

Institutional Review Board

I. Overview

All review of research activities involving human and animal subjects covered by this policy shall be carried out by the West Virginia State University Institutional Review Board following the procedures set forth in this policy.

A. University Commitments

West Virginia State University is committed to safeguarding the rights and welfare of all people who participate in research conducted by University faculty, staff, and students. It is also committed to insuring humane care and use of animals in teaching and research. West Virginia State University supports responsible experimentation that promises to increase knowledge and understanding and encourages the highest ethical standards among University researchers. In addition to assuring compliance with the federal Department of Health and Human Services (DHHS) regulations 45 CFR 46, as specified in the Office for Protection from Research Risks (OPRR) 1983 report, Protection of Human Subjects, the University accepts responsibility for complying with Food and Drug Administration (FDA) regulations (21 CFR 56) and other applicable state and local laws as they may relate to research covered by the DHHS policy. Categories of research exempted from this policy are those specifically listed in 45 CFR 46.101 (2) (B) 1 through 6. However, The Institutional Review Board requires all research—exempt or non-exempt—to be formally proposed and explained to the board. West Virginia State University also abides by the provisions of the DHHS Guide to the Care and Use of Laboratory Animals and Principles for Use of Animals, the Animal Welfare Act PL 85- 544, and the Standards for Accreditation by the American Association for the Accreditation of Laboratory Animal Care (AAALAC), and any other applicable federal regulations.

B. General Goals of the Institutional Review Board

The general goals of the Institutional Review Board are to:

- b.1. Protect the rights of human participants in research studies, including their rights to give informed consent and to have their safety protected from undue risk;
- b.2. Ensure the humane care and use of animals in research and teaching, and to approve only experiments using animals that are justified in benefits for teaching and new knowledge.

C. General Charge to the Institutional Review Board

The Institutional Review Board has the responsibility and authority to review and approve all research projects by West Virginia State University faculty, staff, and students involving human or animal participants. It will approve only those experiments that conform to the professional standards as understood within the relevant discipline.

D. Responsibilities and Authority of the Institutional Review Board

- d.1. Review all new and ongoing projects involving human or animal participants at convened Institutional Review Board meetings at which time the majority of the Board's membership constitutes a quorum, with an Institutional Review Board member whose concerns are primarily in non-scientific areas being included in the quorum. Voting on projects is limited to duly appointed Board members. Excluded from this process are those submissions whose researchers are requesting expedited review.
- d.2. Notify investigators and other signatories on the research proposal of the results of the Board review.
- d.3. Review projects on an annual basis or more frequently as deemed appropriate.

- d.4. Require that the informed consent procedure is in accordance with West Virginia State University Institutional Review Board policy.
- d.5. Observe or have a third party observe the consent process and the research, when appropriate.
- d.6. Require written notification by Investigators when changes in research activity are proposed.
- d.7. Require prompt reporting by Investigators when unanticipated problems involving risks to participants occur.
- d.8. Suspend or terminate approval of research that has been associated with unexpected serious harm to participants or that is not being conducted in accordance with the Board's decisions. If questions arise concerning legal, moral, or ethical issues involved in research, the West Virginia State University Institutional Review Board will meet to discuss the issues, using consultants from the research area at hand, and meet with the researcher, if possible, before suspension. The privacy rights of research subjects and West Virginia State University students are of paramount importance.
- d.9.a. Report to the investigators and their appropriate supervisors (e.g., unit head, department chair, or dean) any suspension or termination of approved research, including the Faculty Senate's Research and Development Committee if that Committee was involved.
- d.9.b. Report to the Secretary of the United States Department of Health and Human Services or any applicable funding agency—when the research activity is funded in whole or in part by a DHHS or other government agency grant, contract, or fellowship—regarding (1) serious or continuing noncompliance by investigators with the requirements and determinations of the Institutional Review Board, (2) suspension or termination of approved research that is not being conducted in accordance with the Institutional Review Board's requirements, or (3) any unexpected serious harm to participants associated with research project.
- d.10. Advise and consent with investigators regarding specific problems associated with protocols involving human subjects.
- d. 11. Distribute University guidelines to aid Principal Investigators in the preparation of their applications for approval of research involving human and animal participants.
- d.12. Maintain complete records.
- d.13. Interpret government and University policies pertaining to the protection of human and animal research participants.
- d.14. Develop and publish University policies and procedures governing research involving human or animal participants.
- d.15. Provide consultation through its Chair to any participant or Principal Investigator.
- d.16. Establish procedures for monitoring implementation of any Institutional Review Board action.
- d.17. Maintain communication with Federal, State, and local agencies and institutions to insure that the Institutional Review Board's procedures are current and consistent.
- d.18. Coordinate review of research carried out at off-campus sites.
- d.19. Report any changes in the Institutional Review Board membership to the University President and Vice President for Research and Public Service through the Board Chair.

