WILLIAM PATERSON UNIVERSITY

Protocol No.: _____

Date Received: _____
For IRB Use Only

Institutional Review Board for Human Subject Research

APPENDIX C2: PROTOCOL FACE SHEET

For use by WPUNJ Doctoral Students

Instructions: Submit one original protocol prior to the initiation of any work involving human subjects or human material to the IRB Administrator c/o the Office of Sponsored Programs, Raubinger Hall, Room 309. A complete protocol includes: (A) this form completed and signed, (B) a complete description of the research plan, (C) one copy of all test instruments, and (4) one copy of all draft informed consent statements. IRB Training Certification for the principal investigator and other investigators* must have been received by the IRB before this protocol is submitted. (*Certification of training is not required for WPU undergraduate or master's degree students. A copy of certifications for investigators affiliated with other institutions should be attached.)

Doctoral Candidate(s) _____

Program and Department _____

Contact Phone and Email _____

Home Address _____

Other Investigators _____

Faculty Sponsor _____

Course _____

Title of Research _____

Research Dates Beginning: _____ Ending: _____

PLEASE ANSWER THE FOLLOWING QUESTIONS:

	Yes	No	
1.	____	____	Is this research part of or related to a previously approved protocol or is it associated with a sponsored project or activity of William Paterson University or another institution? If so, please identify: _____
2.	____	____	Human subjects to be involved in the proposed activity include: (select all that apply)

☐	Children or minors	☐	Mental or behavioral disorder	☐	Limited English Proficiency
☐	Fetuses	☐	Developmental disability	☐	Other:
☐	Abortuses	☐	Physical disorder or disability	☐	
☐	Pregnant women	☐	WPUNJ students	☐	
☐	Prisoners	☐	WPUNJ employees	☐	Adults

3.	____	____	Will subjects be videotaped or audiotaped?
4.	____	____	Does the project involve in-person interviews?
5.	____	____	Does the project involve the use of human blood, blood products, tissues or body fluids?
6.	____	____	If Question #7 is yes, have you attended the Occupational Exposure to Blood-borne pathogens program offered by the WPU College of Science and Health?
7.	____	____	Does the project involve the use of electrical apparatus other than routine care equipment?

8. ____ ____ Are all of the follow items attached to this form?

- Research plan: Including
  a. Research Hypothesis
  b. Purpose and Background of the Research
  c. Methodology: (1) design of research, (2) information to be collected, (3) instruments to be used, (4) how data will be analyzed, (5) plan for storage and disposition of data and recordings, and (6) identification of research locations and whether those locations have agreed to participate in this research
  d. Human Subjects: (1) description of subjects, (2) identification and consideration of vulnerable populations or special classes of subjects, (3) recruitment and selection plan, (4) protection of anonymity and/or confidentiality of subjects, and (5) informed consent process
  e. Risks and Benefits: (1) potential risks, (2) potential benefits, and (3) risk/benefit analysis
- Data collection instruments
- Informed Consent Statements

Signatures:

Doctoral Candidate: _____ Date: _____

Doctoral Candidate: _____ Date: _____

Faculty Sponsor: _____ Date: _____

For Completion by IRB Only

Training Certification Confirmation

Name	Title/Role in Project	Federal Regulations	WPUNJ Policy & Procedures

Initial Review
Reviewers: _____ Type: _____ Decision: _____ Date: _____

IRB Review
Date: _____ Affirmed: Yes ___ No ___: _____

First Continuing Review Date: _____

APPENDIX C2: PROTOCOL FACE SHEET

For use by WPUNJ Doctoral Students

Items to be Included in the Research Plan, which is also known as the "protocol narrative:"

A. Research Hypothesis

B. Purpose and Background of the Research

C. Methodology:

(1) design of research

(2) information to be collected

(3) instruments to be used

(4) how data will be analyzed

(5) plan for storage and disposition of data and recordings

(6) identification of research locations and whether those locations have agreed to participate in this research

