

**Saint Leo University Institutional Review Board**

**Application for IRB Review of Proposed Research\***

**You may not begin your study until your IRB application is approved. Upon approval, your application will be open for one year. Applicants checking one or more items marked with an asterisk (\*) in part 1, MUST complete parts 1 and 2.**

**Applicants NOT checking any of those items, only fill out Part 1.**

**Submit your IRB application as ONE Word doc. All documentation should go at the end of this application. Do not submit a document from a share drive.**

**PART 1 – TO BE FILLED BY ALL APPLICANTS**

**1.** Principal Investigator’s full name (**ONE full name only**): Click or tap here to enter text.

**2.** Organization: Saint Leo University

 If other, Click or tap here to enter text.

**3.** Department: Click or tap here to enter text.

**4.** Program name: Click or tap here to enter text.

**5.** Program level: Choose an item.

**6.** Email address: Click or tap here to enter text. **(NOTE: student email is in the form** **name@email.saintleo.edu****. Please indicate “employee” after your email if you are a student who works at Saint Leo)**

**7.** Local phone number: Click or tap here to enter text.

**8.** Co-investigator(s): Click or tap here to enter text.

**9.** Faculty advisor (if student research; **ONE advisor’s name only**):Click or tap here to enter text.

**10.** Faculty advisor’s email address: Click or tap here to enter text.

**11.** Project title: Click or tap here to enter text.

**12.** Number of research projects that the listed PI has completed as Principal Investigator before the one proposed here: 0

**13.** Number of other research projects in which the listed PI has collected information on human subjects prior to the one proposed here: Choose an item.

**14.** Please describe the purpose(s) or goal(s) of your study. Include your research question(s) or hypothesis(es) if applicable. (limit response to 250 words)

Click or tap here to enter text.

**15.** Research methods (Check all that apply and attach all corresponding documentation for each method)

[ ] Survey(s) (attach questionnaire)

[ ] Interviews (attach questionnaire or interview guide)

[ ] Focus Group(s) (attach questions)

[ ] Experiment (attach description detailed in a protocol and any instruments used)

[ ] Participant observation (attach procedures)

[ ] Unobtrusive observation (skip to item # 19)

[ ] Analysis of publicly available data. Identify all data being used: Click or tap here to enter text. (if yes, and no to 15a below Skip to # 27)

[ ] Analysis of private data that have already been collected (i.e., “archival” data)+ Identify all data being used: Click or tap here to enter text. (If yes, and no to 15a below Skip to # 19)

[ ] Other, specify: Click or tap here to enter text.

*+: For any non-public data, please include permission from the data holder.*

*PLEASE NOTE:*

*1) For any research recruited or conducted within an organization or group a letter of authorization on letterhead with a wet signature is required from an authorized representative of this organization indicating that you have permission to conduct your research there. If this organization has its own IRB, provide proof of IRB approval.*

*2) Be aware that the use of copyrighted material has to be authorized by the copyright holder.*

**15a**. Will the data be linked to the individual participants’ identifying information (such as name, email address, social security number, video, picture, etc.)? This may include identifying information on the data collection instrument or keeping a list of names matched to codes used in the data.

[ ]  Yes\* **(complete section 2)**

[ ]  No, my data will not involve the manual collection of participants’ identifying information.

[ ]  No, my online survey will not collect participants’ identifying information. My online survey tool (i.e., Qualtrics, Survey Monkey, other) will employ the anonymous setting to avoid collecting any identifying information on study participants.

**16.** Type of instrument(s) used (check all that apply):

[ ] Paper questionnaire, Survey, interview guide

[ ] Online questionnaire, Survey, interview guide

[ ] Experimental design (protocol must be attached)

[ ] None (note-taking)

[ ] Other, specify: Click or tap here to enter text.

**17.** How long do you anticipate that it will take the individual participants to complete the research procedure(s)? – (not referring to how long you expect to complete overall data collection).

