AUSTIN PEAY STATE UNIVERSITY
POLICIES AND PROCEDURES MANUAL

Policy Number: 2:002	Supersedes Policy Number: 2:002
Date: November 12, 1999	Dated: August 1, 1986
Subject: Research (Faculty, Staff and/or Student) Involving Human Subjects	
Initiating Authority: Vice President for Academic Affairs	TBR Policy/Guideline Reference:
Approved: [signature] President	

Austin Peay State University, to include all faculty, staff, research associates or students conducting human research, shall comply with the policy for the protection of human subjects participating in activities as outlined in the Department of Health and Human Services (DHHS) rules and regulations (codified at 45 CFR 46). Furthermore, all persons conducting human research at or through Austin Peay State University shall comply with the policies and procedures regarding the inclusion of women, children, and minorities as participants in research involving human subjects.

The following policies and procedures for research by faculty, staff, research associates and/or students involving human subjects have been developed in accordance with the DHHS regulations. Such regulations provide the minimum standards for policies and procedures. However, the policies and procedures set forth by the University may and do surpass the minimum standards set forth in relevant federal regulations.

This policy applies to all research involving human subjects, and all other activities which, even in part, involves such research, regardless of sponsorship, if one or more of the following apply:

A. The research is sponsored by this institution; or

B. The research is conducted by or under the direction of any employee or agent of the institution in connection with his or her institutional responsibilities; or

C. The research is conducted by or under the direction of

any employee or agent of this institution using any property or facility of this institution; or

D. The research involves the use of this institution's non-public information to identify or contact human research subjects or prospective subjects.

DEFINITIONS

A. "Subject at risk" means any individual who may be exposed to the possibility of injury, including physical, psychological, or social injury, as a consequence of participation as a subject in any research, development, or related activity which departs from the application of those established and accepted methods necessary to meet his or her needs, or which increases the ordinary risks of daily life, including the recognized risks inherent in a chosen occupation or field of service.

B. "Informed consent" means the knowing consent of an individual or his or her 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 basic elements of information necessary to such consent include:

1. A fair explanation of the procedures to be followed, and their purposes, including identification of any procedures which are experimental;

2. A description of any attendant discomforts and risks reasonably to be expected;

3. A description of any benefits reasonably to be expected;

4. A disclosure of any appropriate alternative procedures that might be advantageous for the subject;

5. An offer to answer any inquiries concerning the procedures; and

6. An instruction that the person is free to withdraw his or her consent and to discontinue participation in the project or activity at any time without prejudice to the subject.

7. With respect to biomedical or behavioral research

which may result in physical injury, an explanation as to whether compensation and medical treatment are available if physical injury occurs and, if so, what it consists of or where further information may be obtained.

8. A clear and plain statement of reporting requirements related to disclosure of illegal activities.

C. "Research misconduct" is defined by APSU Policy 99:013 to mean the following: Misconduct in research or other creative or scholarly activities is defined to include but is not limited to the following acts committed by faculty, staff, students, and research associates of the University:

1. The fabrication or falsification of data or results, the theft of methods or data from others, plagiarism, or other practices that seriously deviate from those that are commonly accepted within the academic and research community for proposing, conducting or reporting research or other scholarly or creative activities. It does not include error or honest differences in interpretations or judgements of data.

2. Failure to comply with Federal and University requirements pertaining to the conduct of research. This includes but is not limited to: falsification of certifications and representations pertaining to government compliance requirements, failure to obtain proper review and approval by the authorized University Board for research that involves human subjects, animals, radioactive materials or other biohazards, and/or failure to follow directives made by authorized University Boards concerning research subjects, materials or procedures.

3. Failure to meet legal requirements governing the proposing, conducting, or reporting of research.

4. Condoning violations of University research policies. This includes but is not limited to failure to notify appropriate University authorities whenever it becomes obvious or apparent that misconduct probably has occurred, or failure to cooperate in an investigation under the procedures specified by this policy.

5. Retaliation of any kind against a person who in

good faith reported or provided information about suspected or alleged misconduct.

D. "Research" means a systematic investigation (i.e., the gathering and analysis of information) designed to develop or contribute to generalizable knowledge.

E. "Consulting" means a systematic investigation (i.e., the gathering and analysis of information designed to develop or contribute to generalizable knowledge) for use by a non-university related organization.

F. "Investigator" means an individual who either initiates or actually conducts a research investigation, alone or with others.

