Policy on Human Subject Research at William Paterson University

All correspondence and inquiries related to research involving human subjects may be directed to the IRB Chairperson:

Chairperson, Institutional Review Board  
C/o Office of Sponsored Programs, Raubinger Hall 309  
William Paterson University of New Jersey  
300 Pompton Road, Wayne, NJ 07470

Telephone: 973-720-2852; FAX: 973-720-3573  
Webpage: www.wpunj.edu/osp/irb

Approved by the WPU Faculty Senate, February 2014
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Forms: Current forms for use by investigators and the IRB are available on the IRB’s webpage, which is within the Office of Sponsored Programs’ webpage: www.wpunj.edu/osp/irb.

Definitions: Current definitions and references to Federal regulations for use by investigators, the IRB and others are available on the IRB’s webpage, which is within the Office of Sponsored Programs’ webpage: www.wpunj.edu/osp/irb.
INTRODUCTION

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.

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Part I. Regulatory Authority

A. Applicability of this Policy

The Policy on Human Subject Research at WPU is concerned with research conducted by the faculty, staff and students of the University or by outside investigators conducting research at the University, that meets the following criteria (45 CFR Part 46 (102) (d) and (f), paraphrased):

- Research: A systematic investigation designed to develop or contribute to generalizable knowledge without regard to the location or reason for factors motivating the research.
- Human Subject: A living individual about whom an investigator conducting research obtains
  1. personal and individually identifiable data through intervention or interaction with the individual, or
  2. identifiable personal information.

The Policy on Human Subject Research at WPU is implemented and managed by the WPU Institutional Review Board for Human Subject Research, which is commonly known as the IRB.

B. Regulatory Authority

This policy has been developed to assist the University in fulfilling its responsibilities as defined in several Federal regulations, primarily Title 45 Code of Federal Regulations, Part 46 (a.k.a.: 45 CFR Part 46 and The Common Rule regulating the Department of Health and Human Services and 17 other Federal Agencies and Departments). It is also responsive to Title 21 Code of Federal Regulation, Part 50 (21 CFR Part 50 for the Food and Drug Administration). These regulations, and this policy, all subscribe to the ethical foundation for human subject research as defined by The Belmont Report which was published by the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research (1979).

The Common Rule creates a system that provides for local control with federal oversight. The Federal Agency overseeing human subject research conducted by or at William Paterson University is the Office for Human Research Protections (OHRP), Department of Health and Human Services. (This was formerly known as the Office for Protection from Research Risks (OPRR) in the National Institutes of Health.)
The Responsible Institutional Official for William Paterson University is the Associate Provost for Academic Affairs. The Responsible Institutional Official is assisted in the oversight of human subject research by the IRB and the IRB Administrator. The policy was developed by the IRB, reviewed by the Faculty Senate Research Council and approved by the Faculty Senate, and adopted as official university policy by the Provost and Executive Vice President (originally in 1996 with revisions in 1999 and 2006 before this version).

C. Synchronization with Other University Policies

This policy does not conflict with or override other University policies that address related issues, and the requirements of those policies may be applicable to research projects at the same time as this policy. This policy assumes that the terms and requirements of these other policies are respected and fulfilled, and as appropriate, the IRB may request information and/or certification that the individuals involved in research projects involving human subjects are in compliance with those policies.

The IRB will not approve a protocol and will rescind approval of any research that is not in compliance with other WPU policies.

Only the IRB approves research involving the use of human subjects in research, and is the only arbiter of issues regarding the use of human subjects in research whether or not that research was submitted to the IRB for review. No other William Paterson University committee, board or council can over-rule, over-ride or change a decision of the IRB. The University President, Provost or Responsible Institutional Official may, under exceptional circumstances, independently review any research protocol and if they deem necessary to disapprove the implementation of a research protocol even if it has been approved by the IRB. However, University officials may not approve the implementation of any research protocol in lieu of IRB approval, nor may they override IRB decisions disapproving a research protocol.

D. Financial and Other 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, whether their research is or is not reviewed by the IRB (See Part II A and B), 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.

All investigators who submit a protocol to the IRB 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. The Disclosure will be resolved before the IRB review and will be repeated if the IRB’s review requires changes to the research plan than affect the Management Plan for the disclosed conflict.

Compliance with the WPU Sponsored Projects and Research Conflict of Interest and Commitment Disclosure Policy means that the investigator(s) involved in the project are in compliance with the Financial Conflict of Interest regulations of the National Institutes of Health, the National Science Foundation, the US Department of Education, and other Federal and State agencies that sponsor research.
Part II: Review Requirements

A. Studies That Do Not Require Review

The following items do not need to be submitted to the WPU IRB for review. This list is selected from items identified in 45 CFR Part 46, Section 46.101 (b). While these types of research are not reviewed by the IRB, the IRB expects that the investigators have provided documentation of training in the use of human subjects in research (See Part V), 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.

Additionally, for pedagogical research, other regulations and requirement may apply, such as the Family Educational Rights and Privacy Act (FERPA) or school/school district policies on research and videotaping that may be based on New Jersey law or regulation. When pedagogical research is conducted at an institution other than WPU, the rules, regulations and policies of that institution have precedence over this Policy and the decisions of the WPU IRB.

Questions concerning whether a particular research project falls under one of these categories should be directed to the IRB Chair, the IRB Administrator or another member of the IRB.

<table>
<thead>
<tr>
<th>Type of Research</th>
<th>Definition</th>
<th>Examples</th>
<th>Exceptions</th>
</tr>
</thead>
<tbody>
<tr>
<td>Institutional, Departmental and Program Assessment</td>
<td>Research conducted by the administration, faculty and staff on the operation of the University in accomplishing its mission, goals and objectives.</td>
<td>Research by the Office of Institutional Research and Assessment. Program Assessment conducted by an academic unit.</td>
<td>Research on secondary concerns of the University will require review, such as alcohol abuse by students.</td>
</tr>
<tr>
<td>Pedagogical Assessment</td>
<td>The pedagogical 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 are any teachers of record.</td>
<td>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. Research conducted by a reading resource teacher with students that are assigned to her/him.</td>
<td>Evaluation or assessment activities that go beyond the regular activities or expectations of the course or students. This may include: 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, the long-term tracking of students.</td>
</tr>
<tr>
<td>Oral History Projects</td>
<td>Oral history interviews conducted to create an historical record.</td>
<td>Interviews of participants in a strike.</td>
<td>This does not include medical, psychological, sociological or behavioral background/demographic information of subjects.</td>
</tr>
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</tr>
<tr>
<td>External Research that Requires Very Minimal Involvement by the WPU</td>
<td>The recruitment of subjects through the posting of flyers or publication of advertisements in student newspapers for research that is not in any other way connected to WPU. An instructor agreeing to assist a colleague at another institution with their research by distributing anonymous surveys to his/her students.</td>
<td>Advertisement in the Beacon for subjects for a statewide epidemiological study conducted by investigators from Rutgers.</td>
<td>Studies that require WPU to provide email addresses or distribute surveys or recruit subjects for a focus group.</td>
</tr>
</tbody>
</table>
| Certain research by Undergraduate and Master’s degree students | Research that does not include any of the following does not need to be submitted to the IRB (see Part II, Section C):  
- sharing outside of the course;  
- involvement of a special class of subjects  
- collection of personal, identifying information beyond a signature on an Informed Consent Statement  
- collection of sensitive personal information  
- request subjects to undertake an activity that may elicit a significant negative psychological or physical response  
- include potential physical or psychological risks for the researcher or the subject | An anonymous survey for other WPU students on campus cultural or social issues. An interview concerning cultural or social issues that does not collect personal identifying information other than a signature on an informed consent statement. | Studies that may be used as the basis for a presentation at a conference, for training, for sharing with individuals at the workplace where the research was conducted, or at departmental, college-wide, or all University events (such as University Research & Scholarship Day). |
B. Studies by Faculty, Staff, Doctoral Students and External Investigators That Require Review by the WPU IRB

To assure the protection of human subjects and to comply with federal law, WPU requires that all research projects conducted by faculty and staff involving human subjects or human material (that is, materials originating in a human body, such as tissue, cells, fluids or organs) be reviewed and approved by the Institutional Review Board (IRB), unless it is a type of research identified in Part 1, Section A of this policy as not requiring review.

