

Institutional Review Board (IRB) Governance

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1.0 BACKGROUND

1.1 The Institutional Review Board (IRB) for the Protection of Human Research Participants is an independent compliance committee mandated by the U.S. Department of Health and Human Services (DHHS). (See Title 45 Part 46 of the Code of Federal Regulations.) The most recent version of the regulations, adopted in 1991, includes the adoption of the Federal Policy for the Protection of Human Subjects, generally known as the "Common Rule." This policy, promulgated by the sixteen federal agencies that conduct, support, or otherwise regulate research involving human participants, is designed to make uniform the human research participant protection system in all relevant federal agencies and departments.

2.0 PURPOSE

2.1 The role of the IRB is to protect the rights and welfare of individuals recruited to participate in research activities conducted under the auspices of the College of Charleston. The IRB has the authority to approve, require modifications in, or disapprove all research activities involving human participants that fall within its jurisdiction as specified by both the federal regulations and local institutional policy. Research that has been reviewed and approved by the IRB may be subject to review and disapproval by officials of the institution. However, those officials may not approve research if it has been disapproved by the IRB. Research that has been reviewed and approved by the IRB is subject to continuing IRB review and must be reevaluated at least annually, or more frequently if specified by the IRB.

3.0 OPERATIONAL PROCEDURES

3.1 The IRB is comprised of nine (9) regular voting members and one non-voting ex-officio member, the Director of Research & Grants Administration or his/her designee.

3.2 Regular voting IRB members are appointed for a term of three years with reappointment possible.

3.3 The terms of regular voting IRB members are staggered with two members completing their terms each academic year. (The academic year is August 16 to August 15.)

3.4 Alternate members may be appointed by the President to serve and participate on the IRB in the absence of regular members.

3.5 If deemed necessary by the IRB, during the Spring semester of each year, the Director of Research & Grants Administration shall issue a request to the faculty for nominations to replace outgoing IRB members. IRB members and alternates may also submit nominations. Nominations shall be submitted to the Office of Research & Grants Administration.

3.6 The Chair of the IRB and the Director of Research and Grants Administration shall submit to the President a slate of individuals recommended to replace outgoing IRB members and alternates. The President will appoint the new members and alternates.

3.7 An IRB Chair and an IRB Vice-Chair shall each be elected from the regular voting membership by the regular voting members for a one-year term at the first IRB meeting of the academic year, with re-election possible.

3.8 Each academic year, monthly expediting teams will be constituted from the regular voting membership to review and act on applications for expedited review.

3.9 The IRB shall meet at least once per month during the following months: August, September, October, November, January, February, March, April, and June. Meeting dates and correspondence deadlines shall be made public to the College at the beginning of each semester.

3.10 Five (5) members will constitute a quorum. When a quorum of regular members is not present, the IRB Chair may delegate full responsibilities of membership (including voting privileges) to an alternate member for the duration of the meeting. Further, a quorum must include at least one regular voting member or proxy whose primary concerns are in nonscientific areas.

3.11 The Office of Research & Grants Administration (ORGA) provides staff support to the IRB by recording the minutes of its meetings, providing announcements and agendas for its meetings, serving as a repository of all IRB correspondence and records, and the like.

3.12 The Office of Research & Grants Administration serves as the first and primary contact point for inquiries and submissions to the IRB.

3.13 ORGA initially screens all requests for exemption from IRB review and has the authority to approve such requests. If ORGA is uncertain whether exemption should be granted, the request will be forwarded to the Chair for determination.

3.14 ORGA initially screens all applications for expedited review and forwards them to the expediting team of the month for review and action. The expediting teams may in turn refer applications for convened review.

3.15 ORGA initially screens all applications for convened review and forwards them to all IRB members for review and action at the next meeting.

3.16 The IRB may solicit ad hoc reviewers with specific expertise to assist in protocol reviews on a case-by-case basis. Ad hoc reviewers may participate, but not vote, in the designated reviews.

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