WILLIAM PATERSON UNIVERSITY
INSTITUTIONAL REVIEW BOARD **PROTOCOL #_____**

REVIEW FORM for Protocols from Faculty, Staff and Outside Researchers

PROPOSAL TITLE: _____

PRINCIPAL INVESTIGATOR: _____

Instructions

Your review of this protocol will determine (1) whether human subjects are or are not at risk, (2) if informed consent is present and adequate, (3) the type of review that is required for this research, and (4) identify information that is needed to complete the review and/or changes that are needed prior to final action on the protocol.

Your recommend to the IRB will be to (1) to approve the protocol as submitted; (2) to approve the protocol contingent on the provision of additional information or specific revisions; (3) to table the protocol for substantive changes and resubmission to the Committee; (4) disapprove the protocol. Comments on the research design concerning risks to the subject or investigator, subject selection plan, the benefits of research, and feasibility of research as it relates to the subjects are encouraged.

Review

1A: Determination of risk. Please check Yes or No for each of the following. See attached definitions.

	Identification of Risks	**Determination**
1.	Are the risks minimal?	❑ Yes ❑ No
2.	Are risks minimized?	❑ Yes ❑ No
3.	Are risks reasonable in relation to benefits?	❑ Yes ❑ No
4.	Is subject selection equitable (e.g., subject populations included/excluded; risk of coercion in recruitment)?	❑ Yes ❑ No
5.	Is the process for obtaining consent appropriate?	❑ Yes ❑ No
6.	Is there adequate provision for monitoring the data collection to insure safety of subject?	❑ Yes ❑ No
7.	Are the provisions for protecting privacy or anonymity adequate?	❑ Yes ❑ No
8.	Are provisions for maintaining confidentiality adequate?	❑ Yes ❑ No
9.	Are safeguards for subjects vulnerable to coercion or undue influence included?	❑ Yes ❑ No
10.	Does the research setting (e.g., location of research; facilities) provide adequate safeguards for protection (e.g., anonymity, confidentiality or safety) of the human subjects?	❑ Yes ❑ No
11.	There are no concerns about any of the following: sensitivity of questioning; medical records and chart reviews; residual body fluids, tissues and recognizable body parts; possible emergency medical care; use of ionizing radiation; use of blood, blood products, body fluids or tissue specimens.	❑ Yes ❑ No
	Special Classes of Subjects (vulnerable populations)	
12.	Were subjects appropriately identified as one of the WPUNJ Special Classes of Subjects (vulnerable population)?	❑ Yes ❑ No
13.	Are the unique risks or concerns related to these subject addressed and minimized?	❑ Yes ❑ No

1B: If you answered NO to any items, please explain identified risks or concerns and what you would want to see modified to either eliminate or reduce the risk(s). (Please be detailed; last page or additional pages if necessary.):

2. Informed Consent:

A. Is Informed Consent included? ☐ Yes ☐ No ☐ Not Required
Who is Informed Consent provided for? If Consent is not required, why?

B. Is Informed Consent adequate? ☐ Yes ☐ No ☐ Not Applicable
If Informed Consent is NOT adequate, why?

(3) Determination of type of review. Please check one. See attached definitions.

_____Exempted Review _____Expedited Review _____Full Review

(4) Questions and concerns that must be addressed prior to final approval. (Please be detailed, use last page or additional pages as necessary.)

Recommendation

___ Approve the protocol as submitted.

___ Approve the protocol contingent on the provision of additional information or specific revisions are received.

___ Table the protocol for substantive changes and resubmission to the Committee.

___ Disapprove the protocol.

Reviewer Name: _____

Reviewer Signature:_____ **Date:**_____

Definitions

1. Minimal risk: The probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves from those ordinarily encountered in daily life or during the performance of routine physical or psychological examination or tests.

