William Paterson University

Institutional Review Board for Human Subject Research

IRB Procedures Manual

These procedures are posted on the IRB's website. They are updated periodically to reflect changes in process motivated by new guidance, changes to Federal, State or Sponsor regulations, requirements or advice, or improvements to WP's processes related to the use of human subjects in research.

January 2022

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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.

It is the IRB's expectation that every member of the WP community acts ethically at all times.

The IRB expects every investigator to be familiar with WPU's IRB Policy (www.wpunj.edu/osp/irb), the Belmont Report, the Common Rule, the unique requirements of a sponsor, and any State or Federal regulations that may impact the use of subjects but is not specifically part of or a consideration within this policy.

The IRB expects that **ALL** investigators who intend to use human subjects in research have provided documentation of training in the ethics regarding the use of human subjects in research to the IRB (See Part V), that subjects are treated in an appropriate manner, and that subjects have an opportunity to provide informed consent or assent concerning their participation for all research. This expectation includes both research that is reviewed and approved by the IRB and research that is not reviewed by the IRB.

We encourage users of this manual to contact the IRB with questions or concerns regarding this manual (from formatting and section headings to procedures and requirements) so that we can keep it appropriately up-to-date and clear.

Part I: Review Requirements

All WP faculty, staff and students must submit a protocol to the IRB if their study involves human subjects unless it is specifically excluded from the IRB's oversight. For most investigators, a complete protocol includes a signed face sheet, a narrative describing the research, and probably attachments that include consent statements, survey or interview questions, recruitment materials, documentation of human subjects training or other items. Undergraduate and master's degree students have a form to complete and submit, also signed and with attachments. External investigators who wish to conduct research at WP have requirements similar to WP's investigators.

All investigators must conform their research with other WP policies, Federal and State laws, regulations and requirements may apply, such as the Family Educational Rights and Privacy Act (FERPA), and requirements imposed by the site where the research will be undertaken, such as school district policies on research and videotaping. This is a requirement whether or not the IRB reviews and approves the research. These laws, regulations and requirements must be addressed appropriately.

When research, whether approved or not reviewed is conducted at an institution other than WP, the rules, regulations and policies of that institution have precedence over WPU's Policy and the decisions of the WPU IRB.

A. Studies That Do Not Require Review

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.

1. Excluded from review by any IRB by The Common Rule, 45 CFR Part 46:

   (a) Scholarly and journalistic activities (*e.g.,* oral history, journalism, biography, literary criticism, legal research, and historical scholarship), including the collection and use of information that focus directly on the specific individuals about whom the information is collected.

   (b) Public health surveillance activities, including the collection and testing of information or biospecimens, conducted, supported, requested, ordered, required, or authorized by a public health authority. Such activities are limited to those necessary to allow a public health authority to identify, monitor, assess, or investigate potential public health signals, onsets of disease outbreaks, or conditions of public health importance (including trends, signals, risk factors, patterns in diseases, or increases in injuries from using consumer products). Such activities include those associated with providing timely situational awareness and priority setting during the course of an event or crisis that threatens public health (including natural or man-made disasters).

   (c) Collection and analysis of information, biospecimens, or records by or for a criminal justice agency for activities authorized by law or court order solely for criminal justice or criminal investigative purposes.

   (d) Authorized operational activities (as determined by each Federal agency) in support of intelligence, homeland security, defense, or other national security missions.

2. The following less-than-minimal risk research is excluded from review by the WPU IRB. This list is based on the exempt research categories described in 45 CFR Part 46, Section 46.104(d).

Type of Research	Definition	Examples	Exceptions that require review and approval by the IRB.
Institutional, Departmental and Program Assessment	Research conducted by the administration, faculty and staff on the operation of the University in accomplishing its mission, goals, objectives and priorities.	Research by the Office of Institutional Effectiveness. Program Assessment conducted by an academic unit.	Research on secondary concerns of the University will require review.
Pedagogical Assessment by Instructors	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	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.	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,

Type of Research	Definition	Examples	Exceptions that require review and approval by the IRB.
	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.	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.	• 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.
External Research that Requires Very Minimal Involvement by the WPU	The recruitment of subjects through the posting of flyers or publication of advertisements in student newspapers or campus bulletin boards 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. This should be a small-scale effort.	Advertisement in the Beacon for subjects for a statewide epidemiological study conducted by investigators from another institution. Posters in public places recruiting subjects who will be compensated for participating in marketing or scientific research.	Studies that require WPU to partner or enable the research by providing email addresses to the investigator or to distribute surveys or recruit subjects for a focus group on behalf of the investigator.
Research regarding business practice or teaching practice	The study of official policies, procedures and practices in a business setting or educational context.	Contacting a business, public or private school, or non-profit organization for policies, practices, and outcomes regarding their activities, especially when all or some of that information is already publicly available. Contacting administrators and teachers in schools or districts to gather information regarding teaching practice, school/district policies, or	When the research includes collecting the personal opinions of employees or leaders of an organization regarding the policies, practices and outcomes of that organization that are the subject of the research. For example, if an investigator contacts a business for information on its inventory control procedures, this research would be excluded from the IRB's review unless the

Type of Research	Definition	Examples	Exceptions that require review and approval by the IRB.
		other professional topics and questions.	study included questions regarding the impact of the control process on employees.
Secondary Data that is publicly available and anonymous	Data available through a clearinghouse, library, or agency with either no or minimal barriers to access unless that data includes identifiable private information. Social Media: Aggregated data provided by sites, comments that are anonymous or where screen names are not usually personal names, and where privacy policies allow for the use of data and statements in research.	A dataset that is available publicly to anyone at any time. A dataset that is available through a discipline-specific data warehouse that was created to share data among students, professionals or investigators in that discipline. Aggregated data provided through publicly available pages within a website, whether that is available anytime or by request. A social media site that encourages the use of screen names, handles, avatars or other methods for not disclosing user identities (even if some users choose to use their names).	See the section on Secondary Data, III.A.2.b. Privately held data. Data that is provided by an agency or organization for which special permissions are required, the investigators are identified and have specific requirements for managing the data, and WP must endorse the research and the investigators research in order to obtain the data. Data that includes identifiable private information. Data that is subject to protection, such as data that is covered by FERPA or HIPAA. Social Media: Individual-level data drawn from sites where subjects identify themselves, such as Facebook or YouTube. A private social media page where members expect postings to be private conversations or are only meant for other members. Examples include sites operated by a professional association for its members or are moderated sites where members are added based on certain criteria.