E. Composition of the West Virginia State University Institutional Review Board

The West Virginia State University Institutional Review Board is sufficiently qualified through the experience, expertise, and diversity of its members, including sensitivity to community attitudes, to command respect for its advice in safeguarding the rights and welfare of research participants. The West Virginia State University Institutional Review Board shall be composed of at least eight (8) members from the University, representing diverse backgrounds and possessing professional competence necessary to review the specific research activities assigned to it. The Board shall include both genders and various West Virginia State University

professions. It is strongly recommended that at least one member have a background in social science, at least one member have a background in natural science, and at least one member whose primary expertise is in a non-scientific area. In addition, two additional members from the community at large are to be included who have no formal affiliation with the University. At any time, consultants may be sought, but these persons may not participate by vote in the Institutional Review Board actions.

F. Membership Appointment to the West Virginia State University Institutional Review Board. The Chair of the Faculty Senate shall announce during a Senate meeting that one or more members are needed for the West Virginia State University Institutional Review Board. Nominees can put their own names forward or be suggested (with their permission) by others. Potential members of the Institutional Review Board will be then reviewed by the Faculty Senate Executive Committee, then passed on to the University President, who shall appoint the member(s) for a three-year term. The West Virginia State University Institutional Review Board shall elect its chair annually. For the purposes of continuity and rotation, initial members of the Board shall serve staggered one-, two-, and three-year terms.

G. Responsibility and Authority of West Virginia State University.

1. *Legal assistance.* The firm of Steptoe and Johnson, Clarksburg office, is available to the West Virginia State University Institutional Review Board for legal consultation and advice.
2. *Liabilities.* The University is legally responsible for the acts and omissions of its Investigators while acting in the course and scope of their University duties. In the event of a suit against investigators or members of the West Virginia State University Institutional Review Board based on their actions in connection with a research activity involving human or animal participants, the University would be obligated to assume their defense if the research project was approved by the West Virginia State University Institutional Review Board in accordance with this policy. It is assumed that a Principal Investigator has, or should have, knowledge of the applicable University policy requiring that every research activity placing human or animal participants at risk be reviewed by the West Virginia State University Institutional Review Board. If an Investigator fails to obtain such approval prior to involvement of human or animal participants, the Investigator would be acting outside the scope of her/his duties, and the University would not be obligated to defend or indemnify the Investigator if legal actions were initiated by a participant.

II. Information and Instructions for Filing Research Participant Protection Protocols.

A. General Information.

In accordance with federal Department of Health and Human Services regulations, West Virginia State University recognizes three categories of review for research involving human participants: full, exempt, and expedited. It is anticipated that most research activities carried out at West Virginia State University will fall under the exempt and expedited review categories in that they involve relatively low-risk procedures. The following guidelines will allow the Investigator to determine the appropriate application format. The standard review criteria are used regardless of the risk level of the proposed study. It must be emphasized that Institutional Review Board review concerns research, and thus a project must be clearly defined. The nature of the procedures in the study defines the level of review required.

B. Definitions.

The following definitions are used by the Institutional Review Board when research projects involve human participants:

b.1. HUMAN PARTICIPANT is an individual about whom an investigator conducting research obtains data through intervention or interaction with the individual or through identifiable private information.

b.2. RESEARCH is a systematic investigation explicitly designed to develop or contribute to generalizable knowledge. (In-class activities conducted by instructors are not automatically subject to Institutional Review Board review unless they constitute “research” as described herein.)

b.3. RISK AND MINIMAL RISK. The term “minimal risk” means that risks anticipated in the proposed research are not greater, considering probability and magnitude, than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests. Using “minimal risk” as a goal, the Institutional Review Board will use the “reasonable person standard” to compare the risks of research to those in the daily life of a typical person in the anticipated participant population.

b.4. BENEFIT. To a certain extent risk is elevated relative to the potential benefit(s) of the research. The West Virginia Institutional Review Board applies two categories when considering risk/benefit relationships of proposed research:

B.4.a. Research involving greater than minimal risk but presenting the prospect of direct benefit to the individual.

