

# PROCEDURE NO. 309.1

Area: Academic Affairs

Adopted: February 27, 2008

Certified

by \_\_\_\_\_

Colette Pierce Burnette  
Interim Vice-President for  
Administration and Finance

Revisions Approved:

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

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(A) Procedures.

The specific review procedures are as follows:

1. Experienced IRB members are assigned responsibility for preliminary review of all human subject research in a specified department or group of departments.
2. Before beginning a project, the investigator shall submit a "Petition for Approval of Research Involving Human Subjects" form to the designated reviewer. The investigator shall include in the application a description of all research procedures and the manner in which the rights and welfare of the participants are assured, copies of consent forms, and questionnaires to be used.
3. The reviewer makes the determination whether the research is exempt from further review and can begin immediately; can require expedited approval; or requires full board review for approval.
4. Upon receiving notification of approval, the investigator can initiate the research project.
5. Subjects must be informed of the purpose of the research, the procedures to be used, the degree of risk or discomfort, and the anticipated benefits. The subject must know that participation is voluntary and that he/she can withdraw at any time without penalty. Consent of the subject is usually documented on a consent form which the subject or guardian signs. The consent form contains the basic elements of informed consent in language understandable to the subject including information on whom to contact for answers to questions or problems.
6. Any approved investigation which undergoes subsequent modifications affecting the rights or welfare of the human subjects involved must be resubmitted. It shall be the responsibility of the investigator or project director to request such review prior to initiating the modification.

7. Research involving other than legally competent adults (such as children, people with mental disabilities, etc.) shall require written informed consent from parents, guardian, or other appropriate authority as well as the subject's assent.
  - a. For the purpose of this rule, "people with mental disabilities" means persons aged 18 and older with any mental or psychological disorder, such as mental retardation, organic brain syndrome, emotional or mental illness, and specific learning disabilities. Or any other condition defined in Title II of the Americans with Disabilities Act of 1990, 28 CFR 35.
8. Research involving special populations such as pregnant women and prisoners must be conducted in accordance with appropriate regulations.
9. Approval of a proposed investigation is granted for a period of no more than one (1) year. Continuation or renewal proposals must receive the same critical review as initial applications.
10. If a subject registers a complaint, the investigator shall attempt to relieve the complaint. If the investigator finds that the complainant cannot be satisfied, the investigator shall refer the complainant to the IRB or to the Office of Sponsored Programs and Research.
11. If a subject experiences any harm, physical, emotional, or mental, as a result of an approved investigation, the principal investigator must fully report the circumstances to the IRB or to the Office of Sponsored Programs and Research.