Francis Marion University
Institutional Review Board Policies and Procedures

Policy:

The University's Institutional Review Board (IRB) shall supervise the use of human subjects in all research conducted under the direction of agents of the University in accordance with the Office for Human Research Protections (OHRP) of the Department of Health and Human Services guidelines. The IRB is to insure adherence to the OHRP guidelines and the basic goals of the Belmont Report and to insure that the rights and welfare of human participants in research are protected.

Composition of the IRB:

The Provost will appoint the members of the IRB during April of each academic year. Appointments are for one year, but appointments may be renewed. The total membership will consist of the seven full members. All academic appointees will be tenured full-time faculty. The membership of the IRB will be structured in the following manner:

1. One member appointed from the humanities to serve as an academic but non-scientist member. One member from the general community.
2. One member from each of the following areas: biological, physical, social and behavioral sciences
3. A Chair from any discipline with the following qualifications:
4. Experience with the types of research covered in the OHRP guidelines
5. Demonstrated experience with research design and data analysis in human research
6. Any additional members deemed necessary by the Provost or upon request of the IRB.
7. The University attorney will serve as an ex-officio member
8. The Board shall not consist entirely of men or of women or entirely of one academic discipline.
9. No member of the Board may be involved in reviewing or voting on research in which the member has a vested interest including be a principal or co-principal investigator or junior investigator. In such situations, the Chair, or if necessary, the Provost shall appoint an alternate member of the Board to review and vote on such proposals.
10. To conduct business a quorum (50% + 1) of IRB members must be present at scheduled meeting of the Board. Alternate members shall be appointed and invited to all meetings. There will be no proxy votes.
11. The IRB may invite persons with expertise and special competence in areas in which the members of the Board feel additional knowledge and expertise is needed. These individuals will advise the Board, but will not vote on proposals.

General Functions of the IRB:

1. The University's IRB will review all research proposals involving human subjects conducted by faculty, staff or affiliates of the University.
2. The Board will insure that the recommended procedures for obtaining informed consent, risks and benefits for human subjects involved in research studies will be followed.
3. The approval of the Board is required before human research is undertaken.
4. The Board will maintain all records of proposals, modifications, and actions in a central office (currently the Office of Institutional Research).
5. The Board will hold monthly meetings, and additional meetings if needed, to review and vote on research proposals. All members will have full access to all proposal documents and correspondence.
6. The Chair will serve as Primary Reviewer and the IRB members as Secondary Reviewers.
7. The Chair is authorized to sign approval and correspondence on behalf of the Board, provided such actions are approved by the Board or by special guidelines for educational research.
8. The Chair will be responsible for setting agenda, scheduling meetings, initial review of proposals, and correspondence with Principal Investigators.
9. The Chair will supervise the secretarial support functions of designated assistant(s).
10. The Board may accept approval of research proposals from recognized IRBs of other universities or research agencies external to the University. The full Board must vote on such acceptances.
11. The primary documents will include:
    a. Research proposals including informed consent forms
    b. Reports of adverse events
    c. Continuing reviews
    d. Amendments to Proposals
    e. Correspondence between the Board and Principal Investigators
    f. Correspondence with general public and/or participants

Procedures for Submission of Research Proposals:

1. Prior to submission of proposals the principal investigator will file evidence of completion of the IRB-approved human research protections training.
    a. For principal investigator the approved training is provided on-line by the National Institute of Health at: http://www.nihtraining.com/ohsrsite/IRBCBT/instructions.html
    b. Co-investigators and research team members are to file evidence of completion of the IRB-approved human research protections training provided on-line by Office for Human Research Protections at http://ohrp-ed.od.nih.gov/CBTs/Assurance/login.asp

2. The Principal Investigator shall submit the appropriate form(s) through IRB on-line file exchange (all forms are in Word formats and must be completed in 12 point Times New Roman font):
    a. IRB Review Form for new research including request for expedited review
    b. Continuation of Research Form to continue existing research
    c. Adverse Event Form whenever an adverse event occurs
    d. Educational Research Review Report for class-related research projects that are solely for education by be submitted to the IRB Chair with the following guidelines:
        i. A departmental chair and one designee approve the project as solely for educational exercises not to be used for advancement of knowledge and will not be submitted for publication and/or formal conference presentations.
        ii. The departmental chair and designee may certify a recommendation of exemption to the University IRB of a project from University IRB review if
            1. appropriate compliance with OHRP guidelines for participant confidentiality and informed consent are insured
            2. either of the following conditions are met:
                a. the project does not involve active manipulation of independent variable(s)
                b. the project is a repeat ion of previous exercises or studies
                c. the project is an exercise provided in instruction support packages
        iii. The Chair my accept the departmental recommendation or request further information or refer the proposal to the full IRB.

3. The Chair of the IRB shall review all submissions.

    a. If the request for exemption is determined to be appropriate, then the principal investigator will be noted and a copy of the proposal and approval documents will be filed by the Chair.
    b. If the request for an expedited review is determined to be appropriate, then the principal investigator will be noted and a copy of the proposal and approval documents will be included in the agenda for the next meeting of the IRB for expatiated approval.
    c. If the request for a full review is determined to be appropriate, then the principal investigator will be notified and a copy of the proposal will be added to the agenda for the agenda for the next meeting of the IRB.
    d. If necessary, the principal investigator, or designee, will be asked to attend the IRB meeting to answer specific questions.
    e. All documents on proposal and notification documents will be also posted on the IRB on-line site.

Decision Making Procedures of the IRB

1. The chair and full IRB will use the Office of Human Research Protection's decision flowcharts in making final determinations of classification of a proposal for exempt, expedited, or full review.
2. The IRB will follow the basic conventions of the Belmont Report and guiding documents of the OHRP in making decisions of approval or disapproval.
3. In cases in which the chair is unwilling to make a determination of exempt or expedited review, then the chair will request a second opinion from another member of the IRB.
4. If the chair and second reviewer do not agree that the proposal qualifies for exempt or expedited review, then the proposal will be referred to the IRB for a full review.
5. The IRB may give qualified approval which specifies that full approval will be automatically granted if requested changes in the proposal are made.
6. On-line copies of final proposals and decision documents will be posted to the on-line site and a hardcopy with signatures will be maintained by the IRB.