

PROTECTION OF HUMAN SUBJECTS

ORIGINATOR: *Vice Provost for Graduate Studies, Research and Outreach*

DATE: *October 2002 (revised)*

POLICY #84-2

I. APPLICABLE TO: *All employees and students.*

II. POLICY:

Safeguarding the rights and welfare of subjects at risk in any research, development, or related activity is the responsibility of the University. In order to provide for the adequate discharge of this responsibility, it is the policy of the University that no activity involving human subjects be undertaken until those activities have been reviewed and approved according to procedures established by the University Institutional Review Board.

This process of review and approval includes the consideration of the methods to be used in the collecting of data, obtaining informed consent, and in protecting the confidentiality of subjects. Since the "risks" to subjects are affected by these procedures, it is the responsibility of the principal investigator to be fully familiar with the Code of Federal Regulations (45 CFR 46, November 2001), which governs the protection of human subjects and which forms the basis of University policy. An assurance by the principal investigator that approved procedures will be followed in the conduct of activities involving human subjects is a requirement of the application process.

The University of Rhode Island's Federalwide Assurance (FWA) granted by the U. S. Department of Health and Human Services requires that all human subject activities and all activities of the Institutional Review Board, regardless of funding source, be guided by the ethical principles recognized by the Code of Federal Regulations. The Federalwide Assurance (FWA), the Code of Federal Regulations governing the protection of human subjects, and the University of Rhode Island's IRB Policies and Procedures can be reviewed at the Office of the Director of Compliance in the Research Office or at <http://www.uri.edu/research/compliance/humansubj.htm>.

Federal regulations require that research involving human subjects be reviewed by, and receive the approval of, the University's Institutional Review Board. However, the regulations do provide streamlined procedures such as "exempt" or "expedited" review for proposals that are of minimal risk to human subjects. The Chair of the Institutional Review Board and the Director of Compliance determine the category of review.

A calendar of IRB meetings shall be published and distributed prior to the beginning of each semester. Materials must be submitted at least two (2) weeks prior to an IRB meeting in order to be considered for review by the convened board.

At its meeting of December 12, 2002 the Faculty Senate delegated the authority for maintaining and modifying the discretionary portions of the Protection of Human Subjects Policy to the Institutional Review Board.