

POLICY NO. 309

Area: Academic Affairs

Adopted: February 27, 2008

Certified

by _____

Colette Pierce Burnette
Interim Vice-President for
Administration and Finance

Revisions Approved:

**SUBJECT: ADMINISTRATIVE POLICY REGARDING
RESEARCH INVOLVING HUMAN SUBJECTS**

(A) Purpose.

In order to protect the rights, well-being, and personal privacy of individuals; to assure a favorable climate for the conduct of scientific inquiry; and to protect the interests of the university, the policies and procedures described below have been established for the conduct of investigations and educational projects involving human beings. To implement these policies and procedures, the Central State University Institutional Review Board (the human subjects review board hereinafter called IRB), under the direction of the Provost and Vice President of Academic Affairs or designee, will be established. The IRB and policies and procedures are in accordance with United States Department of Health and Human Services regulations for the protection of human research subjects (45 CFR 46, as amended).

(B) Responsibilities of the IRB.

The IRB, under the direction of the Provost and Vice President for Academic Affairs or designee, has the following responsibilities:

1. To review on a continuing basis the university’s policies and procedures with respect to the use of human subjects, and to establish guidelines and to make policy recommendations as desirable or necessary.
2. To review all research projects involving human subjects with authority to approve, require modification, disapprove, or terminate. The IRB must determine that:
 - a. Risks to subjects are minimized,
 - b. Risks are reasonable in relation to benefits,
 - c. Selection of subjects is equitable,
 - d. That informed consent is obtained and documents, when appropriate, and
 - e. There are adequate provisions to protect privacy of subjects and confidentiality of data.

3. To provide assistance and advice in research involving human subjects, and to implement the guidelines and policies of the university and the federal government through the Office of Sponsored Programs and Research which has general administrative responsibility for human subject matters.

(C) General principles.

The following general principles apply equally to all research projects involving human subjects, whether carried out solely with university resources or with the assistance of outside funds. The university has responsibility for communicating and explaining these principles to university personnel, and for providing procedural guidelines to affect their observance.

1. The university and the individual members of its faculty, staff, and student body engaged in research projects recognize their responsibility for protection of the rights and welfare of human subjects.
2. No investigation shall be initiated until approval has been granted by the IRB.
3. All externally funded projects involving human subjects will be reviewed before submission of the proposal or within thirty (30) days after submission if allowed by agency guidelines.
4. Appropriate professional attention and facilities shall be provided to insure the safety and well-being of human subjects. No subject in an investigation shall be exposed to unreasonable risk to physical, psychological, or social health or well-being. In the event of risk it must be determined that the benefits derived outweigh the risks and no appropriate alternative procedures apply.
5. The confidentiality of information received from subjects in experiments or respondents to questionnaires, profiles, and interviews shall be fully protected, both during and after the conduct of an investigation.
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7. Where a consent form is required, the subject must be provided a copy of the form.
8. A request by any subject for withdrawal from an investigation shall be honored promptly without penalty.
9. The university shall negotiate and maintain necessary assurance of compliance as required by the Office for Protection from Research Risks, United States Department of Health and Human Services.

(D) Scope.

It is not the intent of these rules to interfere with the normal delivery of health care and clinical services by members of the university, or with usual instructional practices.

Otherwise, this policy applies as follows:

1. To all research investigations involving human subjects whether supported by university funds, private funds, or governmental funds. This includes student directed research. (For student research the faculty advisor is assumed to be the responsible investigator.)

2. Investigations conducted by university students in connection with academic work must be supervised by a faculty member, who will refer such proposals to the IRB designee for initial review and for decision as to whether full IRB review is necessary.

PROCEDURES:

Administrative Procedures Regarding Research Involving Human Subjects

No. 309.1