 Click or tap here to enter text.

**18.** Number of participants: Click or tap here to enter text.

**19.** Types of participants (Check all that apply):

[ ] Adults (18 and older)

[ ] Elected officials

[ ]  Saint Leo students+

[ ]  Saint Leo University personnel++

[ ] Minors (under 18, includes Saint Leo students+ under 18)\*

[ ] Individuals diagnosed with a mental disorder or illness\*

[ ] Terminally ill patients\*

[ ] Undocumented immigrants\*

[ ] Convicted felons\*

[ ] Other sensitive populations, specify\*: Click or tap here to enter text.

*+ Requires recruitment materials to be included in item # 22.*

*++ Requires additional permission from the VPAA prior to IRB review. Please see the instructions on our website.*

**20.** Are you choosing participants from any specifically targeted categories?

[ ] No

[ ]  N/A, Unobtrusive observation as noted in item # 15

If yes, choose all those that apply

[ ] Race/ethnicity

[ ] Gender

[ ] Occupation

[ ] Age group

[ ] Military status

[ ] Other: Click or tap here to enter text.

**21.** Sampling strategy, choose all that apply:

[ ]  Convenience/availability

[ ]  Random/probability

[ ]  Snowball

[ ] Purposive/judgmental/theoretical

[ ] Other, specify: Click or tap here to enter text.

[ ]  Not Applicable. No sampling will be done (unobtrusive observation or existing data).

**22.** Recruitment strategy (Mark all that apply with an X):

[ ]  Individual contacts (in person, by phone, or by mail)

[ ]  Email announcements

[ ]  Public announcements (including through social media)

[ ]  Flyers

[ ]  Use of external agencies/groups

[ ]  Other, specify: Click or tap here to enter text.

[ ]  Not Applicable. Use of archived or private database.

+From #19 above, if using Saint Leo students, the recruitment statement will be as follows: Click or tap here to enter text.

**23.** Are any external agencies or groups providing approval for the recruitment or data collection of their employees or members (indicate any funders or organizations from which you obtain participants or their data)?

[ ]  No

[ ]  Yes

 If yes, please provide the name of the agency/agencies: Click or tap here to enter text.

 Note: A letter of authorization on letterhead with a wet signature by an authorized individual from the stated agency or group must also accompany the application.

**24.** What type of consent process will you use? (Choose all that apply)

[ ] Implied consent (attach template implied consent statement)

[ ] Informed consent form (attach template informed consent form)

[ ] Assent (attach template assent form or statement)

[ ] Other, specify: Click or tap here to enter text.

[ ]  Consent process not applicable. Research on publicly available data, archival or private database.

**25.** Data recording method (Mark all that apply with an X):

[ ] Electronic (online survey, email, blog, etc.)

[ ] Written (includes notes, participants filling out a paper questionnaire or survey)

[ ] Audio

[ ]  Video\*

[ ] Photo\*

[ ] Other, specify: Click or tap here to enter text.

[ ] Use of existing data

**26.** How will you store your data? (Check all that apply):

[ ] Locked file cabinet

[ ] Password-protected computer

[ ] Locked office

[ ] Locked safe

[ ] External database, provide name of database: Click or tap here to enter text.

[ ] Other, specify: Click or tap here to enter text.

**27.** How will you report your research? (Mark all that apply with an X)

[ ] Undergraduate Senior Thesis project

[ ] Master’s Thesis

[ ] Doctoral Dissertation

[ ] Class paper

[ ] In-class presentation

[ ] Public presentation

[ ] Publication

[ ] Report for an outside organization

[ ] Other, specify: Click or tap here to enter text.

**28.** Does the research involve any deception of the participants?

[ ] Yes\*

[ ] No

**29.** Does the research involve any cost to participants?

[ ] Yes\*

[ ]  No

**30.** Risk involved in participating in this research (Mark all that apply with an X):

See IRB website for a definition of minimal risk.

