Bylaws of the Saint Leo University Institutional Review Board

Article I. NAME

The name of the board is the Saint Leo University Institutional Review Board (hereinafter called "SLU-IRB")

Article II. PURPOSE

The SLU-IRB is to ensure compliance with the Federal Policy for the Protection of Human Subjects (45 CFR Part 46: “Common Rule”) and observance of policies of Saint Leo University regarding the protection of human subjects in any and all research conducted by faculty, students, or staff at Saint Leo University.

Article III. AUTHORITY

The VPAA of Saint Leo University has delegated authority to the SLU-IRB which will be empowered to:

1) review all funded and unfunded research by faculty, students, or staff that involves the use of human subjects 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 to fully inform subjects about the nature, purposes, risks, etc of the research, and 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 proposals based upon the protection of human 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 SLU-IRB membership shall consist of no fewer than five members and shall consist of at least one of the following:
1) representatives from each school
2) members with expertise in ethical issues
3) community representatives
4) members from a Saint Leo University center
5) persons of diverse gender, race, ethnicities, and professional backgrounds
6) persons actively involved in research
7) non-scientific persons.

The members will 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 8-week term of appointment.

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 Board.

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

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

Article V. OFFICERS

The SLU-IRB officers will consist of a Chair and a Co-chair. The Chair and Co-Chair will be elected by the Board members at the Spring 2 meeting of the Board and will serve for a two-year renewable term. Both the Chair and the Co-chair will be voting members of the SLU-IRB. Other officers may be appointed by the Chair and Co-chair to carry out the activities of the board.

Article VI RESPONSIBILITIES

The IRB Chair and Co-chair shall hold leadership responsibility for IRB review and approval of human subject research in accordance with current guidelines, institutional policies, and federal and state regulations governing human subject protections. In addition, the IRB Chair and Co-chair shall:

1) oversee the recruitment, orientation, continuing education and retention of IRB members;
2) check the IRB electronic mailbox and acknowledge receipt of new proposals;
3) Distribute proposals to IRB members on a rotating basis at the appropriate level of review;
4) communicate sanctions relating to known or suspected problems in the conduct of human-subject research to involved investigators
The IRB members shall be responsible to:

1) review proposals and evaluate them in accordance with Federal Policy for the Protection of Human Subjects (45 CFR Part 46: "Common Rule") and policies of Saint Leo University regarding the protection of human subjects;
2) receive IRB proposals, determine the appropriate level of review for the protocol, and notify the principal investigator of determination;
3) participate in IRB deliberations and make recommendations for reduction of risk, improved informed consent process, or other aspects of protection of human subjects;
4) attend all IRB meetings unless there are extenuating circumstances for absence;
5) inform the IRB Chair or Co-chair of human subject research noncompliance problems or ethical issues of which they become aware;
6) maintain the confidentiality of all IRB deliberations.

The IRB Secretary shall be responsible to:

1) receive and log all IRB submissions;
2) maintain a record of IRB determinations and actions in communication with the Chair and Co-chair;
3) schedule meetings and meeting rooms, and notify members of meetings;
4) record and distribute meeting minutes;
5) maintain other administrative tasks as deemed necessary by the IRB Chair and Co-chair.

Article VII. MEETINGS
The SLU-IRB will meet during week three (3) of each eight (8) week term throughout the calendar year. Meetings may be conducted on ground, via elluminate or by VTT. Notice of meeting time and place shall be given at least one week in advance. The Chairpersons 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) all proposals must be submitted prior to the initiation of research; the Board will not approve proposals after the fact
2) the Chairpersons will receive applications and determine the appropriate level of review for the protocol
3) if the proposal is determined to be exempt, the principal investigator will be notified of the status within 10 days of receipt; approved, approved pending minor revision, revise and resubmit, or not approved
4) if the proposal is determined to be expedited, a third 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 proposal
5) if the proposal is determined to require full Board review, the proposal will be reviewed at the next regularly scheduled meeting of the IRB
6) the SLU-IRB reserves the right to make further inquiries, reconsider a proposal, and reverse its own determination based upon changes in legislation or noncompliance with the terms of the proposal
7) the SLU-IRB shall not concern itself with the quality of the protocol or its methodological approach, but rather shall assess the overall risk/benefits to the participants/society;
8) proposals submitted by researchers outside of the institution must have prior approval by their institution to conduct such research.