SHENANDOAH UNIVERSITY

HUMAN SUBJECTS REVIEW BOARD

POLICY

Shenandoah University's policy requires review and approval of all activities which involve using human subjects in research. The Human Subjects Review Board (HSRB) serves as the University's Institutional Review Board (IRB) which is responsible to the Vice President for Academic Affairs. Approval of the HSRB must be obtained prior to involvement of human subjects. Failure to have human subjects research reviewed by the HSRB, including those protocols believed to be exempt, is a violation of University policy and will be reported to the Vice President for Academic Affairs for disciplinary action.

SELECTING YOUR REVIEW CATEGORY

IF YOUR PROJECT MEETS ALL OF THE FOLLOWING CRITERIA, YOU SHOULD SELECT EXEMPTION REQUESTED REVIEW:

- ❑ Research conducted in established or commonly accepted educational settings
- ❑ Research involving the use of educational tests if subjects cannot be identified
- ❑ Research involving surveys, interviews, or observations of public behavior that do not deal with sensitive or critical responses. All research using survey or interview procedures is exempt when the respondents are elected or appointed public officials or candidates for public office.
- ❑ The project will not involve subjects in high risk groups (See Form A, Item 11).
- ❑ Research involving the collection or study of existing data or specimens that are either publicly available, or not individually identifiable.

IF YOUR PROJECT MEETS ANY OF THE FOLLOWING CRITERIA, YOU SHOULD SELECT EXPEDITED REVIEW:

- ❑ Collection of hair, nail clippings, dental plaque and calculus, or teeth in a non-disfiguring manner, or secretions.
- ❑ Recording of data from subjects 18 years of age or older using noninvasive procedures routinely employed in clinical practice.
- ❑ Collection of small (≤ 450 ml per 8 weeks, and ≤ 2 samples per week) amounts of blood by venipuncture from subjects 18 years of age or older and who are in good health and not pregnant.
- ❑ Voice recordings made for research purposes such as investigations of speech defects.
- ❑ Moderate exercise by healthy volunteers.
- ❑ Study of existing data, documents, records, pathological specimens, or diagnostic specimens.
- ❑ Research on individual or group behavior where the investigator does not manipulate subjects' behavior and the research will not involve stress to subjects.
- ❑ Research on drugs or devices for which an investigational new drug exemption or an investigational device exemption is not required.

IF YOUR PROJECT DOES NOT MEET ALL OF THE CRITERIA FOR EXEMPTION REQUESTED REVIEW OR EXPEDITED REVIEW, YOU MUST SELECT FULL REVIEW.

REQUIRED DOCUMENTS

IF YOU SELECTED EXEMPTION REQUESTED REVIEW, YOU MUST SUBMIT THE FOLLOWING ITEMS:

- ❑ Form A
- ❑ Form B
- ❑ Explanation of study for subjects (informed consent-optional)
- ❑ Consent for photographic or voice recording (conditional)
- ❑ Letter of approval from each cooperating organization's institutional review board or administrative representative (conditional)

IF YOU SELECTED EXPEDITED OR FULL REVIEW, YOU MUST SUBMIT THE FOLLOWING ITEMS:

- ❑ Form A
- ❑ Form B
- ❑ Informed consent form
- ❑ Consent for photographic or voice recording (conditional)
- ❑ Letter of approval from each cooperating organization's institutional review board or administrative representative (conditional)
- ❑ Electrical equipment safety check memo (conditional)

BEFORE YOU SUBMIT YOUR PROPOSAL, PLEASE CHECK THE FOLLOWING ITEMS FOR COMPLETENESS:

- ❑ All signatures are obtained on Form A
- ❑ Correct number of copies of non-electronic items are included for distribution to HSRB members
- ❑ Start date will allow sufficient time for review to be completed before involving subjects
- ❑ Current forms are being used (E-mail the compliance coordinator at su_comply@su.edu to verify current versions)
- ❑ Method of confidential storage of data is fully described

IT IS VERY IMPORTANT THAT YOU ALWAYS PROVIDE YOUR PROTOCOL IDENTIFICATION NUMBER WHEN CORRESPONDING WITH THE COMPLIANCE COORDINATOR.

Source: Shenandoah University, Winchester, VA.