Type of Research	Definition	Examples	Exceptions that require review and approval by the IRB.
			Secondary data from any source or social media site when that source's or site's privacy policies include restrictions related to the data an investigator wants to collect or the methodology for collecting that data.
Research by Undergraduate and Master's degree students	Research required for a course or program of study that (a) will not be used or shared outside of the course for which it is undertaken or another setting at WP, or (b) does not include a special class of subjects unless the WP student is conducting pedagogical research involving students for whom they are the teacher-of-record.	An anonymous survey for other WPU students (who are at least 18 years old) on campus educational, personal, cultural or social issues. An interview concerning educational, personal, cultural or social issues that does not collect personal identifying information other than a signature on an informed consent statement. A capstone research project that will be presented to any WPU audience, such as Explorations, Honors Research Week, or a dissertation presentation (including when that presentation may include non-WPU faculty or staff).	Research that involves subjects who are identified by this policy as a special class of subjects (who are not the students of the investigator). Research that involves a special class of subjects that are not normally a group of individuals involved in research by students in the department of the course requiring the research. Research that collects personally identifiable information beyond a name on a consent form. Research that places the student investigator(s) at risk. Research that may be used as the basis for a presentation at a conference, for training, or for sharing with individuals at the workplace where the research was conducted unless that location was WP.

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 regulation, WPU requires that all research projects conducted by faculty and staff involving human subjects or biospecimens (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 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 unless it is a type of research identified in Part 1, Section A of this policy as not requiring review.

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

The IRB will determine if the proposed research should be 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 (www.hhs.gov/ohrp) and the WPU IRB's webpages (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 46.104. 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. 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. WPU Undergraduate and Master's Degree Students That Require Review

Only human subject research by undergraduate or Master's degree students at William Paterson University that will be shared outside of WP requires formal IRB review unless one of the exceptions (below) apply. See Part I, Section A.2 for the description of what should be submitted. For example, an Honor's College capstone project that is presented during Honors Week would not need IRB review unless there was a specific intent before the research begins to present at an academic conference such as the Eastern Psychology Association or a specific academic journal.

The final determination is by the course faculty, probably in conversation with the student, as to whether or not a student's research should be submitted to the IRB.

The only exceptions to this are when the study:

- Involves a special class of subjects (vulnerable population) as described in Part IV. Examples: (1) The study will include an intervention by the investigator with pre-school children would be submitted. (2) An observation of the intervention and then gaining access to the data collected would not be submitted.

- The study collects personal, identifying information beyond a signature on an Informed Consent Statement. Examples: (1) The study collects names, email addresses or phone numbers in an online survey to facilitate contacting subjects for later interviews would be submitted. (2) A link to a separate survey to collect contact information in a separate dataset, whether or not there is a connecting code between the datasets, would not be submitted.

- The study has potential physical or psychological risks for the researcher. Examples: (1) The investigator interviews gang members about gang activity would be submitted. (2) The investigator interviews family members about their gang affiliation and activity would not be submitted.

If a student's research is not submitted to the IRB and then the student and her/his professor decides to present or publish the results of the study, the professor should contact the IRB Administrator.

D. Requirements for Continuing Review after Initial Approval

1. Annual Review

Faculty, Staff, Doctoral Students and Outside Researchers: All research protocols involving human subjects that require review by the IRB must be reviewed at least every 365 days as long as the project is continued. The IRB may require more frequent reviews depending on the risk factors associated with a protocol.

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.** Approval of these protocols will expire and protocols will be administratively closed by the IRB at that time. Should the applicant desire to continue the research beyond this one year period, a continuing review must be submitted to the IRB at least 30 days prior to the expiration of the protocol. Note, once a protocol is expired or administratively closed, all research activities involving human subjects must stop.

While the 2018 revision of 45 CFR Part 46 allows for an IRB to not collect annual reviews for exempted or expedited research, the WP IRB will continue this requirement for expedited protocols. Continuing review requests of full-board and expedited protocols must be submitted to the IRB at least 30 days prior to the expiration of the protocol by the lead investigator.

Failure to submit a continuing review in a timely manner or to submit a complete continuing review package, will result in the administratively close the protocol. Once approval expires or a protocol is closed, all research activities must stop. IRB protocols cannot be "re-opened." Should an investigator desire to

continue prior research under a protocol that has expired, a new protocol must be submitted for review. Note, use of human subjects data collected under the prior IRB approval must be requested as part of this new IRB protocol. Analysis of previously collected human subjects data or materials is not permitted without an approved IRB protocol.

2. Substantive Changes to the Protocol

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 investigator submits Appendix D, with a complete description of all changes to be made as well as revised consent statements, testing instruments, flyers or other items.

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.

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 its 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 II. 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) 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 research protocol will receive an Exempted, Expedited or Full IRB review, or if the research is excluded from review by the IRB (See Part I, Sections A to D).

3. The IRB's role is not to comment on the research design of a proposal except as it impacts subjects. 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. Records are destroyed after 3 fiscal years after a protocol is closed.

5. It is the goal of the IRB that the initial review of all complete protocols be completed in three calendar weeks.

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. IRB board membership consists of: (1) Representatives of each of the University's Colleges as follows: Business, 1 representative; Education, 3 representative; Arts, Humanities and Social Sciences, 2 representatives; and Science & Health, 2 representatives. (2) Outside Members: 1 individual who has no other affiliations with the University (3) Consultants, advisors and other non-voting individuals may be appointed to the IRB as deemed necessary by the IRB and/or the University.