B.4.b. Research involving greater than minimal risk and no prospect of direct benefit to individual participants but likely to yield generalizable knowledge about the participant’s disorder or condition. This risk can be only a “minor increase over minimal risk.” The experience should be reasonably commensurate with those the participant would ordinarily encounter.

b.5. EVALUATIONS OF RISK IN RELATION TO BENEFITS. Risks to subjects are reasonable in relation to anticipated benefits, if any, to subjects, and the importance of the knowledge that may reasonably be expected to result. In evaluating risks and benefits, the West Virginia State University Institutional Review Board will consider only those risks and benefits that may result from the research (as distinguished from risks and benefits of therapy subjects would receive even if not participating in the research). The West Virginia State University Institutional Review Board will not consider possible long-range effects of applying knowledge gained in the research (for example, the possible effects of the research on public policy) as among those research risks that fall within the purview of its responsibility. (45 CFR 46.111(a)(2)).

C. Possible Board Actions.

Applying the criteria for Institutional Review Board research review set forth in 45 CFR 46.111, the West Virginia State University Institutional Review Board will review each proposal and take one of the following actions:

c.1. *Approve the research.* Although the research may involve some risk to the participants, the Institutional Review Board may find that the risk is minimal, and that the Investigator has taken all practical steps to minimize the risk.

c.2. *Conditionally approve the research.* This action entitles the investigator to proceed with the project provided that certain conditions are fulfilled as specified by the Institutional Review Board. Conditions may include items such as revising the consent form to explain the procedure more clearly, adding a foreign language version of the consent form, or receiving clearance from the student health service.

c.3. *Withhold approval of the research with a request for resubmission of the protocol.* This occurs when the West Virginia State University Institutional Review Board believes that it has insufficient information to take action, or when it feels the research design contains flaws or characteristics that should be revised to reduce risks to participants. The West Virginia State University Institutional Review Board may ask the investigator to provide for emergency back-up

medical care, to take further steps to protect the confidentiality of the participants, or to develop a substitute procedure.

D. Informed Consent.

Except as provided in these guidelines and procedures, legally effective informed consent must be obtained from any research participant or the participant's legally authorized representative who, in the course of a research protocol, is exposed to the risk of physical, psychological, or social injury. Informed consent is defined as the knowing consent of an individual or her/his legally authorized representative so situated as to be able to exercise free power of choice without undue inducement or any element of force, fraud, deceit, duress, or other form of constraint or coercion.

The term "participant" shall, where appropriate, mean the participant or the participant's legally authorized representative. Legally effective informed consent includes at a minimum both the investigator's oral explanation of the research to the participant and the potential participant's expected involvement therein, as well as the investigator's response to any or all questions that the participant may have concerning the research protocol. In certain instances, this will require documentation of consent using a West Virginia State University Institutional Review Board approved consent form, which is signed by the Investigator and by the participant. Informed consent can be sought only under circumstances which:

- provide the participant with sufficient opportunity to freely consider whether she/he wishes to be involved in the research and
- minimize any possibility of coercion or undue influence.

In those research settings in which risk to participants may be increased by written records of their names, or in observational studies of naturally-occurring human interaction, the requirement of informed consent must nevertheless be met. The researcher must provide a written explanation to the West Virginia State University Institutional Review Board of how the participants' rights to privacy and anonymity will be protected. It is strongly recommended that in such instances, investigators develop an information letter to be given to the participants. This letter should be submitted with the West Virginia State University Institutional Review Board application, and it will be subject to committee review. Any or all of the requirements for obtaining consent may be waived by the West Virginia State University Institutional Review Board during its review of a proposal, but only under certain circumstances as specified in 45 CFR 46.101 (b). The following guidelines are to be used when preparing a Consent Form:

- d.1. The consent form is to be written in narrative form and include all information the participant should know in making her/his decision whether to participate.
- d.2. Statements must be easily readable and understandable. Technical terminology and abbreviations are not to be used unless clearly defined.
- d.3. The consent form must be in the fluent language of the participant. However, translations of consent forms should not be done until the English-language version has been approved by the IRB. Furthermore, translations **MUST** either be done or verified by a qualified faculty member of the University or someone designated by that faculty member.
- d.4. All participants are to be given sufficient time to consider whether they wish to participate before signing the consent form.
- d.5. The investigator is reminded that the consent form is simply the written documentation of the consent process. Oral explanations are to be given to each prospective participant, and the participant is to be encouraged to ask questions.
- d.6. In reviewing research protocols and consent forms, WVSU-IRB members are particularly cognizant of research involving minors. All research involving minors

must conform to the DHHS regulations, as stated in “Additional Protection for Children Involved as Subjects in Research” (45 CFR 46.401-409). The specific requirements are listed in Section II.d below.

