

Protection of Human Research Participants

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1.0 POLICY

1.1 It is the policy of the Board of Trustees, the President, and the Faculty that all human research conducted within or under the auspices of the College of Charleston conform to all applicable laws, rules, and regulations of the State of South Carolina and Federal sponsoring agencies in order to protect fully the rights and welfare of all research participants. Furthermore, all such research must be performed in compliance with the highest standards of ethics, practice, and conduct of each of the fields or disciplines involved in each of the specific research projects.

1.2 The College of Charleston will provide additional protections pertaining to research, development, and related activities involving fetuses, pregnant women, and in vitro fertilization of human ova and for prisoners involved in research and additional safeguards in research when that research involves children, individuals institutionalized as mentally disabled, and other potentially vulnerable groups in accordance with Federal regulations.

2.0 RESPONSIBILITIES OF THE INSTITUTIONAL REVIEW BOARD (IRB)

2.1 To ensure compliance with its policy, and in conformity with the requirements of the Federal government as exemplified in previously published regulations of the National Institutes of Health (NIH), U.S. Department of Health and Human Services, in 45 CFR 46, and as superseded by the "Common Rule for the Protection of Human Subjects" for all Federal departments and agencies (Federal Register, June 18, 1991), the Board of Trustees has established an Institutional Review Board (IRB) at the College of Charleston.

2.2 It is the intention of the Board of Trustees that, except for those categories specifically exempted by 45 CFR 46, all research involving human participants conducted at, or under the auspices of, any unit of the College of Charleston, whether or not supported by an external agency, be reviewed by the Institutional Review Board. This policy applies to all research projects, research grant applications, grant renewal requests, or contract proposals, contracts, and contract renewal proposals involving, or which may later involve, research participants. The review of all non-exempt research by the IRB will prevent the unequal treatment of research participants in research conducted in different parts of the College and will assure the protection of the rights and welfare of all research participants throughout the College.

2.3 The Institutional Review Board has the responsibility and authority to review, approve, disapprove, or require changes in research activities involving human participants.

2.4 The involvement of humans 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 accordance with Federal regulations.

2.5 Continuing or serious non-compliance with the requirements of this policy will be reported by the IRB to the College of Charleston's administration, the funding agency, and the Office of Human Research Protection (OHRP), U.S. Department of Health and Human Services.

2.6 When research involving humans is conducted through a cooperative research project at, or in cooperation with, another entity, all provisions of this policy remain in effect. The College of Charleston IRB may accept, for the purpose of meeting the IRB review requirements, the review of an IRB established in accordance with U.S. Department of Health and Human Services rules and regulations. Such acceptance must be in writing, approved and signed by an authorized representative of the College of Charleston's Office of Research and Grants Administration, and approved and signed by correlative officials of each of the other cooperating institutions.

3.0 RESPONSIBILITIES OF THE RESEARCH INVESTIGATOR

3.1 Determination of Human Research Participant Involvement

3.1.1 Research Investigators shall make a determination as to whether their research will involve human participants and will indicate such involvement on the College's Office of Research and Grants Administration Pre-Award Proposal Routing Sheet for sponsored projects.

3.1.2 When it is not clear whether the research involves human participants, Research Investigators shall seek assistance from the Office of Research and Grants Administration in making this determination.

3.1.3 Research Investigators may make a preliminary determination of exemption eligibility under Federal regulations utilizing the Human Research Exemption Request form available from the Office of Research and Grants Administration.

3.2 Preparation of the Research Protocol

3.2.1 Research Investigators shall prepare a research protocol, giving a complete description of the proposed research in the Human Research Review Application form available from the Office of Research and Grants Administration. In the protocol, Research Investigators shall make provisions for the adequate protection of the rights and welfare of research participants and shall ensure that pertinent laws and regulations are observed. This requirement is applicable even in cases where the research is exempt under Federal regulations.

3.2.2 Research Investigators shall include the proposed informed consent form with the protocol.

3.3 Submission of the Research Protocol to the Office of Research and Grants Administration

3.3.1 Research Investigators shall ensure that all research protocols involving humans are submitted to the Office of Research and Grants Administration.

