

INSTITUTIONAL REVIEW BOARD FOR HUMAN RESEARCH

BACKGROUND / HISTORY: In order to comply with federal regulations (Title 45 CFR 46; 21 CFR 50 and 21 CFR 56) for the protection of human subjects participating in research, the Medical University of South Carolina is required to maintain this Committee. The IRB began in 1966 as a subcommittee of the URC. The IRB became two independent Boards in 1995. This Charter applies to both Boards. Multiple Project Assurance (#M1012) is the document that assures the University is in compliance with Federal regulations.

CLASSIFICATION / TERMS OF APPOINTMENT: This is a University Standing Committee as required by Federal regulations. Its Charter shall be reviewed annually by ORI and revised as necessary.

FORMAL CHARGES: This Committee shall be responsible for conducting initial and continuing review of all research projects involving human subjects as described in the Multiple Project Assurance on file in the ORI.

REPORTING CHANNELS / PROCEDURES: This Committee reports to the University via the Program Director of ORI to the Associate Provost for Research and then to the appropriate Institutional official.

MEMBERSHIP: Committee membership includes both scientific and non-scientific representatives of psychology, psychiatry, ethics, lay public, M.D., and Ph.D. University faculty and the legal profession. There are fifteen primary reviewers on each Committee.

MEMBERSHIP APPOINTMENT: The Associate Provost for Research shall make all appointments in consultation with the Program Director of ORI.

TERMS OF MEMBERSHIP: Each Primary and Alternate Reviewer shall be appointed for a three-year term. Members may succeed themselves for as many terms as deemed appropriate.

OFFICERS: A Chair is appointed every three years by the Associate Provost for Research upon recommendation from the Program Director of the ORI. The Chair chooses a Vice-Chair from the IRB members.

SUBCOMMITTEES: A subcommittee of the IRB, known as the Subject Advisory Subcommittee, is appointed from members of the IRB. The Subcommittee monitors ongoing projects involving human subjects. Committee members are assigned specific project reviews on an as needed basis.

RELATIONSHIP TO OTHER UNIVERSITY COMMITTEES: This Committee shall maintain close relationships with the IACUC, the IBC, the Radiation Safety Committee, the URC, the Veteran's Administration Research and Development Committee, the Hollings Cancer Center Clinical Review Committee, the Conflict of Interest Committee, and the University Academic Compliance Committee.

FREQUENCY OF MEETINGS: A quorum of the Committee (including the Chair and a non-scientific member) shall meet once a month. Individual members shall maintain contact as necessary to fulfill specific project reviews prior to each meeting. The Chair may call additional meetings.

MEETING AGENDA AND SUPPORT MATERIAL: A written agenda with all appropriate support materials will be distributed to each member prior to each meeting.

COMMITTEE MINUTES: Summary reports of each meeting are given to the Associate Provost for Research. Minutes of meetings shall be maintained in the ORI.

STAFF SUPPORT: Direct staff assistance to the Committees shall be provided by the ORI.

AMENDMENT TO THIS CHARTER: Should any amendment to this Charter be required, the Program Director of ORI and Associate Provost for Research shall review and approve the revision.

THIS UNIVERSITY COMMITTEE IS EFFECTIVE AS OF: March 17, 2000