

Research, entitled Ethical Principles and Guidelines for the Protection of Human Subjects of Research (the Belmont Report)¹. In addition, the university acknowledges that it bears full responsibility for the performance of all research involving human subjects and gives assurance that it will comply with the Department of Health and Human Services (DHHS) regulations for the protection of human subjects (45 Code of Federal Regulations 46) and relevant FDA regulations. In order to carry out this responsibility, individual university faculty, staff and student researchers will also be held responsible for compliance with these regulations and with university policy governing the use of human subjects in research.

2. To advance the above goals and in compliance with the federal regulations referenced above, the Provost shall appoint a Human Subjects Institutional Review Board ("IRB"). The IRB is responsible for reviewing and monitoring research involving human subjects conducted by faculty, students, and investigators seeking access to human subjects under the auspices of the University. The IRB has the authority to prohibit research that does not meet the standards of ethical research practices. It also has the authority to suspend or terminate approval of research that is not being conducted according to such

3. Rights and welfare of subjects are protected and selection of subjects is equitable with the IRB being particularly cognizant of the special problems of research involving vulnerable populations.
 4. Informed consent is sought from each subject and/or the subject's legally authorized representative and is documented as required by law.
 5. Where appropriate, research plans make adequate provision for monitoring the data collected to insure the safety of subjects.
 6. There are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data.
 7. Where any of the subjects are likely to be vulnerable to coercion or undue influence, additional safeguards have been included in the study to protect the rights and welfare of such subjects.
- C. Monitor ongoing research as dictated by funding sources or other needs with respect to human subjects' rights.
- D. Upon request, provide advice to researchers on issues concerning the treatment of human subjects.

3. Board Membership and Terms

The IRB shall be composed of from five to seven regular members and three to five alternate members with varying backgrounds to promote complete and adequate review of research activities commonly conducted by this institution, and sufficiently qualified by expertise and diversity (including consideration of race, gender, and cultural backgrounds) to provide the IRB with the professional competence necessary to review the type of research activities which come before it. In particular, the following requirements shall be met:

- A. The IRB may not consist entirely of members from one academic discipline or profession. It must include both men and women.
- B. At least one member of the IRB shall be a person whose primary expertise or concerns are in a scientific area and one in a nonscientific area.
- C. At least one member of the IRB shall be a person who is not affiliated with the institution, or is not part of the immediate family of a person who is affiliated with the institution.
- D. The IRB may invite individuals with competence in special areas to assist

in the review of issues which require expertise beyond or in addition to that available on the IRB. These individuals may not vote with the IRB.

- E. Members of the IRB are prohibited from participating in the review of research proposals if there is any conflict of interest.

Appointments to the IRB shall be made by the Provost, who has ultimate responsibility for the university's compliance with the above referenced ethical principles and legal requirements. Appointments shall normally be for two years, with terms staggered to allow for some continuity of membership. Appointments may be repeated, but attention will be given to the need to bring in new members from time to time. The Associate Provost will serve as an ex-officio non-voting member of the IRB and as liaison between the IRB and the Office of the Provost.

The Director of Sponsored Programs will serve as an ex-officio, non-voting member of the IRB and as Executive Secretary to the IRB. The Affirmative Action