Outline:

1. **Establishment of the IRB**

    a. **Mission and Purpose**

The mission of the William Paterson Institutional Review Board is to ensure the safe and ethical conduct of research with the goal of protecting human participants conducted within its jurisdiction. IRB members function as advocates for human participants' rights, safety, and welfare. The committee has the power to review, approve, require modifications to, or disapprove of proposed human participants' research activities.

b. IRB Authority

The Institutional Review Board (IRB) has the authority to oversee all research involving human subjects as outlined in this document and in accordance with Federal Policy for the Protection of Human Subjects, codified in 45 CFR 46. Its responsibilities include:

- **Review and Oversight**: Review and approve, require modifications to secure approval, or deny approval for all research activities involving human subjects, including amendments to previously approved protocols.
- **Continuing Review**: Conduct continuing review of approved research at intervals appropriate to the level of risk posed to participants, as required by federal regulations and institutional policy.
- **Observation and Monitoring**: Observe or designate qualified third parties (internal or external to the institution), to observe the informed consent process, research procedures, and review research documentation to ensure compliance and participant protection.
- **Suspension or Termination**: Suspend or terminate IRB approval of research that is not being conducted in accordance with IRB requirements or that has been associated with unexpected serious harm to participants.

These responsibilities are carried out in alignment with the ethical principles outlined in the Belmont Report—**respect for persons, beneficence, and justice**—and in compliance with **45 CFR 46** and other applicable federal and state regulations.

c. IRB Jurisdiction

45 CFR, Part 46, Protection of Human Subjects, defines a human participant as 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.

45 CFR, Part 46, Protection of Human Subjects defines research as “a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge.”

Projects that meet the criteria outlined in the definition of human participants research that are conducted at the University or conducted by university faculty, staff, or students at locations other than those owned by the University are subject to review and approval by the IRB. This policy is applicable regardless of whether the project involves funding from an external agency.

Systematic investigations conducted by graduate or undergraduate students that involve the use of humans as participants and that are intended to contribute to generalizable knowledge must be reviewed and approved by the IRB. This includes, but is not limited to, independent undergraduate research projects, honors theses, graduate theses, and dissertations.

Class projects that are designed to teach research methods to students, however, are not typically classified as research and therefore are not ordinarily subject to IRB review. These projects are overseen by an advising faculty member, who is responsible for ensuring that appropriate precautions are taken with regard to the protection of participants. While most class assignments are designed to teach research methods and are not the type of activities typically overseen by the IRB, there are instances when the nature of these projects is such that participants could be put at risk of harm. Class projects involving participants outside the classroom are subject to IRB review if they meet either of the following criteria:

1. Are undertaken with the intention of producing results that will be submitted for peer-reviewed publication or presentation or otherwise made available to a broad general audience
2. Involve any type of activity that places the participants at more than minimal risk, considering both the probability and the magnitude of harm

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. Laws, regulations, and requirements must be addressed appropriately.

i. Excluded from IRB Review

The following list of activities does not meet the definition of research according to 45 CFR Part 45.102 (l)(1-4). Any activity that falls into these categories does not require IRB review:

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. 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).

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.

In addition to the categories excluded from the definition of research involving human participants indicated above, WP IRB does not require IRB review the following types of projects:

1. Quality Assurance or Quality Improvement projects. Activities such as Institutional, departmental or program assessment projects at WP, and pedagogical assessment by WP Instructors for WP Improvement do not require IRB review.
2. Research conducted by non-WPP affiliated investigators that minimally engages the WP community.
3. This IRB Administrative team may opt to rely on an external IRB for research activities for which the IRB does not have members with appropriate expertise such as FDA Regulated Human Subjects Research, Clinical Trials of investigational drugs or medical devices, biological samples, or research involving people who are incarcerated.

Questions concerning whether a particular research project meets these definitions should be directed to the IRB Administrator or IRB staff or the IRB Chair.

ii. IRB review categories

a. Exempt Review Determinations

Research activities are classified as exempt when the involvement of human participants only falls within one or more of the Federally defined categories, and the study represents no greater than minimal risk to its participants. The inclusion of special classes of vulnerable subjects may preclude the designation of a protocol as exempt from review. If any activities in the proposed project do not fit in the categories below, the project is not eligible for exemption, and the investigator is required to submit for expedited or full review.