3. IRB Alternate members shall also be representative of the university's college, outside members, or other personnel. During the first year of a new IRB member's first term, the IRB member shall serve as an alternate. IRB alternate members are not expected to attend all meeting, but may be called upon to attend in an IRB members absence. IRB alternate members may also be called upon to complete initial reviews of exempt, expedited protocols, or full-board protocols, annual continuing reviews, and other responsibilities of IRB members on an as needed basis.

4. Of the IRB members and alternates 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.

- *HHS regulations at 45 CFR 46.107(c):* Each IRB shall include at least one member whose primary concerns are in scientific areas and at least one member whose primary concerns are in nonscientific areas.

  Scientist/Nonscientist - Members whose training, background, and occupation would incline them to view scientific activities from the standpoint of someone within a behavioral or biomedical research discipline should be considered a scientist, while members whose training, background, and occupation would incline them to view research activities from a standpoint outside of any biomedical or behavioral scientific discipline should be considered a nonscientist. In addition, the IRB must have members with sufficient knowledge of the specific scientific discipline(s) relevant to the research that it reviews.

4. Terms of Office and Appointment/Election: All IRB members will serve a term of three years and may continue to serve terms for at least 2 consecutive terms. Upon completion of the second term, IRB members may elect to serve as an IRB Alternate member or to resign from IRB service. During the first term of service of any board member who had not previously served on the IRB, the member will serve as IRB Alternate. After successful completion of the first year, this member will continue the balance of their three year term as an IRB board member. IRB Alternates are expected to serve one-year terms. All IRB members are appointed by the Responsible Institutional Official on the recommendation of the IRB and the IRB Administrator. 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 the IRB Administrator serve as ex-officio members of the IRB without specific term limits.

5. All members must provide signed resumes to be maintained by the IRB to document their expertise at the time of initially joining the IRB and upon the start of a new term of service. 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 at least three (3) regularly scheduled meetings each semester at which a quorum will consist of a majority of the current members of the IRB (minus the Responsible Institutional Official) 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 subcommittees and IRBs for special purposes and for specific lengths of time. An ad hoc subcommittee may not act on behalf of the IRB. An ad hoc IRB may be empowered to act on behalf of the full IRB and this must be clearly stated in the charge to the IRB when it is created. Minutes of ad hoc subcommittee and IRB meetings will not be required unless the ad hoc subcommittee 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 III. 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, (f) documentation of training in the use of human subjects and in conflicts of interest and (g) a Conflict of Interest and Commitment Disclosure Statement. Submit all documents (PDF or WORD only) via email to the IRB administrator via IRBadministrator@wpunj.edu .

(ii) Outside Investigators submit (a) Appendix B: 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 all documents (PDF or WORD only) via email to the IRB administrator via IRBadministrator@wpunj.edu .

(ii) 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, (e) documentation of certification of training in the use of human subjects and (f) other materials/information as needed. Only fully signed forms will be accepted. Submit all documents (PDF or WORD only) via email to the IRB administrator via IRBadministrator@wpunj.edu .

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 an electronic Appendix D and email revised materials to the IRB Administrator. Investigators may also submit one Appendix D form with a copy of a report on the status of the research, other materials/information attached as needed.

c. Institutional Authorization Agreements (IAA)

Institutional Authorization Agreements (IAA) or "Reliance Agreements" are used to enable an IRB at one institution to be the "IRB-of-record" or "lead institution" for a collaborative research protocol. This is useful in a number of situations, for example:

- An investigator at one institution will be working on research entirely at another institution or location without involving their home institution. Little to no involvement of the "secondary" institution may be needed beyond identifying the investigator's involvement.

- The study is a large, multi-institutional project with a high expectation for consistency or coordination across research sites, and the strict requirements of the research methodology must be carefully followed by each research location. All partners are involved in substantive ways that may require sharing resources and collaboration agreements.

The following procedure will support the use of IAAs at William Paterson University.

1. Identification of Opportunity and Lead Institution: When the research involves a collaborator from outside WP, the research plan is reviewed to determine if the opportunity exists for the use of an IAA and whether WP or the collaborator's institution will serve as the lead institution.

2. Completing IAA when WP is not the lead:
   a. The lead institution provides their template, a copy of the award notice, and a copy of the protocol as it was approved to WP's investigator. WP's investigator completes an Appendix A form and attaches the items provided by the lead institution. The protocol is logged.
   b. The IRB Administrator reviews the protocol package and determines if sufficient information is included in the protocol to fulfill WP's requirements.
      - If there is, the IRB Administration completes the form and submits it to the Associate Provost for Academic Affairs for review and signature.
      - If there is not, the IRB Administrator obtains the additional information from WP's investigator until satisfied and then completes the form and submits it to the Associate Provost for Academic Affairs for review and signature.
   c. The IRB Administrator returns the signed form to the lead institution and receives a fully signed copy back.
   d. The IRB Administrator forwards a copy of the completed IAA to the WP Investigator with an approval notice that includes instructions to follow the requirements of the lead institution's IRB.
   e. Annual Continuing Review and Review of Modifications are not required.
   f. Reporting of adverse reactions and completion of the study are required.
   g. The IRB Administrator will place all reports and updates are received from the collaborating institution to the protocol packet.

3. Completing IAA when WP is the lead:
   a. When the IRB's review of the protocol has been completed, the IRB Administrator will prepare an IAA form and send it to the IRB at the collaborating institution for review, completion and signature.
   b. When the IAA is received back, the IRB Administrator will submit for signature by the Associate Provost for Academic Affairs.
   c. The IRB Administrator will forward copies of the completed form to the WP investigator and the collaborating institution's IRB.
   d. When continuing reviews are completed, a copy of the signed approval notice will be forwarded to the collaborating institution's IRB to document oversight.

