WAYNESBURG UNIVERSITY

Date

Institutional Review Board

Protection of Human Research Subjects

Protocol Statement

Application for Full or Expedited Review

You must receive approval from the IRB prior to beginning your research.

1. Title of Study

2. Investigators: List **principal** investigator (P.I. first) and all sub-investigators. Five additional names can be added to the end of this document. If more space is needed, make copies of the last page before completing it and submit the sheet(s) with the signature page per instructions later in this document. **NIH or CITI training on protection of human subjects must be completed by all investigators, sub-investigators, and other key personnel before submission of application.**

Name (PI)

Dept./University

Home address

Email address Phone

◯ I certify that I have completed NIH or CITI training. Please provide a copy of certificate of completion.

Name

Dept./University

Home address

Email address Phone

Name

Dept./University

Home address

Email address Phone

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3. RESEARCH PERIOD: NO RESEARCH ACTIVITY MAY BE CONDUCTED UNTIL FORMAL IRB APPROVAL. THIS INCLUDES ADVERTISING, SUBJECT RECRUITMENT, DATA COLLECTION, ETC.

Projected start date Projected end date

4. Reason for conducting research

◯ Professional ◯ Dissertation ◯ Thesis ◯ Class assignment ◯ Capstone Project

◯ Other (specify below)

5. Investigators at institutions other than Waynesburg Univeristy ☐ None

Institutional Affiliation

Investigator's Name

Investigator's Title

Role in Study

Institutional Affiliation

Investigator's Name

Investigator's Title

Role in Study

Institutional Affiliation

Investigator's Name

Investigator's Title

Role in Study

Institutional Affiliation

Investigator's Name

Investigator's Title

Role in Study

6. List additional key personnel other than the investigators who will have contact with subjects: ☐ None

Name

Title

Degree(s)

Name

Title

Degree(s)

Name

Title

Degree(s)

Name

Title

Degree(s)

7. Key personnel other than the investigators who will obtain informed consent: ☐ None

Name
Title
Degree(s)

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Degree(s)

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8. Key personnel other than the investigators who will have contact with data ☐ None

Name		Degree		Title	
Name		Degree		Title	
Name		Degree		Title	

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9. Location for interaction with subjects (provide name of institution, address, and brief description).

10. Indicate which of the following populations will be included in the research.

- ☐ Patients
- ☐ Children (under 18)
- ☐ Intellectually or emotionally impaired subjects
- ☐ Elderly subjects (over 65)
- ☐ Pregnant subjects
- ☐ Employees of institutions associated with study
- ☐ Prisoners, parolees, incarcerated subjects
- ☐ Illiterate subjects
- ☐ Students whose primary language is not English
- ☐ Students or trainees
- ☐ Identifiable student or trainees whose professors are named on this protocol
- ☐ Identifiable students or trainees who are academic advisees or mentors of someone named on this protocol.

11. Indicate which, if any, of the following items are involved

- ☐ Data collected from data banks, archives, medical records
- ☐ Data to be stored in data banks, archives, medical records
- ☐ Filming, videotaping, or voice-recording of subjects
- ☐ Questionnaires
- ☐ Pathological or diagnostic tissue or fluids
- ☐ Deception of subjects (describe in question 18a)
- ☐ None

12. Source of Funding

☐ None

13. Will there be any financial remuneration, reward, reimbursement of expenses, or other inducements to participate?

◯ Yes (explain below) ◯ No

14. Will there be any potential added cost to subjects?

◯ Yes (explain below) ◯ No

15. Do you have any evaluation responsibilities over any of your subjects?

◯ No ◯ Yes (explain below)

16. Are you seeking expedited review?

◯ Yes (Explain why you think this project qualifies for expedited review). ◯ No

17. Please provide an abstract (a brief summary of the purpose and procedures), written in language that can be understood by the non-specialist.

18. Provide complete information for each of the following items.

a. Purpose and procedures: State the research methodology, design, and objectives or specific aims of the project. Provide a complete but concise description of the procedures, deceptions (if any), and nature and location of the contact with participants.

b. Research questions: State the research questions you intend to answer with this project.

c. Participants: State the proposed number of participants. Describe and explain the criteria and methods of recruiting, selecting, including, and excluding participants. Also include the smallest number of subjects from which you plan to collect data at one time.

d. Assent and Consent: Indicate methods of obtaining informed consent or assent from children (under age 18) or incompetent subjects.

- ☐ Written consent form (include a copy)
- ☐ written assent form (include a copy)
- ☐ No assent, under age 7 or severely impaired (discuss below)

- ☐ Requesting waiver or alteration of assent process (discuss below)

e. Attachments: Provide a copy of each survey tool, questionnaire, or other test instrument. Attach "permission to use" communication, if proprietary. Provide any other attachments as well.

f. Risks, discomforts, and benefits: Describe and explain any risks, discomforts, and benefits to the subjects, the scientific community, and/or the local community. If no known risks, state same.

g. Intervention: Do you have an intervention?

- ◯ No
- ◯ Yes (Describe and explain the intervention below).

h. Confidentiality:

- ◯ Anonymous
- ◯ Confidential (Explain how and to what extent confidentiality will be maintained for records that identify participants. Please describe how paper, electronic, and/or media files will be stored and secured during the study and how they will be disposed at the end of the study).

i. Advertisements: Attach ALL printed and electronic ads or media used to recruit/communicate with study participants.

19. Signatures: (The IRB will not review the protocol without these signatures. By signing, department chairs acknowledge approval of this study on the basis of scientific merit and compliance with applicable professional standards; deans and other administrators signify their approval of the use of resources and faculty and student effort on the study. Multi-unit protocols require the signatures of each chair and dean).

My signature below indicates: 1) that I am submitting this protocol as the principal investigator and 2) that I have read and had the opportunity to have any questions answered regarding the contents of the Waynesburg University IRB guidelines.

☐ I certify that all sub-investigators have completed NIH or CITI training. Please provide a copy of certificate of completion for each.

Principal Investigator's name

Date

Principal Investigator's signature -- blue ink only

Title of study

We have reviewed the above information and recommend this study for consideration.

Faculty Advisor

Date

Faculty Advisor, if applicable signature -- blue ink only

Department Chair/Program Director

Date

Department Chair/Program Director signature -- blue ink only

20. A printed copy of the original signature page (and any additional lists of sub-investigators that do not fit on this form) must be mailed to Barbara Kirby at 51 W. College St., Waynesburg, PA 15370. If no additional sub-investigators to list on the next page, you can print this form using the button below. (If you have additional names to add, there is another print button at the end of the next page). Then, save and send this form as an e-mail attachment to bkirby@waynesburg.edu. REMEMBER to **mail** the original signature page and any attachments. Your IRB application will remain inactive until original copy of signature page and any applicable attachments are received.

Print Form

21. Extra page to list additional sub-investigators:

Name
Dept./University
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Principal Investigator's name Date/Time Field

Title of study

Print Form