BYLAWS SOUTHERN WESLEYAN UNIVERSITY RESEARCH COMPLIANCE COMMITTEE

Article I. NAME

The name of the board is the Southern Wesleyan University Research Compliance Committee (hereinafter called "SWU RCC")

Article II. PURPOSE

The SWU RCC is to ensure compliance with the following policies:

- 1. Federal Policy for the Protection of Human Subjects (45 CFR Part 46: "Common Rule")
- 2. Animal Welfare Act regulations (P.L. 89-544) and amendments
- 3. Guide for the Care and Use of Laboratory Animals (National Research Council of the National Academies)
- 4. Guide for the Care and Use of Agricultural Animals in Agricultural Research and Teaching (Federation of Animal Science Societies)
- 5. PHS Policy on the Care and Use of Laboratory Animals
- 6. FDA Good Laboratory Practices
- 7. NIH Guidelines for Research Involving Recombinant DNA Molecules revised March 2013
- 8. Observance of policies of Southern Wesleyan University regarding the following:
 - a. protection of human subjects or vertebrate animals in any and all research or applicable teaching activities conducted by faculty, students, or staff
 - b. work with hazardous chemical or biological agents (Policy # TBD)

Article III. AUTHORITY

The Institutional Officer, Dr. Tonya Strickland of Southern Wesleyan University, has delegated authority to the SWU RCC, which will be empowered to do the following:

- 1. review all funded and unfunded research by faculty, students, or staff that involves the use of human subjects, vertebrate animals, or hazardous substances (biological or chemical), prior to the beginning of the research;
- 2. review all research involving human subjects conducted by researchers not directly involved with the university yet who propose to use university faculty, students, staff and/or facilities in their research;
- 3. insure that researchers have procedures in place prior to the start of research to fully inform subjects about the nature, purposes, and risks of the research, and to obtain informed consent as applicable;
- 4. educate the university community as to the responsibilities and duties of those conducting sound and ethical research;
- 5. determine the type of review (exempt, expedited, or full board) the research requires;
- 6. disapprove, recommend modification, or approve research applications based upon the protection of human or animal subjects;
- 7. suspend or terminate any research that is not proposed or conducted with its guidelines;
- 8. require progress reports and/or monitoring as deemed necessary.

Article IV. MEMBERSHIP

The SWU RCC membership shall consist of no fewer than five members and shall consist of at least one of each of the following:

- 1. a representative from each school or college
- 2. persons actively involved in research
- 3. a non-scientist
- 4. a non-affiliated community representative
- 5. a veterinarian with experience with laboratory animals

Some members may fulfill more than one role.

The members will generally serve for a three-year renewable term and may be removed only for stated cause. The year of service is counted from the beginning of the academic year.

Failure to attend three (3) consecutive meetings will constitute cause for removal if no valid excuse is provided. Replacement by another individual will be designated by the Institutional Officer.

Members may be removed by a majority vote of the Committee.

Members receive no compensation. Liability coverage will be provided by the university under its umbrella coverage.

Article V. OFFICERS

The SWU RCC officers will consist of a Chair and a Vice Chair. The Chair is appointed by the Institutional Official. The Vice Chair will be elected by the Committee members at the first RCC meeting of an academic year and will serve for a two-year renewable term. Both the Chair and the Vice Chair will be voting members of the SWU RCC. However, the acting chair of a meeting will vote only in the event of a tie vote. Other officers may be appointed by the Chair to carry out the activities of the Committee.

