

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 "Saint Leo IRB")

Article II. PURPOSE

The Saint Leo 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 Saint Leo-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 applications 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 Saint Leo 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 Saint Leo 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 Saint Leo IRB. Other officers may be appointed by the Chair and Co-chair to carry out the activities of the board.

Article VI RESPONSIBILITIES

The Saint Leo IRB Chair and Co-chair shall hold leadership responsibility for Saint Leo 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 Saint Leo IRB Chair and Co-chair shall:

- 1) Oversee the recruitment, orientation, continuing education and retention of Saint Leo IRB members;

- 2) Check the Saint Leo IRB electronic mailbox and acknowledge receipt of new applications;
- 3) Distribute applications to Saint Leo 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;
- 5) Maintain a record of Saint Leo IRB determinations and actions;
- 6) Oversee the development and implementation of appropriate policies, procedures and guidelines directed at human subject protections and the functions and activities of the Saint Leo IRB;
- 7) Review the Saint Leo IRB's policies and procedures for currency, accuracy and consistency on an ongoing basis;
- 8) Preside over Saint Leo IRB meetings and, in the absence of a Secretary of the Board, schedule, announce, arrange for meeting room, develop and distribute meeting agenda, and delegate note-taking for Saint Leo IRB meetings;
- 9) Represent the Saint Leo IRB in interactions related to issues surrounding the ethical and regulation-compliant conduct of human subject research;
- 10) Report ethical violations by principal investigators to the appropriate Saint Leo University authority.

The Saint Leo IRB members shall be responsible to:

- 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 Saint Leo University regarding the protection of human subjects;
- 2) Receive Saint Leo IRB applications, determine the appropriate level of review for the protocol, and notify the principal investigator of determination;
- 3) Participate in Saint Leo IRB deliberations and make recommendations for reduction of risk, improved informed consent process, or other aspects of protection of human subjects;
- 4) Attend all Saint Leo IRB meetings unless there are extenuating circumstances for absence;
- 5) Inform the Saint Leo 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 Saint Leo IRB deliberations.

The Saint Leo IRB Secretary shall be responsible to:

- 1) Schedule meetings and meeting rooms, and notify members of meetings;
- 2) Record and distribute meeting minutes;
- 3) Maintain other administrative tasks as deemed necessary by the Saint Leo IRB Chair and Co-chair.

Article VII. MEETINGS

The Saint Leo 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 Chair and Co-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) The Saint Leo IRB operates on a 12-month schedule. Reviews are suspended from the day after the end of Fall 2 at the centers to the first business day in January, and from Thursday to Sunday on Thanksgiving;
- 2) All applications must be submitted prior to the initiation of research; the Board will not approve applications after the fact;
- 3) The Chair or Co-chair will receive applications and forward complete applications to a reviewer;
- 4) If the application is determined to be exempt, the reviewer will notify the principal investigator of the recommendation (approved, approved pending minor revision, revise and resubmit, or not approved) within 10 days of receipt of the complete application;
- 5) If the application is determined to be expedited, the Chair or Co-chair will assign two additional reviewers based upon rotation of members and the initial reviewer will notify the principal investigator of the recommendation (approved, approved pending minor revision, revise and resubmit, or not approved) within fifteen (15) days of receipt of the complete application;
- 6) Research on minors always undergoes at least an expedited review;
- 7) If the application is determined to require full Board review, the application will be reviewed by the entire board at the next regularly scheduled meeting of the Saint Leo IRB;

- 8) Research involving institutionalized persons (such as, but not limited to, prisoners) always undergoes a full review;
- 9) Research on prisoners may not involve more than minimal risk and no more than inconvenience to the subjects;
- 10) Whether contract or market research needs to undergo an IRB review will be determined on a case-by-case basis;
- 11) The Saint Leo IRB 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;
- 12) The Saint Leo 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;
- 13) Applications submitted by researchers affiliated with an organization other than Saint Leo University must have prior approval by their organization to conduct their research before submitting an application to the Saint Leo IRB;
- 14) On a case-by-case basis, the Saint Leo IRB may grant conditional approval of applications from outside Saint Leo University, when an outside organization requires Saint Leo IRB approval before conducting its review. Conditional approval is valid for 6 months, after which it will be rescinded if the PI does not submit proof of approval from the outside organization's IRB;
- 15) Saint Leo IRB approval is granted for one year from the date of approval. Researchers wanting to extend their data collection and/or analysis beyond one year must request an extension before reaching the expiration date of their original application;
- 16) Submitted application that have an IRB response other than approved communicated to the principal investigator and no subsequent communication from the principal investigator for at least one year from the date of the last communication will be considered closed;
- 17) Researchers wanting to modify their study must submit a modified application for further approval;
- 18) Ethical violations will be reported as follows:
 - Students will be reported to the Academic Standards Committee
 - Faculty members will be reported to their Dean and the Vice-President of Academic Affairs
 - Staff members will be reported to the Director of Human Resources.
- 19) All IRB correspondence on the irb@saintleo email address, as well as all applications, revisions, and decisions, shall be retained for seven (7) years.

Article IX. SAINT LEO IRB POLICY ON INTERNATIONAL STUDIES

- 1) Research conducted by Saint Leo investigators in any country outside of the United States must be reviewed and approved by the Saint Leo IRB.
- 2) International research shall be limited to Saint Leo faculty, staff, and doctoral students.
- 3) Permission to conduct international research studies requires that Principal Investigators obtain proof of either exemption or permission from an IRB or equivalent research ethics agency with authority in any nation where participants reside. This requirement is generally expected only to apply to archival, survey or interview research that would already be considered exempt.
 - a. The Saint Leo University IRB will provide a *conditional approval* that may be shared with the external IRB(s) to obtain required documentation. Documentation must be submitted within 90 days after receiving conditional approval and formal approval must be granted before beginning research.
- 4) International research studies require that Principal Investigators conduct research studies wholly in English, or that Principal Investigators plan to translate all Consent Forms and Research Instruments into participants' native language(s) before beginning research.
 - a. Researchers are required to provide verifiable proof of translation of consent forms, recruitment materials, survey instruments, and any other relevant materials into the native language of their participants when conducting international research. Verifiable proof would include a statement that research materials have been accurately translated and back-translated by the researcher or by a third-party translator.