E. Research Involving Minor Participants

The federal Department of Health and Human Services issued regulations, effective June 6, 1983, giving additional protection to children involved as participants in research. The regulations, contained in “Additional Protection for Children Involved as Subjects in Research” (45 CFR 46.401-409), must be applied to all research involving minors which is reviewed by the West Virginia State University Institutional Review Board. A minor is a person under age 18 who does not have the legal authority to consent. Emancipated minors, whom the state gives the right to consent and contract as adults, are to be treated as adults. The regulations governing children in research dictate that investigators consider the age, maturity, and psychological state of the participating children and obtain the legal consent from the responsible parent or guardian. If the legal consent is provided by the parent or guardian, in addition, the children’s assent is required. Regulations define “assent” as the child’s affirmative agreement to participate. Further, the regulations dictate that “mere failure to object should not, in the absence of affirmative agreement, be construed as assent.” The assent procedure may be represented by an assent form or by a prepared script of the explanation to be tendered by the investigator. The following areas must be addressed in the assent procedure, utilizing language appropriate to the child’s age and/or developmental level:

- e.1. The rationale for asking the child to participate
- e.2. From the child’s point of view, description of what is to occur
- e.3. The risk to the child
- e.4. The benefit to the child
- e.5. Identification of the researcher by name and telephone number in case questions should arise before and after participation
- e.6. In a non-therapeutic research, a statement that the child has a choice to participate in or to withdraw from the research at any time without any negative consequences
- e.7. A statement that the child can retain a copy of the assent form
- e.8. Date and signature lines for the investigator and, if appropriate, for the child.

F. Procedure for Full Review.

Unless expedited or exempt review is specifically requested, all proposals will undergo full review by the West Virginia State University Institutional Review Board. The Investigator will complete the Application to the West Virginia State University Institutional Review Board for Approval of Research. For full review, the Investigator should submit ten (10) copies of the application, with any applicable supporting material, to the Chair of the West Virginia State University Institutional Review Board. All members of the Board will review the proposal and supply written recommendations. When necessary, the opinions of an outside consultant expert (i.e., medical, legal, etc.) may be sought. At any time during the review process, the West Virginia State University Institutional Review Board may request further information. By a simple majority vote of all its members, the West Virginia State University Institutional Board will take one of the three actions specified in Section II.C, subparts c.1.- c.3. A written decision, with explanation where necessary, will be sent to the investigator and to the signatories on the application. The review process typically will require two weeks.

G. Categories of Human Research Exempt from Full Review.

In accordance with 45 CFR 46.101, the following research activities may be exempt from full review by the West Virginia State University Institutional Review Board:

- g.1. Research conducted at established or commonly accepted educational settings, involving normal educational practices, such as:
 - a. research on regular and special education instructional strategies or
 - b. research on the effectiveness or of the comparison among instructional techniques, curricula, or classroom management methods.
- g.2. Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement) if information taken from these sources is recorded in such a manner that participants cannot be identified, directly or through identifiers linked to the participants.
- g.3. Research involving survey or interview procedures with adults age 18 or over except where all of the conditions below* apply. All research, involving survey or interview procedures is exempt, without exception, when the respondents are elected or appointed public officials or candidates for public office.
- g.4. Research involving the observation (including observation by participants) of public behavior except where all of the conditions below* apply.
 - *g.4.a. Conditions for #3 and #4 above:
 - a.1. Responses/Observations are recorded in such a manner that the human participants can be identified, directly or through identifiers linked to the participants, and,
 - a.2. The participants' responses (or observations recorded about the participant) if they become known outside the research, could reasonably place the participant at risk of criminal or civil liability or be damaging to the participant's financial standing or employability, and
 - a.3. The research deals with sensitive aspects of the participant's own behavior such as illegal conduct, drug use, sexual behavior, or use of alcohol.
- g.5. 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 on such a manner that participants cannot be identified, directly or through identifiers linked to the participants.

H. Procedure for Applying for Exempt from Full Review.

Investigators seeking the exempt from review category will complete the West Virginia State University Institutional Review Board Application for Approval of Research, checking the "exempt from full review" option. This form will assist researchers and Department Chairs in certifying that proposed research qualifies for expedited review and specifying which of the five categories of exempt research listed in 46 CFR 46.101 is/are representative of the proposed research. In questionable cases, Investigators and Department Chairs are strongly urged to consult the Institutional Review Board. Annually, originals or copies of this form are to be forwarded to the Chair of the Board and will be kept on file by the Board Chair or staff.

