

APPLICATION FOR FORMAL REVIEW

Institutional Review Board

Wheeling Jesuit University
Donahue Hall, Room 102
Wheeling, WV 26003
304-243-2216

- Initial Submission
- Resubmit

IRB Use only	
IRB # FML	_____
Rec'd Date	_____
Rec'd by	_____
Resub Date	_____
Rev'd by	_____
Rsp by	_____
Approved Date	_____

PART I

Please submit **original plus one (1) copy** of each of the following: (A) copy of completed application, (B) risk explanation, (C) justification for risks to participants, and (D) informed consent. These copies should be sent to the Associate VP for Academic Affairs, Mark Drnach at drnach@wju.edu. All applications are to be single-sided only. You must complete **all** parts of this form. Incomplete applications will be returned unprocessed.

Please **print, type** or **write legibly**.

Name of Principal Investigator(s) _____

Address _____

Phone _____ **E-Mail** _____

Other Researcher(s) _____

Title of Project _____

WJU Sponsoring Department or Program:

- BOLD/BHRM or Business
- Education
- Political Science
- Administration (specify)
- Classroom of the Future
- Other Department or Program (specify)
- Criminal Justice
- Psychology
- Athletic Training
- Nuclear Medicine
- Nursing
- Physical Therapy
- Respiratory Therapy

Affiliation of Investigator/s (check all that apply):

Researchers not employed by Wheeling Jesuit University and **all** student applicants must specify a research sponsor, which can include faculty, administrator or staff employed by WJU.

- Graduate
- Undergraduate
- Faculty
- Staff
- Administration
- Other _____

Research Sponsor: _____ **E-Mail** _____

- Administration (specify)
- Class Project (not an independent study):
- Other (please explain): _____

Funding:

- Project to be submitted for funding: _____ Yes _____ No If yes, please specify funding source:
 _____ Internal _____ external _____ (specify agency)
 _____ Internal _____ external _____ (specify agency)

PART II. Rationale for Risks to Research Participants:

All applicants must complete all Parts of A, B, C, D, and E.

Part A. Research Methods and Instruments

This research involves the recording and analysis of subjects' behavior through information-gathering instruments specified below (**check all that apply**):

- Educational tests (cognitive, diagnostic, aptitude, achievement)
- Survey procedures
- Interviews
- Observation
- Other (specify and explain)

Part B. Risks Involved in Research

Please identify the types of risks involved in your research goals, methods, procedures, and information. (Check all that apply.)

Research purposes and methods involve:

- Payment of subjects for participation
- Access to subjects through a cooperating institution
- Data collection over a period of longer than (a) 6 months or (b) 12 months [circle item (a) or (b) as applicable]

Research purposes necessitate that information will be recorded in such a manner that

- Subjects must be identified
- Subjects are at justifiable risk for criminal or civil liability
- Subjects are at justifiable risk for loss of financial or academic standing
- Subjects are at justifiable risk of loss of reputation or employability

Research purposes necessitate that subjects must

- Reveal sensitive aspects of the subjects' own behavior, such as: sexual activities, practices, behaviors, preferences/orientation, or history; illegal conduct; drug or alcohol use; religion
- Experience stress (e.g., physiological, psychological) above a level that would be associated with their normal everyday activities
- Donate pathological specimens
- Use drugs or other controlled substances
- Apply any substance (a) internally or (b) externally [circle (a) or (b) as appropriate]
- Donate any fluids (e.g., blood) or tissue from subjects

- Be misled or deceived about any aspect or purpose of the research
- Be selected from vulnerable populations or persons who would be judged to have limited freedom of consent, e.g. (check all that apply)
 - ___ (a) children (minors)
 - ___ (b) prisoners
 - ___ (c) pregnant women
 - ___ (d) mentally disabled persons
 - ___ (e) economically or educationally disadvantaged persons
 - ___ (f) other (specify)

Part C. Justification for Risks to Research Participants.

Please attach an explanation of your study addressing the following concerns. Please also explain any items checked from Parts A and B above.

1. Research Project Title
2. Research purposes, goals, hypotheses, and key variables
3. Research procedures, instruments, and methods
4. Benefits and risks of the research methods and results.
5. Specific procedures of collecting, distributing, reporting, recording, storing, and destroying information in ways that protect against potential risks to subjects, including but not limited to: losses of anonymity, privacy, confidentiality, criminal or civil liability, financial or academic standing, reputation, employability.
6. Specific methods and documents for obtaining informed consent of research subjects and, where applicable, cooperating institutions.
7. Specific methods and justification for selecting subject population(s).
8. Exact copies of consent forms for subjects as well as consent from cooperating institution. (Conditions for informed consent are described in the IRB Consent Form Checklist.)
9. Exact copies of instruments

Part D. Informed Consent Documents

All applicants must complete the following checklist for each consent form.

My consent form(s) include(s) the following elements. In clear and non-technical language, my subjects and cooperating institution are informed of:

- ___ 1. The fact that the study is research.
- ___ 2. The purposes of the research.
- ___ 3. The expected duration of the subject's participation.
- ___ 4. The specific procedures to be followed.
- ___ 5. Any foreseeable risks or discomforts.
- ___ 6. The benefits to the subject or to others which may reasonably be expected from the research.

7. _____ Appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject.

OR

_____ N/A

- _____ 8. The extent to which confidentiality of data and privacy of subjects will be maintained.
- _____ 9. For research involving more than minimal risk, whether any compensation and whether any medical treatments are available if injury occurs.
- _____ 10. The continuing right to ask pertinent questions about the research, subjects' rights, and research-related injury to the subject. Specific names and procedures for contacting appropriate persons to obtain answers to these questions are also provided.
- _____ 11. The fact that participation is voluntary, free from coercion and undue influence and that the subject may withdraw his or her consent at any time without penalty or loss of status.
- _____ 12. The availability of technical documents describing the risks and/or benefits of the research.
- _____ 13. In clear, non-technical language, the subjects must attest that they meet minimum conditions for participation and that they have provided researchers with as honest and accurate information as possible to allow the investigator to assess their fitness to participate in the study.
- _____ 14. The subjects must be assured that the Institutional Review Board of Wheeling Jesuit University has granted permission for the research (subsequent to IRB approval).
- _____ 15. The subjects must be provided with contact information (e.g., name and phone number of current IRB Chair) in case of problems with the research or the subjects' rights.

PART E. Certification of Familiarity with IRB Regulations.

1. I am familiar with the policies and procedures of WJU regarding human subjects. I subscribe to the standards described in the Institutional Review and Approval Process document and will adhere to the policies and procedures explained therein.
2. I am familiar with the published guidelines for the ethical treatment of subjects associated with my field of inquiry (e.g., as published by the American Psychological Association, American Sociological Association).
3. I am familiar with and will adhere to the official policies in my department concerning research activity.
4. If changes in procedures involving human subjects become necessary, I will submit these changes for review before initiating the changes.
5. If this research continues into the next academic year, a resubmission with a research update/extension will be submitted.

Date _____ Signature(s) _____
Researcher(s)

Researchers not employed by Wheeling Jesuit University and **all** student applicants must specify a research sponsor, which can include faculty, administrator or staff employed by WJU.

Date _____ Signature(s) _____
WJU Research Sponsor

All applications must be signed by the appropriate Executive Committee Member or Department Chair of the sponsoring department.

Date _____ Signature(s) _____
Department Chair or WJU Executive Committee Member