Purpose

The purpose of this procedure is to ensure Florida State College at Jacksonville (FSCJ) is in compliance with federal guidelines and standards for research by assuring that human beings exposed to any research procedures are adequately protected.

Procedure

A. Members of the IRB Committee and Process

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

2. An IRB committee will be composed of the Associate Vice President of Institutional Effectiveness (IRB Chair), Director of Institutional Analytics and Research (Human Subjects Administrator), four (4) College administrators (Associate Vice-Presidents, Associate Provosts, or Deans) of which two (2) must have a background in science, the President of the Faculty Senate, or designee, and a non-affiliate to represent the community.

3. 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 (as needed), tracks the process, conducts record keeping, and distributes minutes of IRB meetings, if the full IRB meets for a full review of a research proposal.

B. IRB Review Procedures

1. The College IRB shall review any research as defined in the regulations as a systematic investigation (e.g., 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 applicant must submit proposals to the IRB Chair using the IRB Initial Routing Form for New Projects. The IRB Chair will determine whether the research is exempt from review, can be reviewed through the expedited process, or requires full committee review. Research that does not fit into the exempt or expedited categories shall be reviewed by the IRB upon the applicant's completion of the IRB Routing Form for Full Projects.

    a. The IRB Chair will notify the applicant regarding approval via an electronic memo. At that point, if the proposal is approved, the applicant may begin the research process. Projects must

be reviewed on an annual basis or whenever revisions are made using the IRB Review of Approved Projects Form.

C. 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 demonstrate competence of U.S. Department of Health & Human Services, Office of Human Research Protections (OHRP), Human Subjects Research Compliance Guidelines by completing FSCJ approved (AFPD) training and passing a College-approved knowledge test of subject content. Upon completion, the prospective investigator 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 U.S. Department of Health & Human Services (DHHS) 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 three (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 the OHRP within ninety (90) days of the change.

5. The College shall provide written assurance to the DHHS that it will comply with the federal regulations.

6. All projects shall be reviewed and re-approved by the IRB Chair once a year for the duration of the project. Using the *IRB Review of Approved Projects Form*, any unanticipated issues, non-compliance or change shall be immediately reported to the IRB chair to determine if a committee review is required.

7. Once the project is complete, the researcher will submit the *Project Closing Form* to the IRB chair.

8. A filing system or database will be maintained by the designated Human Subjects Administrator, or designee.

9. IRB records shall be retained for at least three (3) fiscal years; records pertaining to research that is conducted shall be retained for three (3) fiscal years after completion of the research. All records shall be accessible for inspection and copying by authorized representatives.

D. Forms

1. Institutional Review Board (IRB) Policy Handbook
2. IRB Initial Routing Form for New Projects
3. IRB Review of Approved Projects Form
4. Project Closing Form

REFERENCES: F.S. 1001.64, 1001.65, DHHS 45 CFR part 46

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