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

The IRB recognizes that research involving human subjects conducted by investigators at William Paterson University can occur in many different ways and locations. It can be conducted by students, faculty and staff as well as by outside investigators. It can be conducted here, in another state, or in another country. Collaborators may be local, from another state, or from another country. Students may be working with a significant level of independence or may be closely supervised in a lab or clinical setting. WPU's faculty and staff may be the lead investigators but they may also be co-investigators or research assistants.

Every protocol submitted to the IRB needs to provide a complete description of the research that is not reliant on related research plans or protocols reviewed at other institutions. The protocol narrative is the research plan presented according to factors which the IRB considers essential for its review. A protocol narrative must be presented in the following order.

(a) General Requirements for All Protocol Narratives

1. Purpose of the Research

- Summarize the purpose of the study.
- State the hypotheses or the guiding questions for the study.

2. Use of Research Outcomes

- State how and when will the results or outcomes of this research be shared or disseminated to scholars, students, or the general public.
- Identify what publications, conferences or other means for disseminating the results are intended at the outset of the research.

3. Background and Need

- Provide a brief summary of the relevant literature in the area of interest for this research.
- Describe succinctly and clearly your related past studies and their findings, previous sources of support both internal and external awards and describe how they are related to this research, and reports and publications related to previous studies.
- Describe how the outcomes of this research will advance the state of knowledge for this area of interest.

4. Duration and Timeline

- Provide an estimate of the duration of the entire study.
- Provide a timeline for the study.

5. Research design

- Prepare an orderly scientific description of the intended procedures as they directly affect subjects. Include:
    - the number of subjects
    - the estimated length of time for subjects' overall involvement
    - include the length of time for various research tasks (e.g., interviews, completing questionnaires, etc.)
    - the frequency of repetition of tasks
    - activities that may cause discomfort or inconvenience
    - details regarding doses and routes of administration of drugs
    - details regarding the amount of blood to be withdrawn as well as the procedures used in the drawing of blood
    - plans for follow-up or ongoing contact with subjects
- If there is a point at which the study procedures may be discontinued, state how this point will be determined.
- Describe how unexpected events will be identified, reported to the IRB, and managed.
- Attach to the protocol copies of all surveys, questionnaires, rating scales, observations scales, or other data collection materials that will be used.
- Attach copies of invitations, fliers, emails, announcements or other activities to recruit subjects.
- Describe how data will be collected and analyzed. Identify software products and analysis techniques.
- Identify the individuals who will be involved in conducting the study by name or title, institution, their responsibilities, identify whether or not they will have access to confidential information of subjects, and, if they are from another institution, how their involvement in this research will be reviewed and monitored by their institution's IRB.
- <u>If research will be conducted over the Internet</u>: describe how this will occur, name the tool or

program that will be used, describe the tool(s) or programs that will be used, indicate how the tool(s) or programs will insure the confidentiality or anonymity of subjects, and provide both a link to the draft online tool(s) or programs and attach a printed copy.

- 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, how long the recordings will be maintained after creation, and describe how and when the recordings will be destroyed.
- If drugs or devices are administered or used: State if the drug or device has FDA approval. Provide the name of the drug or the device and the company that produces it. If the drug or device is investigational, provide its Investigational New Drug (IND) or Investigational Device Exemption (IDE) number. If the drug or device is already on the market, describe whether or not this research is within the scope of its approval, the dose level or activities you plan, the means for administering doses or enabling use. Clinical drug and medical device trials should have a copy of an indemnification clause attached to them with the appropriate signatures. The IRB encourages attaching flyers, brochures or other information from manufacturers to aid in its understanding of the drug or device and its use in research.

6. Location

- Provide the specific name of the school, business, clinic, hospital or other agency, facility or business from which subjects will be recruited or where the research will take place.
- For research locations other than WPU: provide documentation confirming that the facility has agreed to participate in this research and information regarding IRB review. Please note that 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.

7. Storage and Disposition of Data and Recordings: The IRB **recommends** the following practices regarding the safe storage of data and recordings. These recommendations represent the IRB's core concerns about protecting access to data, subject anonymity and flexibility related to the particular situation of the research. Investigators may offer alternative plans but those plans will be assessed against these recommendations. A detailed plan regarding the safe storage of data and recordings must be included in every protocol.

The data storage requirements of (a) sponsors who are supporting the collection and sharing of data and recordings, (b) publishers, or (c) organizations that provide access to data or datasets (paid or free) must be respected and followed even if they contradict these guidelines. If this is known when the protocol is submitted, this should be included in the protocol. If this is learned after the protocol has been approved, this should be communicated to the IRB as a change using the Continuing Review process.

Length of time data and recordings may be retained and how it may be destroyed:

- *Original data* and recordings ***with identifiable personal or corporate information*** *should be destroyed when it no longer has to be retained. If there is not an alternative requirement, the IRB recommends a period of up to three years after the last publication for when data* and recordings *are destroyed or anonymized.*
  - *Paper records cannot be anonymized and so should be shredded (by the investigator or by WP's Storeroom (call them for details).*
  - *Electronic records should be deleted from all computers and storage devices; this should also include backup files.*
  - *Electronic records can be anonymized by creating a number for each record and removing or coding the identifiable information so that it would be very difficult for a knowledgeable individual to identify subjects.*

  - *Electronic recordings can be anonymized by the digital manipulation of the subjects' voices, the saving of the manipulated file as the only recording, and the deletion of the original recording from all computers and storage devices.*
- *Original data **that never included identifiable personal or corporate information** can be retained as long as practical for the investigator(s). This data does not have to be destroyed.*
- *Original data **from which all identifiable personal information has been removed** can be retained as long as practical for the investigator(s). This data does not have to be destroyed.*