This applies to all social, behavioral and biomedical research involving living human subjects or human material conducted by faculty, staff and students of the University 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.

This also applies to all behavioral and biomedical research involving living human subjects or human material conducted at William Paterson University by any person or entity that is not affiliated with the University.

Hereafter, all references to human subjects will represent both living human subjects and human material unless otherwise specified.

If the study is part of an application to a sponsoring agency, the application must be provided for IRB review prior to submission. (See Part IV, Section F.)

The IRB will determine if the proposed research should be described categorized as “Exempted,” “Expedited,” or “Full Review” (45 CFR 46.101(b) (1) to (6), 45 CFR 46.110 and 21 CFR 56.110). This determination will be made based on the OHRP’s published descriptions at the time that the protocol is initially received by the IRB and again when a continuing review is received. The published descriptions are available on the OHRP’s Website (www.hhs.gov/ohrp) and on the WPU IRB’s webpage (www.wpunj.edu/osp/irb).

Research is considered as appropriate for an “exempted review” when the activities (1) present no risk to human subjects, and (2) involve only procedures listed in one or more of the defined categories in 45 CFR 46.101(b)(1) to (6). The inclusion of special classes of subjects may preclude the designation of a protocol as “exempted.”

Research is considered as appropriate for an “expedited review” 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 defined categories in 45 CFR 46.110 and 21 CFR 56.110. The expedited review procedure may not be used where identification of the subjects and/or their responses would reasonably place them at risk of criminal or civil liability or be damaging to the subjects’ financial standing, employability, insurability, reputation, or be stigmatizing, unless reasonable and appropriate protections will be implemented so that risks related to invasion of privacy and breach of confidentiality are no greater than minimal. The inclusion of special classes of subjects may preclude the designation of a protocol as “expedited.”

Research that is not identified as appropriate for either an “exempt” or “expedited” review will be designed as requiring “Full IRB Review.” “Full Review” may also be used by the discretion of the IRB or when requested by a WPU officer or program that is sponsoring the proposed research.
C. Special Considerations for the Review of Research Conducted by WPU Undergraduate and Master’s Degree Students

Very little human subject research by undergraduate or graduate 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.

The IRB strongly encourages faculty not to submit all student protocols to the IRB for review, not to submit research that is of a type described as not requiring IRB review (Part II, Section A), and not to submit protocols when the outcomes of the research will only be shared with the teacher and/or students in the course. Faculty may contact the IRB Administrator for guidance.

Student protocols should only be submitted when students are actively engaging subjects in significant research that will be shared “beyond the classroom” and that is described by one or more of the following criteria:

1. The study involves a special class of subjects (vulnerable population) as described in Part IV.
2. The study collects personal, identifying information beyond a signature on an Informed Consent Statement.
3. 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.
4. The study includes potential physical or psychological risks for the researcher or the subject.

If a student’s research is not submitted to the IRB because there was not an expectation that it would be shared outside the classroom, and then the student and her/his professor decides it will be, then the professor should contact the IRB Administrator.

D. Studies that Require Continuing or Other Review after Initial Approval

1. Studies that Require Annual Review

Faculty, Staff, Doctoral Students and Outside Researchers: All research studies involving human subjects must be reviewed at least every 12 months as long as the project is continued. Dependent on the risk factors associated with some protocols, the IRB may require more frequent reviews.

WPU Undergraduate and Master’s Degree Students: This policy assumes that research will be completed either during the academic semester in which it was approved or within two semesters following approval. This represents a period of approximately 12 months. Therefore, unless other circumstances are identified during the initial review or afterward by the student and/or instructor, students are not required to submit their research for Continuing Review to the IRB. The completion, close-out or termination report will be the paper submitted to the faculty sponsor who must retain the paper for a period of not less than three years (see Part IV, Section F).

2. Protocol Changes

If the investigator plans to make substantive changes in the research protocol, the requested change must be communicated promptly in writing to the IRB Chairperson. The researcher submits Appendix D, with a complete description of all changes to be made. If the proposed changes necessitate a change in the consent form or a testing instrument, then must be provided for review.
Substantive changes include, but are not limited to: (1) a change in principal investigator or other senior project staff; (2) altering the subject pool, research location or research timetable; (3) altering the research plan, subject contact plan, or other activities involved in the research; (4) adding or deleting questions to the testing instrument(s); and (5) adding or deleting information to the Informed Consent Statement. These changes will be reviewed by the same process as the original protocol unless, during review, it is determined that the protocol must be reviewed by another process (i.e.: a less-than minimal risk project now has greater-than minimal risk to subjects). When this happens, a new review will commence using that required process.

Changes that are not substantive include but are not limited to: (1) editorial or formatting corrections or improvements to Informed Consent Statements or testing instruments that do not change the content of the information/questions approved by the IRB; (2) minor increases or decreases in the number of subjects; (3) changes to the data analysis plan, and (5) changes in project support staff.

3. Reportable Events

If any reportable events occur, such as unexpected outcomes, adverse reactions, complications, unanticipated problems or events develop that are (a) unanticipated AND related to the research or (b) more severe than anticipated, then the investigator must immediately notify the IRB Chairperson, the IRB Administrator or the Associate Provost for Academic Affairs by phone, email or in-person to provide information on the event and to initiate University response as needed. A completed Appendix D form with a formal written report must be received by the IRB within 5 working days of the event, or sooner if requested. The IRB may suspend its approval of the research as per Part IV, Section F, thus suspending the research project. Ultimately, the IRB may withdraw approval thus ending the research project or reinstate its approval with or without conditions. The IRB and/or the University may be required to notify sponsors of the research of reportable events.

4. Completion or Termination

Investigators must notify the IRB Chairperson when a project is completed or terminated. The researcher submits Appendix D and a brief report on the outcome of the research. The report will be reviewed to insure that the research plan was followed and that there were no adverse reactions or complications that were not reported to the IRB. If unapproved changes occurred or adverse reactions were not reported, the investigator will be considered in violation of this policy and the WPU Academic Misconduct and Fraud Policy. Appropriate actions will be taken based on those policies.

Part III. The IRB

The “Responsible Institutional Official” for William Paterson University is the Associate Provost for Academic Affairs, or other similarly senior administrator designated by the Provost. The Responsible Institutional Official is assisted in the oversight of human subject research by the Institutional Review Board for Human Subject Research at William Paterson University (IRB). The “IRB Administrator” is the Director of the Office of Sponsored Programs unless another individual is designated by the Provost.

A. Responsibilities

1. The IRB is established as an Institutional Review Board (IRB) under the National Research Act of 1974, Title 45 Part 46 Code of Federal Regulation to review research involving human subjects conducted at or sponsored by the University. The review of research protocols is necessary to insure that (1) risks to subjects are minimized and are reasonable in relation to potential benefits of the investigation, (2)
Policy on Human Subject Research at William Paterson University

selection of subjects is equitable, (3) informed consent is obtained by adequate and appropriate means, and (4) ongoing research is reviewed at least every 12 months.

2. The IRB determines whether a protocol will receive an Exempted, Expedited or Full IRB review. (See Part II, Sections A to C)

3. The IRB’s role is not to comment on the research design of a proposal. The IRB evaluates the scientific merit of protocols it reviews and can offer constructive suggestions regarding the use of human subjects in the research design or methodology.

4. All records and minutes related to the IRB’s activity and meetings, protocols submitted to the IRB and related support materials, and other materials related to the operation and support of the IRB are maintained by the IRB Administrator.

5. The initial review of protocols will be completed in an expeditious manner. It is the goal of the IRB that the initial review of faculty, staff, doctoral student and external investigator protocols be completed in two to three calendar weeks, and that the initial review of undergraduate and master’s degree student will be completed in 3 to 5 business days.

B. Composition and Terms of Office

1. The responsibility for the administration of this institution’s policies insuring the rights and welfare of human subjects in research and investigation in all schools and departments rests with the Associate Provost for Academic Affairs. The Associate Provost is assisted by the IRB whose members are appointed for the purpose of reviewing programs of investigation and research involving human subjects.