I. Categories of Research Subject to Expedited Review.

In accordance with federal DHHS guidelines (63 FR 60364), research activities with human participants involving no more than minimal risk and involving one or more of the following categories (carried out through standard methods) may be reviewed by the West Virginia State University Institutional Review Board through an expedited review procedure:

- i.1. Clinical studies of drugs and medical devices only when condition (a) or (b) is met:
 - a. Research on drugs for which an investigation new drug application (21 CFR Part 312) is not required. (Note: Research on marketed drugs that significantly increases the risks or decreases the acceptability of the risks associated with the use of the product is not eligible for expedited review.)
 - b. Research on medical devices for which (i) an investigational device exemption application (21 CFR Part 812) is not required or (ii) the medical device is

cleared/approved for marketing and the medical device is being used in accordance with its cleared/approved labeling.

i.2. Collection of blood samples by finger stick, heel stick, ear stick, or venipuncture as follows:

- a. From healthy, non-pregnant adults who weigh at least 110 pounds. For these subjects, the amount drawn may not exceed 550 ml in an eight (8) week period and collection may not occur more frequently than two (2) times per week; or
- b. From other adults and children, considering the age weight and health of the subjects, the collection procedure, the amount of blood to be collected, and the frequency with which it will be collected. For these subjects, the amount drawn may not exceed the lesser of 50 ml or three (3) ml per kg in an eight (8) week period and collection may not occur more frequently than two (2) times per week.

i.3. Prospective collection of biological specimens for research purposes by non-invasive means. Examples:

- (a) hair and nail clippings in a non-disfiguring manner;
- (b) deciduous teeth at time of exfoliation or if routine patient care indicates a need for extraction;
- (c) permanent teeth if routine patient care indicates a need for extraction;
- (d) excreta and external secretions (including sweat);
- (e) uncannulated saliva collected either in an unstimulated fashion or stimulated by chewing gumbase or wax or by applying a dilute citric solution to the tongue;
- (f) placenta removed at delivery;
- (g) amniotic fluid obtained at the time of rupture of the membrane prior to or during labor;
- (h) supra- and sub-lingual dental plaque and calculus, provided the collection procedure is not more invasive than routine prophylactic scaling of the teeth and the process is accomplished in accordance with accepted prophylactic techniques;
- (i) mucosal and skin cells collected by buccal scraping or swab, skin swab, or mouth;
- (j) sputum collected after saline mist nebulization.

i.4. Collection of data through noninvasive procedures (not involving general anesthesia or sedation) routinely employed in clinical practice, excluding procedures involving x-rays or microwaves. Where medical devices are employed, they must be cleared/approved for marketing. (Studies intended to evaluate the safety and effectiveness of the medical device are not generally eligible for expedited review, including studies of cleared medical devices for new indications.) Examples:

- (a) physical sensors that are applied either to the surface of the body or at a distance and do not involve input of significant amounts of energy into the subject or an invasion of the subject's privacy;
- (b) weighing or testing sensory acuity;
- (c) magnetic resonance imaging;
- (d) electrocardiography, electroencephalography, thermography, detection of naturally occurring radioactivity, electroretinography, ultrasound, diagnostic infrared imaging, doppler blood flow, and echocardiography;
- (e) moderate exercise, muscular strength testing, body composition assessment, and flexibility testing where appropriate given the age, weight, and health of the individual.

i.5. Research involving materials (data, documents, records, or specimens) that have been collected or will be collected solely for non-research purposes (such as medical treatment or diagnosis). (NOTE: Some research in this category may be exempt from the federal DHHS regulations for the protection of human subjects 45 CFR 46.101(b)(4). This listing refers only to research that is not exempt.)

i.6. Collection of data from voice, video, digital, or image recordings made for research

purposes.

i.7. Research on individual or group characteristics or behavior (including, but not limited to, research on perception, cognition, motivation, identity, language, communication, cultural beliefs or practices, and social behavior) or research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies. (NOTE: Some research in this category may be exempt from the federal DHHS regulations for the protection of human subjects 45 CFR 46.101 (b)(2) and (b)(3). This listing refers only to research that is not exempt.)

i.8. Continuing review of research previously approved by the convened Institutional Review Board as follows:

- a. Where (i) the research is permanently closed to the enrollment of new subjects; (ii) all subjects have completed all research-related interventions; and (iii) the research remains active only for long-term follow-up of subjects; or
- b. Where no subjects have been enrolled and no additional risks have been identified; or
- c. Where the remaining research activities are limited to data analysis.

i.9. Continuing review of research, not conducted under an investigational new drug application or investigational device exemption where i.2. through i.8. above do not apply, but the Institutional Review Board has determined and documented at a convened meeting that the research involves no greater than minimal risk and no additional risks have been identified.