Minimal risk is defined as 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.
IRB members will review exempt protocols to ensure the following:

1. Activity meets the definition of research and human subjects under 45 CFP 46
2. Activity is minimal risk.
3. Activity aligns with one or more of the exempt review categories.
4. Additional review is not needed. (For vulnerable subjects such as children, prisoners, pregnant people and fetuses)

Once a review is complete, no further actions need to be reported to the IRB for exempt research. Should substantive changes be requested, a new protocol must be submitted to the IRB. Investigators must complete an administrative check-in every three years for exempt protocols.

Exempt Review Categories include:

Category (1) Research, conducted in established or commonly accepted educational settings, that specifically involves normal educational practices that are not likely to adversely impact students' opportunity to learn required educational content or the assessment of educators who provide instruction. This includes most research on regular and special education instructional strategies, and research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.

Category (2) Research that only includes interactions involving educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior (including visual or auditory recording) if at least one of the following criteria is met:

(i) The information obtained is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained, directly or through identifiers linked to the subjects.

(ii) Any disclosure of the human subjects' responses outside the research would not reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, educational advancement, or reputation; or

(iii) The information obtained is recorded by the investigator in such a manner that the identity of the human subjects can readily be ascertained, directly or through identifiers linked to the subjects, and an IRB conducts a limited IRB review to make the determination that there are adequate safeguards to protect the privacy and confidentiality of the subjects.

IMPORTANT: Subpart D: Additional Protections for Children Involved as Subjects in Research restricts Exemption 2 in the following ways:

- For research involving children, exemption 2 (i) and 2 (ii) above may be applied only to research involving educational tests or the observation of public behavior when the investigator(s) do not participate in the activities being observed.
- Exemption 2 may not be applied to survey procedures or interview procedures involving children as subjects.
- Exemption 2 (iii) above may not be applied to research involving children

Category (3) Research involving benign behavioral interventions in conjunction with the collection of information from an adult subject through verbal or written responses (including data entry) or audiovisual recording if the subject prospectively agrees to the intervention and information collection and at least one of the following criteria is met:

(i) The information obtained is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained, directly or through identifiers linked to the subjects;

(ii) Any disclosure of the human subjects' responses outside the research would not reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, educational advancement, or reputation; or

(iii) The information obtained is recorded by the investigator in such a manner that the identity of the human subjects can readily be ascertained, directly or through identifiers linked to the subjects, and an IRB conducts a limited IRB review to make the determination that there are adequate safeguards to protect the privacy and confidentiality of the subjects.

*For the purpose of this provision, benign behavioral interventions are brief in duration, harmless, painless, not physically invasive, not likely to have a significant adverse lasting impact on the subjects, and the investigator has no reason to think the subjects will find the interventions offensive or embarrassing. Provided all such criteria are met, examples of such benign behavioral interventions would include having the subjects play an online game, having them solve puzzles under various noise conditions, or having them decide how to allocate a nominal amount of received cash between themselves and someone else.

IMPORTANT: Note that this exemption applies only to adult subjects and cannot be applied to research involving children. If the research involves deceiving the subjects regarding the nature or purposes of the research, this exemption is not applicable unless the subject authorizes the deception through a prospective agreement to participate in research in circumstances in which the subject is informed that he or she will be unaware of or misled regarding the nature or purposes of the research.

Category (4) Secondary research for which consent is not required: Secondary research uses of identifiable private information or identifiable biospecimens, if at least one of the following criteria is met:

(i) The identifiable private information or identifiable biospecimens are publicly available;
(ii) Information, which may include information about biospecimens, is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained directly or through identifiers linked to the subjects, the investigator does not contact the subjects, and the investigator will not re-identify subjects;
(iii) The research involves only information collection and analysis involving the investigator's use of identifiable health information when that use is regulated under 45 CFR parts 160 and 164, subparts A and E, for the purposes of "health care operations" or "research" as those terms are defined at 45 CFR 164.501 or for "public health activities and purposes" as described under 45 CFR 164.512(b); or
(iv) The research is conducted by, or on behalf of, a Federal department or agency using government-generated or government-collected information obtained for nonresearch activities, if the research generates identifiable private information that is or will be maintained on information technology that is subject to and in compliance with section 208(b) of the E-Government Act of 2002, 44 U.S.C. 3501 note, if all of the identifiable private information collected, used, or generated as part of the activity will be maintained in systems of records subject to the Privacy Act of 1974, 5 U.S.C. 552a, and, if applicable, the information used in the research was collected subject to the Paperwork Reduction Act of 1995, 44 U.S.C. 3501 et seq.