3.4 Submission of a Supplement to an Original Research Protocol

3.4.1 Research Investigators shall submit a supplement to the IRB when:

3.4.1.1 It is proposed to involve research participants and the activity previously had only indefinite plans for their involvement; or

3.4.1.2 It is proposed to involve research participants and the activity previously had no plans for their involvement; or

3.4.1.3 It is proposed to change the involvement of research participants and that their involvement is significantly different from that which was initially approved by the IRB.

3.5 Complying with IRB Decisions

3.5.1 Research Investigators shall comply with all IRB decisions, conditions, and requirements.

3.6 Obtaining Informed Consent

3.6.1 Research Investigators shall obtain informed consent from research participants in accordance with Section 5.0 of this policy statement.

3.7 Retention of Signed Consent Documents

3.7.1 Research Investigators shall ensure that original signed consent forms are retained and maintained in the Research Investigator's office files on the College of Charleston campus where they are accessible to IRB monitors. These consent forms may not be removed from the campus without the prior approval of the Office of Research and Grants Administration.

3.8 Submission of Progress Reports

3.8.1 Research Investigators shall report the progress of the research to the IRB as often as, and in the manner, prescribed by the IRB, but not less than once per year.

3.9 Submission of Injury Reports and Reports of Unanticipated Problems Involving Risks

3.9.1 Research Investigators shall report promptly to the IRB any injuries to research participants.

3.9.2 Research Investigators shall report promptly to the IRB any unanticipated problems which involve risks to the research participants or others.

3.10 Reporting Changes in the Research Protocol

3.10.1 Research Investigators shall submit to the IRB any proposed changes in a research activity on a Protocol Modification, Continuing Review, & Final Report Form.

3.10.2 Changes in a research activity during the period for which IRB approval has already been given shall not be initiated by Research Investigators without prior IRB review and approval, except when necessary to eliminate apparent immediate hazards to the research participant.

3.11 Reporting Non-Compliance

3.11.1 Research Investigators shall report promptly to the IRB any serious or continuing non-compliance with the requirements of this policy or the determinations of the IRB.

3.12 Attending IRB Meetings

3.12.1 To facilitate the review of research and the protection of the rights and welfare of research participants, Research Investigators are encouraged to attend IRB meetings when invited by the IRB.

3.13 Notification Concerning Investigational New Drugs or Devices

3.13.1 Research Investigators shall notify the Office of Research and Grants Administration and the Food and Drug Administration (FDA) when it is anticipated that an investigational new drug or device exemption will be required.

4.0 RESPONSIBILITIES OF THE DEPARTMENT CHAIR/COGNIZANT ADMINISTRATOR

4.1 Department Chairs (or cognizant administrators) shall initially review and approve all applications for exemption under Federal regulations prior to their submission to the Office of Research and Grants Administration for consideration by the IRB.

4.2 Department Chairs (or cognizant administrators), through appropriate procedures established within their respective departments/units, shall review applications for IRB review for ethical considerations and scientific merit.

4.3 In conjunction with Research Investigators, Department Chairs (or cognizant administrators) shall report promptly to the IRB any serious or continuing non-compliance with the requirements of this policy or the determinations of the IRB.

4.4 To facilitate the review of research and the protection of the rights and welfare of research participants, Department Chairs (or cognizant administrators) are encouraged to attend IRB meetings when invited by the IRB.

5.0 REQUIREMENTS FOR INFORMED CONSENT

5.1 Obtaining Informed Consent

5.1.1 Unless informed consent has been specifically waived by the IRB in accordance with Federal regulations, no Research Investigator shall involve any individual as a participant in research unless the Research Investigator has obtained the legally effective informed consent of the participant or the participant's legally authorized representative.

5.1.1.1 Research Investigators shall obtain informed consent in accordance with Federal regulations and for ensuring that no research participant will be involved in the research prior to obtaining the consent.

