Valdosta State University
Office of Sponsored Programs & Research Administration
Institutional Policy for the Protection of Human Research Participants

RELATED POLICY STATEMENT:
2403.1 PROTECTION OF HUMAN RESEARCH PARTICIPANTS

Valdosta State University is committed to conduct excellent teaching, research, and public service with the highest possible ethical standards. The University is guided by the ethical principles set forth in the:

- *Declaration of Helsinki* (adopted by the World Medical Assembly in June 1964 and amended in 1975, 1983, and 1989);
- *The Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects of Research* (National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, 1989);
- Title 45 Code of Federal Regulations, Part 46 (45CFR46) – Protection of Human Subjects; and
- *Federal Policy for the Protection of Human Subjects; Notices and Rules* (Federal Register, Vol. 56, No. 117, 1991).

The responsibility for safeguarding the rights and welfare of human research participants is delegated by the President to the Institutional Review Board (IRB) for Protection of Human Research Participants.

0.0 CONTENTS

1.0 STATEMENT OF ETHICAL PRINCIPLES
2.0 APPLICATION OF ETHIC AL PRINCIPLES

1.0 STATEMENT OF ETHICAL PRINCIPLES

The following broad ethical principles are the basis for development of the Institutional Review Board's procedures for review and approval of research involving human participants:

1.1 Because the participation of humans in research may raise fundamental ethical and civil rights questions, no distinctions in the oversight of projects will be drawn between funded and unfunded projects; externally and internally sponsored projects; research undertaken by faculty, students, or other University employees; or research conducted on or off campus.

1.2 All activities involving humans as research participants must provide for the safety, health, and welfare of every individual. Rights, including the right of privacy, must not be unduly infringed upon.

1.3 The direct or potential benefits to the participant, and/or the importance of the knowledge gained, must outweigh the inherent risks to the individual.

1.4 Participation in research must be voluntary, and documented informed consent must be obtained from all participants unless consent requirements are modified or waived by the Institutional Review Board.

1.5 An individual does not abdicate any rights by consenting to be a research participant. The participant has the right to withdraw from a research project at any time or may refuse to participate without loss of benefits to which he/she is otherwise entitled.

1.6 Safeguarding information about an individual that has been obtained in the course of an investigation is a primary obligation of the investigator.

2.0 APPLICATION OF ETHICAL PRINCIPLES

The ethical principles outlined in the *Belmont Report*, which underpin 45CFR46, are incorporated in the Institutional Review Board's review and approval of proposed research protocols, requested modifications to previously approved protocols, and continuing review of research. Research protocols will meet the following requirements:

2.1 Risks to participants are minimized through the use of procedures that are consistent with sound research design, that do not unnecessarily expose participants to risk and, whenever appropriate, by use of procedures already being performed on the participant for diagnostic or treatment purposes.

2.2 Risks to participants are reasonable in relation to anticipated benefits, if any, to participants and the importance of the knowledge that may reasonably be expected to result. In evaluating risks and benefits, the IRB shall consider only those risks and benefits that may result from the research (as distinguished from risks and benefits of interventions participants would receive even if not participating in research).

2.3 Selection of participants is equitable. In making this assessment, the IRB shall take into account the purposes of the research and the setting in which the research will be conducted.

2.4 Informed consent will be sought from each prospective participant or the prospective participant's legally authorized representative in accordance with, and to the extent required by, Federal regulations and IRB requirements.

2.5 Informed consent will be appropriately documented in accordance with, and to the extent required by, Federal regulations and IRB requirements.

2.6 Where appropriate, the research plan makes adequate provisions for monitoring the data collected to insure safety of participants.

2.7 Where appropriate, there are adequate provisions to protect the privacy of participants and to maintain the confidentiality of data. Where some or all of the participants are likely to be vulnerable to coercion or undue influence, such as persons with acute or severe physical or mental illness or persons who are economically or educationally disadvantaged, appropriate additional safeguards will be included in the study to protect the rights and welfare of these individuals.