Review” during the review process. Following the guidance of the Belmont Report and The Common Rule, research is considered as **“exempt”** when the activities (1) present no risk to

human subjects, and (2) involve only procedures listed in one or more of the Common Rule's categories, and is considered as **"expedited"** when the activities (1) present no more than minimal risk to human subjects, and (2) involve only procedures listed in one or more of the Common Rule's categories. The inclusion of special classes of subjects may preclude the designation of a protocol as "exempted." Research that is not identified as appropriate for either an "exempt" or "expedited" review will be designed as requiring **"Full IRB Review"** by the IRB. In practice, the WPU IRB reviews "exempt" and "expedited" proposals using the same process.

Initial Review of Protocols

The initial review of all protocols will be completed in an expeditious manner so as not to unnecessarily delay the initiation of the proposed research.

Faculty, Staff, and Doctoral Student Protocols are reviewed by two members of the IRB, questions, modifications and final approvals are coordinated by the IRB Administrator. Later, the full IRB will review all approved protocols and may open any protocol for further consideration. A complete protocol submitted by a WPU faculty, staff, or doctoral students includes the following items:

1. Appendix A: Face Sheet completed in full, including required signatures
2. Protocol narrative
3. Informed Consent Statement (unsigned, content described below)
4. Testing instruments
5. Other materials/information as needed, and
6. Conflict of Interest and Commitment Disclosure Statement if required.

Outside Investigator Protocols are reviewed by two members of the IRB, questions, modifications and final approvals are coordinated by the IRB Administrator. Later, the full IRB will review all approved protocols and may open any protocol for further consideration. A complete protocol submitted by an outside investigator includes the following items:

1. Appendix B: Face Sheet completed in full, including required signatures
2. The protocol as approved by their home institution's IRB
3. The approval notice from their home institution, and
4. Documentation of certification of training in the use of human subjects obtained as per the requirements of their home institution

The approval notice will identify the protocol by name and control number; indicate whether it is considered as "exempt" or "expedited" and if there are vulnerable populations associated with the research; and include the approval date and the date by which an report must be submitted for the annual continuing review of the protocol.

Continuing Review of Protocols

The IRB is required to review research at least every 12 months as long as the project is continued. The IRB provides the Continuing Review process for investigators to provide substantial changes or to otherwise update their protocol, to report unanticipated events, and to notify the IRB when their research has been completed. These are discussed in detail in The Policy. The IRB may require more frequent reviews depending on the risk factors associated with a protocol.

Failure to submit for a continuing review will mean that the research is no longer being conducted in accordance with William Paterson University's IRB policy and will (a) significantly limit the University's support and assistance of an investigator if there is an unanticipated event, challenge or other crisis regarding the research, and (b) prevent the review of new protocols.

Approval Notices to Begin or Continue Research

After the IRB has approved a protocol submitted for either an Initial or Continuing Review, an Approval Notice is generated and sent to the investigator. The notice identifies which type of review was completed (exempted, expedited, full), if a special class of subjects is involved in the study, the date when the protocol was approved, and the expiration date of the approval. Other information regarding the approval and the investigator's responsibilities is also provided. The notice also includes a certification statement and signature line for the investigator to acknowledge their responsibility and commitments concerning the ethical use of human subjects in research and the William Paterson IRB Policy.

For new protocols, an investigator is not authorized to begin their research until the approval notice has been signed by the investigator, returned to the IRB, and acknowledgement of its receipt has be emailed to the investigator. Any research undertaken before this process has been completed will be considered to have been done outside the parameters of the protocol and may lead to the suspension or termination of the protocol by the IRB.

For continuing review protocols, authorization to begin is not a concern. However, failure to return a signed approval notice may also lead to the suspension or termination of the protocol by the IRB.

Contents of a Protocol Narrative

The protocol narrative is a detailed description of the research plan. The protocol narrative should be prepared according to the following outline.

- Purpose of the research
- Duration and timeline
- Background
- Research design
- Location of the research
- Storage and disposition of data and recordings
- Subject, recruitment and selection of subjects
- Protection of subjects
- Consent procedures
- Potential risks
- Potential benefits
- Risk/Benefit Analysis

Storage and Disposition of Data

The IRB is especially concerned about where and how informed consent statements and data are securely stored and the length of time that **original consent statements and data with identifying information** are held after the research has been completed and/or published. A guide is available on the IRB website that offers suggested methods and timelines. There are some basic expectations that should always be included in a research plan:

- Data with identifying information and signed informed consent statements must be stored in a way that will effectively limit or control opportunities for anyone other than the investigator or research team to physically or electronically access the data. Locked rooms, locked filing cabinets and password-protected desktop or network computers are always a good starting point. Data and consent statements must be stored separately but could be kept in the same location.
- Electronic information can be stored and transported in many ways to support a project. The IRB suggests that the use of laptops or tablet computers, flash drives and cloud drives be limited to temporary storage of data with identifying information (i.e.: when collected at a remote location and then transported back to the lab/office) but could be used for long-term use of de-identified data sets. The IRB's concern is related to the opportunity to misplace or lose devices as well as for hacking or the accidental access of identifiable information by family or associates. While this can happen with a desktop or network computer, the IRB feels that risk increases with portability.
- A specific period of time should be anticipated for keeping **original data with identifying information and consent statements**. The IRB recommends 3 years from the date of the last publication but 7 years is not an unusual length of time required by publishers and sponsors. The

difficulty of maintaining effective secure storage of original data and consent statements with identifying information for an unlimited length of time is very difficult to achieve. The likelihood of data being challenged also decreases over time. De-identified or fully anonymized data can be stored indefinitely and can effectively defend or answer questions concerning the research.

Informed Consent

An "Informed Consent Statement" should be a succinct statement which gives reasonable information about the study, its procedures, benefits, risks, duration and alternatives (when appropriate) to enable the subject to make a meaningful decision and freely choose to participate in the research. WP recognizes four types of informed consent.

Passive Informed Consent: This may only be used for anonymous surveys and questionnaires and must be provided or printed at the beginning of the survey or questionnaire. If the research is using an online survey, the informed consent statement would be the first thing subjects see when they access the survey.

Active Informed Consent: This should be used for all purposes except anonymous surveys and questionnaires. It must be a separate document from the testing instrument and include a place to sign and date the statement. If consent is for another person (i.e.: a parent providing consent for their child), the name of the subject must be included in the consent. Subject must receive a copy of the informed consent statement.

Assent to Participate: This is provided by individuals who are (a) children or minors or (b) adults with a cognitive, physical or developmental impairment, or other factors that limit or prevent them from signing an active consent statement. The method for obtaining assent will vary based on the individual subject's circumstance, age and ability to communicate.

Waiver of Consent: Waiver of Consent is approved by the IRB when it is impracticable to obtain consent or when the obtaining of consent will affect the outcome of the research, such as the observation of public behavior.

For a subject to provide active or passive consent, or to assent to participate, it is the investigator's responsibility to ensure that the subject understands what they will do and freely volunteers to the research. How this is determined will be related to the complexity, details and risk of the research. Issues such as allowing subjects time to consult family and limited English proficiency are just two examples of what may need to be considered. A subject should, before they begin their research tasks, be able to explain in their own words what they will be asked to do, what risks are involved, and why the research is beneficial.

Witnesses will be used when an adult subject has a cognitive, physical or developmental impairment, is not fluent in English, or has other limitations that prevent them from either understanding or responding to the terms and conditions of an Informed Consent Statement. The witness will be present at the time of consent to (a) confirm that the patient understands and agrees to the terms and conditions of the consent statement, or (b) agrees to the terms and conditions of the consent statement on behalf of the subject, and will be present throughout the subject's engagement in the research.

Consent statements should be written in clear, understandable English or the language of the subject population. The following points must be covered in a consent form.

Required Heading

- Name of Institution
- Title of research

investigator(s)
- Date of IRB approval of research

- Name and contact information of

Body of the Statement

- Purpose
- Selection of Subjects
- Procedures
- Risks
- Benefits
- Payments
- Alternatives
- Confidentiality
- Withdrawal
- Injury/ Complications
- Radiation Considerations
- Collection of Specimens

Conclusion and Consent

- Contact for Information
- Signature

Institutional Endorsement of Research Plan included in Proposals for Funding

When IRB review is required by either an external sponsor or a WPU internal funding program prior to submission of a proposal, the IRB will review the proposal to determine if the research plan indicates that subjects will be treated ethically and appropriately. If it is not acceptable, it will be returned to the author of the proposal for revision and resubmission. If it is acceptable, the University will provide an *Institutional Endorsement*. After the proposal has been funded, the investigator will be required to submit a complete protocol to the IRB following the normal process.

Suspension or Termination of Approval

The IRB may suspend or terminate its approval of a protocol (a) during the continuing review process or (b) if the IRB learns that information contained in a protocol was incorrect. A "notice of suspension" will be sent to the investigator by the IRB Chair and IRB Administrator immediately upon confirming the situation, with a copy to all members of the IRB. The full IRB will review the situation at either a special meeting or the next regularly scheduled meeting to confirm or reverse the decision. The investigator may be invited to, or may elect to, attend the meeting.