2. Vulnerable populations (Special Classes of Subjects): Those individuals or groups of individuals lacking or perceiving the lack of freedom to choose to participate in research. Federal regulations required full review unless specific exemptions are met for the following groups: children & minors (exempt and expedited categories apply unless for biomedical research; parental consent required), prisoners (no exemptions; initial consent/approval by prison IRB), fetuses and pregnant women (to be considered vulnerable for biomedical research only). WPU extends the definition to include any person or groups or people who may feel that their participation in a particular research study may have an adverse affect on their educational experience, employment, health care, personal safety, or other condition(s), can include WPU students, faculty or staff.

3. Informed Consent: The statement provided for prospective research subjects that will let the subjects make an informed choice to participate in the proposed research. The statement must include basic information about the research and who is conducting it, what is expected of the subjects, that they do not have to participate, and that they may stop their participation at any point. The statement must, as needed, include risks to the subject, benefits accrued through the research, compensation of subjects, contact names and phone numbers for questions or concerns. It can be passive (signature is not required) or active (signature required) as determined by the methodology and target subject characteristics. Parent/guardian consent required for children & minors, and then assent to participate by children & minors is also required.

4. Exempted Review: Research for which there is no risk to the subject. This may be reviewed by one member of the IRB with Committee review approval at next meeting. Includes (a) research involving the use of education tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior unless information collected could identify the subjects, places the subject at risk, if the subject is an elected or appointed public official or candidate, or if Federal statute requires confidentiality; (b) research involving the collection or study of existing data, documents, records, pathological or diagnostic specimens if publicly available and available before the study begins and if the subjects cannot be identified; and (c) taste and food quality evaluation and consumer acceptance studies if (1) wholesome food without additives is consumed, or (2) if wholesome food with approved additives are consumed. Exempted review cannot be used for research involving vulnerable populations.

5. Expedited Review: Research for which there is not more than a minimal risk to the subject. This may be reviewed by one member of the IRB with Committee review approval at next meeting. Includes (1) research involving interview procedures, (2) research on drugs or devices for which an "investigational new drug" or an "investigational new device" exemption is not required; (3) research requiring the collection of blood samples by finger stick, heel stick, ear stick, or venipuncture from (i) healthy nonpregnant adults who weigh at least 110 pounds and amounts do not exceed 550 ml in an 8 week period and collection is not more than twice per week, or (ii) from other adults if the amount drawn does not exceed 50 ml in an 8 week period and is not more than twice per week; (4) research requiring collection of biological specimens by noninvasive means; (5) research requiring collection of data through non-invasive procedures routinely employed in clinical practice, excluding x-rays and microwaves; (6) research involving materials (data, documents, records or specimens) that have been collected or will be collected solely for non-research purposes; (7) research involving the collection of data from voice, video, digital or image recordings made for research purposes; (8) research on individual or group characteristics or behavior, or research employing survey, interview, oral history, focus group, program evaluation or quality assurance methodologies.

6. Full Review: Research for which there is more than a minimal risk to the subject. May be reviewed only by the full IRB Committee. Includes research that does not fit under the exempted or expedited categories.

7. Studies that WPU does not require to be reviewed: (1) Research conducted by the administration of the University involving its faculty, staff, students, alumni or other related constituencies and concerning the operation of the University, its interaction with its various constituencies, or for other administrative purposes. (2) Research evaluating the conduct or outcome of a project, program, course or other activity sponsored by the University, except when it is a research project specifically including human subjects. (3) The pedagogical assessment or evaluation of the effectiveness or efficacy of curriculum materials, resources and educational techniques by faculty, staff and WPU students when that research does not offer substantially different learning outcomes. This specifically includes an instructor looking at his/her work product or the work product of his/her students with the goal of improving future classroom practices. When the study includes the classroom or programs of an instructor(s) who is not the investigator, it would require IRB review. (4) Oral history projects when the study does not include biomedical or socio-behavioral questions.

Form adapted from a checklist prepared by University of Kentucky which is based on a checklist prepared by the University County Hospital, Tampa, Florida. Adaptation prepared by Martin B. Williams, December 1997; revised September 1998, December 1999, and December 2008.

Continuation of Responses to Review Questions (please identify)