D. Human Subjects:

(1) description of subjects

(2) identification and consideration of vulnerable populations or special classes of subjects

(3) recruitment and selection plan

(4) protection of anonymity and/or confidentiality of subjects

(5) informed consent process

E. Risks and Benefits:

(1) potential risks

(2) potential benefits

(3) risk/benefit analysis

F. Data collection instruments

G. Informed Consent Statements

APPENDIX D.1: Passive Informed Consent for Surveys or Questionnaires

The following is a sample consent form written in the format that is requested by the IRB. There are sections with required statements which are to be used in all consent forms and also a few sections have selected statements you may choose from depending on the type of study you are going to do. When writing your consent form(s), please use one tense throughout the document (either "I" or "You") for consistency and use headings if needed. When your consent form is approved, date it with the approval date. If a revision is approved change the date on all forms used after the approval, update them as well. The name of the research project must be on each page of the statement and each page must be numbered.

****

Required Heading for Student Research:

William Paterson University
Project Title: _____
Principal Investigator: _____
Other Investigators: _____
Faculty Sponsor: _____
Contact Phone Number: _____
Department: _____
Course Name and Number: _____
Date: _____

Required Heading for Non-Student Research:

William Paterson University
Project Title: _____
Principal Investigator: _____
Contact Phone Number: _____
Other Investigators: _____
Department: _____
Date: _____

****

This [insert survey or questionnaire] concerns [insert descriptive statement]. [If student research, insert: It is being conducted to fulfill the requirements of the above named course.] I understand that my participation is voluntary and I may stop completing the [insert survey or questionnaire] at any time and I do not have to answer any question(s) I choose not to answer. Risks associated with my completing this [insert survey or questionnaire] are [insert risks] and I accept them. I understand that my identity will not be revealed in any way through my participation in this study; I will not write my name on this document and the results will not be reported in a way that will reveal individual participants. If I do not want to complete this [insert survey or questionnaire] I may return it uncompleted as instructed for completed documents or I may keep it. If I choose to participate, I will complete and return this document by [insert return instructions].

APPENDIX D.2.a: Active Informed Consent for Interviews and Other Minimal Risk Studies

The following is a sample consent form written in the format that is requested by the IRB. There are sections with required statements which are to be used in all consent forms and also a few sections have selected statements you may choose from depending on the type of study you are going to do. When writing your consent form(s), please use one tense throughout the document (either "I" or "You") for consistency and use headings if needed. When your consent form is approved, date it with the approval date. If a revision is approved change the date on all forms used after the approval. Update them as well. The name of the research project must be on each page of the statement and each page must be numbered.

****

Required Heading for Student Research:

William Paterson University
Project Title: _____
Principal Investigator: _____
Other Investigators: _____
Faculty Sponsor: _____
Contact Phone Number: _____
Department: _____
Course Name and Number: _____
Date: _____

Required Heading for Non-Student Research:

William Paterson University
Project Title: _____
Principal Investigator: _____
Contact Phone Number: _____
Other Investigators: _____
Department: _____
Date: _____
****

I have been asked to participate in a research study on [insert descriptive statement]. The purpose of this study will be to [insert descriptive statement]. I understand that I will be asked to [insert activity(s)]. Potential risks from participating in this survey include [insert list], they have been explained to me and I accept them.

I understand that my participation is entirely voluntary and I may end my participation in this research at any time. I understand that my identity will be protected at all times and that my name will not be used without my separate written permission. I understand that the results of this study will not be reported in a way that would identify individual participants. [If this is for a focus group or if multiple participants are present, insert: I understand that I must protect the identity of the other participants in this study and may not tell anyone outside this group what was said by any member of the group.]

I may call the investigators [insert name(s)] or the other individuals listed in the heading of this document if I have any questions or concerns about this research and my participation. I may call the Associate Provost for Academic Affairs (973-720-2565) for information regarding my rights as a research subject.

By signing this consent form, I am agreeing to participate in this research study.