Special Classes of Subjects

The IRB will work with investigators to insure that all possible issues concerning the vulnerability of subjects are addressed prior to the approval of a protocol. The IRB will address concerns for the three special classes of subjects identified in The Common Rule (prisoners, children and minors, pregnant women and fetuses) as required. The IRB also recognizes that there are other groups of subjects who may need safeguards to insure their privacy, health and wellbeing. These include the following groups.

- Subjects who may perceive that their ability to participate freely and honestly is limited because of their specific personal circumstances and the subject or methodology of the research,
- Subjects who have a cognitive or developmental impairment, who are not fluent in English, or have other limitations that prevent them from either understanding or responding to the terms and conditions of an Informed Consent Statement,
- WP students who are in the classes of the investigator, especially when their identify will be known to the investigator
- WP employees, especially when their identify will be known to the investigator

Special Considerations

The following areas are of special concern to the IRB. If these issues are included in a research plan, or may potentially occur during the course of the research, the IRB expects that there will be a section of the plan

dedicated to addressing these concerns. Information that is expected for each item is included in The Policy.

- Sensitivity of Questioning
- Medical Records and Chart Review
- Student Records
- Residual Body Fluids, Tissues and Recognizable Body Parts
- Emergency Approval for Medical Care
- Research Involving Administration and Use of Ionizing Radiation
- Research Involving Human Blood, Blood Products, Body Fluids or Tissue Specimens

Certification of Training Requirement

To insure that investigators involved in human subject research and faculty teaching courses that include research on human subjects have an adequate background in the ethical principles and requirements governing research involving human subjects as well as the requirements and processes related to the conduct of human subject research at WPU, these investigators and faculty must provide certification of human subject research or research ethics training to the IRB. Certification must be received prior to the acceptance of a research protocol for review. Protocols from students of an instructor who has not been certified will not be accepted.

This requirement applies to (a) faculty, staff, doctoral students and outside investigators who are directly engaged in undertaking research involving human subjects, and includes the all senior investigators, support staff who have direct contact with subjects or the personally identifying information of a subject, (b) faculty and staff who are supervising students who are involving human subjects in research, and (c) the members of the IRB, the Responsible Institutional Official, and the IRB Administrator.

Undergraduate and Master's degree students are only required to obtain training when they are undertaking human subject research for a course that does not normally include human subject research AND when the course faculty is not certified.

WP administrators who are not directly involved in research involving human subjects but who are in a supervisory position over an investigator are required to provide certification of training as needed.

This requirement does not apply to project staff who do not have contact with subjects, original data or identifying information as well as undergraduate and master's degree students who are in a course taught by an instructor who has received certification. Certification for undergraduate and master's degree students will be the certification of their instructor.

Duration of Certification

A certification will remain effective as long as the investigator completes and submits certification of completion or certification refresher courses every three years. The three-year time period will insure that investigators are up-to-date with changes to regulations and processes. New certifications will be required for all investigators if their certification has lapsed.

Research by WP Undergraduate and Master's Degree Students

Very little human subject research by undergraduate or master's degree students at William Paterson University should go beyond normal classroom or course assignments to require formal institutional review. Course faculty determines if their students' research should be presented to the IRB for review based on the conditions described below. Faculty may contact the IRB Administrator for guidance.

Student protocols should only be submitted when one of these examples is related their research:

1. The results of the study will be shared outside the course through a paper, presentation, poster or report to – FOR EXAMPLE – the WP community, professional groups, or locations where the research was conducted.
2. The study involves a special class of subjects (vulnerable population).
3. The study collects personal, identifying information beyond a signature on an Informed Consent Statement.
4. The study collects sensitive personal information and/or requests the subject to undertake an activity that may elicit a significant negative psychological or physical response.
5. The study includes potential physical or psychological risks for the researcher or the subject.

The IRB assumes that student research will be completed either during the academic semester or within a period of approximately than 12 months. Therefore students are not required to submit a Continuing Review Face Sheet unless substantial work on the project will continue beyond the expected time.

A complete student protocol includes:

- Appendix C: Student Protocol Review Request,
- Draft Informed Consent Statement(s) that are unsigned,
- testing instrument(s),
- draft recruitment letters, emails, posters, or other communication items that will be used to interact with subjects or research sites, and
- other materials/information as needed

The IRB will respond to students by email within 5 business days by providing either an approval notice or a request for additional information.

Undergraduate and Master's Degree students do not need to obtain Certification of Training in the use of human subjects in research. Their professor is responsible for their research, and their professor must have provided Certification to the IRB. The IRB provides an optional special training module for the students that covers the ethics of using human subjects in research from both the investigator's and the subject's perspectives.