J. Procedure for Applying for Expedited Review.

Those investigators seeking the expedited review should submit three (3) copies of the West Virginia Application for Approval of Research, checking the “expedited review” option. The Board will appoint a three-person subcommittee to review the registration form. When two members have read and approved the application, it is referred to the Chair of the West Virginia State University Institutional Review Board, who reviews and, if in agreement, signs an approval letter. The approval letter is then sent to the Investigator and the action is reported to the full committee at the next scheduled meeting. The full committee is likely to approve but has the option of requesting more information or withholding approval. Any of the three reviewers may object to expedited review or may have further questions and has the option of referring the application to the full West Virginia State University Institutional Review Board. Investigators should be aware that although applications for expedited review are simpler and involve less paper and duplication than in full review, the review and evaluation process may be no faster than that of the full review procedure. Researchers should allow three (3) weeks for the process (before the time planned to commence research).

K. Institutional Animal Care and Use Committee (IACUC).

Assurance of Compliance with Public Health Service (PHS) Policy on Humane Care and Use of Laboratory Animals

West Virginia State University, hereinafter referred to as Institution, hereby gives assurance that it will comply with the Public Health Service Policy on Humane Care and Use of Laboratory Animals, hereinafter referred to as PHS Policy.

1. Applicability

This assurance is applicable to all research, research training, experimentation, and biological testing and related activities, hereinafter referred to as activities, involving live, vertebrate animals supported by the Public Health Service (PHS) and conducted at this institution, or at another institution as a consequence of sub-granting or sub-contracting of a PHS-conducted or supported activity by this institution.

2. Institutional Policy

- a. This institution will comply with all applicable provisions of the Animal Welfare Act and other Federal statutes and regulations relating to animals.
- b. This institution is guided by the "U.S. Government Principles for the Utilization and Care of Vertebrate Animals Used in Testing, Research, and Training."
- c. This institution acknowledges and accepts responsibility for the care and use of animals involved in activities covered by this Assurance. As partial fulfillment of this responsibility this institution will make a reasonable effort to insure that all individuals involved in the care and use of laboratory animals understand their individual and collective responsibilities for compliance with this Assurance as well as all other applicable laws and regulations pertaining to animal care and use.
- d. This institution has established and will maintain a program for activities involving animals in accordance with the "Guide for the Care and Use of Laboratory Animals."

3. Institutional Program for Animal Care and Use

- a. The lines of authority and responsibility for administering the program and ensuring compliance with these guidelines and procedures begin with the individual Investigator. The Investigator submits relevant research and teaching applications and progress reports to the Institutional Animal Care and Use Committee (IACUC). This committee is composed of at least five members in accordance with PHS Policy at IV.A.3.b. The veterinarian of the IACUC will provide independent reports to the West Virginia State University Institutional Review Board or to any other requesting official of the University. The Board will report at least once a month to the President or his designee.
- b. Veterinary care will be provided by a licensed Doctor of Veterinary Medicine. The veterinarian will be very familiar with the animal colonies at the institution and will provide both routine care and acute and chronic treatment of colony animals as needed. The veterinarian will provide appropriate treatment and supervision in addition to any emergency care and to participating in all IACUC meetings. The veterinarian will operate in complete conformance with Section 3 of the Guide to the Care and Use of Laboratory Animals. This includes: a) routine observations of colony animals to assess their health and welfare; b) use of appropriate preventative, diagnostic, control, and treatment methods; c) guidance to users in animal handling, immobilization, anesthesia, analgesia, and euthanasia; and d) oversight of surgical and post-surgical care.
- c. This institution has established an Institutional Animal Care and Use Committee (IACUC), which is qualified through the experience and expertise of its members to oversee the institution's animal program, facilities, and procedures. The IACUC consists of at least five members, and its membership meets the compositional requirements set forth in the Public Health Service policy at IV.A.3.b.
- d. The IACUC will:
 1. Review at least once every six months the institution's program for humane care and use of animals, using the Guide as a basis for evaluation.
 2. Inspect at least once every six months all of the institution's animal facilities using the Guide as a basis for evaluation.
 3. Prepare reports of the IACUC evaluations as set forth in PHS Policy at IV.B.3. and submit the reports to the University President, or his designee, and to the West Virginia State University Institutional Review Board.
 4. Review concerns involving the care and use of animals at the institution.
 5. Make written recommendations to President of the University or his designee and to the West Virginia State University Institutional Review Board regarding any aspect of the institution's animal program, facilities, or personnel training.