[ ] **None above those incurred in daily life**

[ ] Physical injury, illness, or exposure to toxic or noxious substances\*

[ ] Emotional or psychological harm\*

[ ] Social (such as: embarrassment, damage to one’s reputation)\*

[ ] Legal\*

[ ] Financial\*

[ ] Other, specify\*: Click or tap here to enter text.

**PART 2 – TO BE FILLED BY APPLICANTS WHO CHECKED ONE OR MORE BOX(ES) FOR ITEMS FOLLOWED BY AN ASTERISK (\*). If you didn’t check any boxes followed by an asterisk, proceed to the PI Statement of Responsibility. *(if you are not filling out this section, just leave blank; you do not have to type “N/A” throughout)***

Please provide ***detailed*** answers to the questions below.

**1.** Describe the objective(s) of your study. What do you hope to accomplish?

 Click or tap here to enter text.

**2.** What are the expected benefit(s) of your research to the participants themselves, to society, and/or to the academic community?

Click or tap here to enter text.

**3.** What type(s) of participants will you be using? Include any demographic information, such as age, gender, ethnicity, and any other social categories or groups that your research involves.

Click or tap here to enter text.

**4.** How will you contact and recruit participants for your study?

Click or tap here to enter text.

**5.** How will you secure informed consent from your participants?

Click or tap here to enter text.

**6.** Describe fully how you will collect, store, manage, analyze, and report your data. Include information regarding paper or electronic copies. If your data is linked or identifiable in any way, you must also describe how you will securely store your data and procedures for de-identification and study close out. If your data is collected electronically then you must also describe the program and security features that you will use.

Click or tap here to enter text.

**7.** How will you ensure participant anonymity or the confidentiality of the data during data collection, storage, analysis, and reporting? Please note that anonymity means that no information that can identify participants is collected in the data, while confidentiality means that such information is collected, but access to it is restricted.

Click or tap here to enter text.

**8.** Who will have access to the data? For what purposes?

Click or tap here to enter text.

**9.** How long will you keep the data, and why?

Click or tap here to enter text.

**10.** Describe fully any and all risks beyond those of daily life to which participants may be exposed as a result of participation in your study (legal, social, emotional, etc.).

Click or tap here to enter text.

**11.** How will you minimize the existing risk(s)?

Click or tap here to enter text.

**12.** If you answered “yes” to item #29 in Part 1 of the application, describe the nature of the participant deception and how you will debrief them.

Click or tap here to enter text.

**PI Statement of Responsibility**

**I, the Principal Investigator, certify that I have followed the guidelines as outlined in this application and in the instructions available on the IRB webpage, including (check all that apply):**

[ ]  I checked one or more item(s) followed with an asterisk **(\*\*\*)** and I have answered every single question in Part 2 of the application, leaving none blank

[ ]  I have provided an answer to every single question in Part 1 of the application, leaving none blank. I understand that incomplete applications will be returned without review.

[ ]  I am submitting this application, including all supplemental documents, as ONE Word document. I understand that any other type of submission will be returned without review.

[ ]  I have answered all questions truthfully. I understand that failure to do so will result in immediate revocation of any IRB approval, with the potential for further disciplinary action through my home institution.

[ ]  **I am including Saint Leo employees as research subjects** and have obtained the required approval from the Vice President of Academic Affairs to do so.

**If a student…**

[ ]  I have received guidance from my faculty advisor and obtained his/her signature

[ ]  As a **first-time undergraduate** Principal Investigator, my research involves no risk greater than those encountered in daily life.

[ ]  As a **Doctoral student**, I give permission for an IRB representative to discuss this application with my faculty advisor and/or program Chair/Director

**I also certify that I have included all necessary supplemental documentation, as applicable to my research (check all that apply):**

**Ethical Training:**

[ ]  I have obtained the required ethics training certification, as described on the IRB webpage

[ ]  Proof of completion of ethical training with at least 6 months’ validity, to be renewed if the study extends beyond that date. For more information, see the IRB webpage.