POLICY ON HUMAN RESEARCH

The policy stated below is designated to protect the rights and welfare of human subjects in all research and training programs at Austin Peay State University. This policy applies to all investigations and training programs which involve the use of human subjects in any way. The policy will be enforced by the Chairperson of the Graduate and Research Council and the Austin Peay Institutional Review Board (APIRB). This Board shall be familiar with and guided by the Nuremburg Code, the Belmont Report, the Declaration of Helsinki, the Ethical Principles in the Conduct of Research with Human Participants of the American Psychological Association, the Ethical Standards for Research with Children of the Society for Research in Child Development, and codes developed by other professional and scientific organizations relevant to specific areas of research.

Copies of relevant codes developed by professional and scientific organizations, as they apply to specific areas of research, shall be maintained in the Office of Grants and Sponsored Research. An additional copy shall be maintained by the Chair of the APIRB. Further, all members of the APIRB shall have a copy of such codes for their use.

A. Research involving human subjects must conform to the moral and scientific principles that justify such research and shall be based on established professional and/or scientific ideas.

B. Research involving human subjects shall be conducted only by qualified persons and under the supervision of a trained researcher. An individual who does not possess a graduate degree or other appropriate training that required the conduct of independent research shall have an appropriately trained and knowledgeable sponsor for

all research involving human subjects.

C. Research on human subjects shall not be carried out unless the sum of the benefit to the subjects and the importance of the objective substantially outweigh the inherent risk to the subjects.

D. Research on human subjects must not be undertaken without the legally effective informed consent of the subjects after being informed of the risks involved. No such informed consent shall include any exculpatory language through which subjects are made to waive, or appear to waive, any of their legal rights, including any release of the institution or its agents from liability for negligence.

E. Subjects participating in a research project should be in such a mental, physical, and legal state as to be able to exercise fully their power of choice and to grant informed consent. If they are not, then the legally effective informed consent of the subjects' legally authorized representative(s) must be obtained. Furthermore, the APIRB may require the investigator to attain the assent of human subjects in cases including, but not limited to, children and the mentally infirm.

F. Consent must, as a rule, be obtained in writing. If written consent is not obtainable, then full documentation of the reasons must be submitted for approval and retention by the Board, and must include assurance that risk to the subject is minimal as outlined in 45 CRF Part 46.10.

G. Extreme caution shall be exercised by the investigator in performing research on human subjects in which the personality of the subjects may be altered or disturbed by experimental procedures.

H. Research and training programs involving human subjects must respect the rights of subjects' privacy and assure that maximum confidentiality of personal information is maintained.

I. In the purely scientific application of research carried out on human subjects, it is the duty of the investigator to protect the life, health, and welfare of the subjects, within the context of the research situation.

J. The nature, purpose, and risk of the research must be explained to the subjects by the investigator including, but not limited to, the duty to report disclosure of

illegal activities. If, for any reason, the nature and purpose of the research cannot be explained to the subjects, the investigator must demonstrate the necessity of this approach to a Board of his or her peers, as well as indicate the provisions for safeguards that may be needed.

K. A debriefing will be required in all human research which involves deception, except in such cases where debriefing has the potential to be harmful, such as with young children. The APIRB shall determine the appropriateness of the debriefing plan. The principal investigator has the responsibility for providing justification for waiving the debriefing requirement. Justification for waiving the debriefing requirement shall be included in the research protocol submitted to the APIRB.

L. The responsibility for the care and protection of subjects in research always remains with the research worker; it never falls on the subjects after consent is obtained.

M. The investigator must respect the right of each individual to safeguard his/her personal integrity, especially if the subject is in a dependent relationship to the investigator.

N. The subject or his/her guardian must be informed that he/she is free at any time during the course of the research to withdraw consent for research to be continued without prejudice to the subject.

O. The investigator or the investigating team shall discontinue the research if it is judged that an individual has been or will be harmed if the research is continued and shall notify the Chairperson of the Human Research Review Board of such action immediately.

P. The University is the agent which assumes official responsibility for the subjects at risk. Therefore, the University, through the delegation of authority to the APIRB, will conduct review of the activities of such research at timely intervals and must be informed of any changes or unanticipated problems involving the human subjects.

POLICIES AND PROCEDURES TO INSURE PROTECTION OF HUMAN SUBJECTS

I. Policies

A. All research, development, and related activities involving human subjects must be reviewed and approved by the Human Research Review Board prior to conducting any research, and for application for grants from external agencies prior to submission of proposal. This policy requires all research protocols involving human subjects to be submitted for either full Board review or expedited review whether or not such research is considered exempt under federal regulations. No research at Austin Peay will be exempt from the review and approval policies and procedures.