Category (5) Research and demonstration projects that are conducted or supported by a Federal department or agency, or otherwise subject to the approval of department or agency heads (or the approval of the heads of bureaus or other subordinate agencies that have been delegated authority to conduct the research and demonstration projects), and that are designed to study, evaluate, improve, or otherwise examine public benefit or service programs, including procedures for obtaining benefits or services under those programs, possible changes in or alternatives to those programs or procedures, or possible changes in methods or levels of payment for benefits or services under those programs. Such projects include, but are not limited to, internal studies by Federal employees, and studies under contracts or consulting arrangements, cooperative agreements, or grants. Exempt projects also include waivers of otherwise mandatory requirements using authorities such as sections 1115 and 1115A of the Social Security Act, as amended. Each Federal department or agency conducting or supporting the research and demonstration projects must establish, on a publicly accessible Federal Web site or in such

other manner as the department or agency head may determine, a list of the research and demonstration projects that the Federal department or agency conducts or supports under this provision. The research or demonstration project must be published on this list prior to commencing the research involving human subjects.

Category (6) Taste and food quality evaluation and consumer acceptance studies:

(i) If wholesome foods without additives are consumed, or

(ii) If a food is consumed that contains a food ingredient at or below the level and for a use found to be safe, or agricultural chemical or environmental contaminant at or below the level found to be safe, by the Food and Drug Administration or approved by the Environmental Protection Agency or the Food Safety and Inspection Service of the U.S. Department of Agriculture.

Federal regulations permit the use of two additional categories of exempt review that apply only to research covered under a broad consent process. the use of broad consent procedures requires an infrastructure for the secure storage of Biospecimens that is not currently available university wide. In addition, the tracking requirements are burdensome for both the investigator and the IRB. Because of this WPUNJ does not utilize the broad consent position currently and therefore
Exempt Categories 7 and 8 are not included in the list of exempt categories. There are several other options for researchers using Biospecimens which these research protocols can be reviewed under.

b. Expedited Review Categories

Research activities may be reviewed through **Expedited Review when the only involvement of human** participants **falls within one or more of the Federally defined review categories, and the study represent no greater than minimal risk to participants.**

Categories one (1) through seven (7) below pertain to both initial and continuing IRB review (45 CFR 46 XX).

Category (1) Clinical studies of drugs and medical devices only when condition (a) or (b) is met.

(a) Research on drugs for which an investigational new drug application (21 CFR Part 312) is not required. (Note: Research on marketed drugs that significantly increases the risks or decreases the acceptability of the risks associated with the use of the product is not eligible for expedited review.)

(b) Research on medical devices for which (i) an investigational device exemption application (21 CFR Part 812) is not required; or (ii) the medical device is cleared/approved for marketing, and the medical device is being used in accordance with its cleared/approved labeling.

Category (2) Collection of blood samples by finger stick, heel stick, ear stick, or venipuncture as follows:

(a) from healthy, nonpregnant adults who weigh at least 110 pounds. For these subjects, the amounts drawn may not exceed 550 ml in an 8 week period and collection may not occur more frequently than 2 times per week; or

(b) from other adults and children [2], considering the age, weight, and health of the subjects, the collection procedure, the amount of blood to be collected, and the frequency with which it will be collected. For these subjects, the amount drawn may not exceed the lesser of 50 ml or 3 ml per kg in an 8 week period and collection may not occur more frequently than 2 times per week.

Category (3) Prospective collection of biological specimens for research purposes by noninvasive means.