Basic Considerations for All WP Investigators

- During the period when data is being collected and analyzed, it must be stored in a secure location with limited or controlled access by anyone other than the investigator(s).
- During the period when data is being collected and analyzed, signed consent forms (if used in the project) must be kept separately from the original data and any forms of the data that are not anonymized.
- If there is a document or file used to connect consent and/or contact information with data (example: a key or code sheet), it must be stored safely and securely, separately from the data and consent forms.
- Data stored electronically must be on a password protected *desktop or network* computer or a password protected external hard drive. This applies to data that DOES or DOES NOT include identifiable personal information. Campus computers and network storage drives are password protected and safe for data storage.
- The use of "cloud drives" is discouraged for long-term storage of data but could be allowable if (a) the data is a de-identified copy of the original data that is stored on a secure computer, (b) the level of password protection is considered highly secure (a 13+ character password using upper and lower case letters, numbers and symbols), and (c) there are a small number of individuals with access to the data.
- Laptop and tablet computers, flash drives (aka: thumb, memory card, memory stick), cloud drives and other portable memory devices should only be used for the temporary storage of data. The device or the files should be password protected. This data should be transferred to a password protected computer or hard drive at the investigator's earliest opportunity.

Additional considerations for WP Faculty, Staff and Doctoral Students

- For doctoral students, original data and consent statements may be stored at home in a manner that meets the Basic Considerations.
- For faculty and staff, original data and consent statements should be stored on campus using WPU's secure servers and offices.
- Copies of anonymized data can be stored at home or in other locations in a manner that meets the Basic Considerations.
- When data sharing is required by a sponsor of the research, or if data is voluntarily shared with other investigators, the data provided must be anonymized.
- When the research is part of a multi-site project, the protocol should be clear in indicating which institution will be responsible for storing data and, if it is not WP, to provide a summary of the data storage plan.

8. 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 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 incentives or 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 in person by group. All draft advertisements, letters, emails, or other recruitment tools must be attached to the protocol.
- If applicable, describe in detail how subjects will be recruited electronically 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-party supporters of the research (such as a professional association or a physician's office) are providing the source for subjects and how they may be involved in recruiting subjects. Third-party recruitment letters, emails and other communication with prospective subjects must be included as an attachment to the protocol.

9. Protection of subjects: The protection of the identity of subjects is a primary expectation of the Belmont Report, the Common rule, and WPU. The WPU IRB recommends that data be collected anonymously or that codes be used to mask identifiable private information whenever possible. The WPU IRB requires that individual data is never reported, and that aggregate data is not published in a way that could potentially identify subjects. A detailed plan for protecting the identity of subjects must be included in each protocol. The plan should include the following, based on the structure and needs of the research:

- 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 that include witnesses, describe how witnesses will be advised regarding the information they learn about subjects.
- 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.

10. Consent Procedures

- Part III, Section 5 for information regarding types of consent and language that is required to be included in an informed consent statement.

- Describe consent procedures to be followed, including how, when, where, and by whom informed consent will be obtained.
- Describe assent procedures to be followed for subjects for whom consent was provided by a parent/guardian, legal or medical power-of-attorney, or another individual/agency.
- For research that includes witnesses of consent, a complete justification must be provided as to why obtaining consent is impracticable without witnesses. Include a description of their role and detail their engagement with the subject throughout the research
- 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.
- For electronic research using passive consent, describe how subjects will confirm their consent to participate.
- For electronic research using active consent, describe how subjects will provide their name or other identifying information to confirm their consent, how investigators will determine if the subject provided that consent, and, if no other identifiable personal information is collected, how names will immediately be removed from or masked within the data to protect the anonymity of subjects.
- Attach all informed consent statements.
- If subjects will have limited ability to understand 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.

11. 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.

12. Potential benefits

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

13. Risk/Benefit Analysis

- Analyze the ratio of the benefit and risk to be obtained from the study relative to the risks involved.

(b) Secondary Data: Items 7, 8 and 9 of (a) General Requirements are replaced by this section.

7. Subject Recruitment and Selection

- Identify the name and source of the data that will be used.
- Identify any security, special conditions, and endorsement/signature requirements established by the source of the data.
- Identify the data elements included in the original dataset, including those elements that include identifiable private information.
- Identify the data elements that will be used for this research.

8. **Protection of Subjects**
   - If the original data contains identifiable private information, how will that information be masked, removed or shielded from investigators during the research?
   - How will data be reported to limit the ability of knowledgeable individuals from identifying subjects or research locations?

9. **Consent Procedures**
   - Identify whether or not subjects provided informed consent when the data was collected or how the data was collected without consent.
   - For data sets created after January 19, 2019, provide documentation that subjects provided broad consent and describe how information from subjects who did not provide broad consent will be excluded from this research.

(c) Biospecimens: Items 7, 8 and 9 of the General Requirements are replaced by this section.

7. **Subject Recruitment and Selection**
   - Identify the name, source and type of the biospecimens that will be used.
   - Identify any security, special conditions, and endorsement/signature requirements established by the source of the data.
   - Identify if personal information regarding the source of the biospecimens (apart from the DNA) is included with the biospecimens.

8. **Protection of Subjects**
   - Describe the conditions that the investigator and WPU will be required to fulfill regarding the storage and use of the biospecimens. Describe the investigator's and WPU's plan for fulfilling these requirements.
   - If the biospecimens are received with data containing identifiable private information, how will that information be masked, removed or shielded from investigators during the research?
   - How will access to the biospecimens be controlled to limit the opportunity for DNA analysis of biospecimens.

9. **Consent Procedures**
   - Identify whether or not subjects provided informed consent when the biospecimens were collected or how the biospecimens were collected without consent.
   - For biospecimens obtained after January 19, 2019, provide documentation that subjects provided broad consent and describe how the specimens from subjects who did not provide broad consent will be excluded from this research.

2. Protocol Narrative Content Requirements for Outside Investigators

Outside investigators must submit an Appendix B Face Sheet, copy of the approval notice from their home institution AND the protocol as it was approved by their home institution, including all attachments. If information specific to conducting the research at WPU is not included in the protocol, provide this as an additional attachment.

