APPENDIX IV: HUMAN SUBJECT RESEARCH POLICY

A. General Policy

It is the policy of Washburn University to safeguard the rights, safety and welfare of human subjects participating in research projects conducted under the auspices of the University.

B. Scope

This policy is applicable to all research projects involving human subjects conducted under the auspices of Washburn University.

C. Definitions

1. "Director' means the director of a research project who shall be a faculty or staff member of Washburn University.

2. "Human Subject" means an individual about whom a researcher obtains data or obtains information about the individual's behavior.

3. "IRB" means the Institutional Review Board established in part D of these regulations.

4. "Informed Consent" means consent freely given by a human subject for his or her participation in a research project as provided in part F of these guidelines.

5. "Minimal Risk" means that the risks of harm to the human subject expected in the proposed research project are not greater than those ordinarily encountered in daily living or in the performance of routine physical or psychological examinations or tests.

6. "Research" means a systematic investigation designed to develop or contribute to generalizeable knowledge or information.

D. Institutional Review Board (IRB); Establishment and Membership

1. The Institutional Review Board shall consist of at least seven appointed members. The President and Provost & Vice President of Academic Affairs will serve as ex officio members.

2. Membership

a. Members shall be appointed by the President of the University.

b. Members shall have diverse backgrounds and shall not be of the same profession, nor shall all members be of the same sex.

c. Membership shall include the following:
1. At least one member shall be appointed from each of the five major academic areas. The number of members from one academic area may not vary by more than one from any other area.
2. At least one member, but no more than three members, shall be appointed who is not affiliated with the University, nor is related to anyone affiliated with the University.
3. At least one member shall be appointed who is a full-time upper-division or graduate student with a 3.0 grade point average or better.

E. Institutional Review Board, Powers and Duties

The Institutional Review Board shall:

1. Review and have authority to approve or disapprove all research activities involving human subjects conducted under the auspices of the University;

2. Require that information given to human subjects as part of the informed consent process be in accord with 45 C.F.R. 46.116 and this policy;

3. Require documentation of informed consent as provided in 45 C.F.R. 46.117 and Part 11 hereof;

4. Notify the director of a proposed research project and the University, in writing, of its decision to approve or disapprove a proposed research project or modifications necessary in a proposed project to secure approval;

5. Conduct continuing review of research involving human subjects at intervals appropriate to the degree of risk but in no event less than once a year and shall have the authority to observe or have a third party observe any ongoing research project and informed consent process;

6. Have authority to suspend or terminate any research project involving human subjects that is not being conducted in accordance with IRB requirements or that has been associated with unexpected harm to subjects.

F. Institutional Review Board; Reports and Documentation

The Institutional Review Board shall prepare and maintain adequate documentation of its activities including:

1. Copies of all research proposals reviewed, scientific evaluations, accompanying research proposals, approved sample consent documents, progress reports submitted by directors, and reports of injuries, if any, to subjects;

2. Records (written or electronic) of actions taken; the vote on actions approving or disapproving research proposals, including the number of members voting for, against, and abstaining; the basis for requiring changes in, or disapproving, research; and a record of the discussion of controversial issues and a resolution;

3. Records of continuing review activities of research projects;

4. Copies of all correspondence between the IRB and the directors;

5. A list of IRB members;

6. The written procedures of the IRB required by these guidelines and 45 C.F.R. 46.103 (b) (4); significant new findings provided to subjects as required by 45 C.F.R. 46.116 (b) (5).

G. Application for IRB Approval

1. A director shall submit an application for IRB approval for a proposed research project involving human subjects to the IRB for its review and approval before commencing any research activity. The application shall contain at a minimum, the following information:

a. Research Project Title;

b. Director of the Research Project and Director's department;

c. A statement that the Director shall conduct the research project in accordance with the University's policies and requirements involving research, including any financial reporting required;

d. A description of the actual procedures to which the human subject will be subjected or exposed;

e. A description of the subject population for the proposed research project and how individual subjects will be recruited;

f. A description of the potential benefits of the proposed research projects;

g. A description of the risk to the human subjects and a detailed description of the steps to be taken to safeguard the rights, safety and welfare of the human subjects;

h. A description of the methods to be used in obtaining the informed consent of the subjects, including a copy of the proposed informed consent form and a copy of the information which will be provided to the potential human subjects regarding the proposed research activity as required by the informed consent process; and,

i. Any additional information requested by the IRB.

H. IRB Review of Application and Approval

1. The Chairperson of the IRB will coordinate the distribution of forms to applicants and proposals for review to IRB members.

2. Normal review process.
The Investigator is to submit nine (9) hard copies or one (1) electronic copy of the application to the Chairperson of the IRB. The application will be assigned a number, recorded and distributed to IRB members for review. The application will be evaluated, recorded and an "IRB PROPOSAL EVALUATION" form will be returned to the Principle Investigator or the Faculty Supervisor. The IRB keeps the original application on file along with a copy of the IRB PROPOSAL EVALUATION.

