APPLICATION FOR EXPEDITED REVIEW
Institutional Review Board

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

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

Please submit **one (1)** copy of each of the following: (1) completed application form; (2) rationale for Exempt review (Section D) narrative; (3) informed consent document; (4) exact copies of instruments used to gather the data; and (5) copies of IRB training certificates for ALL researchers, including research sponsor. All applications are to be single-sided only. These copies should be sent to **IRB@wju.edu**.

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

Name of Principal Investigator(s) _____

Address _____

_____

Phone _____ **E-Mail** _____

Other Researcher(s) _____

Title of Project _____

WU Sponsoring Department or Program:

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

Affiliation of Investigator/s (check all that apply):
Researchers not employed by Wheeling University and **all** student applicants must specify a research sponsor, which can include faculty, administrator or staff employed by WU.

☐ Graduate ☐ Undergraduate ☐ Faculty ☐ Staff ☐ Administration ☐ Other _____

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

Type of Research Activities:

Type of Project:

- ☐ Graduate Thesis
- ☐ Independent Study
- ☐ Undergraduate Thesis
- ☐ Demonstration of a Procedure
- ☐ Non-Thesis Research
- ☐ Faculty/Staff Research (specify number and title of class)
- ☐ Administration (specify)
- ☐ Class Project (not an independent study):
- ☐ Other (please explain): _____

Funding:

☐ Project not to be submitted for funding

☐ Project to be submitted for funding: _____

☐ internal ☐ external (specify agency): _____

Rationale for Expedited Review of Research Status:

All applicants for expedited review must complete all of Parts A, B, C, D, and E below. Applicants for expedited review in the health and clinical sciences, psychological or educational studies or fitness studies must also complete the **Supplemental Form for Expedited Review** (attach copy of completed form).

Part A. Nature of Information to be Obtained

Please identify the category(s) under which you are applying for your research to be considered eligible for expedited review.

☐ **Type 1.** This research is conducted in established or commonly accepted educational settings and involves only normal educational practices and information obtained will remain confidential and anonymous and place no more than minimal risk to subjects in that all conditions below are met. (Please refer to Section **Type 2(b)** below. Check all items in **Type 2(b)** below that apply.)

☐ **Type 2.** [Design procedures must meet all conditions of one time (b)]. This research involves only the recording and analysis of subjects' public behavior.

(a) through information-gathering instruments specified below (check all that apply):

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

and

(b) information obtained will remain confidential and anonymous and place no more than minimal risk to subjects in that all conditions below are met:

- ☐ Information obtained will be recorded in such a manner that the subjects cannot be identified
- ☐ Subjects run no risk of loss of financial or academic standing
- ☐ Subjects run no risk of loss of reputation or employability
- ☐ Research purposes and information in no way deal with sensitive aspects of the subject's own behavior, such as: sexual activities, practices, behaviors, or history, illegal conduct, drug or alcohol use

☐ **Type 3.** This research involved only the collection or study of existing data, documents, records, or pathological specimens that are (specify one):

- ☐ Publicly available (specify source) _____

or

- ☐ Recorded in such a manner that subjects cannot be identified

and

For studies involving collection of pathological specimens, exercise and medical data, and psychological information **only**.

- ☐ The information to be collected meets the criteria specified on the **IRB**

Part B. Nature of Subject Access, Treatment, and Participation
Please indicate if your research involves any of the following (check all that apply):

☐ Payment of subjects for participation (Specify):

☐ Access to subjects through cooperating institution . (Specify)

The IRB chair/Committee will determine if an agreement from the cooperating institution is due prior to IRB approval being provided or if contingent approval will be provided, asking the researchers to provide agreement before data collection begins. This will be determined on a case by case basis.