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

Undergraduate and Master's degree students must complete the decision tree provided in Appendix C:

Student Research Protocol Review Request to determine if a protocol must be submitted to the IRB for review. Most student research should not need to be submitted to the IRB, but if it is, students and their professor should complete and submit an Appendix C. If the research does not have to be submitted, the faculty mentor/supervisor will be responsible for reviewing the research and insuring that subjects are engaged ethically and appropriately in the research. If the answers to Appendix C's questions a to d describe research that should not be reviewed by the IRB, the protocol will be returned to the student and their faculty sponsor.

A complete Appendix C: Student Research Protocol Review Request includes both student and faculty signatures, informed consent, and data collection tools. 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:

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

b. Context of the Research: Where and when will the research be undertaken? What is the investigator's relationship or connection to the location of the research? If any of the decision tree questions were answered "no" and it was decided that protocol should be submitted, or if a yes/no determination could not be made, provide a justification for submitting the protocol to the IRB.

c. Use of Outcomes: Describe where the outcomes of this research will be submitted for presentation or publication outside of William Paterson University. Be specific by naming the publisher, organization, dates and processes, as they are known. The sharing of research outcomes in professional meetings and conversations are not a consideration for the IRB.

d. At-risk and Protected Subjects: Identify the at-risk or protected classes of subjects who will be involved in this research. Identify if someone else will provide consent and then subjects assent to their participation. Identify the risks associated with their participation. If the student investigators will encounter risks during this project, identify the risk and describe how the students will be protected.

e. 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.

f. 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. How will subjects provide informed consent? Will your 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.

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

h. 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?

i. 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?

j. Storage and disposition of data and informed consent statements: considerations for WP Undergraduate and Master's degree students

- All Basic Considerations apply, see: Part III.A.2.f
- For undergraduate or master's degree student research that IS NOT REVIEWED by the IRB, the professor will be responsible for approving and monitoring data use as well as the destruction of original data at the end of the semester course.
- For undergraduate or master's degree student research that IS REVIEWED by the IRB, the professor will be responsible for insuring that the plan for destroying data included in their student's protocol has been completed.
- Students may keep a copy of the aggregated, de-identified, anonymized data after the course.

h. 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 five 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 may be either separate from the survey or printed at the beginning of the survey or questionnaire. It must meet the standards for Informed Consent provided below. Paper Format: The consent statement is presented before the survey or questionnaire with instruction for subject to complete the survey to provide consent or not to complete the complete the survey to withhold consent. Electronic Format: The consent statement is the first screen/information a subject sees when they enter an online survey with the instruction for subjects to "click continue" to provide consent and then complete the survey or "click exit" to withhold consent and exit the survey. No initials or identifying information may be requested. An alternate would be to have subject provide an affirmative "yes" or "no" before clicking "continue" and then either moving into or out of the survey. Alternative methods will be considered.

Active Informed Consent: Active Informed Consent should be used for all purposes except anonymous surveys and questionnaires. It must meet the standards for Informed Consent provided below. Paper Format: The Consent Statement must be a separate document from the testing instruments and provide a place for subjects and investigators to sign and date the Statement. Electronic Format: An appropriate process must be provided to obtain documentable consent prior to the initiation of the research. This may mean collecting a paper-based consent before the subject receives a link to the online tools. Obtaining documentable and verifiable electronic signatures is acceptable when the signature can be verified by either the investigator or the IRB. Alternative methods will be considered.

If consent is being provided by a 3rd party, such as a parent providing consent for their child, medical power-of-attorney, etc., the name of the subject and their relationship to the person(s)

signing must be included on the Informed Consent Statement along with information on how Assent will be obtained from the subject. The 3rd party as well as the subject (when appropriate) will receive a copy of the informed consent statement. Examples of times when subject would not receive a copy of the consent statement would include when the subject is too young to read, when providing it would be impractical (as in a classroom setting), or when the subject is not conscious.

Assent to Participate: (A) All subjects assent to participate throughout the research process and may choose to disengage from the research for any purpose at any time without penalty. (B) Assent is provided by individuals for whom consent was already provided by a 3rd party, such as (a) children or minors or (b) adults with a cognitive, physical or developmental impairments or other 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. It must meet the standards for Informed Consent provided below. 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. An example of providing this opportunity is when the subject is a minor and can be included in the conversation regarding their participation.

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.

Broad Consent:

(A) Language is included in a Passive Consent Statement that will allow the investigator to use the data that is collected for subsequent related or unrelated research. This language should be presented within the body of the consent statement. Consent will then cover the immediate as well as future use of the data.

(B) Language is included in an Active Consent Statement that will allow the investigator to use the data that is collected for subsequent related or unrelated research. This language should be presented separately from the remainder of the consent statement so that it can be accepted separately by the subject. Investigators who include Broad Consent must include in their protocol a plan for differentiating between data that was collected with and without Broad Consent, how they will they will manage requests for sharing the data and/or posting the data for other investigators to access, and how they will manage this in perpetuity until all copies of the original data from those subjects who did not provide Broad Consent has been destroyed whether or not the data is anonymous.

(C) When data that was previously collected is proposed for use (i.e.: see section on Secondary Data) and the data was collected after January 18, 2019, investigators must disclose to the IRB whether or not Broad Consent was obtained from subjects prior to it being made available for the investigator.

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 only 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) agree 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 to monitor the subject's continuing assent to participate and will be present for any subsequent renewal of informed consent unless the IRB waives this requirement in its approval of the research.

For Passive Consent, subjects are not required to receive a copy of the Consent Statement but may receive it on request. For Active 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.

All consent statements must 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 information must be included in a consent statement:

Information Category	Description of contents
Heading of the Statement	
	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.

