AUSTIN PEAY STATE UNIVERSITY
POLICIES AND PROCEDURES MANUAL

Policy Number:	Supersedes Policy Number:
2:002	III:01:18
Date:	Dated:
August 1, 1986	February 15, 1984
Subject:	
Research (Faculty and/or Student) Involving Human Subjects	
Initiating Authority:	SBR Policy/Guideline Reference:
Vice President for Academic Affairs	
Approved: President	

Austin Peay State University will comply with the policy for the protection of human subjects participating in activities as outlined in the Department of Health, Education and Welfare rules and regulations (46.1) and supported directly or indirectly by grants and contracts from DHEW. The following policies and procedures for research of faculty and/or students involving human subjects have been developed in accordance with the DHEW regulations.

DEFINITIONS

1. "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 needs, or which increases the ordinary risks of daily life, including the recognized risks inherent in a chosen occupation or field of service.

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

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

b. a description of any attendant discomforts and risks reasonably to be expected;

c. a description of any benefits reasonably to be expected;

d. a disclosure of any appropriate alternative procedures that might be advantageous for the subject;

e. an offer to answer any inquiries concerning the procedures; and

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

g. With respect to biomedical or behavioral research which may result in physical injury, an explanation as to whether compensation and medical treatment is available if physical injury occurs and, if so, what it consists of or where further information may be obtained.

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. The 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 Human Research Review Committee. This Committee shall be familiar with and guided by 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.

1. 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.

2. Research involving human subjects shall be conducted only by qualified persons and under the supervision of a senior researcher.

3. 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.

4. 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.

5. 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.

6. Consent shall, 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 Committee, and must include assurance that risk to the subject is minimal as outlined in 45 CRF Part 46.10.

7. 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.

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

9. 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.

10. The nature, purpose, and risk of the research must be explained to the subjects by the investigator. 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 committee of his or her peers, as well as indicate the provisions for safeguards that may be needed.

11. 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.

12. 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.

13. 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.

14. 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 Committee of such action immediately.

15. The University is the agent which assumes official responsibility for the subjects at risk. Therefore, the University 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 Committee prior to conducting any research, and for application for grants from external agencies prior to submission of proposal. If an application for support to an outside agency is involved, there will be one exception to obtaining Committee approval before the document is forwarded to the awarding agency: If, because of imminent deadlines for submission of projects to granting agencies or other questions of timing, review by a quorum of the Committee cannot be arranged, the Chairperson of the Committee, with or without consultation with other members, may review the proposal and release it for submission. This does not constitute formal approval of the project, but places it on the agenda for the next meeting. Such provision clearance is restricted to projects where:

1. there is no risk or minimal risk to the subjects; or

2. an identical proposal has been approved previously by the Committee for submission to another agency; or

3. the proposal was previously approved by the full Committee, and the investigator proposes to continue his/her work without significant changes for another specified interval.

B. A "related" activity is one defined as other than research or development as, for instance, training, demonstration, improvement, or support, but which nevertheless contains a research and development component.

C. If a study is in progress not involving investigational use of human subjects and it becomes apparent to the investigator that human subjects should be used, the investigator is required to submit plans to the HRRC before proceeding with human subject research.

D. The Human Research Review Committee and all departmental review personnel will apply the principles stated in codes appropriate for the discipline and areas of research.

II. Procedures

A. Responsibilities of the University Human Research Review Committee:

1. After review of the project considering the risk factors, the Committee shall determine whether there are possible risks, and if so, that:

a. the risks to the subjects are so outweighed by the sum of the benefits to the subjects and the importance of the knowledge to be gained as to warrant a decision to allow the subjects to accept the risks;

b. the rights and welfare of any such subjects will be protected;

c. legally effective informed consent will be obtained by adequate and appropriate methods in accordance with the provisions; and

d. the conduct of the activity will be reviewed at timely intervals, depending on the nature of the study.

2. Review considerations by the Committee shall also include:

a. acceptability in terms of institutional commitments and regulations;

b. applicable law;

c. standards of professional conduct and practice;

d. community attitudes; and

e. departmental guidelines for project review.

B. The Human Research Review Committee

1. The HRR Committee shall be composed of:

a. The Chairperson of the Graduate and Research Council, who shall act as or designate the Committee chairperson;

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; and

d. a pool of University faculty representing those disciplines involved in research with human subjects, such that:

(1) three different disciplines are represented at each meeting;

(2) one of these representatives is from the discipline within the investigative area of the proposal and acts as the departmental reviewer;

(3) the departmental representative is not a voting member in regard to proposals within his/her area; therefore,

(4) the functioning Committee consists of five voting members.