> Examples: (a) hair and nail clippings in a non-disfiguring manner; (b) deciduous teeth at time of exfoliation or if routine patient care indicates a need for extraction; (c) permanent teeth if routine patient care indicates a need for extraction; (d) excreta and external secretions (including sweat); Uncannulated saliva collected either in an unstimulated fashion or stimulated by chewing gumbase or wax or by applying a dilute citric solution to the tongue; (f) placenta removed at delivery; (g) amniotic fluid obtained at the time of rupture of the membrane prior to or during labor; (h) supra- and subgingival dental plaque and calculus, provided the collection procedure is not more invasive than routine prophylactic scaling of the teeth and the process is accomplished in accordance with accepted prophylactic techniques; (i) mucosal and skin cells collected by buccal scraping or swab, skin swab, or mouth washings; (j) sputum collected after saline mist nebulization.

Category (4) Collection of data through noninvasive procedures (not involving general anesthesia or sedation) routinely employed in clinical practice, excluding procedures involving x-rays or microwaves. Where medical devices are employed, they must be cleared/approved for marketing. (Studies intended to evaluate the safety and effectiveness of the medical device are not generally eligible for expedited review, including studies of cleared medical devices for new indications.)

> Examples: (a) physical sensors that are applied either to the surface of the body or at a distance and do not involve input of significant amounts of energy into the subject or an invasion of the subject=s privacy; (b) weighing or testing sensory acuity; (c) magnetic resonance imaging; (d) electrocardiography, electroencephalography, thermography, detection of naturally occurring radioactivity, electroretinography, ultrasound, diagnostic infrared imaging, doppler blood flow, and echocardiography; I moderate exercise, muscular strength testing, body composition assessment, and flexibility testing where appropriate given the age, weight, and health of the individual.

Category (5) Research involving materials (data, documents, records, or specimens) that have been collected, or will be collected solely for non-research purposes (such as medical treatment or diagnosis). (NOTE: Some research in this category may be exempt from the HHS regulations for the protection of human subjects. 45 CFR 46.101(b)(4). This listing refers only to research that is not exempt.)

Category (6) Collection of data from voice, video, digital, or image recordings made for research purposes.

Category (7) Research on individual or group characteristics or behavior (including, but not limited to, research on perception, cognition, motivation, identity, language, communication, cultural beliefs or practices, and social behavior) or research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies. (NOTE: Some research in this category may be exempt from the HHS regulations for the protection of human subjects. 45 CFR 46.101(b)(2) and (b)(3). This listing refers only to research that is not exempt.)

Review Categories eight (8) and nine (9) apply only for continuing review.

Category (8) Continuing review of research previously approved by the convened IRB as follows:

(a) where (i) the research is permanently closed to the enrollment of new subjects; (ii) all subjects have completed all research-related interventions; and (iii) the research remains active only for long-term follow-up of subjects; or
(b) where no subjects have been enrolled and no additional risks have been identified; or
(c) where the remaining research activities are limited to data analysis.

Category (9) Continuing review of research, not conducted under an investigational new drug application or investigational device exemption where categories two (2) through eight (8) do not apply but the IRB has determined and documented at a convened meeting that the research involves no greater than minimal risk and no additional risks have been identified.

The investigator must be aware of the following information regarding expedited research:

- The categories in the expedited research list apply regardless of the age of participants, except as noted.
- The expedited review procedure may not be used where identification of the participants and/or their responses would reasonably place them at risk of criminal or civil liability or be damaging to the participants in terms of 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 expedited review procedure may not be used for classified research involving human participants.
- The standard requirements for informed consent (or its waiver, alteration, or exception) apply regardless of the type of review—expedited or full board—utilized by the IRB.

c. Full Board Review

Research activities that present greater than minimal risk to participants, activities that fall outside of Federally defined review categories, or research that involves vulnerable participants (that is not reviewed under and exempt or expedited category) require Full Board Review. Full Board Review may also be used at the discretion of the IRB Members, Alternates, Administrator or Responsible Institutional Official or program that is sponsoring the proposed research.

To approve a non-exempt study involving human participants, Federal regulations require that the IRB be able to determine that all the following requirements are satisfied (§46.111).

1. **Risks to subjects are minimized:** (i) By using procedures that are consistent with sound research design and that do not unnecessarily expose participants to risk, and (ii) Whenever appropriate, by using procedures already being performed on the participants for` diagnostic or treatment purposes.
2. **Risks to subjects are reasonable in relation to anticipated benefits**, if any, to participants, and the importance of the knowledge that may reasonably be expected to result. In evaluating risks and benefits, the IRB should consider only those risks and benefits that may result from the research (as distinguished from risks and benefits of therapies participants would receive even if not participating in the research). The IRB should not consider possible long-range effects of applying knowledge gained in the research (i.e., the possible effects of the research on public policy) as among those research risks that fall within the purview of its responsibility.