6. Review and approve, require modifications in (to secure approval) or withhold approval of those activities related to the care and use of animals as set forth in the PHS Policy at IV.C.
 7. Review and approve, require modifications in (to secure approval) or withhold approval of proposed significant changes regarding the use of animals in ongoing activities, as set forth in the PHS Policy at IV.C.
 8. Notify investigators and the institution in writing of its decision to approve or withhold approval of those activities related to the care and use of animals, or of modifications required to secure IACUC approval as set forth in PHS Policy at IV.C.4.
 9. Be authorized to suspend an activity involving animals as set forth in the PHS Policy at IV.C.6.
- e. The procedures which the IACUC will follow to fulfill the requirements set forth in the PHS Policy at IV.B. are as follows:
1. The purpose of the IACUC meetings will meet be to review new proposals and progress reports and to conduct and evaluate site visit reports on continuing research.
 2. The IACUC will inspect the primary animal facility at least every six months. Inspections will not be advertised, and they may occur more frequently if deemed necessary at any level of the reporting process as specified in Section III.A. of this Assurance. The inspection committee will be composed of at least three members of IACUC, including the veterinarian. The inspection committee will be designated at the first IACUC meeting of the academic year.
 3. The inspection of animal facilities will include, but not be limited to the following major areas:
 - a. Inspection of animal cages. All animals shall be housed in IACUC-approved cages. Excrement trays will be fully covered with sanitary bedding less than 24 hours old.
 - b. Inspection of cage sanitizer to insure satisfactory operation.
 - c. Inspection of dishwasher and autoclave. Glassware and plastic water bottles shall be inspected for soap residue and cleanliness. Cultures will be taken randomly from water bottles and evaluated in the College laboratories for the presence of microbial contamination. Reports will be provided directly to the IACUC.
 - d. Evaluation of air circulation and temperature.
 - e. Inspection of bedding and food. Bedding and food will be kept in a separate storage closet, which will be routinely inspected in terms of adequacy. Random samples of food will be collected and evaluated in the West Virginia State University College of Natural Sciences and Mathematics and/or Gus R. Douglass Land-Grant Institute laboratories for the presence of contamination. Reports will be provided directly to the IACUC.
 - f. Safety inspection. The facility will be evaluated for compliance with local and state occupational safety codes. Included will be the assurance that all hazardous materials are kept in approved containers and stored in an area separate from the animal housing area.
 4. The Inspection Committee shall complete an evaluation form which will be filed with the IACUC. A separate Veterinary Report will be completed by the IACUC veterinarian and filed with the IACUC. The Veterinary Report will be filed monthly. The IACUC shall review the Inspection Committee Report. Where concerns are indicated, the following actions will occur:
 - a. The Facilities Director will be notified in writing by IACUC. The director will have five days upon receipt of notice from the IACUC to file a report to the

IACUC indicating either that the problem has been corrected or indicating a schedule for correcting the problem.

b. The Principal Investigator of all affected projects will be notified in writing by the IACUC.

5. The IACUC will report to the chair of the West Virginia State University Institutional Review Board, who is the institutional official assuring PHS compliance, within three days of each IACUC meeting. The West Virginia State University Institutional Review Board Chair will be informed of any problems or deficiencies, and a timetable will be given for the correction of problems and for the resumption of compliance with IACUC guidelines.

F. The individual authorized by this institution to verify IACUC approval of those sections of applications and proposals related to the care and use of animals is the Chair of the West Virginia State University Institutional Review Board.

G. The health program for personnel who work in laboratory animal facilities or have frequent contact with animals includes the following:

1. Medical examinations by University medical staff every academic semester.

2. Seminars in animal care and handling by the IACUC Veterinarian presented to animal care personnel every academic semester. These seminars cover the importance of appropriate laboratory garments (lab coats, masks, and gloves), cleanliness of garments, and the importance of personal hygiene before and after animal contact. Basic first aid is also covered.

3. In-service courses covering correct washing and sterilization procedures, animal handling and feeding, cage maintenance, microbial assay (culturing), and room cleaning.

H. The West Virginia State University animal care facility shall consist of 120 square feet. The largest animals contained will be 3-Kilogram rabbits, which will be housed in 20" x 40" cages. There will be two animals per cage, and there will never be more than six animals housed in the facility. Rats and mice will be housed in 12" x 12" plastic cages, with two to three animals per cage, and no more than 20 animals in the facility. All cages are PHS-approved, and they are cleaned and sanitized daily with a sterilized water delivery system. Facility staff is sensitive to housing animals with compatible behavior qualities.

I. The training or instruction available to scientists, animal technicians, and other personnel involved in animal care, treatment, and use are offered by the Vivarium staff during regular seminars, and by those academic departments directly involved in the sponsoring of animal research. All research will be evaluated by the West Virginia State University Institutional Review Board to insure that animal distress will be minimized and that the minimum number of animals will be used to obtain valid results.

