

Institutional Review Board (IRB) Policy and Procedures for Processing External Requests to Recruit Research Participants

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1.0 PURPOSE

1.1 As part of its mandate, the Institutional Review Board (IRB) is charged with ensuring that all research involving human participants under the auspices of the College of Charleston is conducted in conformance with applicable State and Federal laws and regulations. The purpose of this policy is to provide these same protections to students, faculty, and staff of the College of Charleston who are recruited on campus to participate in investigative studies performed by researchers not affiliated with the College (hereinafter referred to as "external investigator").

2.0 DEFINITIONS

2.1 Benefit – By "benefit" it is meant how the project will directly benefit the College of Charleston students, faculty, staff and administration or how the project aligns with or helps further the mission of the College.

2.2 Minimal Risk – the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examination or tests. When making a decision about risk consider the following:

2.2.1 Both magnitude and likelihood of risk. A more serious event may be permissible if its probability is extremely low. Example: having a healthy athlete participate in a low-level cardiovascular endurance exercise carries a risk of death, but the likelihood of this happening is remote.

2.2.2 Risks of ordinary, non-invasive diagnostic tests are acceptable. Examples: routine blood draws in adults, general physical exams, pen-and-paper tests, ultrasound exams (at accepted levels).

2.2.3 Minimal risk may be age- or context-dependent Example: Blood draw may be minimal risk for someone old enough to give consent, but not for a young, and needle-shy child.

2.2.4 Remember that risks need not be "physical" in order to be "more than minimal" Example: A serious privacy risk, confidentiality risk, informational risk or risk of embarrassment may be enough to categorize a study as "greater than minimal risk."

3.0 ROLES AND RESPONSIBILITIES

3.1 Any request from an external researcher to recruit on campus for students, faculty, and/or staff to participate in research shall be reviewed by the College of Charleston IRB.

3.2 The IRB may, as it deems appropriate, establish a fee schedule for review of requests by external investigators to recruit research participants on the College of Charleston campus.

3.3 The IRB reserves the right to grant or deny permission to external investigators to recruit subjects on campus. The decision of the IRB to deny permission for participant recruitment by an external investigator may not be reversed by any other College of Charleston authority.

3.4 Decisions made by the IRB to grant permission to an external investigator to recruit research participants on campus may be reversed by the Board of Trustees of the College or by the President of the College, acting on their behalf, if it is in the best interests of the College to do so.

4.0 POLICY

4.1 If the external investigator's IRB does not have a Federalwide Assurance, the College of Charleston IRB reserves the right to review the protocol and make a determination based on the same criteria applied to a College of Charleston investigator.

4.2 External Requests to recruit students, faculty, or staff at the College of Charleston may be permitted under the following conditions:

4.2.1 For all studies that meet exemption criteria, as determined by the Office of Research and Grants Administration (ORGA) staff or the IRB Chair, regardless of researcher affiliation or research topic and whether or not they have been exempted by an external IRB.

4.2.2 For nonexempt research on higher education when:

4.2.2.1 The investigators demonstrate that the research will provide direct or indirect benefit to College of Charleston participants or the institution, as determined by the IRB and

4.2.2.2 The study has either been approved by another federally assured IRB or the investigator agrees to enter into an Unaffiliated Investigator Agreement with the College of Charleston IRB, thus giving the College of Charleston IRB jurisdiction over the College of Charleston component of the research protocol, and

4.2.2.3 The principal investigators for the study arrange for a member of the College of Charleston faculty or staff to serve as a liaison between the College and the sponsor of the research. The liaison will be responsible for the conduct of the study for the College of Charleston component of the protocol, as approved by an external IRB or the College of Charleston IRB, and will serve as the primary communication channel between the College and the sponsor of the

research. The liaison must submit a certificate of completion of one of the approved ethical guidelines and regulations training activities.

4.2.3 For non-exempt studies (that are not higher education research) conducted by for-profit entities and non-profit entities when:

4.2.3.1 The investigators receive approval from an independent (commercial) IRB, and

4.2.3.2 In addition to meeting the criteria applied to internal research, the investigator can demonstrate that the research will provide direct or indirect benefit to College of Charleston participants or the institution as determined by the IRB and

4.2.3.3 The study does not place College of Charleston participants in a situation with more than a low probability of negative consequences, as defined by the College of Charleston IRB and

4.2.3.4 The College of Charleston IRB would support an internal study with the same magnitude of risk.

4.3 External investigators may not begin recruitment of study participants on campus by any means until the College of Charleston IRB has given permission to do so via a letter of approval.

5.0 PROCEDURES

5.1 If the external investigator's protocol has been approved by another Institution holding a Federalwide Assurance, a copy of the full application package to, and the determination of, that external IRB must be submitted along with the External Request to Recruit Research Participants. Copies of any modifications and continuation requests and approval of such actions must also be included in the package.

5.2 If the external investigator's protocol has not been approved by another Institution holding a Federalwide Assurance, a complete research protocol, to include informed consent documents, an Unaffiliated Investigator Agreement, and an External Request to Recruit Research Participants are to be submitted to the College of Charleston IRB.

5.3 Nonexempt research on higher education repeated annually will receive an approval for up to five years as long as there are no major changes in the content or administration of the research. Small changes in the wording or a question are minor changes. On the other hand, the addition of new questions is potentially a major change and the liaison must discuss this with the ORGA staff.