3. **The selection of subjects is equitable**. In making this assessment, the IRB should take into account the purposes of the research and the setting in which the research will be conducted. The IRB should be particularly cognizant of the special problems of research that involves a category of participants who are vulnerable to coercion or undue influence, such as children, prisoners, individuals with impaired decision-making capacity, or economically or educationally disadvantaged persons.
4. **Informed consent will be sought** from each prospective subject or the subject's legally authorized representative, in accordance with, and to the extent required by Federal regulations.
5. **Informed consent will be appropriately documented** or appropriately waived in accordance with Federal regulations.
6. When appropriate, the research plan makes adequate provision for monitoring the data collected to ensure the safety of participants.
7. When appropriate, there are adequate provisions to protect the privacy of participants and to maintain confidentiality of data.

When some or all the participants are likely to be vulnerable to coercion or undue influence, such as children, prisoners, individuals with impaired decision-making capacity, or economically or educationally disadvantaged persons, additional safeguards are needed to protect the rights and welfare of these participants (§46.111).

Non-exempt activities will be reviewed by the IRB on an annual basis or more frequently, if requested by the IRB.

2. Administration and Operation of the IRB

a. IRB Administration

The IRB is supported by the following roles: Responsible Institutional Official (IO), IRB Administrator, IRB Analyst, IRB Members, IRB Alternates, and IRB Chair.

i. Responsible Institutional Official

The Responsible Institutional Official (IO) is the individual authorized to act for the institution and obligates the institution to the terms of the Federal-wide Assurance and for the administration of the University's policies and procedures related Protection of Human Subjects. At WP, the Responsible Institutional Official is the Associate Provost for Academic Affairs or other similarly senior administrator designated by the Provost. Responsibilities include:

- Designating one or more IRBs that will review research covered by the institution's FWA.
- Providing sufficient resources, space, and staff to support the IRB's functions.
- Making available training and educational opportunities for the IRB and investigators.
- Setting the "tone" for an institutional culture of respect for human participants.
- Ensuring effective institution-wide communication and guidance on human participants research.
- Ensuring that all faculty, staff, and students engaged in the conduct or oversight of human participants research receive training in human participants research ethics.
- Serving as a knowledgeable point of contact for OHRP or delegating this responsibility to the IRB Administrator or other appropriate individual.

The Institutional Official (IO) makes appointments to the IRB, based on consultation with the IRB Chair, Administrator, and members.

ii. IRB Administrator

The IRB Administrator is an Assistant Director in the Office of Sponsored Programs, or another individual is designated by the Provost. The IRB Administrator may delegate responsibilities to the IRB Analyst to ensure compliance with University Policies and Procedures. The IRB Administrator is designated by the Institutional Official to oversee and manage the IRB and its operations, including working in collaboration with the Board in the development and maintenance of appropriate policy, procedures, processes, and records. Responsibilities include:

Communication & Education

- Promoting communication among department heads, investigators, human participants, and the IO to maintain a high level of awareness regarding the ethical conduct of research and to safeguard the rights and welfare of participants.
- Maintaining access to the institution's FWA, copies of pertinent Federal regulations, policies, and guidelines related to the engagement of human participants in research, and institutional policies and procedures.
- Educating the members of its research community in order to establish and maintain a culture of compliance with federal regulations and institutional policies relevant to the protection of human participants.

Record Keeping & Reporting

- Ensuring that IRB records are being maintained per federal regulations and that the records are accessible, upon request, to authorized federal officials. The IRB Administrator shall oversee procedures for the retention of university IRB records and documents for at least three (3) years past completion of the research activity.
- Provides certification of IRB approval of research to the appropriate federal agency, as required.
- Ensuring that changes in approved research, during the period for which IRB approval has already been given, are not initiated without IRB review and approval, except when necessary to eliminate apparent, immediate hazards to participants.
- Ensuring prompt reporting to the IRB of all proposed changes in a research activity.
- Ensuring prompt reporting to the IRB, appropriate institutional officials, any sponsoring federal agency, and any other appropriate agency of:
  a) any unanticipated problems involving risks to participants or others;
  b) any serious or continuing non-compliance with the regulations or requirements of the IRB; and c) any suspension or termination of IRB approval for research.