Information Category	Description of contents
	The study title should be carried at the top of each page of the consent statement.
Body of the 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.
Confiden-tiality	• Informed consent must be provided to assure subjects of the security of stored identifiable information, of identifiable information in databases, and of audio and

Information Category	Description of contents
	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.
Special Considerations: To be used only as needed.	
Broad Consent	• The subject must be informed that they are free to decide whether or not the data that they will provide may be used for other research purposes in the future. • See the beginning of this section for requirements for Broad Consent.
Injury/ Complica-tions	• 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.
Radiation Considera-tions	• 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	
Contact for Information	• This is both a restatement of the contact information in the heading as well as information on how to contact the Associate Provost for Academic Affairs.
Signature	Statement indicating subject's understanding of the consent statement and willingness to participate followed by: Passive Consent:

Information Category	Description of contents
	• Instructions on how to proceed and complete the survey if subjects want to participate. • Instructions on how to end their involvement if the subject does not want to participate. Active Consent • A place for the subject and to write the date that consent was provided. • A place for the investigator to print their name, sign their name, and to write the date that consent was obtained. • 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. • 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. 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:

All complete protocols must be reviewed and acknowledged by the investigator's department chair (or dean if the applicant is the chair) prior to submission to the IRB. Through this approval, the chair acknowledges and accepts responsibility for the investigator's activities, use of departmental resources and to protect human subjects in research by overseeing the activities of faculty in their department.

For projects involving investigators from multiple departments, the protocol must be submitted to the chair of each department for review. If any of the investigators are the department chair, then their Dean/Vice President will review the protocol, and 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.

For projects involving investigators external to WPU as co-investigators, approvals must be sought by chair and dean of the college of the lead PI as well as the Vice President for Academic Affairs prior to submission to the IRB.

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 obtain approval form their faculty sponsor/advisor. This approval will indicate that the faculty sponsor/advisor has reviewed the research, supports the project, all investigators on the project

have provided documentation of certification of training in the use of human subjects, and accepts responsibility for the actions of the student in undertaking the project.

2. Review by the IRB

a. **The IRB will review all protocols that are submitted for review through a two-step process.**

1. Completeness Evaluation:

To ensure timely, appropriate, ethical reviews of all IRB protocols, the IRB expects to be provided with all of the required documentation at the time of initial submission. The IRB staff will evaluate the protocol package to ensure that all of the necessary documents have been provided by the investigator and will confirm receipt of the protocol. Complete IRB protocols will be distributed to the IRB reviewers within no less than seven (7) business days of receipt of the complete package. For Incomplete protocols, the IRB staff will notify the applicant of the missing materials and expects to receive missing materials within no less than 7 business days of a request. Incomplete protocols will not be forwarded to the IRB members for review. Failure to respond to IRB requests may result in a protocol being returned without review.

2. IRB review: Initial Review

IRB members or the committee will review all complete protocols that meet the requirements of exempt, expedited or full board review for initial review. The IRB members will evaluate the protocol to ensure that risks to subjects are minimized and are reasonable in relation to potential benefits of the investigation, selection of subjects is equitable, informed consent is obtained by and appropriate process, and to establish the category of review and the frequency of continuing review. As part of the review process, the IRB members may request changes or additional information from the applicant. All investigators must respond to requests for additional information in within 30 business days to ensure timely processing of the protocol.

As part of the review process, the IRB members are responsible for determining the level of review (exempt, expedited, or full board). In an effort to provide sufficient protections for human subjects, the IRB will pursue the more protective review category. The list of all of the approved Exempt and Expedited protocols reviewed since the last IRB meeting will be included on the IRB meeting agenda of each regularly scheduled meeting.

If the proposal qualifies for a Full IRB review, it is reviewed by all IRB members and discussed at the next regular meeting (or a special meeting is scheduled for the review). After review is completed, the investigator is notified of the IRB's actions.

b. **Protocols from WPU Faculty, staff, doctoral students, and outside investigators**

All exempt and expedited protocols are reviewed initially by one IRB member. The protocol is then sent, along with the comments from the first reviewer to a second reviewer, who will complete their review, incorporating the comments/concerns of the first reviewer. The second reviewer works with the IRB staff to communicate the determination, including the negotiation of any questions or requests for revisions of the protocol to the applicant.

All protocols requiring full board review will follow the process as outlined above, however, the protocol will be forwarded to the full board for review, discussion and consideration at least one week prior to the next regularly scheduled meeting. The protocol will be discussed by the committee and a vote will be held to establish the decisions of the board.

c. **Protocols from WPU undergraduates and Master's Degree students**

All exempt and expedited protocols are reviewed initially by one IRB member. The reviewer works with the

IRB staff to communicate the determination, including the negotiation of any questions or requests for revisions of the protocol to the applicant.

All protocols requiring full board review will follow the process as outlined above, however, the protocol will be forwarded to the full board for review, discussion and consideration at least one week prior to the next regularly scheduled meeting. The protocol will be discussed by the committee and a vote will be held to establish the decisions of the board.

d. Approval Notices and Other IRB-related Correspondences (such as Determination Letters):

The IRB Administrator or designee will provide the lead investigator (PI and other investigators, as needed) with a copy of the IRB approval notice or other determination after completion of the IRB member or authorized party's review of the protocol.

The lead investigator (PI) is responsible for maintaining all IRB documentation, including but not limited to the IRB-approved protocol, IRB-approved consent forms, IRB-approval notice or other determination letters, IRB-approved data collection forms, recruitment materials, etc. The lead investigator is responsible for reporting to the IRB in a timely manner any deviations from the approved protocol or any adverse experiences or reactions that may result during the conduct of the research. Only approved human subjects research is permitted.

Any research involving human subjects conducted prior to the receipt of an approval notice (before the date on the notice) from the IRB will be as if it had not been reviewed by the IRB. Regardless of the source of discovery (i.e. IRB, WP Faculty, staff or other officials) this is considered research misconduct and will be reported to the to the Provost Office for further action.

d. All complete protocols are generally reviewed within 3 weeks of submission unless it is received immediately before or during a break period for the IRB or institution. These review periods are contingent on the timely submission of a complete application. 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. Full board reviews need to be submitted by the deadlines posted on the IRB website. *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):

- 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.

