College Operating Procedures (COP)	FLORIDA SOUTHWESTERN STATE COLLEGE

Procedure Title:	Institutional Review Board (IRB)
Procedure Number:	03-1601
Originating Department:	Provost/Vice President of Academic Affairs
Specific Authority:	
Board Policy	n/a
Florida Statute	1001.65(16)
Florida Administrative Code	n/a
Procedure Actions:	Adopted: 10/06/15
Purpose Statement:	The IRB purpose is to ensure that the College is in compliance with federal guidelines and standards for research by assuring that human subjects exposed to any research procedures are adequately protected.

Membership and Process:

1. The College President will serve as the Institutional Signatory Official providing oversight on the performance and conduct of the IRB.

2. The Institutional Review Board (IRB) is composed of the Director of Effectiveness and Accountability (Human Subjects Administrator), an Academic Dean, four faculty appointed by the Provost/VPAA with at least one being either the President or Vice President of the Faculty Senate Executive Committee, and a non-affiliate to represent the community. A member of the College's General Counsel Staff will also serve as a non-voting member of this committee.

3. The Chair will be one of the faculty members who serve on the IRB. The IRB Chair will be appointed by the Provost/VPAA and will receive a stipend on an annual basis. The IRB Chair will decide if the research is exempt from review, can be reviewed through the expedited process, or requires full committee review.

4. The Human Subjects Administrator defines the procedures, makes sure they are followed, sets up meetings, tracks the process, conducts record keeping, and distributes minutes of IRB meetings.

IRB Review Procedures

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. Programs and proposals that may be exempted or waived shall be presented to the IRB Human Subjects Administrator.

3. Research that does not fit into the Exempt or Expedited Categories shall be reviewed by the IRB.

4. Continuing projects must be reviewed on an annual basis.

Compliance Procedures

1. Funds for any project may be terminated or suspended if there is a failure to comply with the regulations.

2. 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.

3. 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 that period of time to remain effective, even if no changes have occurred.

4. Any changes to the composition or policies of the IRB shall be submitted to OHRP within 90 days of the change.

5. The College shall provide written assurance to the Department of Health and Human Services (DHHS) that it will comply with the federal regulations.

6. All long-term projects shall be reviewed and re-approved by the IRB Chair once a year for the duration of the project. Any unanticipated issues, non-compliance, or change shall be immediately reported to the IRB chairman to determine if a committee review is required.

7. A database will be maintained by the designated Human Subjects Administrator.

8. IRB records shall be retained for at least three years; records pertaining to research that is conducted shall be retained for three years after completion of the research. All records shall be accessible for inspection and copying by authorized representatives.

9. It is the responsibility of the researcher to obtain the proper approval before conducting any human subjects research.