



Protocol No.: _____
Date Received: _____ For IRB Use Only

**Institutional Review Board for Human Subject Research**

**APPENDIX A: PROTOCOL FACE SHEET**

For use by WPUNJ Faculty and Staff and by Outside Researchers

**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 107. A complete protocol includes: (1) a completed and signed Appendix A: Protocol Face Sheet, (2) a complete description of the research plan, (3) single copies of all test instruments, and (4) all informed consent statements. IRB Training Certification, if not on file with the IRB, and the WPUNJ Conflict of Interest and Commitment Disclosure Form, if not on file with the OSP, must be attached as well for each investigator listed below.

Principal Investigator, \_\_\_\_\_  
 Title and Department \_\_\_\_\_  
 Campus Mailing Address \_\_\_\_\_  
 Campus Phone, Email Address \_\_\_\_\_  
 Other Investigators \_\_\_\_\_  
 Project Title \_\_\_\_\_

Research Dates Beginning: \_\_\_\_\_ Ending: \_\_\_\_\_

If Applicable:  
 Funding Agency or Sponsor \_\_\_\_\_  
 OSP Proposal Number \_\_\_\_\_

**PLEASE ANSWER THE FOLLOWING QUESTIONS:**

	Yes	No																
1.	_____	_____	Is this application for a fellowship/stipend only?															
2.	_____	_____	Is this application for an internal WPU funding program? Program: _____															
3.	_____	_____	Is this project to be undertaken as part of a previously approved research, training, program development or program implementation grant? Funding agency, project title and project director=s name and institution if not WPUNJ: _____															
4.	_____	_____	Human subjects to be involved in the proposed activity are or have (mark all that apply): <table border="0" style="width: 100%;"> <tr> <td>_____ Children or minors</td> <td>_____ Mental or behavioral disorder</td> <td>_____ Limited English Proficiency</td> </tr> <tr> <td>_____ Fetuses</td> <td>_____ Developmental disability</td> <td></td> </tr> <tr> <td>_____ Abortuses</td> <td>_____ Physical disorder or disability</td> <td>_____ Other:</td> </tr> <tr> <td>_____ Pregnant women</td> <td>_____ WPUNJ students</td> <td></td> </tr> <tr> <td>_____ Prisoners</td> <td>_____ WPUNJ employees</td> <td>_____ Adults</td> </tr> </table>	_____ Children or minors	_____ Mental or behavioral disorder	_____ Limited English Proficiency	_____ Fetuses	_____ Developmental disability		_____ Abortuses	_____ Physical disorder or disability	_____ Other:	_____ Pregnant women	_____ WPUNJ students		_____ Prisoners	_____ WPUNJ employees	_____ Adults
_____ Children or minors	_____ Mental or behavioral disorder	_____ Limited English Proficiency																
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_____ Pregnant women	_____ WPUNJ students																	
_____ Prisoners	_____ WPUNJ employees	_____ Adults																
5.	_____	_____	Will subjects be videotaped or audiotaped?															
6.	_____	_____	Does the project involve in-person interviews with open-ended questions?															
7.	_____	_____	Does the project involve the use of human blood, blood products, tissues or body fluids?															
8.	_____	_____	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?															
9.	_____	_____	Does the project involve administration of ionizing radiation t subjects for other than clinical purposes?															

10    Yes    No  
 \_\_\_\_\_    \_\_\_\_\_    Does the project involve the testing of investigational drugs or devices?, If YES, please provide:  
 Name of Drug or Device    \_\_\_\_\_  
 IND# or IDE#    \_\_\_\_\_  
 Name of Manufacturer    \_\_\_\_\_

Attach one copy of a brochure, flyer or other information concerning the drug or device.

11    \_\_\_\_\_    \_\_\_\_\_    Does the project involve the use of electrical apparatus at WPUNJ other than routine care equipment?

12    \_\_\_\_\_    \_\_\_\_\_    Are the follow items attached to this Appendix A: Protocol Face Sheet?

13    \_\_\_\_\_    \_\_\_\_\_  
 there is a    there is  
 conflict    not a  
                   conflict

I certify that this proposal complies with the WPUNJ *Conflict of Interest and Commitment Policy* (<http://ww3.wpunj.edu/osp>). If a potential conflict may exist for me or any other senior project personnel, a *Conflict of Interest and Commitment Disclosure Form* is attached.

- Research plan: Including Purpose, Duration, Subject Recruitment and Selection, Location, Background, Research Design, Potential Risks, Consent Procedures, Protection of Subjects, Potential Benefits, and Risk/Benefit Statement.
- Data collection instruments
- Informed Consent Statements
- IRB Training Certification if not already on file with the IRB.
- WPUNJ Conflict of Interest and Commitment Disclosure Form if “yes” is checked.

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 Signatures:

Principal Investigator: \_\_\_\_\_ Date: \_\_\_\_\_

Other Investigator: \_\_\_\_\_ Date: \_\_\_\_\_

\*Department Chairperson: \_\_\_\_\_ Date: \_\_\_\_\_

Department: \_\_\_\_\_

\*Other: \_\_\_\_\_ Date: \_\_\_\_\_

Unit: \_\_\_\_\_

\*The signature of each department chairperson with faculty involved, is required. A Dean's signature must be obtained if the investigator is also the chairperson. If additional signatures are required, please attach a second Page 2 for those signatures.

Training Certification Confirmation

To be completed by Principal Investigator		To be completed by IRB		
Name	Title/Role in Project	Federal Regulations	WPUNJ Policy & Procedures	Conflic of Interest Disclosure

..... For Completion by IRB Only .....

Initial Reviewer: \_\_\_\_\_ Type: \_\_\_\_\_ Decision: \_\_\_\_\_ Date: \_\_\_\_\_

Committee Review Date: \_\_\_\_\_ Affirmed: Yes \_\_\_ No \_\_\_: \_\_\_\_\_

First Continuing Review Date: \_\_\_\_\_