Article VI RESPONSIBILITIES

The SWU RCC Chair (or in their absence, the Vice Chair) shall hold leadership responsibility for RCC review and approval of human subject, vertebrate animal, or hazardous material research in accordance with current guidelines, institutional policies, and federal and state regulations governing these areas of research. In addition, the Chair shall also act in the following ways:

- 1. oversee the orientation and continuing education of RCC members;
- 2. acknowledge receipt of new applications;
- distribute applications to RCC members on a rotating basis at the appropriate level of review;
- 4. communicate known or suspected problems in the conduct of research to involved personnel;
- 5. maintain a record of RCC determinations and actions;
- oversee the development and implementation of appropriate policies, procedures and guidelines directed at human subject protections, animal research subject protections, and the functions and activities of the RCC;

- review the RCC's policies and procedures for currency, accuracy and consistency on an ongoing basis;
- 8. preside over RCC meetings and schedule, announce, arrange for meeting room, develop and distribute meeting agenda, and delegate note-taking for RCC meetings;
- 9. represent the RCC in interactions related to issues surrounding the ethical and regulation-compliant conduct of research;
- 10. report ethical violations by principal investigators to the appropriate Southern Wesleyan University authority.

The Vice Chair shall be responsible for the following:

- 1. record and distribute minutes of RCC meetings;
- 2. assist the Chair with their responsibilities, when needed.

All RCC members shall be responsible for the following:

- 1. review applications and evaluate them in accordance with Federal Policy for the Protection of Human Subjects (45 CFR Part 46: "Common Rule") and policies of Southern Wesleyan University regarding the protection of human subjects;
- participate in RCC deliberations and make recommendations for reduction of risk, improved informed consent process, or other aspects of protection of human subjects;
- 3. attend all RCC meetings unless there are extenuating circumstances for absence;
- 4. inform the RCC Chair or Vice Chair of human subject research noncompliance problems or ethical issues of which they become aware;
- 5. maintain the confidentiality of all RCC deliberations.

Article VII. MEETINGS

The SWU RCC will meet quarterly unless there is no business to conduct.

Notice of meeting time and place shall be given at least one week in advance. The Chair may call a special meeting upon three (3) days written or telephone notice. A quorum shall consist of a simple majority.

Minutes of each meeting shall be kept and a list of actions taken since the previous meeting shall be attached to the meeting minutes.

Article VIII. PROCEDURES

- 1. Applications must be submitted and approved prior to the initiation of research. The SWU RCC will not approve applications when research has commenced prior to approval.
- 2. The RCC Chair will receive applications and determine the appropriate level of review for the protocol.
- 3. Process for IRB applications
 - a. If the application is determined to be exempt, the principal investigator will be notified of the status within 10 days of receipt as approved, approved pending minor modification, revise and resubmit, or not approved.
 - b. If the application is determined to be expedited, a reviewer will be selected based upon rotation of members, and the principal investigator will be notified within fifteen (15) days of receipt of a complete application as approved, approved pending minor modification, revise and resubmit, or not approved.

- c. If the application is determined to require full Committee review, the application will be reviewed at the next regularly scheduled meeting of the RCC for which the submission deadline has been met.
- d. IRB applications submitted by researchers outside of the institution will follow the additional requirements set forth in Policy 1 "Human Subjects Research with No Affiliation with Southern Wesleyan University."
- 4. Process for IACUC & IBC applications
 - a. If the application is determined to allow for designated review, a reviewer will be selected based upon rotation of members, and the principal investigator will be notified within fifteen (15) days of receipt of a complete application as approved, approved pending minor modification, revise and resubmit, or not approved
 - b. If the application is determined to require full Committee review, the application will be reviewed at the next regularly scheduled meeting of the RCC for which the submission deadline has been met.
- 5. The SWU RCC reserves the right to make further inquiries, reconsider an application, and reverse its own determination based upon changes in legislation or noncompliance with the terms of the application.
- 6. The SWU RCC shall assess the overall risk/benefits to the participants/society. The quality of the protocol or its methodological approach may be important factors in determining the risk/benefit to society.
- Approved applications may be amended by submission of the appropriate form to the RCC Chair. Notification of approval of new methods or changes to the original application should be received before implantation.
- 8. Primary investigators are expected to complete annual and end-of-research reports as requested by the SWU RCC.
- 9. The By-Laws of the SWU RCC and approved policies may be amended with 2/3 majority vote of the membership.
- 10. Non-compliance and research misconduct will be reported as follows:
 - Students will be reported to the Vice President of Student Life
 - Faculty members will be reported to their Dean and the Institutional Officer.
 - Staff members will be reported to the Director of Human Resources.