2. Composition: The IRB consists of: (1) Representatives of each of the University’s Colleges as follows: Arts & Communication, 1 representative; Business, 1 representative; Education, 1 representative; Humanities & Social Sciences, 2 representatives; and Science & Health, 2 representatives. (2) Outside Members: 2 individuals who have no other affiliations with the University and who share one vote between them (if both are present at an IRB meeting, the senior outside member by length of service votes while the junior member has no vote). (3) The Associate Provost for Academic Affairs and the Director, Office of Sponsored Programs. Consultants, advisors and other non-voting individuals may be appointed to the IRB as deemed necessary by the IRB and/or the University.

3. Of the IRB members who are not ex-officio, at least one will be designated as a “scientist” and one will be designated as a non-scientist. In order to promote respect for its advice and counsel in safeguarding the rights and welfare of human subjects, persons serving on the IRB will be sufficiently qualified through experience and expertise, will be diverse as to race, gender and cultural background, and will be sensitive to such issues as community attitudes.

4. Terms of Office and Appointment/Election: Each member of the IRB may serve up to two three year terms (6 years total) and is appointed by the Provost on the recommendation of the IRB and the Responsible Institutional Official. The IRB Chair may serve up to three one year terms (3 years total) and is elected by the IRB. The Responsible Institutional Official and and the IRB Administrator serve as ex officio members of the IRB without specific term limits.

5. No member of the IRB may review protocols or vote at meeting if he/she has not provided Certification of Training in the use of human subjects in research (Part V). A member of the IRB who has not provided Certification of Training by the end of the academic semester following his/her appointment will forfeit the remainder of her/his term.
C. Meetings

The IRB has two (2) regularly scheduled meetings each semester at which a quorum will consist of a majority of the current members of the IRB and where both a scientist and non-scientist are present. Additional meetings may be convened by the IRB Chairperson as necessary.

The IRB may establish ad hoc IRBs for special purposes and for specific lengths of time. An ad hoc IRB may be empowered to act on behalf of the full IRB but this must be clearly stated in the charge to the IRB when it is created. Minutes of ad hoc IRB meetings will not be required unless the IRB is acting on behalf of the full IRB, otherwise a report of the IRBs activities will be sufficient documentation of its activities.

D. Registration and Federal Wide Assurance

The IRB Administrator will maintain the IRB’s registration with the Office of Human Research Protections. The IRB Administrator will, with the advice and approval of the Responsible Institutional Official, the IRB Chair and the IRB, submit and support William Paterson University’s Federal Wide Assurance for the Protection of Human Subjects through the Office of Human Research Protections.

Part IV. Review Processes

A. Protocol Preparation Guidelines

1. Protocol Submission Requirements

a. Initial Reviews

(i) Faculty, Staff, and Doctoral Students submit (a) Appendix A: Face Sheet completed in full, including required signatures, (b) the protocol narrative, (c) Informed Consent Statement, (d) testing instruments, (e) other materials/information as needed, and (f) a Conflict of Interest and Commitment Disclosure Statement if required. Submit one original. Only hard copy originals are acceptable, electronic copies are not accepted because originals must bear signatures.

(ii) Outside Investigators submit (a) Appendix A1: Face Sheet completed in full, including required signatures, (b) the protocol as approved by their home institution’s IRB, (c) the approval notice from their home institution, and (d) documentation of certification of training in the use of human subjects obtained as per the requirements of their home institution. Submit one original. Electronic copies that include the required signature may be accepted.

(iii) Undergraduate and master’s degree students as well as outside investigators who are undergraduate students submit (a) Appendix C: Student Protocol Review Request completed in full, including required signatures, (b) Informed Consent Statement, (c) testing instruments, (d) draft recruitment letters, emails, posters, or other communication items that will be used to interact with subjects or research sites, and (e) other materials/information as needed. Submit one original. Hard copy originals are preferred for WPU students, however fully signed electronic copies are accepted in situations where the student is primarily off-campus and both the faculty sponsor and student are prevented from mailing a hard copy to the IRB; electronic copies may be faxed or emailed to the IRB Administrator.

b. Continuing Reviews

Everyone who is required to submit a continuing review (Part IV, Section D) will do so prior to the
submission date identified on their protocol approval notice. Investigators will submit one original Appendix D with a copy of a report on the status of the research, other materials/information attached as needed, and a Conflict of Interest and Commitment Disclosure Statement if required.

2. Protocol Narrative Content Requirements for Faculty, Staff, Doctoral Students, and Outside Researchers

The protocol narrative must be a summary of the research plan outlined according to factors which the IRB considers essential for its review. The protocol narrative should be prepared according to the following outline.

<table>
<thead>
<tr>
<th>Information Category</th>
<th>Description of Required Information</th>
</tr>
</thead>
</table>
| Purpose of the Research | • Summarize the purpose of the study.  
                              • How the results of the study will be used.  
                              • State the hypotheses or the guiding questions for the study |
| Duration and Timeline  | • Provide an estimate of the duration of the entire study.  
                              • Provide a timeline for study. |
| Background            | • Describe succinctly and clearly related past findings.  
                              • A summary of the relevant literature in the area of interest and reports of previous studies may be included. |
| Research design       | • Prepare an orderly scientific description of the intended procedures as they directly affect the subject. Include the number and estimated length of time, length of time for various procedures (e.g., interviews, completing questionnaires, etc.); frequency of repetition; randomization; any manipulation which may cause discomfort or inconvenience; doses and routes of administration of drugs; amount of blood to be withdrawn; plans for follow-up hospitalizations; etc.  
                              • If there is a point at which the study procedures may be discontinued, state how this point will be determined. Include measures which will be taken to treat side effects or to handle or refer problems identified during the study.  
                              • Copies of all surveys, questionnaires, rating scales, observations scales, or other data collection materials to be used must be attached to the protocol.  
                              • If research will be conducted over the Internet, name the tool or program that will be used, describe the survey or data collection tool(s), indicate how the tool or resource will anonymize responses to protect the confidentiality of subjects. A link to the draft online survey or data collection tool(s) must be included in the protocol and a printed copy attached to the protocol.  
                              • If subjects will be audio- or video-recorded, describe how that will be accomplished, how the recordings will be used, whether or not they will be transcribed, and how long the recordings will be maintained after creation must be included.  
                              • If drugs or devices are administered or used, the following questions must be answered: Does the drug or device have FDA approval? What is the name of the drug or device company? If the drug or device is investigational, does it have an Investigational New Drug (IND) or Investigational Device Exemption (IDE)? What is the IND or IDE Number? If the drug or device is marketed, is it approved at the dose level you plan, for this purpose, or by this means of administration or use?  
                              • Clinical drug and medical device trials should have a copy of an indemnification clause attached to them with the appropriate signatures. |
| Location | • Provide the specific name of the school, business, clinic, hospital or other agency from which subjects will be recruited and where the research will take place.  
• For locations other than WPU facilities, documentation must be submitted that supervisory personnel of the facility have agreed to their involvement in the study.  
• The rules and regulations for conducting research at non-WPU facilities take precedence over the IRB’s action on a protocol. It is the investigator’s responsibility to identify and fulfill requirements at non-WPU facilities and to provide proof of WPU IRB review and approval if it is required. |
|---|---|
| Storage and Disposition of Data and Recordings | • Describe where and how signed informed consent statements, data and recordings will be stored in a secure location during and after the study to protect participants’ identity and the information they provide.  
• When and how data, recordings and other items that may include identifiable information will be destroyed. |
| Subject Recruitment and Selection | • Provide the numbers of subjects to be invited to participate  
• Identify, if appropriate, how many will be in experimental groups and how many will be in the control group.  
• Describe the key characteristics of subjects by group.  
• Identify and describe special classes of subjects who will be included in the study (Part IV) and how their particular requirements will be addressed. Please note that administrative or researcher convenience is generally not a justification for use of special groups with limited capacity to give consent if alternative groups are available.  
• Describe the criteria for accepting or excluding subjects (such as age, gender, economic status, race, or other characteristics) by group or class.  
• Describe any inducements which will be offered to subjects (such as cash payments, gifts, raffles, credit vouchers, free hospitalization, medication, clinical testing) and how they will be offered.  
• Describe how subjects will be recruited by group. All advertisements, letters, emails or other recruitment tools must be attached to the protocol.  
• If applicable, describe in detail how subjects will be recruited by email, through an Internet-based social media site(s), or by other electronic means. All advertisements, letters, emails or other recruitment tools must be included as an attachment to the protocol.  
• Describe how third-parties who are providing the source for subjects, or where subjects are patients of an attending or referring physician, are either involved in recruiting subjects or are provided a reasonable opportunity to affect the manner in which their patients are invited to participate. Third-party recruitment letters, emails and other communication with prospective subjects must be included as an attachment to the protocol. |
| Protection of subjects | • Describe the procedures for protecting against or minimizing potential risks, and assessment of their likely effectiveness.  
• Describe procedures for protecting the anonymity of subjects.  
• Describe procedures for protecting the confidentiality of subjects.  
• Describe how the confidentiality of subjects will be achieved through coding or
other techniques so that data cannot be easily connected to subjects who signed informed consent statements.