- 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 determination is made and, if approved, may begin their research after receipt of the approval notice. All approved Exempted and Expedited protocols will be listed on the agenda at the IRB's next full board meeting.

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.

(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 Chair 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.

4. Activities related to each action will proceed as follows:

(a) Approve 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) Approve contingent upon clarifications of or minor revisions to the protocol package: The investigator will be sent a notice describing the revisions, clarifications or additional details to be provided through an email response that will be added to a protocol. If the revisions are deemed satisfactory by the IRB Administrator, an approval notice will be sent to the investigator. If the investigator disagrees with requested revisions, he/she may work with the IRB Administrator until a satisfactory and agreeable outcome is arrived at. Once the IRB Administrator decide that the information received from the investigator fulfills the concerns of the original reviewers, the protocol will be approved, and the investigator will receive an approval notice.

(c) Tabled for substantive change and additional information: The investigator will be sent a notice describing the reason for tabling IRB decisions and outlining revisions or clarifications to the protocol package necessary for reconsideration. The investigator will revise and resubmit his/her protocol with the requested changes or additional information to the IRB Administrator for distribution to the original reviewers to re-initiate the review process. If the investigator disagrees with the requested revisions, he/she may present in writing the reasons to the IRB Administrator. The IRB Administrator will review this

response and negotiate with the investigator and then submit the changes to the original reviewers for action as if this was a new protocol. Once the IRB Administrator decide that the information received from the investigator fulfills the concerns of the original reviewers, the protocol will be approved and the investigator will receive an approval notice.

(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.

(e) Rubric: Suggested levels of concern to aid reviewers in choosing type of approval. Not all of the concerns mentioned need to be present for a category to be chosen. The major difference between the "Approve Contingent" and "Table for Revision" is assessment of the line between minor and significant changes. Incomplete or poorly stated information would be considered minor while missing sections would be considered significant. For example, not clearly identifying where data will be stored is minor compared to a protocol that does not include any information regarding the safe storage of data.

Type of Response	Face Sheet	Narrative	Consent	Instruments
Approve as Submitted	All items correct	All information complete	Fulfills requirements	Appropriate
Approve Contingent on Minor Changes	Incomplete or incorrect information. Missing approvals.	Information incomplete, missing or not presented clearly.	Minor revisions and clarifications, modify consent method, modify signatories.	Revise minor questions or way the instrument is presented.
Table for Substantive Revision	Inaccurate, incorrect, or incomplete information. Missing approvals.	Substantial amount of missing or inaccurate information, problems with methodology, or unmanaged/unidentified risks for subjects.	Significant revisions, incorrect subjects and signatories.	Revise significant questions or presentation issues.
Decline Approval	Inaccurate, incorrect, or incomplete information. Missing approvals.	Unmanageable level of risk to subjects.	Inappropriate statements.	Unmanageable level of risk to subjects.

C. Continuing Review Approval Process

For studies described in Part II, Section D that require an annual review, that have changes or modifications, where there is a reportable event, or have been completed or terminated, need to submit a Continuing Review to the IRB. This can be submitted electronically: https://wpunj.qualtrics.com/SE/?SID=SV_9Yo0MU0SEI7GgUI. Supporting materials should then be emailed, referencing the continuing review submission, to IRBadministrator@wpunj.edu. The electronically submitted report and the supporting materials will be sent 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. End Dates for Approved Protocols

An approved protocol must stay open and active until the first manuscript is submitted and/or de-identified data has been posted in a data warehouse for access by other investigators. This will continue the protections of subjects, data security and other elements of the protocol through to when the dataset can no longer be modified. An investigator will notify the IRB of the completion of their research through the Continuing Review Process.

However, if an approved protocol was not initiated or it was terminated before completion, then the protocol will be closed. An investigator will notify the IRB that a protocol should be closed through the Continuing Review Process. Failure of an investigator to complete the continuing review process in a timely manner will result in the administrative closure of the protocol Once a protocol has been closed, either by the investigator or administratively by the IRB, all research involving human subjects must stop. Research involving human subjects occurring without IRB approval is considered research misconduct and will be reported to the Provost Office.

Approved protocols for research by Undergraduate and Master's Degree students are expected to be completed within one year of the approval of a protocol. Neither Undergraduate or Master's Degree students need to report the completion of their research to the IRB.

E. Audits of Approved Protocols

The IRB may audit the records, data, consent statements, and other documentation regarding any approved protocol, or selected elements of a protocol, at any time it is deemed necessary to do so. If the IRB determines there is a reason to audit an approved protocol, the IRB Administrator will contact the PI to notify him/her about the audit, its purpose and scope, and to arrange a mutually agreeable time for the IRB to review records within two weeks of the notice. If an acceptable date is not agreed upon, the IRB may suspend the protocol until such time as the review can occur.

F. Suspension or Termination of Approval

The IRB may suspend or terminate its approval of a protocol (a) during the continuing review process, (b) if the IRB learns that information contained in a protocol was incorrect, or (c) failure to fulfill IRB requests, such as signing and returning an approval notice. 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.

G. 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 at least 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.

3. Data that includes identifiable private information must be destroyed or de-identified in the manner and within the timeline described in the approved protocol. Signed Informed Consent Statements must be destroyed within the timeline described in the approved protocol.

4. Data that does not include identifiable private information may be retained indefinitely.

5. For data that was collected after January 19, 2019, only that data for which broad consent has been received may be (a) used by the investigators of the study it was collected for or (b) shared with other investigators for use in other studies.

Part IV. 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. 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. 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 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.

3. Student Records

Studies which involve the collection and 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 V. Training Certification

A. Requirement

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

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. Currently WPU uses the online CITI Program for this service. The certification must represent a course of study covering all issues deemed essential by the IRB.

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. All students who participate in any protocol requiring IRB for review and approval.

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

e. 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.)

B. Process

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.

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. This new certification will be required prior to the approval of a new protocol.