General Guidelines

1. Type or word process the application.

2. Complete the form by spelling out agencies or other frequently used terms once, using abbreviations afterwards. Omit items, if necessary, by writing “not applicable.”

3. Indicate the duration of the project as accurately as you can.

4. Federal guidelines require that you submit Full-Review Projects that continue more than a year for annual approval. This progress report and request for renewal is due not later than 11 months after the previous approval date.

5. All submissions must include a sample of the Informed Consent form for your project. (See pp. 6-7 in the Policy).

6. Submit 10 complete copies of your application to the chair of the WVSU-IRB. If there is copious supporting information (such as funding sources, articulation agreements with other institutions), one copy of that is sufficient. None of this material will be returned to you.

7. To be considered for full review, all your materials must be submitted to the chair of the IRB at least three weeks before you need the decision.
West Virginia State University Institutional Review Board

Application for Approval of Research with Human or Animal Subjects

__Full review requested
__Expedited review requested
__Exempt from full review requested

Attach a rationale for your research, explaining the category of Title 45, Code of Federal Regulations, Part 46, Protection of Human Subjects, that applies to your work. An explanation of the exemptions is available from the WVSU-IRB (see p. 31).

Title of Project:

Date of Submission: ___________ / ___________ / ___________

Type of Project: ___ new ___ continuation ___ course related: ____________________________

(Number & Name of course)

Investigators
Principal investigator:

______________________________

Name Status: faculty, staff, graduate student, undergraduate student Department/Unit

Other investigators: (attach list of additional investigators if necessary)

______________________________

Name Status: faculty, staff, graduate student, undergraduate student Department/Unit

______________________________

Name Status: faculty, staff, graduate student, undergraduate student Department/Unit

If this is a student project, who is the faculty sponsor?

______________________________

Name Position/Department

Contact Information
Mailing address of Principal Investigator or Faculty Sponsor:

______________________________

E-mail: ____________________________ Telephone ___________

Project duration: from ___________ to ___________

Project Description: Attach page(s) that enable the WVSU-IRB to understand (1) the project’s objectives, (2) methods of research, and (3) significance.
Check any of the following which are involved in your project:

- students as subjects
- students as researchers
- patients as subjects
- non-patient volunteers
- trainees as subjects
- subjects under 18 years of age
- subjects whose major language is not English
- subjects with a mental disability
- subjects with a physical disability
- subjects with a developmental disability
- prisoners, parolees, or incarcerated subjects
- subjects not at West Virginia State University
- subjects in the active duty Armed Services
- filming, video-taping, or voice-recording subjects
- data banks, data archives, and/or registration records
- subjects to be paid

The principal investigator must assure the WVSU-IRB that all procedures performed under the project will be conducted by individuals legally and responsibly entitled to do so. Any deviation from the project—for example, a change in principal investigator, research methods, subject recruitment process, etc.—must be submitted to the WVSU-IRB for approval prior to implementation.

I acknowledge that all procedures will meet relevant local, state, and federal regulations regarding the use of human subjects in research.

__________________________________________________________________________
Principal investigator’s signature  date

__________________________________________________________________________
Faculty sponsor’s signature (if applicable)  date

__________________________________________________________________________
Department chair’s signature  date

__________________________________________________________________________
Dean’s or Supervisor’s signature  date
Explanations of Exemptions


Research activities in which the only involvement of human subjects will be in one or more of the following categories may be exempt from the full review:

1. Research conducted in established or commonly accepted educational settings, involving normal educational practices, such as
   (i) research on regular or special educational instructional strategies, or
   (ii) research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.

2. Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior, unless
   (i) information obtained is recorded in such a manner that human subjects can be identified, directly or through identifiers linked to the subjects; and
   (ii) any disclosure of the human subjects’ responses outside the research could reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects’ financial standing, employability, or reputation.

3. Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior that is not exempt under 2 above, if
   (i) the human subjects are elected or appointed officials or candidates for public office; or
   (ii) Federal statute(s) require(s) without exception that the confidentiality of the personally identifiable information will be maintained throughout the research and thereafter.

4. Research involving the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens, if these sources are publicly available or if the information is recorded by the investigator in such a manner that the subjects cannot be identified, directly or through identifiers linked to the subjects.

5. Research and demonstration projects which are conducted by or subject to the approval of Department or Agency heads, and which are designed to study, evaluate, or otherwise examine
   (i) public benefit or service programs;
   (ii) procedures for obtaining benefits or services under those programs;
   (iii) possible changes in or alternatives to those programs or procedures; or
   (iv) possible changes in methods or levels of payment for benefits or services under those programs.

* http://ohrp.osophs.dhhs.gov/humansubjects/guidance/45cfr46.htm
6. Taste and food quality evaluation and consumer acceptance studies,

(i) if wholesome foods without additives are consumed or (ii) if a food is consumed that contains a food ingredient at or below the level and for a use found to be safe, or agricultural chemical or environmental contaminant at or below the level found to be safe, by the Food and Drug Administration or approved by the Environmental Protection Agency or the Food Safety and Inspection Service of the U.S. Department of Agriculture.

(ii) if a food is consumed that contains a food ingredient at or below the level and for a use found to be safe, or agricultural chemical or environmental contaminant at or below the level found to be safe, by the Food and Drug Administration or approved by the Environmental Protection Agency or the Food Safety and Inspection Service of the U.S. Department of Agriculture.