- For studies that may elicit negative emotional or psychological responses, describe how subjects will be protected and how emergency counseling or treatment will be provided if needed.
- For studies requiring physical activity by subjects, describe how subjects will be determined to be appropriately healthy to participate.
- For studies including drugs or medical devices, describe patient care and observation, emergency treatment if needed. A Sample Indemnification form is included as Appendix E. These indemnification documents must be between the Trustees of the William Paterson University and the Sponsor. All indemnification agreements must be signed by the Associate Provost for Academic Affairs. An IND or IDE number must be submitted for all investigational drugs and devices as well as an investigator brochure with background information and experience to date on the specific test article.

| Consent procedures                          | Describe consent procedures to be followed, including how, when, where, and by whom informed consent will be obtained.
|                                            | For requests to waive consent, a complete justification must be provided as to why obtaining consent is impracticable and/or the negative outcome that will result to the research if consent is obtained.
|                                            | Attach all informed consent statements.
|                                            | If witnesses will be used, justify the need for a witness, describe their role, and detail their engagement with the subject throughout the research.
|                                            | If subjects will not have at least a good ability to read English, consent statements in the language that is best for those subjects must be provided.
|                                            | For studies that will have repeated contact with subjects over a long period of time, describe how and when informed consent will be renewed by subjects.

| Potential risks                            | Describe and assess any potential risks to subjects by group and class (such as physical, psychological, social, economic, monetary, legal or other) and assess the likelihood and seriousness of such risks.
|                                            | Explain the need for all the various methodologies employed by this protocol, including, when appropriate for more than minimal risk studies, the lack of alternatives or the relative risk of alternatives methods for collecting information.

| Potential benefits                          | Assess the potential benefits to be gained by the individual subject, as well as benefits which may accrue to society in general.

| Risk/Benefit Analysis                      | Analyze the ratio of the benefit and risk to be obtained from the study relative to the risks involved.

For outside investigators who submit a copy of the protocol that was approved by their home institution, if information specific to conducting the research at WPU is not included, provide this as an attachment to Appendix B.

### 3. Protocol Narrative Content Requirements for Undergraduate and Master’s Degree Students

Undergraduate and Master’s degree students complete Appendix C: Student Research Protocol Review Request by providing responses to a series of questions that will define the proposed research in a consistent manner for the IRB. The form must be signed by both the student and the faculty sponsor. In the case of a group project, only the “lead student” has to sign the form but all investigators may sign it. Information provided will include:
Policy on Human Subject Research at William Paterson University

a. Intent of the Research: What is the intent or goal of the study? What is your hypothesis?

b. Research Design: What is the research design of the study? How will it be conducted? What information will be collected? How will it be collected? How will it be analyzed? Will subjects be audio- or video-recorded or photographed? For studies collecting information through the Internet: name the online products/sites/tools/resources that will be used and describe how submissions will be anonymous. Describe how data and recordings will be stored and disposed of at the end of the study.

c. Your Human Subjects: Who are your intended subjects? How will you select or contact them? Are your subjects children or minors, prisoners, or vulnerable for some other reason? Explain how the rights, identify and confidentiality of your subjects will be protected. Will subjects require a witness to confirm that the subject understands the research and their involvement in it, that their participation is voluntary, and understands their rights? If the study will be off campus, identify specifically where will it be done and indicate that you have obtained permission to use this/these location/s? If the study will be Internet-based, describe how subjects’ anonymity will be protected during recruitment, how subjects will receive the opportunity to provide informed consent, and how anonymity will be protected during and after submission of responses.

d. Outcomes: What is the anticipated outcome of this research? How will you use the results of this research?

e. Benefits: What are the benefits of this research? Are there any direct benefits to the subjects? How will this information add to the general body of knowledge for your area of study?

f. Risks: What are they physical or emotional risks to your subjects? How do you plan to minimize these risks? What are the physical or emotional risks to the researchers involved in this study? How do you plan to minimize these risks?

g. What are the anticipated start and completion dates of your study?

4. Informed Consent

The “Informed Consent Statement” should be a succinct statement which gives reasonable information about the study, its procedures, benefits, risks, duration and alternate therapy to enable the subject to make a meaningful decision about participation. The University recognizes three types of informed consent. In all cases, subjects must freely choose to participate.

Passive Informed Consent: Passive Informed Consent may only be used for anonymous surveys and questionnaires and must be printed at the beginning of the survey or questionnaire. A subject may be given a second copy of the survey or questionnaire if they request it so that they may have a copy of the informed consent statement. Alternative methods will be considered.

Active Informed Consent: Active Informed Consent should be used for all purposes except anonymous surveys and questionnaires. It must be a separate document from the testing instrument. It must describe the research, what is expected of the subject, and the subject’s rights concerning his/her participation. If consent is for another person (i.e.: a parent providing consent for their child), the name of that person must be included on the Informed Consent Statement. It must include a place to sign and date the statement. The subject will receive a copy of the informed consent statement.
Assent to Participate: Assent is provided by individuals who are (a) children or minors or (b) adults with a cognitive, physical or developmental impairment, or have other limitations that limitations that 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. Assent is generally a separate process in which the investigator explains what will happen and then asks the subject if they want to participate. Assent can also be provided as a signature on an Active Informed Consent Statement.

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. As examples, this may be used for observation of public behavior or for textual analysis of postings on publicly available websites. Waiver of Consent should be rarely used. If an investigator is considering requesting a waiver of consent, he/she should contact either the IRB Administrator or IRB Chair before submitting his/her protocol.

For Active and Passive Consent, subjects must receive information that they can use to contact the investigator or WPU concerning their involvement in the study and their rights as a subject. Subjects must be provided with the name and contact information of the investigator(s), the faculty sponsor for student research, and the contact information for the Responsible Institutional Official.

For Active and Passive Consent and Assent to Participate, subject understanding must be ensured by the investigator prior to the initiation of research activity with the subject. The subject should be encouraged to ask questions in order to be fully informed of the proposed research study. If the proposed procedures are complex or hazardous, subjects should be encouraged to discuss them with other appropriate experts, family or friends (e.g., their own physician, mentor, teacher, spouse, etc.) before making a decision. If the experiment involves a considerable degree of risk, the subject must be briefed twice with at least 2 days intervening between briefings. If the subject is not a fluent speaker and reader of English an interpreter should be present at the time that the informed consent statement is discussed and a statement should be provided to the subject in his/her primary language. Prior to signing the consent form, the subject should be asked to reply, in his or her own words, and without immediate reference to the consent form, to questions like the following: What is the purpose of this study? What will be done? What risks and discomforts may occur from participating in this study? What benefits may accrue to subjects from participating in this study?

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. Such witnesses will be one of the following as defined in the research protocol and approved to by the IRB: legally-appointed guardians, immediate family members, counselors, teachers, or other appropriate individuals. Witnesses will remain present for the research and will be present for any subsequent renewal of informed consent unless the IRB waives this requirement in its approval of the research.

For Active and Passive consent, each person involved in providing consent must receive a copy of the signed document. The principal investigator must retain in his/her confidential files copies of consent forms signed by each subject in the study. The consent forms may not be kept with the data and any keys linking the consent statements and data must be kept in a third separate location.

