William Paterson University

Institutional Review Board (IRB)

Instructions for submission of a protocol by WPU faculty, staff and doctoral students using IRB Policy Appendix A: Protocol Face Sheet

William Paterson University is deeply concerned with safeguarding the rights and welfare of all human subjects who participate in research conducted under its aegis. Through the Institutional Review Board for Human Subject Research (IRB), the University reviews, approves and monitors all research by faculty, staff and outside researchers, as well as some students.

Most research involving living human beings that is conducted by a member of the WPU community must be submitted to the IRB for review and then approved prior to the initiation of the research. Before you begin preparing a protocol, review the requirements to determine if your research has to be submitted to the IRB and to anticipate which review category your study may fit if it is submitted for review. The policy is on the IRB webpage: www.wpunj.osp/irb.

These instructions are only for WPU faculty, staff and doctoral students using the Appendix A: Protocol Face Sheet to submit their protocol. If you are an outside investigator, please use Appendix B and follow the instructions included on that form. If you are an undergraduate or master’s degree student, please use Appendix C and follow the instructions included on that form.

Certification of Training in the Use of Human Subjects in Research

All investigators and senior personnel on research projects involving human subjects must have completed a training program in the use of human subjects in research in order for their protocol to be approved by the IRB. If you have not completed this training and have a certificate on file with the WPU IRB, please click here for additional information.

Submission of a Protocol for Review

Complete instructions are included in the IRB Policy concerning the format and content of a protocol, requirements for informed consent, the protection of data and subject confidentiality, and other issues related to a research project involving human subjects. This package is not a substitute or repetition of the information included in the IRB Policy.

1. Complete the contact information
2. Answer the questions.
   a. If you answer yes to Question 4, be sure to identify all of the characteristics of your prospective
subjects.
  b. If you identify that there may be potential conflict of interest for the principal or other investigators, please attach a Conflict of Interest and Commitment Disclosure Form.

3. Attach Protocol Narrative (see checklist, below)

4. Attach items as needed.

5. Obtain signatures. Attach additional pages as needed.
   a. The principal and other investigators sign as indicated. If the “other” investigators are student assistants (any type of student), they do not need to sign.
   b. If the principal investigator is a doctoral student, her/his faculty advisor must sign.
   c. The department chair signs unless the lead investigator is the department chair.
   d. If any of the “other investigators” are from other departments, the chairs of those departments sign.
   e. College deans sign only when one of the investigators is a department chair.

6. Deliver one complete copy of the IRB Protocol Application package to the IRB:
   Institutional Review Board
   Office of Sponsored Programs
   Raubinger Hall, Room 309
   William Paterson University, Wayne, NJ 07470

**IRB Protocol Review Process**

Once submitted and accepted for review, the IRB’s review has two stages. The first is a review and finding by two members of the IRB. Questions may be offered during this review as well as requests for modifications to forms, processes or data collection tools. When a protocol is approved by the initial reviewers, the principal investigator will receive an approval notice that must be signed and returned before the research may begin.

The second stage is a review by the full IRB, after which other questions, concerns or modifications may be offered or requested. If the initial reviewers decide that the protocol requires a full committee review, it is placed on the agenda for the next committee meeting or a special meeting is called to review the protocol.

**How long does it take to review a protocol?**

Please plan for the submission of your protocol appropriately based on when you would like to begin involving human subjects in your research activities. In general, the review of a proposal that is determined to fit either the Exempted or Expedited categories will be completed between ten (10) and fifteen (15) days while a Full Review will probably take a minimum of thirty (30) days to complete. The review of protocols submitted between semesters or during the summer will be longer.

**Questions or concerns?**

Contact the Office of Sponsored Programs at 973-720-2852, Fax: 973-720-3573, or visit the OSP and IRB webpage: [www.wpunj.edu/osp](http://www.wpunj.edu/osp) and [www.wpunj.osp/irb](http://www.wpunj.osp/irb).
Guidance for the Safe Storage and Management of Research Data

February 1, 2016

The IRB recognizes that research involving human subjects conducted by investigators at William Paterson University can occur in many different ways and locations. It can be conducted by students, faculty and staff as well as by outside investigators. Students, in particular, may be working with a significant level of independence or may be closely supervised in a lab or clinical setting. Because of this great variety, the IRB has established the following recommendations regarding the safe storage of data that conveys its core concerns about protecting access and subject anonymity as well as the flexible implementation related to the particular situation of the research.

A detailed data protection and storage plan must be included in every protocol submitted to the IRB. Investigators may offer alternative plans to what is recommended in this guidance but must include a justification for the alternative.