[ ]  If I am submitting this application as a student, proof of completion of ethical training for my faculty advisor

**Experimental Design Information and Materials:**

[ ]  Data collection instrument(s), such as survey, interview questionnaire(s), or protocols for experiments

[ ]  If using Saint Leo students and/or a vulnerable population marked with an asterisk in item 19, recruitment materials (email announcements, flyers, etc. to match the recruitment methods listed in item 22)

**Consent Form(s):**

[ ]  Implied consent statement template(s)

[ ]  Informed Consent form template(s)

[ ]  Assent form template(s)

**Supplemental Information:**

[ ]  Letter of Authorization from outside agency or group on their letterhead with wet signature from an authorized individual to conduct the specific research from outside agency

[ ]  Proof of approval from outside agency IRB

[ ]  If not a member of the Saint Leo community, proof of approval from my organization’s IRB

[ ]  **I am including Saint Leo employees as research subjects** and have attached the approval form from the Vice President of Academic Affairs.

**I accept the following responsibilities (please check each after reviewing):**

[ ]  I will not start collecting any data for this project before obtaining IRB approval of the proposal.

[ ]  I will obtain approval from the Saint Leo IRB prior to instituting any change in the project protocol.

[ ]  I will bring to the attention of the Saint Leo IRB the development of any unexpected risks or ethical concerns.

[ ]  I understand that the approval period is for exactly one year, and that all study activities will either cease prior to expiration, or I will submit a request for an extension prior to the expiration date.

[ ]  I have read, understand, and acknowledge the IRB bylaws.

[ ]  I will keep signed informed consent forms (if required by the project) from each participant for five years after the completion of the project and will ensure proper storage.

PI’s signature: Click or tap here to enter text. Date: Click or tap to enter a date.

**37.** (***Student research only***) Faculty advisor statement of responsibility

**I, the faculty advisor for this research project, certify the following:**

[ ]  I have reviewed this entire application and assisted the PI in designing his/her research project.

[ ]  I have ensured that the PI has followed all instructions to fill out this application according to the guidelines provided by the Saint Leo IRB.

[ ]  I approve the research project as outlined in this application.

[ ]  I will assist the PI in making any revisions requested by the Saint Leo IRB.

[ ]  I will assist the PI in the completion of the research and will continuously monitor all study related activities throughout the research period.

[ ]  I will ensure that the PI submits a modified application for review, should any modifications to the research plan occur.

[ ]  I will ensure that the PI submits a request for continuation in a timely fashion, should the research be extended beyond the one-year IRB approval.

[ ]  My ethics certification is valid for at least another 6 months and is attached to this application.

 [ ]  I will renew my ethics certification at expiration, if it expires before the PI’s research project is completed.

[ ]  **I understand that I will be held legally responsible in case of any violation of the IRB regulations by the research team.**

Faculty Advisor’s Signature: Click or tap here to enter text. Date: Click or tap to enter a date.

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***FOR IRB USE ONLY <do not delete; do not complete>:***

*Verification of ethics training certification*

 PI: [ ] Valid certification (Expiration date: Click or tap to enter a date. )

 [ ] Certification expired

 [ ] No certification

Faculty Advisor: [ ] N/A

 [ ] Valid certification (Expiration date: Click or tap to enter a date.)

[ ] Certification expired

[ ] No certification

*Type of review:* [ ] Exempt [ ] Expedited [ ] Full

*Decision:* [ ] Approved

[ ] Minor Revisions Required

Minor revisions required: Click or tap here to enter text.

 [ ] Revise and resubmit

Revisions required: Click or tap here to enter text.

 [ ] Not approved

Justification for non-approval: Click or tap here to enter text.

IRB representative’s signature: Click or tap here to enter text. Date: Click or tap to enter a date.

Add supporting documents after this page. Submit as ONE Word document. Do not submit from a share drive.