William Paterson University Policy
Functional Policy

SUBJECT:	Human Subject Research		**TITLE:**	Policy on Human Subject Research at William Paterson University	
CATEGORY: Check One	**Board of Trustees** ☐	**University** ☐	**Functional** ☒	**School/Unit** ☐	
Responsible Executive:	Provost & Senior Vice President for Academic Affairs		**Responsible Office:**	Sponsored Programs	
CODING:	02-20—80-00-05*	**ADOPTED:**	3/1996	**AMENDED:**	5/2/2019
				LAST REVIEWED:	xx/xx/xx*

I. PURPOSE

The purpose of this policy is to enable William Paterson University to be in compliance with the Federal laws, regulations and guidance regarding the use of human subjects in research. This policy embraces the ethical position that integrity, objectivity, honesty, and the avoidance of self-dealing and conflicts of interest 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.

II. ACCOUNTABILITY

The Policy on Human Subject Research at William Paterson University (hereafter, Policy) will be implemented by the Institutional Review Board for the Use of Human Subjects in Research (IRB). The IRB is supported by the Office of Sponsored Programs which is an office under the Provost and Senior Vice President for Academic Affairs. The Faculty Senate's Research and Scholarship Council (RSC) will periodically review the IRB Procedures to determine if they are effectively implementing the IRB Policy and report to both the Faculty Senate and the Provost and Executive Vice President for Academic Affairs.

This Policy has been developed to assist the University in fulfilling its responsibilities as defined in several Federal regulations. These regulations include *Title 45 Code of Federal Regulations, Part 46* (a.k.a.: "45 CFR Part 46" and "The Common Rule" which regulates the Department of Health and Human Services and many other Federal Agencies and Departments), regulations by Federal Agencies and Departments that have not adopted The Common Rule, and *Title 21 Code of Federal Regulation, Part 50* (21 CFR Part 50 which regulates the Food and Drug Administration). These regulations, and this policy, all subscribe to the ethical foundation for human subject research as defined by *The Belmont Report* which was published by the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research (1979).

III. APPLICABILITY

A. Research with Human Subjects

The Policy is concerned with research conducted by the faculty, staff and students of the University, as well as by outside investigators, with living individuals about whom the investigator obtains information or biospecimens through intervention or interaction with the individual, and uses, studies, analyzes, or generates identifiable private information or identifiable biospecimens as an outcome of the research.

The Policy is applicable to research methodologies included or excluded in 45 CFR, Part 46, Section 102(l). Included research is defined as "a systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge. Activities that meet this definition constitute research

... whether or not they are conducted or supported under a program that is considered research for other purposes. [Some] demonstration and service programs may include research activities." Excluded research is defined as (1) 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. (2) 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... (3) 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. (4) Authorized operational activities (as determined by each Federal agency) in support of intelligence, homeland security, defense, or other national security missions."

The Policy recognizes that the Federal agencies that develop and oversee regulations regarding the use of human subjects in research, particularly 45 CFR Part 46, may adjust and update these definitions from time to time. Subsequent revisions regarding definitions and the inclusion or exclusion of certain types of research will supersede those cited here.

B. Conflicts of Interest

Federal and State regulations require that WPU employees embrace the ethical position that integrity, objectivity, honesty and the avoidance of self-dealing are essential elements in ethical conduct and critical for excellence as well as public trust. This policy requires all investigators using human subjects, whether their research is or is not reviewed by the IRB (See Part II A and B), to be acting in accordance with the **State of New Jersey Uniform Ethics Code** and the **Plain Language Guide to New Jersey Executive Branch Ethical Standards**.

All WP faculty and staff investigators, and outside investigators who are not affiliated with an institution, who submit a protocol to the IRB must indicate that they have read the **WPU Sponsored Projects and Research Conflict of Interest and Commitment Disclosure Policy.** If there is a conflict that must be disclosed, investigators must complete the required training and attach the **WPU Sponsored Projects and Research Conflict of Interest Disclosure Form** to their protocol for review as per the process included in the WPU Sponsored Projects and Research Conflict of Interest and Commitment Disclosure Policy.

IV. DEFINITIONS

IRB means an institutional review board established in accord with and for the purposes of operationalizing and supporting this Policy as required by 45 CFR Part 46. The WP IRB is comprised of faculty and staff, is chaired by a faculty representative, and is administered by an individual appointed by the Provost and Senior Vice President for Academic Affairs.

Human subject means a living individual about whom an investigator (whether professional or student) conducting research: (1) obtains information or biospecimens through intervention or interaction with the individual, and uses, studies, or analyzes the information or biospecimens; or (2) obtains, uses, studies, analyzes, or generates identifiable private information or identifiable biospecimens.

Intervention includes both physical procedures by which information or biospecimens are gathered (e.g., venipuncture) and manipulations of the subject or the subject's environment that are performed for research purposes.

