

THE UNIVERSITY OF TEXAS AT DALLAS
NUMBERED POLICY MEMORANDA

POLICY MEMORANDUM 79-I.2-31

Issued: August 1, 1979
Revised: September 2, 1980
Revised: September 1, 1983
Editorial Amendments: February 2, 1998
Editorial Amendments: September 1, 2000
Revised: February 15, 2005
Editorial Amendments: April 10, 2006
Editorial Amendments: January 11, 2007

COMMITTEE ON RESEARCH INVOLVING HUMAN SUBJECTS
(INSTITUTIONAL REVIEW BOARD)

The Institutional Review Board (IRB) is a University-wide Standing Committee appointed by the President not reporting to the Academic Senate of The University of Texas at Dallas.

The IRB operates under the Department of Health and Human Services (HHS) regulations for the protection of Human Research Subjects (45 CFR 46).

A. Applicability

The responsibilities of the IRB are applicable to all activities which, in whole or in part involve research with human subjects if:

1. the research is sponsored by this institution, or
2. the research is conducted by or under the direction of any employee or agent of this institution in connection with his or her institutional responsibilities, or
3. the research is conducted by or under the direction of any employee or agent of this institution using any property or facility of this institution, or
4. the research involves the use of this institution's nonpublic information to identify or contact human research subjects or prospective subjects.

B. Institutional Policy

1. This institution acknowledges and accepts its responsibilities for protecting the rights and welfare of human subjects of research covered by this policy.

2. It is the policy of this institution that, except for those categories specifically exempted by 45 CFR 46, all research covered by this policy will be reviewed and approved by the University's Institutional Review Board which has been established under a policy of compliance negotiated with HHS. The involvement of human subjects in research covered by this policy will not be permitted until the IRB has reviewed and approved the research protocol and informed consent has been obtained in accord with and to the extent required by 45 CFR 46.116. Certification of the IRB's review and approval for all HHS funded research involving human subjects will be submitted to HHS no later than sixty days following the submission of an application or proposal for funding. Further, the IRB's review of research on a continuing basis will be conducted at appropriate intervals but not less than once per year.
3. It is the policy of this institution that unless informed consent has been specifically waived by the IRB in accordance with 45 CFR 46.116, no research investigator shall involve any human being as a subject in research unless the research investigator has obtained the legally effective informed consent of the subject or the subject's legally authorized representative.
4. This institution acknowledges that it bears full responsibility for the performance of all research involving human subjects, covered by this policy.
5. This institution bears full responsibility for complying with federal, state or local laws as they may relate to research covered by this policy.
6. This institution has established and will maintain one IRB in accordance with 45 CFR 46. The IRB has the responsibility and authority to review, approve, disapprove or require changes in appropriate research activities so that the rights and welfare of human subjects will be protected.
7. This institution has provided and will continue to provide both meeting space for the IRB and sufficient staff to support the IRB's review and recordkeeping duties.
8. This institution encourages and promotes constructive communication among the research administrators, department heads, research investigators, clinical care staff, IRB, other institutional officials and human subjects as a means of maintaining a high level of awareness regarding the safeguarding of the rights and welfare of the subjects.
9. This institution will maintain documentation of IRB activities as prescribed by 45 CFR 46.115.
10. This institution will exercise appropriate administrative overview carried out at least annually to insure that its practices and procedures designed for the

protection of the rights and welfare of human subjects are being effectively applied and are in compliance with the requirements of 45 CFR 46 and this policy.

11. This institution will comply with the policies set forth in 45 CFR 46 Subpart B, which provide additional protections to research, development, and related activities involving fetuses, pregnant women, and in vitro fertilization of human ova.
12. This institution will comply with the policies set forth in 45 CFR 46 Subpart C, which provide additional protections for prisoners involved in research.
13. This institution, in addition to complying with the requirements of 45 CFR 46, will consider additional safeguards in research when that research involved children, individuals institutionalized as mentally disabled and other potentially vulnerable groups.
14. This institution will comply with the requirements set forth in 45 CFR 46.114 regarding cooperative research projects. When research covered by this policy is conducted at or in cooperation with another entity, all provisions of this policy remain in effect for that research. This institution may accept, for the purpose of meeting the IRB review requirements, the review of an IRB established under another policy of compliance with HHS. Such acceptance must be in writing, approved and signed by this institution's Office of the Vice President for Research, approved and signed by correlative officials of each of the other cooperating institutions. A copy of the signed agreement must be forwarded to the Office for Protection for Research Risks (OPRR), HHS.
15. Copies of the general policy will be available to all faculty through the Office of the Vice President for Research, the offices of the Deans and the Department Heads, and the Chair of the IRB. This institution will also provide each individual at the institution conducting or reviewing human subject research a summary of the rules and regulations including any future modifications and an outline of the procedures to be followed in any research involving human subjects as covered by this policy.

C. IRB Structure

1. Institutional Establishment of the IRB
 - a. The IRB is established at The University of Texas at Dallas to review all research involving human subjects. The IRB membership is appointed by the President of the University and shall be composed of no fewer than nine members.
 - b. At least one member shall not be affiliated with the University apart from his/her membership on the Committee. In addition, the Vice President for Research

serves as the ex officio member of the IRB, without vote, who has the federally required authority to act and speak for the University. The term of office of the Committee members shall be for two years, effective September 1 to August 31, and members may be reappointed by the President for additional terms. If for any reason a Committee member resigns, the President shall appoint another individual to serve the remainder of the unexpired term.

- c. To ensure continuity, initial appointments of Committee members will be for staggered terms so that one-half of the appointments expire August 31 of each academic year.
- d. The Chair and Vice Chair of the Committee shall be appointed by the President annually.

2. IRB Membership Requirements

- a. The IRB is comprised of members from diverse backgrounds to promote complete and adequate review of research activities covered by this policy, and has the professional competence necessary to review the specific research activities which will be assigned to it.
- b. The IRB is sufficiently qualified through the experience and expertise of its members, and the diversity of the members' backgrounds, including consideration of the racial and cultural backgrounds of members and sensitivity to such issues as community attitudes, to promote respect for its advice and counsel in safeguarding the rights and welfare of human subjects.
- c. When research is reviewed involving a category of vulnerable subjects (e.g., prisoners, children, individuals institutionalized as mentally disabled), the IRB shall include in its reviewing body one or more individuals who have as a primary concern the welfare of these subjects.
- d. The IRB includes both male and female members.
- e. The IRB includes members representing a variety of professions.
- f. The IRB includes at least one member whose primary expertise is in a non-scientific area.

- g. The IRB includes at least one member who is not otherwise affiliated with the institution and who is not a part of the immediate family of a person affiliated with the institution.

3. Responsible University Official

- a. The Vice President for Research shall be the Responsible University Official for the Committee.
- b. All information concerning Committee activities, reports, and other related documents and approvals shall be housed in the Office of the Vice President for Research.
- c. The Vice President for Research shall be responsible for the submission of annual reports to appropriate government agencies.