

## RESEARCH INVOLVING HUMAN SUBJECTS AT STETSON UNIVERSITY

- I. General Principles: In keeping with the University's desire to further the concern for ethics among faculty, staff, and students, the following policy has been adopted to guide those who conduct research involving human subjects. Research that strays from the spirit of these principles violates University policy.
  - A. Research procedures should minimize the risk of psychological and physical harm to the subjects.
  - B. Any remaining risk must be reasonable in relation to anticipated benefits.
  - C. Research must respect the privacy of subjects.
  - D. The researcher shall make available to the subjects information they request about any aspect of the research likely to be significant to the subject.
  - E. The research shall not induce subjects to participate by means that might affect the subject's ability to decide freely about his or her participation.
  - F. Researchers who promise confidentiality are responsible for maintaining it and for informing subjects of limits on their capacity to meet that responsibility.
  - G. Researchers shall explain to subjects, prior to their participation, the purposes of the research. Deception, if necessary, must be followed by a debriefing.
  - H. Selection of subjects and assignment to conditions must be done equitably.
  - I. Informed consent must be obtained. The researcher shall not use an individual as a subject unless satisfied that the subject, or those legally responsible for the subject, consent to participation in the study knowingly and willingly.
  - J. Data must be maintained so as to ensure confidentiality and privacy.
  
- II. Human Subject Research Requiring Review by the University Institutional Review Board
  - A. Unless the research is exempt from review, all research involving human subjects must be approved in advance and reviewed annually by the University Institutional Review Board.
    - 1. The University Institutional Review Board will evaluate the research according to the general principles enunciated in Part I.
    - 2. In particular, the University Institutional Review Board will evaluate the effectiveness of the researcher's informed consent procedures.
  
  - B. Except for externally funded research, research involving human subjects is exempt from review by the University Institutional Review Board if the only involvement of human subjects falls into one or more of the following categories:

1. Research conducted in established or commonly accepted educational settings, involving normal educational practices.
2. Research involving the use of educational tests if information taken from these sources is recorded in such a manner that subjects cannot be identified
3. Research involving survey or interview procedures, except where all of the following conditions exist:
  - a. Responses are recorded in such a manner that the human subjects can be identified.
  - b. The subject's responses, if they became known outside the research, could reasonably place the subject at risk of criminal or civil liability or be damaging to the subject's financial standing or employability
  - c. The research deals with sensitive aspects of the subject's own behavior, such as illegal conduct, drug use, sexual behavior, or use of alcohol
4. Research involving the observation of public behavior, except where all of the conditions specified in Part II(B) (3) exist.
5. Research involving the collection or study of existing data, documents, or records, if these sources are publicly available, or if the information is recorded by the investigator in such a manner that subjects cannot be identified.

C. Each unit of the University shall establish procedures for determining whether research involving human subjects conducted under the authority of that unit (except for externally funded research) is exempt from review.

1. For research conducted by faculty, this procedure must be at the least require consultation with another colleague in the researcher's department and a written record of the determination.
2. For research conducted by staff, this procedure must at the least require consultation with a superior and a written record of the determination.
3. For research conducted by students, this procedure must at the least require consultation with the supervising faculty member and a written record of the determination.
4. Questions regarding the exempt status of research may be referred to the University Institutional Review Board.

D. In addition to complying with the University procedures indicated above, externally funded research involving human subjects must adhere to all applicable external regulations regarding the protection of human

subjects, including required approval and review by the University Institutional Review Board.

1. Regardless of compliance with the University procedures indicated above, externally funded research involving human subjects is exempt from review by the University Institutional Review Board only if the applicable external regulations allow such an exemption.
2. Regardless of compliance with the University procedures indicated above, only the University Institutional Review Board may determine whether externally funded research involving human subjects is exempt from review under the applicable external regulations.

### III. Definitions

- A. “Research” means a systematic investigation designed to develop or contribute to generalized knowledge.
- B. Research “involves a human subject” when a researcher either obtains data through intervention or interaction with a living individual, or obtains identifiable private information about a living individual.
  1. “Private information” includes information about behavior occurring in a context in which the individual can reasonably expect that no observation or recording is taking place, and information that has been provided for specific purposes by the individual and which the individual can reasonably expect will not be made public.
  2. “Interaction” includes communication or interpersonal contact between a researcher and the individual.
  3. “Private information” includes information about behavior occurring in a context in which the individual can reasonably expect that no observation or recording is taking place, and information that has been provided for specific purposes by the individual and which the individual can reasonably expect will not be made public.
- C. “Informed consent” shall be sought only under circumstances that provide the prospective subject, or the subject’s legally authorized representative, sufficient opportunity to consider whether to participate, and that minimize the possibility of coercion or undue influence.
  1. The information given to the subject or to the subject’s representative shall be in language understandable to the subject or representative.
  2. No informed consent, whether written or oral, may include any exculpatory language through which the subject or the subject’s representative is made to waive or appear to waive any of the subject’s legal rights, or to release or appear to release the researcher, the University, or its agents from liability for negligence.
- D. “Externally funded research” is research funded in whole or in part from sources other than the University.

- E. **“Unit of the University” means any department, office, or individual using University facilities, acting under the authority of the University.**