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

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

4. Formal minutes for the Committee 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 Committee, the listing of any issues on which the Committee felt it needed more clarification, and any recommendations made by the Committee; and

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

5. Records of the Committee 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 Committee.

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

7. The Committee 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 Committee 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 of the subject as well. Approval of activities involving these subjects are limited to those which provide, or can be reasonably expected to provide, benefit to the participant.

8. After review of the information submitted by the investigator, including the formal proposal, supporting documents, and any additional evidence obtained by the Committee, 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.

9. When actions 8.b or 8.d are taken, the investigator's options are:

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

b. discuss the action with the Committee; or

c. withdraw the proposal.

10. When action 8.c is taken, any further action is contingent on the investigator's supplying the Committee with the appropriate information.

11. Following approval from the Committee, the investigator is responsible for the following:

a. obtaining approval from the Committee prior to introducing any changes in protocol;

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

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

C. 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.

2. The investigator shall submit the proposal to the designated departmental reviewer.

3. The departmental reviewer shall ascertain if the proposal addresses the points to be considered by the Committee. The departmental reviewer may consult with the investigator and recommend changes. However, the departmental reviewer may not act on the proposal.

4. The proposal shall be sent to the Human Research Review Committee Chairperson for review.

5. The Committee shall submit its recommendations to

the Chairperson of the Graduate and Research Council.

6. The investigator shall be notified of the Committee's actions and the available options.

AUSTIN PEAY STATE UNIVERSITY

CHECKLIST FOR RESEARCH INVOLVING HUMAN SUBJECTS
(MUST BE TYPEWRITTEN)

TITLE_____

_____

FUNDING SOURCE_____

PRINCIPAL INVESTIGATOR_____ DEPARTMENT_____

SPONSOR (if student research)_____

1. Give a brief description or outline of your research procedures as they related to the use of human subjects. This should include a description of the subjects themselves, instructions given to them, activities in which they engage, special incentives, and tests and questionnaires. If new or non-standard tests for questionnaires are used, copies should be attached to this form. Note if the subjects are minors or "vulnerable" (children, prisoners, mentally or physically infirm, etc.).

2. Does this research entail possible risk to psychic, legal, physical, or social harm to the subjects? Please explain. What steps have been taken to minimize these risks? What provisions have been made to insure that appropriate facilities and professional attention necessary for the health and safety of the subjects are available and will be utilized?

CHECKLIST FOR RESEARCH INVOLVING HUMAN SUBJECTS

3. The potential benefits of this activity to the subjects and to mankind in general outweigh any possible risks. This opinion is justified by the following reasons:

4. Will legally effective, informed consent be obtained from all subjects or their legally authorized representative?

5. Will the confidentiality/anonymity of all subjects be maintained? How is this accomplished? (If not, has a formal release been obtained? Attach.) (a) If data will be stored by electronic media, what steps will be taken to assure confidentiality/anonymity? (b) If data will be stored by non-electric media, what steps will be taken to assure confidentiality/anonymity?

6. Do the data to be collected relate to illegal activities? If yes, explain.

7. Are all subjects protected from the future potentially harmful use of the data collected in this investigation? How is this accomplished?

I have read the Austin Peay State University Policies and Procedures on Human Research and agree to abide by them. I also agree to report to the Human Research Review Committee any significant and relevant changes in procedures and instruments as they relate to subjects.

_____ _____

Signature Date

Student research directed by faculty should be co-signed by faculty supervisor.

_____

Signature

RESEARCH INVOLVING HUMAN SUBJECTS

Title of Proposal:

Principal Investigator:

Sponsor (if student):

Action of the human Research Review Committee:

___A. Approved as described. Researcher is responsible for obtaining approval from the Committee prior to introducing any changes in protocol; for keeping signed consent statements for the duration of the project and 3 years thereafter; and informing the Committee of an unexpected physical or psychological effects on subjects.

___B. Approved with recommendations as follows:

Researcher may revise the project in accordance with recommendations and communicate in writing the changes which have been made; discuss the action with the Committee; or withdraw the proposal.

___C. Proposal deferred for additional evidence as follows:

Further action is contingent on the investigator supplying the committee with appropriate information.

___D. Proposal not approved for the following reasons:

Researcher may revise the project or discuss the action with the Committee.

Reviewed by: ___Chairperson,
Human Research Review Committee _____
Signature

___Membership,
Human Research Review Committee _____
Signature

Copies to: Investigator
File with proposal

_____
Date

APSU/AA/AA/5124 (11-80) PPM FORM 2:002:b