Name of Subject_____ Signature of Subject_____
Date: _____
Name of Investigator_____ Signature of Investigator_____
Date:_____
Name of Witness_____ Signature of Witness_____
Date:_____ Only include witness signature For vulnerable populations or other special needs

APPENDIX D.2.b: Active Informed Consent for Studies with More than Minimal Risk

Following is a sample consent form written in the format that is requested by the IRB. There are sections with required statements which are to be used in all consent forms and also a few sections have selected statements you may choose from depending on the type of study you are going to do. When writing your consent form(s), please use one tense throughout the document (either "I" or "You") for consistency and use the bold headings provided. When you submit your consent form(s), please date them and when a revision is submitted for review, update them as well. The name of the research project must be on each page of the statement and each page must be numbered.

****

Required Heading:

William Paterson University
Project Title: _____
Principal Investigator: _____
Contact Phone Number: _____
Other Investigators: _____
Department: _____
Date: _____

****

INVITATION TO PARTICIPATE: I am being asked to participate in a research study because, etc.

PURPOSE: The purpose of the study should be expressed in lay language and should clearly state the nature of the research project.

PROCEDURES: The subject must be informed exactly what his/her participation will involve. This may include the length and frequency of hospitalization; types of medication; placebo administration; types and number of tests; amount of blood to be drawn (in terms a lay person can understand such as ounces, tablespoons, teaspoons); randomization; questionnaires, including the type of information to be asked; video-taping; diets; withholding of standard treatment; follow-up studies; duration of participation; etc. If a test article is involved, the consent form should explain that: 1) It is routinely used for the proposed purposes of the study; and 2) It is experimental and not approved for general use in the United States but has been approved for the use in this study.

RISKS: Describe potential physical and psychological risks in lay language.

BENEFITS: Direct or to society. If there is not direct benefit to the subject, a statement reflecting this fact must be recorded.

ALTERNATIVES: Describe in lay language how the patient would be treated if not otherwise in a research study and any potential adverse effects from the alternatives.

COMPENSATION: Describe any fees (dollar amount) to be paid to the subject for participation, describe partial payment or no payment for early termination or bonus for completion. Or a statement that there will not be financial compensation for participation.

CONFIDENTIALITY: There are two standard statements of confidentiality, one of which needs to be included in this section.

For clinical trials: I understand that all information collected in this study will be kept strictly confidential, except as may be required by law. I further understand that representatives of the Sponsor, as well as the Food and Drug Administration, may review the data collected from this study and my medical records. If any publication results from this research, I will not be identified by name.

For non-clinical trial studies: I understand that all information collected in this study will be kept strictly confidential, except as may be required by law. If any publication results from this research, I will not be identified by name.

ADDITIONAL INFORMATION: A statement that any significant new findings developed during the course of the study that may relate to the subject's willingness to continue participation will be provided to the subject. The investigator must provide the subject and the IRB with a written statement concerning any significant finding(s) that may potentially influence a subject's decision to continue participating in the study. In this circumstance the investigator must renegotiate informed consent.

For Clinical Trials involving investigational medications: I understand that there is no guarantee that I may continue receiving the medication at the end of this study.

PREGNANCY: The following statement (as is or amended as appropriate) must be included in the informed consent only if the study drug/device could effect women of child-bearing age, the unborn fetus or a women breast-feeding a child.

Due to the effect of this drug/device, there could be serious harm to unborn children (or children who are breast-feeding) and it could also jeopardize the health of the mother. In addition, it is possible that harmful side effects that are not yet known could occur to both the mother and unborn or breast-feeding child. For this reason, if I am pregnant, I will inform you and understand I will not be included in the study. If I am still capable of becoming pregnant, I will be given a pregnancy test prior to entry into the study. I also understand that I will practice a medically approved method of birth control during my participation in the study. Further, I understand that while I am taking this drug/device I should not become pregnant, and if I do become pregnant, I must discontinue the drug/device and consider termination of the pregnancy.