4. Institutional Status.

As specified in the PHS Policy at IV.A.2., as Category 1, all of the institution's programs and facilities (including satellite facilities) for activities involving animals are being evaluated for accreditation by the American Association for Accreditation of Laboratory Animal Care. All of this institution's programs and facilities for activities involving animals have also been evaluated by the IACUC and will be reevaluated by the IACUC at least once every six months.

5. Recordkeeping Requirements.

A. This institution shall maintain for a period of at least three years the following documents:

1. A copy of this Assurance and any modifications thereto, as approved by PHS.

2. Minutes of IACUC meetings, including records of attendance, activities of the committee, and committee deliberations.

3. Records of applications, proposals, and proposed significant changes in the care and use of animals and whether IACUC approval was given or withheld.

4. Records of semiannual IACUC reports and recommendations as forwarded to the President or his designee and to the West Virginia State University Institutional Review Board.

5. Records of accrediting body determinations.

B. This institution will maintain records that relate directly to application, proposals, and proposed changes in ongoing activities reviewed and approved by the IACUC for the duration of the activity and for an additional three years after completion of the activity.

C. All records shall be accessible for inspection and copying by authorized OPRR or other PHS representatives at reasonable times and in a reasonable manner.

6. *Reporting Requirements.*

A. At least once every 12 months, the IACUC, through the Authorized Institutional Official, will report the following in writing to the Office of Protection from Research Risks (OPRR, DHHS).

1. Any change in the status of the institution (e.g., if the institution becomes accredited by AAALAC or AAALAC accreditation is revoked), any change in the description of the institution's program for animal care and use as described in this Assurance, or any changes in IACUC membership. If there are no changes to report, this institution will submit a letter to OPRR stating that there are no changes.

2. Notification of the date that the IACUC conducted its semi-annual evaluations of the institution's program and facilities (including satellite facilities) and submitted the evaluations to the University President, or his designee, and to the West Virginia State University Institutional Review Board.

B. The IACUC, through the Institutional Official, will provide the OPRR promptly with a full explanation of the circumstances and actions taken with respect to the following:

1. Any serious or continuing noncompliance with the PHS policy.

2. Any serious deviations from the provisions of the Guide.

3. Any suspension of an activity by the IACUC.

C. Reports filed under VI.A.2. and VI.B. above shall include any minority views filed by members of the IACUC.

I. **United States Interagency Research Animal Committee.**

*Principles for the Utilization and Care of Vertebrate Animals Used in Testing, Research and Training**

The development of knowledge necessary for the improvement of the health and wellbeing of humans as well as other animals requires in vivo experimentation with a wide variety of animal species. Whenever Federal Government agencies develop requirements for testing, research, or training procedures involving the use of vertebrate animals, the following principles shall be considered; and whenever these agencies actually perform or sponsor such procedures, the responsible institutional official shall ensure that these principles are adhered to:

1. The transportation, care, and use of animals should be in accordance with the Animal Welfare Act (7 U.S.C. 2131 et. sep.) and other applicable Federal laws, guidelines, and policies.*

2. Procedures involving animals should be designed and performed with due consideration of their relevance to human or animal health, the advancement of knowledge, or the good of society.

3. The animals selected for a procedure should be of an appropriate species and quality and the minimum number required to obtain valid results. Methods such as mathematical models, computer simulation, and in vitro biological systems should be considered.

4. Proper uses of animals, including the avoidance or minimization of discomfort, distress, and pain when consistent with sound scientific practices, are imperative. Unless the contrary is

established, investigators should consider that procedures that cause pain or distress in human beings may cause pain or distress in other animals.

5. Procedures with animals that may cause more than momentary or slight pain or distress should be performed with appropriate sedation, analgesia, or anesthesia. Surgical or other painful procedures should not be performed on un-anesthetized animals paralyzed by chemical agents.

6. Animals that would otherwise suffer severe or chronic pain or distress that cannot be relieved should be painlessly killed at the end of the procedure or, if appropriate, during the procedure.

7. The living conditions of animals should be appropriate for their species and contribute to their health and comfort. Normally, the housing, feeding, and care of all animals used for biomedical purposes must be directed by a veterinarian.

* For guidance throughout these Principles, the reader is referred to the Guide for the Care and Use of Laboratory Animals prepared by the Institute of Laboratory Animal Resources, National Academy of Sciences.

J. Explanation of Exemptions.

The Code of Federal Regulations, Title 45, Public Welfare, Department of Health and Human Services (DHHS), National Institutes of Health (NIH), and the Office for Protection from Research Risks, Part 46, Protection of Human Subjects, Revised November 13, 2001, Effective December 13, 2001,* states that "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.ht>

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.