

PROCEDURE

Subject	Institutional Review Board Procedures		Number: 1.44.01
Reference (Rule #) 6HX14-1.44			
President's Approval/Date:	 Tammy Hughey		6 Jan 2026

I. PURPOSE:

This procedure will help ensure that the Institutional Review Board of State College of Florida, Manatee-Sarasota (“SCF IRB”) comprises a broad spectrum in representative capacities and disciplines and to assure that appropriate steps are taken by the SCF IRB, both in advance and by periodic review, that the rights and welfare of humans participating as subjects in the research are protected and to support the design and conduct of sound research. Further, this procedure will help the SCF IRB in the oversight of research conducted within the institution or by the staff of the institution. To accomplish this purpose, the SCF IRB uses a group process to review research protocols and related materials (e.g., informed consent documents and investigator brochures) to ensure protection of the rights and welfare of human subjects of research.

II. PROCEDURE:

The SCF IRB duties are governed by this procedure. Applicable policies and processes are provided in the **State College of Florida, Manatee-Sarasota Institutional Review Board Operations Policies Manual** (hereinafter “**SCF IRB Policies Manual**”).

The SCF IRB Policies Manual is subject to revision by the SCF IRB as needed to fully comply with this procedure and applicable laws. A copy of the current SCF IRB Operations Policies Manual is available from the SCF IRB Chair.

III. APPLICABLE POLICIES:

The **SCF IRB Policies Manual** shall include SCF IRB operations policies for the following research activities:

1. Policies for the initial review of proposed research.
2. Policies for the initial review of research commensurate to the levels of exempt, expedited, and full-board review respectively.
3. Policies that the SCF IRB will follow for reporting its findings and actions to investigators and the institution.
4. Policies that the SCF IRB will follow for conducting its continuing review of research.

5. Policies that the SCF IRB will follow in determining which projects require review more than annually.
6. Policies which the SCF IRB will follow in determining which projects require verification from sources other than the investigators that no material changes have occurred since previous SCF IRB review.
7. Policies which the SCF IRB will follow in ensuring prompt reporting to the IRB of proposed changes in research activity, and for ensuring that such changes in approved research, during the period for which SCF IRB approval has already been given, may not be initiated without SCF IRB review and approval except when necessary to eliminate apparent immediate hazards to the subject.
8. Policies which the SCF IRB will follow in ensuring prompt reporting to the SCF IRB, appropriate institutional officials, and the Department or Agency head of (i) any unanticipated problems involving risks to subjects or others or any serious or continuing noncompliance with this policy or the requirements or determinations of the SCF IRB; and (ii) any suspension or termination of SCF IRB approval.
9. Policies which the SCF IRB will follow when there is non-compliance.
10. Authorization to make additional policies that the College and the SCF IRB determine appropriate to comply with this Procedure and/or applicable laws.

IV. APPLICABLE FORMS:

The following forms apply to this Procedure. These forms shall be incorporated into the **SCF IRB Policies Manual** and are subject to revision by the SCF IRB as needed to fully comply with this procedure, the **SCF IRB Policies Manual**, and applicable laws. Copies of the current forms are available from the SCF IRB Chair:

- FORM A: SCF INSTITUTIONAL REVIEW BOARD PROTOCOL
- FORM B: SIGNATURES FORM
- FORM C: INTERVIEW QUESTIONNAIRE FOR CONTINUATION OR CLOSURE OF A RESEARCH PROJECT
- FORM D: COVER MEMO TEMPLATE (EXPEDITED REVIEW)
- FORM E: INSTRUCTIONS FOR LEAD REVIEWERS OF EXPEDITED PROPOSALS

V. COMPOSITION AND DUTIES OF THE SCF IRB:

A. The purpose of the SCF IRB:

1. Protections for human subjects of research are required under Department of Health and Human Services (HHS) regulations, codified as 45 CFR 46. These regulations make up the federal policy for the Protection of Human Subjects known as the Common Rule, adopted by an additional 16 Executive Branch Departments and Agencies.
2. In accordance with the Common Rule, an IRB is an appropriately constituted group formally designated to review and monitor research involving human subjects. The SCF IRB has responsibility for approving, requiring protocol modification (to secure

approval), or disapproving research. The SCF IRB also has the authority to suspend or terminate research for continued noncompliance with the Common Rule or the SCF IRB's own conditions, findings, determinations, or procedures tied to initial or continuing review.

3. In accordance with this Procedure, the SCF IRB has the authority to make additional policies that the College and the SCF IRB deem appropriate to comply with the purpose of this Procedure and/or applicable laws.
4. Maintain, amend, revise, and distribute the **SCF IRB Policies Manual** and all applicable forms.

B. The SCF IRB membership is composed as follows:

1. The SCF IRB membership shall consist of at least five voting members. Alternates and non-voting members may also be appointed, with alternates authorized to vote at convened meetings only in the absence of the member for whom they are the designated alternate. Although an alternate may be designated for more than one SCF IRB member, each alternate may represent only one regular member at a convened meeting. All appointments are made and approved by the College's Vice President for Institutional Effectiveness (VPIE) and reported to the President's Cabinet.
2. The SCF IRB membership will consist of people of varying backgrounds and expertise in specific areas to provide complete and adequate review of the research. Committee members should possess not only broad specific competence sufficient to comprehend the nature of the research, but also other competencies necessary for judgments as to acceptability of the research in terms of SCF regulations, relevant law, ethical standards, and standards of professional practice. Consultants may be used to review proposals for which additional expertise is needed.
3. The SCF IRB membership must include both men and women, at least one member whose primary concerns are in science areas, one whose primary concerns are nonscientific areas, and at least one member who is not otherwise affiliated (either directly or through immediate family) with SCF.
4. No person shall be excluded from serving on the SCF IRB based on sex, pregnancy, race, religion, age, national origin/ethnicity, color, marital and veteran status, disability, genetic information, or sexual orientation.
5. SCF IRB members make a commitment to three (3) years of service, which may be extended for a second term of three (3) years. Further extensions are decided on a case-by-case basis.
6. There is no remuneration for participation in the SCF IRB.