The consent statement should be written in clear, understandable English or the language of the subject population. It must explain the purpose of the study and precisely what will be done to or with the subject. It must provide adequate information for the subject to decide whether or not to participate. It may not
include language by which the subject is made to waive, or appear to waive, any of his/her legal rights or to release the institution or its agents from liability for negligence. It is recommended that all consent forms be written in the same person throughout (i.e.: “I understand that...”), and that scientific terminology be defined for a lay person’s understanding. Documents must also be thoroughly edited for spelling and typographical errors. The following points must be covered in a consent form:

<table>
<thead>
<tr>
<th>Information Category</th>
<th>Description of contents</th>
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</thead>
</table>
| Heading              | For all types of Informed Consent Statements, the heading must:  
  • identify William Paterson University,  
  • the title of the study,  
  • identify the name(s) and telephone number(s) of the responsible faculty or outside investigator(s) or just the name of a student investigator,  
  • identify the course name and the name and telephone number of the faculty sponsor for student research, and  
  • Identify the date of the IRB’s approval of the study or consent form. |
| Body of the Statement | The study title should be carried at the top of each page of the consent statement. |
| Purpose              | • The general purpose of the study should be expressed in lay terms and should clearly state the nature of the research project.  
  • The subject should be told that he/she is being asked to participate in research. |
| Selection of Subjects | • The subject must be informed of the reason why he/she has been invited to participate in this study. |
| Procedures           | • The subject must be informed exactly what his/her participation will involve.  
  • This may include randomization, questionnaires, video-taping, diets, withholding of standard treatment, follow-up studies, the length and frequency of hospitalization, types of medication, placebo administration, types and numbers of tests, and amount of blood to be withdrawn (in terms a lay person can understand such as ounces, tablespoons, teaspoons). |
| Note: Slight forms of deception are allowable to insure that subjects are not biased when engaged in the study. For example, stating that research is about campus facilities rather than about parking on campus. However, whenever deception is used, the deception must be revealed at the conclusion of contact with a subject and there must be a debriefing about the deception at the end of the research procedures. |
| Risks                | • It must be clearly stated if participation in this study may bear some known or unforeseeable hazards, discomforts, or inconveniences. These may include side effects of drugs, procedural hazards, withholding of therapeutic regimen of proved value, time involved, or an emotional or psychological response.  
  • The disclosure of risks must include the implications of randomization of subjects and of placebo administration. If double-blind studies are involved, it should be made clear to the subjects that neither the investigator nor the subject will know which treatments the subject is receiving during the study.  
  • Special implications of crossover studies should be explained (e.g., the subject who has a beneficial response to the experimental drug may have to do without it for the placebo phase). For any double-blind drug study, the subject must be informed that the code will be broken in the event of an emergency.  
  • Special consent forms are required for special protocols involving radioactivity. |
| Note: If the deception will mask a risk, it may not be used. |
| **Benefits** | • The benefits to the subject, if any, are to be explained.  
• If there are no benefits for subjects, this must be explained. |
| **Payments** | • Subjects should be told specifically what charges if any, they are responsible for related to their participation and what expenses will be will be paid for by WPU or the sponsor of the study.  
• If subjects are to be paid for participation, the schedule of payment and the form of payment (dollars, gift cards, etc.) must be documented with specificity. |
| **Alternatives** | • In therapeutic studies, alternatives should be described. The description would include other accepted treatment regimens, as well as a brief description of the benefits and risks of each alternative. |
| **Confidentiality** | • Informed consent must be provided to assure subjects of the security of stored identifiable information, of identifiable information in databases, and of audio and video recordings. This may include identifying who engaged in the study does and does not have access to identifiable information.  
• Information must be provided concerning the disposition and anonymizing of files, databases and recordings at the conclusion of the study.  
• In some cases, instructions concerning who may be contacted for answers to pertinent questions and/or who will receive information derived from the study should be addressed.  
• Research subjects involved in clinical trials must be told in the consent form that representatives of the drug/device company and the FDA may review the data collected for the study and that the information will be kept confidential except as may be required by law.  
• In studies receiving Federal funding support, research subjects must be told that personal information will be kept confidential except as may be required by law. |
| **Withdrawal** | • The subject must be informed that he/she is free to decide whether or not to participate, is free to withdraw from the study at any time, and that they do not have to answer all of the questions posed them or complete all of the tasks requested of them.  
• Subject must be assured that non-participation or withdrawal from the project will not affect the standard care in a health care setting, or the evaluation of performance or grades in an educational setting, or other services he/she will receive in other settings as appropriate.  
• There must also be an assurance that a decision not to participate will not prejudice future interactions with the faculty member, investigator, or institution particularly if any potentially coercive relationship exists between the investigator and subject, such as physician-patient, employer-employee, faculty-student, etc. |
| **Injury/Complications** | • Prospective subjects should be advised as to the availability or non-availability of medical or psychological treatment or compensation for injury incurred as a result of participating in biomedical or behavioral research.  
• For research involving more than minimal risk, an explanation as to whether any compensation and/or medical treatment and/or counseling is available if injury occurs and, if so, what they consist of, or where further information may be obtained.  

**Note:** Studies where no threat of injury exists, no additional statement is necessary. |
| **Radiation Considerations** | • If the research involves the administration of ionizing radiation to subjects for other than clinical purposes, the consent form must describe in lay terms some assessment or description of the radiation effect and risks. |
| **Collection of Specimens** | • If the research includes the collection of bodily specimens, such as blood, tissue, nail clippings, hair, and saliva, safety precautions must be described for the collection as well as storage/handling of the specimens after they are collected. |
Conclusion and Consent

<table>
<thead>
<tr>
<th>Contact for Information</th>
<th>Statement indicating subject’s understanding of the consent statement and willingness to participate followed by:</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Passive Consent:</td>
</tr>
<tr>
<td></td>
<td>• Instructions on how to proceed and complete the survey if subjects want to participate.</td>
</tr>
<tr>
<td></td>
<td>• Instructions on how to end their involvement if the subject does not want to participate.</td>
</tr>
<tr>
<td></td>
<td>Active Consent</td>
</tr>
<tr>
<td></td>
<td>• A place for the subject and to write the date that consent was provided.</td>
</tr>
<tr>
<td></td>
<td>• A place for the investigator to print their name, sign their name, and to write the date that consent was obtained.</td>
</tr>
<tr>
<td></td>
<td>• A place, when applicable and justified, for a witness to write their name, sign their name, and to write the date that consent was witnessed.</td>
</tr>
<tr>
<td></td>
<td>• A place for a parent or guardian to print the name of the person they are providing consent for, to print their own name, sign their name, and to write the date that consent was provided.</td>
</tr>
</tbody>
</table>

Note: For online studies, consent should be offered at each step with instructions specific for moving to the next step.

Note: Care must be taken not to require a witness when subjects are fully capable of providing consent for themselves because this unnecessarily discloses the identity of the subject and abridges confidentiality.

B. Initial Review Approval Processes and Actions

1. Review Prior to Submission to the IRB

a. Appendix A: Protocol Face Sheet for Research by WPU Faculty, Staff and Doctoral Students, and Appendix B: Protocol Face Sheet for Outside Investigators: After preparation of the protocol and prior to its submission to the IRB, the investigator must submit the complete protocol to his/her department chairperson for review and acknowledgement of the investigator’s activities and use of departmental resources as well as to accept her/his responsibility to protect human subjects in research by overseeing the activities of faculty in his/her department. For projects involving personnel from more than one department, investigators must submit the protocol to the chairperson of each department. If any of the investigators are the department chairperson, then their Dean/Vice President will sign the protocol to acknowledge submission of the protocol and accept oversight responsibility for both departmental and college/unit support for the research. For Doctoral Students, the faculty sponsor will also sign Appendix A.

b. Appendix C: Undergraduate and Master’s Degree Student Research Protocol Form: After preparation of the protocol and prior to its submission to the IRB, undergraduate and master’s degree students must submit the protocol to an appropriate faculty sponsor for signature. This will indicate that the sponsor has reviewed the research, supports the project, has completed and submitted certification in the use of human subjects in research, and accepts responsibility for the actions of the student in undertaking the project.