DISCLAIMER/WITHDRAWAL: There are two standard statements of disclaimer/withdrawal, one of which needs to be included in this section.

For medical studies: I agree that my participation in this study is completely voluntary and that I may withdraw at any time without prejudicing my present or future care. I also understand that should my physician find it necessary, and/or in my best interest, he/she may withdraw me from the study.

For non-medical studies: I agree that my participation in this study is completely voluntary and that I may withdraw at any time without prejudicing my standing within William Paterson University or my class.

INJURY/COMPLICATIONS: The following statement is used in 95% of all consent forms:
I understand that in the event of an injury resulting from the research procedures, medical treatment in excess of that covered by third party payers will be provided without cost to me, but financial compensation is not available.

For studies where an adverse effect is not separately identifiable from a patient's disease process:

I understand that complications may arise during the course of therapy either due to my disease or due to the treatment. I have been advised that my doctors will carry out therapy for any such complications and third party payers may provide costs associated with such care. I have been advised that no compensation will be provided to me as a result of my participation in this study.

SUBJECT RIGHTS: I understand that if I wish further information regarding my rights as a research subject, I may contact the Associate Provost for Academic Affairs by telephoning 973-720-2565. I also understand that if I have any questions pertaining to my participation in this particular research study, I may contact the investigator by calling the telephone number(s) listed at the top of page one. I have been given the opportunity to ask questions and have had them answered to my satisfaction.

CONCLUSION: I have read and understand the consent form. I agree to participate in this research study. Upon signing below, I will receive a copy of the consent form.

Name of Subject_____ Signature of Subject_____
Date: _____

Name of Investigator_____ Signature of Investigator_____
Date:_____

Name of Witness_____ Signature of Witness_____
Date:_____ Only include witness signature for vulnerable populations or other special needs

APPENDIX D.2.c: Active Informed Consent for Venipuncture and Other Simple Invasive Procedures

Following is a sample consent form written in the format that is requested by the IRB. There are sections with required statements which are to be used in all consent forms and also a few sections have selected statements you may choose from depending on the type of study you are going to do. When writing your consent form(s), please use one tense throughout the document (either "I" or "You") for consistency and use the bold headings provided. When you submit your consent form(s), please date them and when a revision is submitted for review, update them as well. The name of the research project must be on each page of the statement and each page must be numbered.

****

Required Heading:

William Paterson University
Project Title: _____
Principal Investigator: _____
Contact Phone Number: _____
Other Investigators: _____
Department: _____
Date: _____
****

Additional consent for [insert name for procedure].

This research is studying [insert descriptive statement]. I understand that approximately [insert amount as formula and words as appropriate] of my blood will be needed. [Insert description of procedure, such as: The procedure involves placing a needle in a vein in my arm to take blood and will require no more than [insert number] minutes. Occasionally there are minor complications, and I may experience bruising, swelling and/or black and blue marks at the site.]

I understand that although the results of this test may not benefit me directly, they can be made available to your physician upon request. I understand that data collected during this study will be confidential, except as may be required by law, and any publication resulting from the research will not personally identify any participants. All risks have been explained to me and I accept them. I understand that my decision to take part in this study is voluntary and that medical care will not be affected if I refuse to participate. I may end my participation anytime without prejudice to present or future care. I will be given a copy of this consent form.

Should I wish further information regarding your rights as a research subject, I may contact the Associate Provost for Academic Affairs at 973-720-2565.

I understand that in the event of physical injury resulting from the research procedure, medical treatment in excess of that covered by third party payers will be provided at no cost to me. I understand that financial compensation is not available for participation in this research.

By signing below, I consent to my participation in the procedure described above.

Name of Subject_____Signature of Subject_____
Date: _____

Name of Physician_____Physician's Phone_____
Date: _____

Name of Investigator_____Signature of Investigator_____
Date:_____

Name of Witness_____Signature of Witness_____
Date:_____ Only include witness signature For vulnerable populations or other special needs