Monitoring & Oversight

- Ensuring that appropriate oversight mechanisms have been implemented to ensure compliance with the determinations of the IRB.
- Ensuring that all cooperating performance sites conducting research primarily under the direction of the institution have appropriate OHRP-approved FWA and provide certifications of IRB approval to the appropriate federal authorities, when appropriate.
- Ensuring that cooperative IRB review arrangements are documented in writing, in accordance with OHRP guidance.

iii. IRB Analyst

The IRB Analyst is a professional staff member in the Office of Sponsored Programs, or another individual designated by the Provost. The IRB Analyst works under the direct supervision of the IRB Administrator in the same office. The IRB Analyst is delegated specific responsibilities by the IRB Administrator to assist in the management of daily IRB operations and to ensure compliance with University Policies and Procedures. The IRB Analyst actively supports the administration of protocols, particularly through the William Paterson University IRB processes outlined in the 'Cayuse IRB Sign Off Process.' Responsibilities include:

Communication & Education

- Carrying out communications for IRB Cayuse Human Ethics protocols, serving as a primary liaison between investigators, reviewers, and other external parties involved with research.
- Assisting the IRB Administrator in promoting communication among department heads, investigators, and human participants to maintain a high level of awareness regarding the ethical conduct of research.
- Providing operational guidance and system support to the research community to navigate the "Cayuse IRB Sign Off Process" and to establish and maintain a culture of compliance with federal regulations.

Record Keeping & Reporting

- Ensuring that IRB records within the Cayuse Human Ethics system are maintained per federal regulations and that the records are securely stored and accessible. The IRB Analyst assists in the retention of university IRB records and documents for at least three (3) years past completion of the research activity.
- Processing Cayuse IRB protocols to ensure all required investigator sign-offs and departmental approvals are documented prior to formal IRB review.
- Monitoring active protocols to ensure that changes in approved research are properly submitted via the Cayuse system and not initiated without IRB review and approval, except when necessary to eliminate apparent hazards.
- Assisting the IRB Administrator in ensuring prompt reporting to the IRB of proposed changes, as well as compiling data regarding: a) unanticipated problems involving risks to participants or others; b) any serious or continuing non-compliance; and c) any suspension or termination of IRB approval for research.

Monitoring & Oversight

- Assisting in the daily implementation of appropriate oversight mechanisms, ensuring that administrative processes comply with the determinations of the IRB.
- Tracking and documenting that cooperating performance sites have appropriate OHRP-approved FWAs and logging external certifications of IRB approval within the institution's record-keeping system.
- Ensuring that the specific workflows and administrative requirements detailed in the William Paterson University 'Cayuse IRB Sign Off Process' are consistently applied and tracked for all cooperative and internal IRB review arrangements.

iv. IRB Member and IRB Alternate Responsibilities

1. Board Composition

The WP IRB Board will be made up of at least 7 members whose background represents at least one scientist, one non-scientist, and one non-affiliated member. Members should also reflect the diversity of WP in terms of race, ethnicity, gender, and cultural backgrounds with expertise in various disciplines. The IRB shall not be composed entirely of members of one profession, and efforts will be made to assure a diverse membership regarding gender, ethnicity, and culture. All IRB members are appointed by the Institutional Official on the recommendation of the IRB and the IRB Administrator. Two or more alternates may also be appointed to function in the absence of a voting member if necessary.

IRB Membership is governed by the following criteria:

- The IRB membership shall include faculty/staff members representing areas in which human subject research typically occurs and at least one person with no affiliations with the University.
- The IRB may, at its discretion, invite individuals with expertise in special areas to assist in the review of issues which require expertise beyond that available on the IRB; these individuals may not vote with the IRB.

- No IRB member shall participate in the review of any project in which the member has conflicting interests except to provide information requested by the IRB.
- 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.
- All members must complete Human Subjects Research Training and IRB member-specific training. Members who do not complete training within a timely manner will be removed from the board.
- All IRB members will serve a term of no more than three years and may opt to continue to serve after the initial term has been completed or may opt to serve as an IRB Alternate or to resign from IRB service.