2. Review by the IRB

a. Faculty, staff, doctoral students, undergraduate and master’s degree students, and outside
investigators will prepare and submit the appropriate form following the specific instructions on or attached to that form.

b. Protocols will be sent to the IRB Administrator who will coordinate the review and all actions concerning all protocols. Protocols from WPU Faculty, staff, doctoral students, and outside investigators are first reviewed by either a member of the IRB as a delegate of the IRB Chair. If the proposal qualifies for an Exempted or Expedited Review, it is reviewed by that same person as well as by another member of the IRB, if changes are required these will be negotiated by the IRB Administrator, and then the investigator is notified of the reviewer’s decision. Approved Exempted and Expedited protocols are forwarded to the IRB for affirmation; the IRB may choose to read and discuss approved protocols, may choose to hear a report from the first or second readers, or may accept protocols without further review. Exempted and Expedited protocols that are not approved by the readers are sent to the IRB for additional review at its next regular meeting. If the proposal qualifies for a Full IRB review, it is reviewed by the IRB at the next regular meeting (or a special meeting is scheduled for the review) and then the investigator is notified of the IRB’s action.

c. WPU faculty, staff and doctoral students who are the primary investigators on the protocol are required to sign and return the approval notice to the IRB Administrator before they initiate their research. When the notice is sent (typically by email), all investigators, department chairs and deans named on the protocol. When the signed notice is received by the IRB Administrator, he/she will acknowledge receipt to the same group that received the initial notice. If the signed notice is not received in a timely manner, one reminder will be sent to the investigator and this group. If the signed notice is still not received, the investigator and this group will be notified that the approval of the research has been suspended. The suspension would be lifted when the signed notice is received and approved by the IRB at its next meeting.

Any research conducted before the signed approval notice is received by the IRB Administrator will be as if it had not been reviewed by the IRB and, when this is determined to be the case by the IRB or any other WPU faculty or official, would be reported as research misconduct.

d. Protocols received from undergraduate or master’s degree students are reviewed by the IRB Administrator who determines if it qualifies for an exempted or expedited review, completes the review if it does not require review by the full IRB, either negotiates changes to protocols or assigns oversight of changes to the sponsor, notifies the investigator(s) of the reviewer’s decision. The protocol is then sent to the IRB for affirmation. If the proposal qualifies for a Full IRB review, it is reviewed by the IRB at the next regular meeting (or a special meeting is scheduled for the review) and then the investigator is notified of the IRB’s action.

e. Faculty and staff protocols are reviewed within 2 weeks of submission unless it is received immediately before or during a University holiday or semester break. Student protocols are reviewed within 3 to 5 working days of submission. These review periods are contingent on the need to request or gather information related to the review. Every effort will be made to review protocols in a timely manner, but no guarantees can be made as to when a particular protocol will be reviewed and they are assigned on a first-come-first-served basis. Investigators are urged to submit their studies as far in advance of a beginning date of their research as possible in order to insure timely review, especially when the submission of an application for funding is contingent on IRB approval. While the IRB wishes to be helpful to all investigators, it cannot make exceptions for last minute requests.

3. Actions by the IRB

1. Decisions by the IRB, the IRB Chair, or Chair Delegates

Decisions will be based on the criteria established in 45 CFR Part 46.111 (a) and (b):
Policy on Human Subject Research at William Paterson University

- Risks to subjects will be minimized;
- Risks to subjects are reasonable in relation to anticipated benefits, if any, to subjects, and the importance of knowledge that may reasonably be expected to result;
- Selection of subjects are equitable; informed consent will be sought from each prospective subject or the subject’s legally authorized representative; informed consent will be appropriately documented;
- The research plan makes adequate provision for monitoring the data to be collected to ensure the safety of subjects;
- There are adequate provisions to protect the privacy of subjects and maintain the confidentiality of data; and,
- When some or all subjects are likely to be vulnerable to coercion or undue influence (such as children, prisoners, pregnant women, mentally disabled persons, economically or educationally disadvantaged, or are persons with limited English proficiency), additional safeguards have been included in the study to protect their rights and welfare.

2. IRB Review of Exempted and Expedited Protocols

The investigator will be notified after the initial reviewer makes his/her determination and, if approved, may begin their research. All approved exempted and expedited protocols are reviewed by the full IRB at its next meeting. The IRB may affirm or change the reviewer’s determination. The investigator will not be notified if the IRB affirms the initial determination. The investigator will be contacted by the IRB Chair and/or Administrator if the IRB does not affirm the initial determination to discuss the decision, the issues involved, if the research is to be temporarily suspended or terminated, what is required to obtain the approval of the IRB, and a date for fulfilling any requirements or answering any questions or concerns.

3. Full IRB Review Process

(i) After a protocol has been identified for full IRB review it is placed on the agenda of the next regular IRB meeting, the investigator is notified that the protocol will receive a full IRB review and when the meeting will take place. If the next regular meeting has not been scheduled, a meeting will be scheduled.

(ii) A list of all protocols for full IRB review is sent to each IRB member. A copy of each protocol is sent to the IRB Chairperson and at least one additional IRB member who, with the IRB Chairperson, are assigned as primary reviewers. The primary reviewers are responsible for recommending the IRB to: 1) approve the protocol as submitted; 2) approve the protocol contingent on specific revisions; 3) table the protocol for substantive change and resubmission to the IRB, or 4) disapprove the protocol. At the IRB meeting, each protocol is discussed by the entire IRB. The IRB may ask the investigator or other individuals to attend the meeting to discuss the research and/or provide information to the IRB on the area of research, research methodology or other issues related to the protocol. The IRB then determines if it will accept or not accept the recommendation of the primary reviewers. If the primary reviewers' recommendations are not accepted, the IRB may determine the disposition of the protocol. The IRB Chairperson will notify the investigator in writing of the action as soon as possible after the determination is made.

Activities related to each action will proceed as follows:

(a) Approval as submitted: The investigator will be sent an approval notice including a statement of his/her responsibility to report adverse reactions and request IRB review of modifications or revisions to the protocol. The investigator will also be informed of his/her responsibility to submit a summary of the project every twelve months for continuing review or more often if requested by the IRB.

(b) Approval contingent upon specific revisions: The investigator will be sent a notice describing the revisions requested with specific reply-by date. After revising the protocol and/or consent form and/or
testing instrument, the investigator will return one copy with the revisions underlined or highlighted to the IRB Chairperson. If the revisions are deemed satisfactory by the primary reviewers, an approval notice will be sent to the investigator. If the investigator disagrees with requested revisions, he/she may present in writing the reasons to the IRB Chairperson or IRB Administrator. The Chairperson/Administrator will review this response and negotiate with the investigator or request the investigator to attend the next IRB meeting to answer questions and discuss relevant matters. The investigator will be notified in writing of the IRB's final decision.

(c) **Tabled for substantive change or additional information**: The investigator will be sent a notice describing the reason for tabling IRB decisions and outlining revisions or clarifications necessary for reconsideration with a specific reply-by date. The investigator will submit his/her response to the IRB Chairperson for distribution to and review by the IRB. If the investigator disagrees with requested revisions, he/she may present in writing the reasons to the IRB Chairperson or IRB Administrator. The IRB Chairperson or IRB Administrator will review this response and negotiate with the investigator and then submit the changes to the IRB for action or may request the investigator to attend the next IRB meeting to answer questions and discuss relevant matters. Once the IRB Chairperson or IRB Administrator decide that the information received from the investigator fulfills the concerns of the full IRB, he/she will place it on the agenda of the next regular meeting.

(d) **Disapproval**: The investigator will be sent a notice describing the reasons for disapproving the protocol. Disapproval of the protocol usually occurs when the IRB determines that the risk of the procedures outweighs any benefit to be gained. The investigator may discuss the IRB's review with the Chairperson and/or submit a new or revised protocol for review at the next scheduled meeting. The investigator may request to appear at the next IRB meeting to discuss the protocol, the IRB's previous decision and relevant matters during the IRB's discussion of the revised protocol.