5.1.1.2 Unless otherwise authorized by the IRB, Research Investigators shall ensure that legally effective informed consent:

5.1.1.2.1 Is obtained from the research participant or his/her legally authorized representative;

5.1.1.2.2 Is in lay language understandable to the research participant or the representative;

5.1.1.2.3 Is obtained under circumstances that offer the prospective research participant or the representative sufficient opportunity to consider whether the prospective participant should or should not participate; and

5.1.1.2.4 Does not include exculpatory language through which the research participant or the representative is made to waive, or appear to waive, any of the participant's legal rights, or which releases, or appears to release, the Research Investigator, the sponsor, or the institution or its agents from liability for negligence.

5.2 Providing Basic Elements of Informed Consent

5.2.1 Unless otherwise authorized by the IRB, Research Investigators, as a minimum, shall provide the following information to each research prospective research participant, which is to be included in the informed consent document:

5.2.1.1 A statement that the study involves research, an explanation of the purposes of the research, and the expected duration of the prospective participant's involvement in the study; a description of procedures to be followed; and the identification of procedures which are experimental;

5.2.1.2 A description of any reasonable foreseeable risks and/or discomforts to the research participant;

5.2.1.3 A description of any benefits to the research participant or to others which may reasonably be expected from the research;

5.2.1.4 A disclosure of appropriate alternative procedures or courses of treatment (if any) that might be advantageous to the research participant;

5.2.1.5 A statement describing the extent (if any) to which confidentiality of research records identifying the research participant will be maintained;

5.2.1.6 An explanation as to whether any compensation and/or medical treatments are available if any injury occurs and, if so, what they consist of, or where further information may be obtained;

5.2.1.7 An explanation of whom to contact for answers to pertinent questions about the research and the research participant's rights, and whom to contact in the event of a research-related injury to the participant;

5.2.1.8 A statement that participation is voluntary and that refusal to participate will involve no penalty or loss of benefits to which the research participant is otherwise entitled; and the research participant may discontinue participation at any time without penalty or loss of benefits to which he/she is otherwise entitled; and

5.2.1.9 A statement that the research participant will receive an executed copy of the informed consent document.

5.3 Providing Additional Elements of Informed Consent

5.3.1 When required by the IRB, the Research Investigator shall provide one or more of the following additional elements of information to each research participant:

5.3.1.1 A statement that the particular treatment or procedure may involve risks to the participant (or to the embryo or fetus, if the participant is or may become pregnant) which are currently unforeseeable;

5.3.1.2 Anticipated circumstances under which the individual's participation may be terminated by the Research Investigator without regard to his/her consent;

5.3.1.3 Any additional costs to the research participant that may result from participation in the research

5.3.1.4 The consequences of a participant's decision to withdraw from the research and procedures for orderly termination of participation; search and procedures for orderly termination of participation by the subject;

5.3.1.5 A statement that significant new findings developed during the course of the research which may relate to the participant's willingness to continue participation will be provided to him/her; and

5.3.1.6 The approximate number of research participants involved in the study.

5.4 Documentation of Informed Consent

5.4.1 Research Investigators shall ensure that informed consent is documented by the use of a written consent form, approved and dated by the IRB and signed by the participant or his/her legally authorized representative, unless this requirement is specifically waived by the IRB.

5.4.2 Research Investigators shall ensure that the participant signing the written consent form is given a copy of that form after it has been completed and signed. e written consent form is given a copy of that form after it has been completed and signed.

5.4.3 Research Investigators may use a consent form which is either:

5.4.3.1 A written consent document that embodies the elements of informed consent required by Federal regulations. This form may be read to the prospective participant or his/her legally authorized representative, but in any event, the Research Investigator shall give either the prospective participant or the representative adequate opportunity to read the form before signing it; or

5.4.3.2 A "short form" written consent document stating that the elements of informed consent required by Federal regulations have been presented orally to the prospective participant or his/her legally authorized representative. When the "short form" is used, Research Investigators shall ensure that:

5.4.3.2.1 The written summary of what is to be said to the prospective participant or the representative receives prior approval of the IRB;

5.4.3.2.2 A witness is present at the oral presentation;

5.4.3.2.3 The short form is signed by the research participant or his/her representative;

5.4.3.2.4 The witness signs both the short form and a copy of the written summary of the oral presentation;

5.4.3.2.5 The person obtaining consent signs a copy of the summary;

5.4.3.2.6 A copy of both the short form and the summary is given to the research participant or his/her representative.

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