IRB Alternates

Two or more alternates may also be appointed to function in the absence of a voting member if necessary. Requirements outlined above also apply to IRB Alternates. IRB Alternates shall be representative of the university's college, outside members, or other personnel or may be unaffiliated, and shall comply with the following:

- During the first year of a new IRB Member's first term of service, the IRB Member shall serve as an Alternate.
- IRB Members, after completing a three-year term, may opt to continue service as Alternates for one-year terms of appointment.
- Meeting attendance for IRB Alternates is voluntary. IRB Alternates may be called upon to attend in an IRB Members absence.
- IRB Alternate may also be called upon to complete all types of reviews and to fulfill other responsibilities of IRB Members on an as needed basis.

Unaffiliated Board Members: At WP, an unaffiliated IRB board member has no current ties to William Paterson or does not have any immediate family ties with Willim Paterson. The unaffiliated member provides an essential community perspective representing different rates, genders, cultural and economic backgrounds and may or may not also be a non-scientist. The role is to represent the public interest and to broaden the viewpoint of the IRB to advocate for the rights and welfare of research participants.

Non-Scientist Members: A non-scientist member is a member or alternate whose training, background or occupation inclines them to view research from a non-scientist perspective, bringing community, ethical or legal viewpoints to protect participants. Their perspective focuses on participant understanding, community impact and ethical considerations. In order to ensure that board members come from a varied and diverse background, the WP IRB membership aims to consist of at least one member whose primary concerns are in scientific areas and at least one member whose primary concerns are in nonscientific areas. Examples of non-scientist member include people who view research activities from a standpoint outside of any biomedical or behavioral scientific discipline, such as education, the humanities, or law. Physical or biological scientists or clinical personnel such as nurses, or physicians can satisfy the requirement for at least one scientist.

Examples of scientific members include practicing physician or nurse, bench scientist, medical laboratory technician, and non-scientific members include attorney, clergy member, ethicist, etc.

2. **Responsibilities**

IRB Members and Alternates must complete CITI Human Subjects Research Training, CITI IRB Member training, and CITI Conflict of Interest training ever three years, complete Outside Interest disclosures on an annual basis and within 30 days of a new disclosure. New IRB Members and IRB Alternates must attend initial orientation and system overview training with the IRB Administrator and/or IRB Analyst, and review and discuss at least three sample protocols as part of their initial onboarding. Additionally, new IRB Members and IRB Alternates are encouraged to attend IRB meetings during the on-boarding process.

Responsibilities of all IRB Members and Alternates include:

- Being familiar with the requirements of federal regulations, applicable state laws, the university's FWA, and institutional policies and procedures for the protection of human participants.
- Having effective knowledge of subject populations and other factors involved in determination of risks and benefits to participants as well as informed consent.
- Being able to judge the adequacy and accuracy of information in the informed consent document, recruitment, advertising, and any other materials to be presented to participants.
- Having the professional competence necessary to review the specific research activities presented for approval.
- Preparing for and actively participating in the review process in full board meetings as well as participating in expedited and exempt reviews as assigned. Specifically:
    - 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.
- Promoting positive communication and awareness on campus of the role of the IRB and ethical research principles regarding human participants in research.

v. IRB Chair

The Chair of the IRB is designated by the Institutional Official, based on the recommendations of the IRB members and the IRB Administrator. The Chair's responsibilities include all of those listed for IRB members in general, and in addition include:

- Maintaining an in-depth knowledge of the regulations and regulatory guidance, and expertise in the review of human participant research.
- Providing leadership and oversight, in partnership with the IRB Administrator, for the policies, procedures, practices, and functioning of the IRB and human participants in research at the institution.
- Serve as an IRB expert liaison to the greater research community to answer questions about IRB review and processes. Provide informal training and support to new members.
- Facilitating Board meetings and serving as the lead reviewer for full board reviews.

b. Registration of the FWA

The IRB Administrator will submit and maintain William Paterson University's Federal Wide Assurance for the Protection of Human Subjects through the Office of Human Research Protections. The IRB administrator will update the FWA as necessary to reflect current membership. The requirements of the FWA will only be applied to sponsored human subjects research that must be reviewed under an FWA.