☐ Data collection over a period of longer than
- ☐ (a) 6 months or
- ☐ (b) 12 months

☐ Drugs or other controlled substances

☐ Subjects taking internally or having externally applied any substance(s)

☐ Removing any fluids (e.g., blood) or tissue from subjects

☐ Subjects experiencing stress (e.g., physiological, psychological) above a level that would be associated with their normal everyday activities

☐ Any procedures or activities that might place the subjects in risk (e.g., psychological, physiological, social, academic, or employment-related)

☐ Misleading or deceiving subjects about any aspect or purpose of the research

☐ Subjects who would be judged to have limited freedom of consent (e.g., minors, mentally retarded or ill, some older adults, prisoners)

☐ Collecting data related to privacy issues (e.g., sexual preferences/orientation, practices, history, etc.; religion)

Part C. Rationale for Expedited Review. Applications that meet the criteria specified in Parts A and B might not be eligible for approval by expedited review. Please **attach description of your study** addressing the following concerns and following the outline below. **Please also explain any items checked from Parts A and B above.**

1. Research purposes and goals, as well as benefits and risks.
2. Research instruments and methods.
3. Specific methods and procedures of collecting, distributing, reporting, and recording information in ways that protect against potential risks to subjects.
4. Specific methods and documents for obtaining informed consent of research subjects and cooperating institutions (where applicable).
5. Specific methods and justifications for selection of subject population(s).
6. Exact copies of consent forms for subjects as well as consent from cooperating institution. (Conditions for informed consent are described in the Consent Form Checklist.)
7. 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.

OR

_____ N/A

_____ 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.

OR

_____ N/A

_____ 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.

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

SUPPLEMENT FORM FOR APPLICATION FOR EXPEDITED REVIEW

Institutional Review Board
Wheeling University
Donahue Hall, Room 102
Wheeling, WV 26003
304-243-2216

Complete this form if you are applying for expedited review of your study in the health or clinical sciences, psychological or educational studies, or fitness studies. If your study meets any of the conditions specified below, your study may be eligible for approval by expedited review.

Please submit **two (2)** copies of this completed form and your **Application for Expedited Review (IRB Form EXP)** to IRB, c/o Ms. Jackie Davis, IRB Administrative Assistant, Donahue Hall Room 102. You must complete **all** parts of this form. Incomplete applications will be returned unprocessed.

Part I.

Name(s) of Researcher(s) _____

Address _____

_____

Phone _____ E-mail _____

Title of Project _____

_____

Part II.
Nature of Data Collection

Your study must meet **both** conditions (a) and (b) below:
(a) research activities involve no more than minimal risks to subjects

(b) involvement of human subjects will be in one or more of the following categories **and** carried out through standard methods **(attach all explanations):**

☐ 1. Collection of hair and nail clippings, in a nondisfiguring manner; deciduous teeth; and permanent teeth, if patient care indicates a need for extraction.

☐ 2. Collection of extra and external secretions including sweat, uncannulated saliva.

☐ 3. Recording of data from subjects 18 years of age or older using noninvasive procedures routinely employed in clinical practice, which do not affect evaluation of that subject's clinical performance, and which include the use of physical sensors that are applied either to the surface of the body or at a distance and do not involve input of matter or significant amounts of energy into the subject or an invasion of the subject's privacy. This also includes procedures such as weighing, testing sensory acuity, electrocardiography, electroencephalography, thermography, detection of naturally occurring radioactivity, diagnostic echography, and electroretinography. It does not include exposure to electromagnetic radiation outside the visible range (e.g., x-rays, microwaves).

☐ 4. Collection of blood sample by venipuncture, in amounts not exceeding 450 milliliters in an eight-week period and no more often than two times per week, from subjects 18 yeaqrs of age or older and who are in good health and not pregnant.

☐ 5. Collection of both supra-and subgingival dental plaque and calculus, provided that the procedure is not more invasive than routine prophylactic scaling of the teeth and the process is accomplished in accordance with accepted prophylactic techniques.

☐ 6. Voice recordings made for research purposes such as investigations of speech defects.

☐ 7. Moderate exercise by healthy volunteers.

☐ 8. The study of existing data, records, pathological specimens, or diagnostic specimens.

☐ 9. Research on individual or group behavior or characteristics of individuals, such as studies of perception, cognition, game theory, or test development, where the investigator does not manipulate the subjects' behavior and the research will not involve stress to subjects.

☐ 10. Research on drugs or devices for which an investigational new drug exemption or an investigational device exemption is not required.