B. If the type of research to be conducted involves the repeated use of a standard research protocol, and the nature of the research requires immediate action (ex: telephone opinion sampling in response to current events), departments or department members conducting or supervising such research shall submit a request for approval of a standing protocol providing all relevant information pertinent to said research. Once approved, the standing protocol shall remain valid for no more than one year. In the event of an anticipated departure from the standing protocol, the research supervisor or sponsor shall submit a new, specific protocol for the project for approval by the APIRB.

II. Procedures

A. Submission and Review Process

1. The investigator submitting the proposal must be a member of the faculty or staff of Austin Peay State University. In the case of student research, a faculty member must act as the sponsor. In the case of staff, without research training, a trained researcher must act as the sponsor. No human subjects research at Austin Peay will be exempt from the review and approval policies and procedures.

2. The proposal shall be submitted to the Office of Grants and Sponsored Research. If the proposal is complete, the office, in conjunction with the Chairperson of the APIRB, will determine whether the proposal requires full or expedited review. No human subjects research at Austin Peay will be exempt from the review and approval policies and procedures.

3. If research involves no more than minimal risk, and meets the federal criteria to be eligible for

expedited review, then the proposal may be reviewed and approved by the APIRB Chairperson, or by his or her designee.

4. In the case of expedited review, the Office of Grants and Sponsored Research will review the application for completeness.

   a. The reviewer may exercise all of the authority of the APIRB, except that the reviewer may not disapprove research.

   b. To approve the research, the reviewer must make the determination that all of the requirements specified in 45 CFR 46.111 are satisfied.

   c. All members of the APIRB must be advised, no later than the next regularly scheduled meeting, of all research proposals approved using expedited procedures.

   d. Full review must be conducted at a convened meeting.

   e. Once complete, an application requiring full Board review will be scheduled on the agenda of the APIRB. The investigator(s) may attend the meeting of the APIRB when their protocol is on the agenda for consideration. The Board may direct questions to the investigator regarding the research protocol and make suggestions directly to the researcher. The investigator may not be present during Board debate and vote on a protocol.

   f. The investigator shall receive a written notification of the Board's actions and the available options. Such notification will be made as timely as possible.

B. The Austin Peay Institutional Review Board

In order to conduct a full review of a research proposal, the APIRB must have at least five members with varying backgrounds to promote complete and adequate review research activities commonly conducted at the University.

The Board shall meet at least twice during each semester of the regular academic year.

1. Members of the Board shall be appointed for three-year renewable terms. The Board will be composed of:

   a. A Chairperson who shall be the Chair of the Graduate and Research Council, or his or her designee;

   b. One individual from the community-at-large who has no direct affiliation with the University;

   c. One student who is currently attending the University;

   d. A pool of University faculty representing those disciplines involved in research with human subjects;

   e. One or more individuals experienced and knowledgeable about working with vulnerable categories of participants, such as, children, prisoners, pregnant women, mentally or physically disabled persons, and,

   f. One individual whose primary concerns are in nonscientific areas.

2. Decisions regarding proposals shall be made by a quorum of the Board. A quorum shall consist of a simple majority of the Board.

3. At least one member whose primary concerns are in nonscientific areas must be present at the meeting.

4. To approve research, the APIRB must determine that all of the requirements specified in 45 CFR 46.111 are satisfied.

5. Decisions regarding proposals shall be made on the basis of the opinion of the majority of those voting members present.

6. APIRB members who have a conflicting interest in a research project cannot participate in the review except to provide information, and shall leave the room when any vote is taken on the project involving the conflict.

7. Formal minutes for the Board meetings shall be kept. The minutes will consist of three parts:

a. A summary listing members present, the projects reviewed, and the action taken on each;

b. An individual summary for each proposal listing the action taken by the Board, the listing of any issues on which the Board felt it needed more clarification, and any recommendations made by the Board; and

c. A copy of the memorandum sent by the Chairperson to each investigator, informing him/her of the decision or recommendations of the Board.

8. Records of the Board shall be maintained by the Chairperson of the Graduate and Research Council or the Chairperson's designee. The records shall consist of:

a. The minutes of the meetings;

b. The research proposals; and

c. All other substantiating information submitted by investigators, outside experts, etc., pertaining to each case considered by the Board.