Interaction includes communication or interpersonal contact between investigator and subject.

Private Information includes information about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place, and information that has been provided for specific purposes by an individual and that the individual can reasonably expect will not be made public (e.g., a medical record).

Identifiable private information is private information for which the identity of the subject is or may readily be ascertained by the investigator or associated with the information.

Identifiable biospecimen is a biospecimen for which the identity of the subject is or may readily be ascertained by the investigator or associated with the biospecimen.

Secondary data is data that was previously collected will be used for a new purpose.

Anonymous means that either identifiable private information or identifiable biospecimens are not collected and that research results are not presented in a way that a knowledgeable reader can identify or infer the identity of a subject.

Confidential means identifiable private information or identifiable biospecimens are collected and are protected in a manner that would make it difficult to identify individual subjects or for a knowledgeable reader to identify or infer the identity of a subject.

Informed Consent is permission granted in the knowledge of the possible consequences by a research subject to an investigator prior to the subject before the research begins. A legally authorized representative – such as a parent or individual holding power-of-attorney – may also provide consent but each individual maintains the right to assent if the subject is able.

IRB approval means the determination of the IRB that the research has been reviewed and may be conducted at an institution within the constraints set forth by the IRB and by other institutional and federal requirements.

Minimal risk means that the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.

V. BACKGROUND

This Policy replaces previous versions of that were adopted by the WPU Faculty Senate and the Provost and Executive Vice President for Academic Affairs in March 1996, March 1999, February 2006 and February 2014.

The Common Rule creates a system that provides for local control with federal oversight. The Federal Agency overseeing human subject research conducted by or at William Paterson University is the Office for Human Research Protections (OHRP), Department of Health and Human Services. This policy and its related procedures are also attentive to the OHRP's requirements and resources.

VI. REFERENCES

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

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

Only the IRB approves research involving the use of human subjects in research, and is the only arbiter of issues regarding the use of human subjects in research whether or not that research was submitted to the IRB for review. No other William Paterson University committee, board or council can over-rule, over-ride or change a decision of the IRB. The University President, Provost or Responsible Institutional Official may, under exceptional circumstances, independently review any research protocol and if they deem necessary to disapprove the

implementation of a research protocol even if it has been approved by the IRB. However, University officials may not approve the implementation of any research protocol in lieu of IRB approval, nor may they override IRB decisions disapproving a research protocol.

VII. POLICY

A. Requirements:

1. The IRB will be responsible for the implementation of this policy with the support of the Office of Sponsored Programs and the Provost and Senior Vice President for Academic Affairs. The Office of Sponsored Programs will support the IRB by serving as its liaison with Federal and other agencies as well as the WP community, providing access to policies, procedures, forms and other information, and enabling its activities. WP faculty, staff and student investigators who intend to use human subjects in research must comply with the requirements of this policy and all related procedures. Individuals from outside WP who wish to conduct research involving human subjects at WP must comply with the requirements of this policy and all related procedures.
2. The types of research covered by this policy, the methods for obtaining approval (initial review) and maintaining approval (continuing review) of research involving human subjects, the requirements for engaging human subjects, the responsibilities of the IRB, and the operation of the IRB are described in the **IRB Procedures, Appendix A**. These procedures may be revised as needed to insure ongoing compliance with Federal regulations and William Paterson University requirements.

B. Enforcement:

The IRB may suspend or terminate a protocol (a) during the continuing review process, (b) if the IRB learns that information contained in a protocol was incorrect, (c) if the IRB learns that an investigator (or investigators) have acted unethically, or (d) if the IRB has reason to believe that the research has been affected by a conflict-of-interest. The IRB will issue a "notice of suspension or termination" to the primary investigator that includes the reason for the action and the process for lifting the notice. If the IRB has reason to believe that other WP Policies or requirements have been affected, it may contact the responsible individual for that policy or requirement.

C. Signature Authority:

The Provost and Senior Vice President for Academic Affairs is the responsible WPU official for the IRB. The Provost delegates his/her authority to the Associate Provost for Academic Affairs for all official communications and representations with the OHRP or other Federal Agencies regarding the IRB Policy or the composition of the IRB. The Provost delegates her/his authority to the IRB Administrator and the IRB Chair to serve as the agent for the IRB, to issue award notices to investigators, and to provide information regarding the actions of the IRB to the OHRP, other Federal Agencies, other sponsors, publishers, or organizations as appropriate.

VIII. PROCEDURE(S):

The IRB will create and maintain procedures to implement this policy. These procedures will be made available on the IRB's webpage and through the Office of Sponsored Programs. These procedures may be revised as needed to insure ongoing compliance with Federal regulations and William Paterson University requirements.

By Direction of the Provost and Senior Vice President for Academic Affairs:

Sandra D. Young

Date: June 3, 2019