3. Expedited review process.
If the Investigator requests an expedited review, he/she must submit three (3) hard copies or one (1) electronic copy of the application. The Chairperson of the IRB and one other committee member will make the evaluation and return the IRB PROPOSAL EVALUATION. If either one or both decide that the proposal requires full committee review then the Investigator is notified with a request for six (6) more copies of the proposal (assuming hard copies of the application were originally submitted) and it will follow the normal review procedure.

a. All the below are eligible for expedited review (functionally, this means that a proposal can be reviewed within a week or two after receipt by the IRB).
Research activities involving no more than minimal risk and in which the only involvement of human subjects will be in one or more of the following categories (carried out through standard methods) may be reviewed by the Institutional Review Board through the expedited review procedure authorized in ?46.110 of 45 CFR Part 46.
Collection of: hair and nail clippings, in a nondisfiguring manner; deciduous teeth; and permanent teeth if patient care indicates a need for extraction.
Collection of excreta and external secretions including sweat, uncannulated saliva, placenta removed at delivery, and amniotic fluid at the time of rupture of the membrane prior to or during labor.

Recording of data from subjects 18 years of age or older using noninvasive procedures routinely employed in clinical practice. This includes 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. It also includes such procedures 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 (for example, xrays, microwaves).

Collection of blood samples 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 years of age or older and who are in good health and not pregnant.

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

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

Moderate exercise by healthy volunteers. The study of existing data, documents, records, pathological specimens, or diagnostic specimens.

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 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 is not required.

b. The Institutional Review Board may expedite research from the requirements of this policy which, in its judgement, involves:

i. Normal educational practices, such as:

1. Research on regular and special education instructional strategies; or

2. Research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.

ii. The use of educational tests (cognitive, diagnostic, aptitude, achievement), if information taken from these sources is recorded in such a manner that subjects cannot be identified, directly or through identifiers linked to the subjects.

iii. survey or interview procedures, unless the following conditions exist:

- information obtained is recorded in such a manner that human subjects can be identified, directly or through identifiers linked to the subjects; and
- 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.

iv. The observation (including observation by participants) of public behavior, unless the following conditions exist:

- Observations are recorded in such a manner that the human subjects can be identified, directly or through identifiers linked to the subjects;
- The observations recorded about the individual, if they became known outside the research, could reasonably place the subject at risk of criminal or civil liability or be damaging to the subject's financial standing or employability; and

- The research deals with sensitive aspects of the subject's own behavior such as illegal conduct, drug use, sexual behavior, or use of alcohol.

v. 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 subjects cannot be identified, directly or through identifiers linked to the subjects. Note: Expedited review and IRB monitoring as described above may not apply to research involving vulnerable populations such as children, prisoners, pregnant women, mentally impaired individuals and fetuses.

I. Institutional Review Board; Disapproval of Proposed Research Project

If the Institutional Review Board decides to disapprove a proposed research project, it shall notify the Director in writing of its disapproval and shall advise the Director of its reasons of the decision and give the Director the opportunity to respond in writing or in person.

J. Institutional Review Board; Suspension or Termination of Approved Research

If the Institutional Review Board suspends or terminates a research project which it has previously approved, it shall notify the Director of its decision in writing and shall include a statement of the reasons for the decision. The IRB shall also notify the University and, where appropriate, the Secretary of the U.S. Department of Health and Human Services and funding agency.

K. Informed Consent

Informed Consent must be obtained from any person who will be participating in any research as a subject.

1. Basic elements of the informed consent include:

a. Providing all information required to be given to the subject, or his/her representative, by these guidelines in a language understandable to the subject or his/her representative;

b. A statement of the purpose of the research project;

c. A statement of the duration of the research;

d. A description of procedures to be followed in the research identifying those which are experimental;

e. A description of foreseeable risks or discomforts together with a description of any benefits to the subject;

f. A statement describing the method by and extent to which the confidentiality of the subject will be preserved;

g. An explanation of whom the subject may contact for information about the research and the subject's rights;

h. A statement that the subject's participation is voluntary and that the subject's participation may be withdrawn or terminated by either the research project investigators or the subject at any time without any penalty or loss of benefits to which he would otherwise be entitled; and

i. When appropriate, those elements contained in 45 C.f.R. 46.116 (b) (6) the IRB deems necessary.

2. Modification or Waiver of Informed Consent

The IRB may alter, modify, change or waive some or all of the requirements to obtain informed consent contained in the Part 6A if the Board finds and documents:

a. The research is for the purpose of documentary or evaluating benefit or service programs which are not themselves research projects or procedures for obtaining benefits or services from such programs or changes or alternatives to such programs;

b. The research involves no more than minimal risks to the right subjects;

c. The waiver or alteration will not adversely affect the rights and welfare of the subjects; or

d. The research could not practicably be carried out without the waiver or alteration.

3. Documentation

Except when the Board finds and documents that a written and signed consent form would comprise the only record linking the subject and the research activity or that the research presents no more than minimal risk of harm and involves no procedures for which consent is usually required, informed consent obtained shall be documented in writing and signed by the subject. The informed consent document to be signed by the subject shall contain all elements required by the Board. A copy of the informed consent form signed by the subject shall be provided the subject or his/her representative for his/her records.

History of Changes to Appendix Four

11 September 1997
Part H was changed entirely to reflect and better explain IRB practices. Part L was removed, as its contents are covered in the revised part H

11 May 2010
Part D was changed to allow expansion of the IRB Committee in order to deal with the increased number of submissions and describes how the expanded membership will be determined. Part F.2. was modified to reflect that most IRB reviews are now conducted electronically rather than in face to face meetings. Part H.2. and Part H.3. were modified to reflect the capability of submitting IRB proposals electronically.