A. Basic Considerations for All WP Investigators

- Data must be stored in a secure location with limited or controlled access by anyone other than the investigator.
- Signed consent forms to be kept separately from the original data and any forms of the data that are not anonymized.
- Data stored electronically must be on a password protected desktop or network computer or a password protected external hard drive. This applies to data that DOES or DOES NOT include identifiable personal information. Campus computers and network storage drives are password protected and safe for data storage.
- The use of “cloud drives” is discouraged for long-term storage of data but could be allowable if (a) the data is a de-identified copy of the original data that is stored on a secure computer, (b) the level of password protection is considered highly secure (a 13+ character password using upper and lower case letters, numbers and symbols), and (c) there are a small number of individuals with access to the data.
- Laptop and tablet computers, flash drives (aka: thumb, memory card, memory stick), cloud drives and other portable memory devices should only be used for the temporary storage of data. The device or the files should be password protected. This data should be transferred to a password protected computer or hard drive at the investigator’s earliest opportunity.
B. Additional considerations for WP Faculty, Staff and Doctoral Students

- All Basic Considerations apply.
- For doctoral students, original data and consent statements may be stored at home in a manner that meets the Basic Considerations.
- For faculty and staff, original data and consent statements should be stored on campus.
- Copies of data can be stored at home or in other locations in a manner that meets the Basic Considerations.
- When data sharing is required by a sponsor of the research, or if data is voluntarily shared with other investigators, the data provided must be anonymized.
- For published data: data should be stored for a period of not more than 3 years following the publication of the last article.
- For unpublished data: the data should be stored for a period of not more than 3 years after when the investigator considers the research to have been completed or terminated.
- Original data with identifiable personal information should be destroyed when it no longer has to be retained. Paper records should be shredded; WP’s Storeroom provides shredding services, call them for details. Electronic records should be deleted from all computers and storage devices; this should also include backup files as practical.
- The data storage requirements of (a) sponsors who are supporting the collection and sharing of data, (b) publishers, or (c) organizations that provide access to data or datasets (paid or free) must be respected and followed even if they contradict these guidelines. If this is known when the protocol is submitted, this should be included in the protocol. If this is learned after the protocol has been approved, this should be communicated to the IRB as a change using the Continuing Review process.
- When the research is part of a multi-site project, the protocol should be clear in indicating which institution will be responsible for storing data and, if it is not WP, to provide a summary of the data storage plan.

C. Additional considerations for WP Undergraduate and Master’s degree students

- All Basic Considerations apply.
- For undergraduate or master’s degree student research that IS NOT REVIEWED by the IRB, the professor will be responsible for approving and monitoring data use as well as the destruction of original data at the end of the semester course.
- For undergraduate or master’s degree student research that IS REVIEWED by the IRB, the professor will be responsible for insuring that the plan for destroying data included in their student’s protocol has been completed.
- Students may keep a copy of the aggregated, de-identified, anonymized data after the course.

D. Outside Investigators

A data storage and protection plan must be included in the protocol approved by the investigator’s host institution or a plan must be provided in the submission to the WPU IRB. The WPU IRB expects that other intuitions will have different rules or requirements concerning the safe storage and management of data. An outside investigator’s host institution’s rules and requirements will be the standard for that investigator’s protocol.
IRB Protocol Checklist

1. **IRB Protocol Face Sheet with signatures**

2. **Protocol narrative, including:**
   a. **Research abstract**: Provide a brief summary of your research.
   b. **Protocol Narrative**: Provide details for each of the following items.
      1. Purpose of the research
      2. Duration
      3. Subject recruitment and selection
      4. Location of the research
      5. Background
      6. **Research Plan**
         • If the study will use an online survey: (a) provide the name of program, resource or provider you will use (such as Survey Monkey), (b) state whether or not the program identifies participants, and (c) what format the results of the survey will be provided to you for use (Excel, SPSS or another file type).
      7. **Informed Consent Process**
      8. Storage and disposition of data and recordings
      9. Potential risks to subjects
     10. Potential benefits to subjects
     11. Analysis of how benefits outweigh risks
   c. **Informed consent**. Research subjects must have the opportunity to provide “informed consent” before participating in research. Provide sample consent statements for each type of subject as well as (a) recruitment letters, emails or posters, (b) parent/guardian consent statements, and (c) other items related to recruitment and consent.
   d. **Attachments**. This can include, but is not limited to,
      • copies of all data collection tools, such as: tests, questionnaires, surveys, interview questions, observation sheets, etc.,
      • support letters from off-campus research locations or collaborators,
      • brochures describing investigational devices or drugs, and
      • information on potential funding agencies or programs.

3. **Deliver one copy of the IRB Protocol Application package to the IRB**