College Operating Procedures (COP)	FLORIDA SOUTHWESTERN STATE COLLEGE

Procedure Title:	Institutional Review Board (IRB)
Procedure Number:	03-1601
Originating Department:	Provost
Specific Authority:	
Board Policy	n/a
Florida Statute	1001.65(16)
Florida Administrative Code	n/a
Procedure Actions:	Adopted: 10/06/15; 11/07/17; 02/14/2025
Purpose Statement:	The purpose is to ensure College's compliance with federal guidelines and standards for human subject research.

The College's IRB shall be registered with the Office for Human Research Protections (OHRP) and obtain a Federal-wide Assurance for the Protection of Human Subjects (FWA). The IRB registration is effective for 3 years and shall be renewed at the end of each term to remain effective, even if no changes have occurred. The College shall provide written assurance to the Department of Health and Human Services (DHHS) that it will comply with the federal regulations. Any changes to the composition or policies of the IRB shall be submitted to OHRP within 90 days of the change. The College will maintain communication with the OHRP of any continuing non-compliance.

If the College is the primary awardee in any cooperative agreement or the coordinating center for any federally-supported research, it is the responsibility of the College to ensure that all collaborating institutions and independent investigators operate under an approved IRB. If the collaborating institution does not have an IRB, it may operate under the College's IRB with approval of the agency supporting the research. Independent Investigators shall sign a formal, written agreement of commitment to relevant human subject protection policies and IRB review.

IRB Committee Members:

1. The Institutional Review Board (IRB) is convened by the Asst. Vice President of Institutional Research, Assessment, and Effectiveness (Human Subjects Administrator). The FSW IRB shall at a minimum be represented by an Academic Dean, at least one faculty representative from the School of Pure & Applied Sciences, at least one from the School of Arts, Humanities, and Social Sciences, at least one from the School of Health Professions, one non-FSW affiliated member, and one non-voting representative from the College's General Counsel Office. Once the above criteria are met, the IRB can host additional faculty to serve as alternates. The FSW IRB shall at minimum be seven members and not to exceed 10 members (excluding alternates).
2. FSW IRB members serve a 3-year term based on the recommendation of their respective Dean. A member can serve longer if no replacement has been recommended at the end

of term. Non-FSW affiliated IRB members are appointed by the Human Subjects Administrator with approval from the current IRB and also serve a 3-year term. The chairperson is selected by the current IRB members to serve a 3-year term. First alternates can replace voting member in their respective area when voting member's term expires with approval from the respective Dean.

3. The Human Subjects Administrator may, at the request of the Chair or the majority of the IRB, invite additional individuals with proper expertise in specific areas associated with a given research submission to convene with the IRB.

IRB Duties

1. The College IRB shall review any research involving human subjects, defined in the regulations as a systematic investigation (including research development, testing, and evaluation designed to develop or contribute to generalizable knowledge), including research done as a part of grants, cooperative agreements or contracts and dissertation proposals.
2. The Human Subjects Administrator defines the procedures, makes sure they are followed, sets up meetings to occur twice yearly, tracks the process, conducts record keeping, evaluates members for appropriate expertise, investigates potential for conflict of interest by any parties involved in a case- by-case basis, maintains open line of communications with research investigators, administration, and the community, as necessary, and serves as a liaison with federal compliances offices. The Human Subjects Administrator (or designee) shall archive and maintain a database of all materials pertaining to review process and approval for each IRB application.
3. The Chairperson will decide if the research is exempt from review, can be reviewed through the expedited process, or requires full committee review, and will conduct an annual review of any continuing projects lasting longer than one year; the Chairperson may make the determination upon initial approval that review may take place at varying intervals so long as the timespan between reviews is not in excess of one year.
4. The Human Subjects Administrator will serve as the Institutional Review Board Signatory Official providing oversight on the performance and conduct of the IRB.

Review Process and Procedures

1. Programs and proposals that may be exempt or expedited shall be presented to the IRB Human Subjects Administrator. If the research is exempt or expedited, the review can be completed without committee convening with records pertaining to both the research and the decision reported to the Human Subjects Administrator.
2. Research that does not fit into the Exempt or Expedited categories shall be reviewed by the IRB at the next bi-annual meeting, or in special circumstances, during an ad hoc session at the request of the principal investigator.
3. The principal investigator may not engage in research activities until approval from the IRB is granted. If there are multiple co-principal investigators it is the responsibility of the principal investigator to communicate approval to their collaborator(s).
4. Funds for any project may not be expended if requirements herein entailed are not satisfied.
5. Any unanticipated issues, non-compliance, or change to the project shall be immediately reported to the IRB Chairperson and Human Subjects Administrator to determine if a committee review is required.