9. Investigators will submit signed proposals on specially designed forms. The form will elicit the type of information required by the Board to meet its obligations under II.A.1. and II.A.2. of this document.

10. The Board shall give special consideration with respect of consent involving subjects partly or totally unable to give consent on their own behalf. Such subjects include, among others, minors and the mentally infirm. In these cases, the Board shall require that informed consent be obtained in writing from the parent, legal guardian, or other appropriate custodian of the subject, and, whenever possible, written consent or assent of the subject as well.

11. After review of the information submitted by the investigator, including the formal proposal, supporting documents, and any additional evidence obtained by the Board, the following actions may be taken:

a. Approval;

b. Approval with communication to the investigator regarding specific recommendations;

c. Deferral for additional evidence; or

d. Disapproval.

12. When actions 11.b or 11.d are taken, the investigator's options are:

a. Revise the project in accordance with Board recommendations and communicate in writing the changes which have been made;

b. Discuss the action with the Board; or

c. Withdraw the proposal.

13. When action 11.c is taken, any further action is contingent on the investigator's supplying the Board with the appropriate information.

14. Subsequent to approval from the Board, the investigator is responsible for the following:

a. Obtaining approval from the Board prior to introducing any changes in procedures;

b. Keeping signed consent statements for the duration of the project and for a period thereafter designated by the Board; and

c. Informing the Board of any unexpected physical or psychological effects on subjects for re-evaluation of the protocol approval.

15. Continuing review of approved research must be conducted at intervals appropriate to the degree of risk. The APIRB cannot approve a project for more than twelve months.

16. Continuing review must be conducted using full review procedures unless the original protocol was otherwise reviewed and approved.

C. Responsibilities of the University Institutional Review Board

1. Before approving research, the APIRB shall determine that the regulations codified in 45 CFR 46.111 are met, including the following:

   a. The risks to subjects are minimized;

   b. The risks are reasonable in relation to anticipated benefits, if any, to subjects and to the advancement of knowledge;

   c. The selection of subjects is equitable;

   d. Informed consent will be sought;

   e. Informed consent will be documented;

   f. Where appropriate, the procedures make adequate provision for monitoring data collection to insure safety of subjects;

   g. There are adequate provisions to protect the privacy of subjects, and to maintain the confidentiality of data; and,

   h. Where any of the subjects are likely to be vulnerable to coercion or undue influence, additional safeguards have been included in the study to protect the subjects.

2. Other review considerations by the Board shall include, but are not limited to:

   a. Acceptability in terms of institutional commitments and regulations;

   b. Applicable law;

   c. Standards of professional conduct and practice; and,

   d. Community attitudes.

D. Investigator Responsibility

1. Research investigators are responsible for submitting all research projects for IRB approval prior to initiation of data collection. This policy applies to all research conducted at the University. No human subjects research at Austin Peay will be exempt from the review and approval policies and procedures.

2. Research investigators will promptly report proposed changes in previously approved human research activities to the APIRB. The proposed changes will not be initiated without IRB review and approval, except where necessary to eliminate apparent immediate hazards to the subjects.

3. Research investigators are responsible for providing a copy of the IRB-approved informed consent document to each subject at the time of consent, unless the IRB has specifically waived this requirement. All signed consent documents are to be retained in a manner approved by the Office of Grants and Sponsored Research.

4. Research investigators are responsible for reporting progress of approved research to the Office of Grants and Sponsored Research, as of, and in the manner prescribed by, the approving IRB on the basis of risks to subjects. In no case shall such progress reports be submitted in intervals exceeding twelve months.

5. Protocols for human subject research shall not be approved for more than twelve (12) months. To continue human subjects research beyond the twelve (12) month period, the investigator must submit the protocol for reapproval by the APIRB. A request for reapproval must be accompanied by a progress report which includes, but is not limited to:

   a. The number of subjects studied;

   b. A summary of any and all adverse events that occurred during the approved period;

   c. The actions taken in response to any and all adverse events; and,

   d. A clear statement of any modifications of the procedures which will be made.

6. Research investigators will promptly report to the IRB any injuries or other problems involving risks to subjects whether anticipated or not.

E. Research Misconduct

Engaging in research involving Human Subjects without appropriate IRB approvals and/or without full compliance with this policy will be considered an act of scholarly

misconduct pursuant to the APSU policy (99:013) governing misconduct in research and other scholarly activities.