C. **Continuing Review Approval Process**

For studies described in Part II, Section D that require an annual review, that have changes, where there is a reportable event, or have been completed or terminated, the Continuing Review Face Sheet and attached materials are to be submitted to the IRB Administrator. The IRB Administrator will (a) review and determine if the investigator may continue the research until the IRB meets or should suspend the research, (b) if another response is required (as with a reportable event), (c) send the investigator a notice of this decision, and then (d) submit the submission to the IRB for review. The approval process will then follow the same process as the original protocol unless it is determined that the original type of review is no longer appropriate. If a new type of review is required, it will be handled as a new submission, beginning with the materials that the IRB already has in its possession.

D. **Institutional Endorsement**

Many external funding agencies or sponsors as well as WPU internal funding programs (such as the College of Science & Health's Center for Research) that fund research involving human subjects require certification by an authorized official of the institution that the research involving human subjects as described in the application has been approved for submission by an IRB. If the description of the research in the narrative description of the research and any related attachments that are part of the proposal is accepted by the IRB as a reasonable description of proposed practices regarding human subjects, the University will provide the sponsor with appropriate documentation of the IRB's approval of the proposal. Since the IRB Administrator is also the Director of the Office of Sponsored Programs, the IRB Administrator may only send the proposal to another member of the IRB for review and action to avoid the appearance of a conflict of interest. The member of the IRB who is assigned to the review will determine if the project will likely require an Exempted/Expedited review or if it will likely require a Full IRB review. If the research falls under either the
Exempted or Expedited review categories, the review can be completed by that reviewer. For research that will require a full IRB review, that reviewer as well as a second IRB member will review the proposal.

Institutional Endorsement is a “contingent approval” that is applicable only to the proposal that was reviewed. After the proposal has been funded, the investigator must submit a complete protocol to the IRB following the normal process and timeline. If the funding agency sets a “respond by” date for the IRB’s action, the IRB will make every effort to complete its review to meet this deadline.

E. 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. The decision to suspend or terminate will follow the process outlined above for disapproval of a protocol. For a situation outside of the continuing review process, 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. Either a special meeting of the IRB will then be called or the issue will be added to the agenda of the next regularly scheduled meeting by the IRB Chair to discuss, confirm or reverse the decision. The investigator may be invited to, or may elect to, attend the meeting.

F. IRB Records Retention

1. The WPU IRB, through the support of the IRB Administrator and the Office of Sponsored Programs, shall prepare and maintain adequate records documenting its activities, including copies of all research proposals, attachments and correspondence; minutes of IRB meetings which shall be of sufficient detail to show attendance, actions taken, votes by members, basis for changes to research or disapproval or suspension, and discussion of issues and their resolution; records of continuing reviews; list of IRB members with roles; and statements of significant findings provided to subjects. The IRB will maintain these records for a minimum of 3 years.

2. Investigators will retain records related to their research for a minimum of 3 years after the completion of their research, and such records will be accessible for inspection and copying by authorized representatives of the IRB and the sponsor at reasonable times, in a reasonable manner, and with reasonable notice.

Part V. Special Classes of Subjects and Special Considerations

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.

A. Federally Stipulated Special Classes of Subjects

Federal regulations provide specific requirements for three classes of subjects. Any research involving these classes of subjects must be reviewed by the full IRB unless the specific exemptions for each class are met. The primary reviewers and the IRB will refer to the appropriate subpart of 45 CFR Part 46 during its consideration of the protocol.

1. Fetuses and Pregnant Women (45 CFR Part 46, Subpart A). Exemptions for Fetuses: None. Exemptions for Pregnant Women: Only if there are no biomedical elements to the research plan, then Part II, Sections A and B apply.
2. **Children and Minors (45 CFR Part 46, Subpart B).** Exemption for Children aged 0 to 13 Years and for Minors aged 14 to 18 Years: Exempted and Expedited Review items as described in Part II A: Studies That Do Not Require Review and Part II B: Studies That Require Review if there are no biomedical elements to the research plan and the research does not collect sensitive personal information and/or request the subject to undertake an activity that may elicit a significant negative psychological or physical response. All children and minors must assent to their participation in research along with their parent/guardian’s approval for their participation; children and minors aged 7 to 15 years must also be involved in discussing the Informed Consent Statement and must sign the statement along with their parent/guardian to indicate their assent to participate. For research where the IRB judges that there is no sensitivity involved in the research topic or questions and where there is less than a minimal risk to participants, minors aged 16 to 18 may consent to participate without first obtaining consent from parents/guardians.

3. **Prisoners (45 CFR Part 46, Subpart B).** Exemptions: None. Since WPU cannot meet all of the requirements of the 45 CFR Part 46, Subpart B, all research involving prisoners (including individually confined or detained in a penal institution, detained in other facilities which provide alternatives to criminal prosecution or incarceration in a penal institution, or are detained pending arraignment, trial or sentencing) shall also be reviewed and approved by the IRB that is, or IRBs that are, appropriate for the subject population before it can be initiated. This will be included as a stipulation of the approval of the research.

**B. William Paterson University Stipulated Special Classes of Subjects**

1. **Individuals with Limited Ability to Voluntarily Participate in Research**

   a. Subjects who may perceive that their ability to participate freely and honestly is limited because of their specific personal circumstances and the subject of the research. This can be: (a) residents of a hospital, nursing home or other health care facility when the focus of the research is on the quality of their care, the type of procedures or tests they are or have received, or the facility’s staff; (b) employees of a business when the focus of the research is on the workplace, the employer or other employees; (c) students in a course or class when the investigator is the instructor and the subject of the research is not related to the course or exempt as per Part II, Section A; or (d) subjects who may be open to criminal prosecution, deportation, or civil liability based solely on their participation or their responses to questions. In these cases, additional safeguards will be used to shield responses from all individuals except the investigator and other project staff, to separate informed consent statements from testing instruments, by finding appropriate alternate means for documenting consent, and by avoiding questions or opportunities which require subjects to specifically identify themselves, other individuals or specific situations.

   b. 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, will have a witness 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. Such witnesses will be one of the following as defined in the research protocol and approved to by the IRB: legally-appointed guardians, immediate family members, counselors, teachers, or other appropriate individuals. Witnesses will remain present for the research and will be present for any subsequent renewal of informed consent unless the IRB waives this requirement in its approval of the research.

2. **WPU Students or Employees as Research Subjects**

   a. For students and instances where WPU faculty or staff use WPU students in research studies, the following guidelines are intended to (1) protect students from unintended coercion or unequal benefit from participating in research that involves face-to-face interviews or testing, observation in a controlled
location, or a similar activity that is beyond the scope of an anonymous survey, and (2) encourage students to voluntarily participate in research activities with option of providing extra credit. These guidelines do not supersede any course requirements, are not intended to restrict any faculty member’s freedom to make assignments or conduct their classes, offer extra credit, or infringe on any aspect of achieving the goals of individual courses unless these activities are in clear contradiction to the University’s IRB Policy.

A WPU faculty person may include students who are currently in his/her classes in research he/she is undertaking within the following contexts:

(i) Controlled, out-of-classroom, laboratory-based research.

(a) The professor will offer equal credit to his/her students in his/her class who: (a) participate in a research study for not more than 3 hours during the semester; (b) completes a ungraded short paper or other appropriate academic activity related to research as determined by the professor; (c) attends a research colloquium; and (d) other options.

(b) The professor will recruit students in his/her classes as he/she would recruit other students or WPU employees to be employees. These activities may include: (a) a publicly posted notice Volunteers register by calling the investigator, or (b) direct recruitment in his/her class, by other faculty in their classes, or individually as opportunities are presented. Volunteers may register on-the-spot or contact the faculty researcher directly later on. Recruitment posters or announcements will include information taken from the informed consent statement.

(c) The amount of optional credit toward a student’s final grade point average for participating in one of the three research activities would be up to the discretion of the professor. The IRB suggests a rate of 1 credit/100 credits toward the student’s final average for the class.

(d) Students would not be penalized beyond not receiving their extra credit for not showing up for a scheduled research appointment, for not completing a paper or for not attending a colloquium.

(ii) In-class or classroom-based research.

(a) When the identification of students is a required part of the study, students must be fully informed of the study and be provided with an appropriate method for not participating in the study, such as not completing but handing in a survey with a cover page masking answers. No course credits will be offered for participation and no penalties will be assessed for non-participation. To insure student confidentiality and to eliminate the potential impact on grades because of a choice not to participate, survey or other responses will remain sealed until the end of the semester and grades are submitted, and no student names will be used reporting results.

