I. Statement of Purpose

Valparaiso University is committed to safeguarding the welfare, rights and privacy of all persons who participate as subjects in research projects conducted under its auspices, and to ensuring that the subjects of such research are aware of the rights and the protections available to them. Moreover, the University is required to assure the federal government that such safeguards are being provided and enforced for all federally funded grants. These safeguards derive from the following ethical principles, which were first articulated in the <u>Belmont Report</u> issued by the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research in 1979.

Respect for persons: recognition of the personal dignity and autonomy of individuals and special protection of those persons with diminished autonomy or particular vulnerabilities, including prisoners, children, individuals with impaired decision-making capacity, or economically or educationally disadvantaged persons. Human subjects should enter into research voluntarily and with adequate information.

Beneficence: the obligation to protect persons from harm by maximizing anticipated benefits and minimizing possible risks. Possible risks to human subjects should be weighed against possible benefits to the subjects, as well as against the possible improvement of knowledge.

Justice: fairness in the distribution of research benefits and burdens. In selecting human subjects for research, investigators should ensure that no group of participants is either consistently selected to participate in research, or consistently deprived of the opportunity to do so.

II. Authority

The Institutional Review Board (IRB) is the body charged with reviewing and approving all proposed research involving human subjects, whether funded or not, conducted under the auspices of Valparaiso University by its faculty, students or staff, or by outside investigators using Valparaiso University students, personnel, facilities, or data collected at the University.

"Research" is defined as "systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalized knowledge" (45 CFR 46.102d).

The procedures for review described below adhere to the regulations of the Department of Health and Human Services (45CFR 46), as amended and published in the Federal

Register on June 18, 1991 and any subsequent amendments), and to the Assurances filed by the University with the Office of Human Research Protections (OHRP).

III. Ethics Training

Valparaiso University requires all individuals involved in the conduct of human subjects research to complete human subjects protection training and to recertify every 4 years. IRB approval will be withheld if these training requirements are not met. These requirements apply to all persons with a significant role in the research, including but not limited to:

- Principal Investigator and Co-investigators,
- Individuals named on a proposal,
- Individuals named as a contact person in the informed consent document(s) or recruitment materials for research,
- Individuals who obtain informed consent from prospective participants in research.

IV. Faculty Role in Research Projects with Student Investigators

For research projects that are subject to IRB review, faculty supervisors have the following responsibilities.

- 1. Sponsoring faculty members are required to educate students on the IRB process.
- 2. Sponsoring faculty are required to help and guide students in completing their IRB applications.
- 3. Sponsoring faculty members <u>must</u> sign off on a student application before the student submits the application to the IRB. By signing off on the application, faculty members are acknowledging that they have educated students about the IRB process, have guided them through the application process, and have read students' completed application and deemed it acceptable prior to submission to the IRB.
- 4. IRB regulations do not differentiate between students and investigators that are more experienced. Therefore, the IRB will review student applications with the same scrutiny as other applications. Student applications that are lacking may result in additional review time and a student not being able to complete a project within an academic semester.