



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

Institutional Review Board for Human Subject Research

APPENDIX A-1: PROTOCOL FACE SHEET FOR OUTSIDE INVESTIGATORS

For use only by investigators who are not affiliated with WPUNJ.

Instructions:

1. This form is to be used when the principal investigator is not affiliated with WPUNJ; this includes undergraduate students, graduate students, faculty and other individuals. If a senior investigator on this project is affiliated with WPUNJ, he/she may submit a protocol on behalf of this project to the WPUNJ IRB using Appendix A and the related process.
2. A previous contact must have been made with someone at WPUNJ, they must have agreed to support this research, to be the on-campus research representative and their role must be stated on this form.
3. Submit one original protocol prior to the initiation of any work involving human subjects at William Paterson University to the IRB Administrator c/o the Office of Sponsored Programs, Raubinger Hall, 300 Pompton Road, Wayne, NJ 07470. A complete protocol from an outside investigator includes: (1) a completed and signed Appendix A-1: Protocol Face Sheet for Outside Investigators, (2) a copy of the protocol submitted to her/his home institution's IRB, (3) a copy of the approval notice from her/his home institution's IRB, (4) single copies of all test instruments, (5) all informed consent statements, and (6) copies of Training Certification in the Use of Human Subjects in Research for lead and other senior investigators.

Principal Investigator,
Title, Department and Home
Institution

Mailing Address

Phone, Email Address

Other Senior Investigators

Project Title

Research Dates

Beginning:

Ending:

If Applicable:

Funding Agency or Sponsor

WPUNJ Contact,

Title and Department

Role and activities of your

WPUNJ Contact in this research.

(Confirmation will be requested.)

Has WPUNJ Contact agreed to
assist you with this research?

PLEASE ANSWER THE FOLLOWING QUESTIONS:

- | | | | |
|----|-------|-------|---|
| | Yes | No | |
| 1. | _____ | _____ | Has this research been approved at your home institution?
If yes, then you must attach copies of the protocol that was submitted to your host institution's IRB and their approval notice to you.
If no, then provide information about their review in your research plan. |
| 2. | _____ | _____ | Has this research been funded by an agency other than your home institution?
Funding agency, project title, project director's name and institution, and period of the award: |

- | Yes | No | |
|-----|-------------------------|--|
| 4. | _____ | Human subjects to be involved in the proposed activity are or have (mark all that apply): |
| | _____ | Children or minors |
| | _____ | Fetuses |
| | _____ | Abortuses |
| | _____ | Pregnant women |
| | _____ | Prisoners |
| | _____ | Mental or behavioral disorder |
| | _____ | Developmental disability |
| | _____ | Physical disorder or disability |
| | _____ | WPUNJ students |
| | _____ | WPUNJ employees |
| | _____ | Limited English Proficiency |
| | _____ | Other: _____ |
| | _____ | Adults |
| 5. | _____ | Will subjects be videotaped or audiotaped? |
| 6. | _____ | Does the project involve in-person interviews or focus groups? |
| 7. | _____ | Does the project include access to WPUNJ student or personnel records, email addresses or any other identifying information? |
| 8. | _____ | If Question #7 is yes, have you discussed this with your WPUNJ contact and other WPUNJ offices that will be involved in providing this information if it will not be gathered directly from your subjects? |
| 9. | _____ | Does the project involve the use of human blood, blood products, tissues or body fluids? |
| 10. | _____ | If Question #8 is yes, have you completed appropriate training? |
| 11. | _____ | Does the project involve administration of ionizing radiation to subjects for other than clinical purposes? |
| 12. | _____ | If Question #11 is yes, have you completed appropriate training? |
| 13. | _____ | 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. |
| 14. | _____ | Does the project involve the use of electrical apparatus at WPUNJ other than routine care equipment? |
| 15. | _____ | I certify that this proposal complies with the WPUNJ <i>Conflict of Interest and Commitment Policy</i> (http://ww3.wpunj.edu/osp). If a potential conflict may exist for me or any other senior project personnel, a <i>Conflict of Interest and Commitment Disclosure Form</i> is attached. |
| | there is a conflict | |
| | there is not a conflict | |
| 16. | _____ | Are the follow items attached to this Appendix A-1: Protocol Face Sheet? |
| | | <ul style="list-style-type: none"> • <u>Protocol Submitted and Approved by Your Home IRB</u>: The Protocol should include Purpose, Duration, Subject Recruitment and Selection, Location, Background, Research Design, Potential Risks, Consent Procedures, Protection of Subjects, Potential Benefits, and Risk/Benefit Statement. • <u>Approval Notice Received from Your Home IRB</u> • <u>Data collection instrument(s)</u> • <u>Informed Consent Statement(s)</u> • <u>IRB Training Certification for Principal Investigator and other Senior Investigators</u> • <u>WPUNJ Conflict of Interest and Commitment Disclosure Form</u> if “yes” is checked. |

Signature: _____

Principal Investigator: _____ Date: _____

..... For Completion by IRB Only

WPUNJ Contact Confirmation of Role and Activities to Support Research:

Initial Reviewer: _____ Type: _____ Decision: _____ Date: _____

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

First Continuing Review Date: _____