When the research involves after-the-course analysis of student work product, such as reports, tests or participation in online course software tools, students must still be offered the opportunity of informed consent but consent statements will remain sealed until the end of the semester and grades are submitted, and no student names will be used in reporting results.

(b) When the identification of students is not a required part of the study (that is, participation is anonymous), students must be fully informed of the study and be provided with an appropriate method for not participating in the study, such as not completing but handing in a survey with a cover page masking the unanswered survey. A WPU faculty person may not include students who are currently in his/her classes if the research involves an issue that may affect the faculty’s perception of that student (such as sensitive issues like sexual attitudes or behaviors, racial attitudes, mental health, the use of alcohol or illicit drugs, cheating, plagiarism, or illegal activity). Surveys or other research tools will remain sealed
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until the end of the semester and grades are submitted because of the potential that answers will have an impact on one or more students. Additional confidentiality safeguards may be required by the IRB based on the research plan and need to identify individual student’s data.

b. For employees, the same concerns and process in paragraph 2 (a) of this section applies. The IRB encourages the use of employees in research undertaken at WPU.

C. Other Special Considerations

1. Sensitivity of Questioning

Subjects can be harmed psychologically in the course of a survey or interview study as well as in manipulative experimental situations. It requires sensitive anticipation to avoid these apparently innocuous intrusions. Subjects are often asked to reveal unpopular attitudes, such as resentments toward some social group, or possible demeaning social characteristics, such as low income or receipt of welfare payments. The subjects may be led into admissions or behaviors that in later reflection they find to be deviant, immoral, unjust, humiliating or overly embarrassing. Such research situations should be designed carefully, to provide a supportive context, and only carried forward if the threats to subjects’ comfort are essential and severely minimized.

2. Medical Records and Chart Review

Studies which involve only chart and record review sometimes pose significant risk to patients. The most common breach of confidentiality is exposure of possible embarrassing information without the knowledge or consent of the patient. Such studies may also lead to recruitment of patients into future non-therapeutic studies in a manner which may provoke the patient to ask how his/her record was revealed to someone not part of his/her therapeutic team. The present policy is to require review of studies involving chart review or data collection and analysis to:

a. When the possibility of contacting patients or their physicians is contemplated.

b. If identifiable information will be collected or disclosed to anyone other than the investigators. An expedited review should be requested for studies in this category. (See Part III.A for studies eligible for expedited review).

If the research will be conducted at a “covered entity,” the investigator may be required by HIPPA to obtain authorization from the entity’s privacy board before the research may be initiated.

3. Student Records

Studies which involve the collection an use of information from student records may fall under FERPA or other laws and regulations. Students, and their parents/guardians when appropriate, must provide specific approval to the investigator for their records to be accessed. This would not include pedagogical research as described in Part II, Section A unless it is considered an exception.

4. Residual Body Fluids, Tissues and Recognizable Body Parts

Studies which utilize residual bodily fluids, tissues and/or recognizable body parts from clinical laboratories, pathology laboratories, or other clinical or hospital settings which may or may not be personally identified or linked to a subject must be reviewed. Investigators conducting research of this nature should be familiar with the policies regarding recognizable human body parts and the promulgated standard entitled, "Occupational Exposure to Blood-borne Pathogens." Information in this regard may be obtained by
contacting the IRB Chairperson and/or IRB Administrator. Expedited review of such studies may be authorized if all of the following circumstances exist:

a. The fluid, tissue or body part is obtained in a procedure that is entirely predicated on clinical grounds or donated through the Gift Registry.

b. Consent has been obtained for the procedure.

c. Extra fluid or tissue is not removed, and the materials used for research is that remaining after clinical use.

5. Emergency Approval for Medical Care

Nothing in these regulations is intended to limit the ability to provide emergency first aid or limit the authority of a physician to provide emergency medical care, to the extent the physician is permitted to do so under applicable federal, state, or local law. Questions concerning emergency approval should be directed to the IRB Chairperson and/or the IRB Administrator.

6. Research Involving Administration and Use of Ionizing Radiation

To comply with regulations of the U.S. Nuclear Regulatory Commission, any use of radiation or radioactive materials requires approval by the University. Information in this regard is available from the IRB Chairperson. In addition to submission for full IRB review, all protocols involving ionizing radiation for other than clinical management must be approved by a cooperating sponsoring institution with a nuclear license. Questions concerning the administration and use of ionizing radiation should be directed to the IRB Chairperson and/or the IRB Administrator.

7. Research Involving Human Blood, Blood Products, Body Fluids or Tissue Specimens

The Occupational Safety and Health Administration (OSHA) promulgated a standard entitled, "Occupational Exposure to Blood-borne Pathogens" that took effect March 6, 1992. The standard, which recognizes unique hazards to health care workers, applies to all laboratories and clinical settings that use human blood, blood products, tissue specimens or body fluids. It requires the employer to provide annual training in the proper handling of blood-borne pathogens. Training is available for University personnel. Proof of training should be attached to the protocol. Questions concerning research involving human blood, blood products or tissue specimens should be directed to the IRB Chairperson and/or the IRB Administrator.

If blood is going to be drawn, it must be drawn by a trained health care professional (such as a physician, nurse, phlebotomist, physician’s assistant who is affiliated with a licensed practice or facility, etc.). If none of these are available, then the person who will be drawing blood must be identified and proof of proper training is required for that person.

Part VI. Training Certification

A. Requirement

1. 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.

Certification of the successful study of the ethical principles governing research involving human subjects and the requirements and processes related to the conduct of human subject research at WPU will be provided by reputable organizations selected or approved by the IRB or the Associate Provost for Academic Affairs. The certification must represent a course of study covering all issues deemed essential by the IRB.

2. This requirement applies to:

a. Faculty, professional staff and others who are the principal investigator, co-investigators, senior-level project support, or other project support staff who have direct contact with subjects in any manner, with original data collection tools/resources, or with information that identifies subjects.

b. Faculty teaching courses requiring students to actively engage human subjects in research that falls under the purview of this policy.

c. Master’s degree and undergraduate students who are undertaking human subject research for a course that does not normally include human subject research AND when the course faculty is not certified.

d. Master’s degree and undergraduate students who are undertaking human subject research for a course that does not normally include human subject research AND when the course faculty is not certified.

f. Doctoral students who will be actively engaging human subjects in research as part of their degree requirements.

d. All members of the IRB, the Responsible Institutional Official, the IRB Chair, and the IRB Administrator.

e. Administrators not directly involved in the research but who are in a supervisory position over an investigator, such as Vice Presidents, Associate and Assistant Vice Presidents, Directors of administrative units, Deans and Department Chairs of academic units will be required as needed if faculty and staff in their units are involved in human subject research and/or have courses and/or students that include or undertake human subject research.

g. Outside researchers who wish to undertake research on the WPU campus or involving WPU students, faculty, staff or visitors. (Certification obtained by at the home institutions of outside researchers may be submitted for review by the WPU IRB; the WPU IRB may accept an appropriate level of knowledge competency of the WPU requirements and processes as demonstrated in the outside researcher’s protocol.)

3. This requirement does not apply to: (a) Project staff that does not have contact with subjects, original data or identifying information. (b) Undergraduate and master’s degree students 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.

B. Process

Certification: To assist investigators, project staff, instructors, students, administrators and others in the fulfillment of this requirement, an online training certification program will be developed and maintained that will be accessible through the IRB’s webpage (www.wpunj.edu/osp/irb). The program will address both Federal and local concerns and requirements. The University will maintain a record of certifications.

Alternate Certification: The University will review and accept/reject certification from other institutions and require completion of a WPU-specific module as needed if (a) the certification or a subsequent refresher
certification is not more than three (3) years old and (b) the course did not cover primarily bio-medical human research ethical concerns.

C. 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 or the program they completed does not have a refresher course within three years of completion. This new certification will be required prior to the approval of a new protocol.

For faculty or staff who were initially certified through the Alternate Certification process, they must complete a new certification when it is time for their refresher course. While this will require duplicating training, subsequent refresher courses will then occur as they would for other investigators.