

**Saint Leo University Institutional Review Board**

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

**\*Item-by-item instructions to fill out the application are available at** [**https://www.saintleo.edu/application-directions-and-forms**](https://www.saintleo.edu/application-directions-and-forms)

**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.**

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

**1.** Principal Investigator’s full name (**ONE full name only**):

**2.** Organization:

**3.** Department:

**4.** Program name:

**5.** Program level: \_\_\_ Undergraduate \_\_\_ Graduate \_\_\_ N/A

**6.** Email address:

**7.** Local phone number:

**8.** Co-investigator(s):

**9.** Faculty advisor (if student research; **ONE advisor’s name only**):

**10.** Faculty advisor’s email address:

**11.** Project title:

**12.** Expected project start date:

**13.** Projected end date:

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

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

**16.** Please describe the purpose(s) or goal(s) of your study. Include your research question(s) or hypothesis(es) if applicable.

**17.** Research methods (Mark all that apply with an X)

\_\_\_ Survey (attach questionnaire)

\_\_\_ Interviews (attach questionnaire or interview guide)

\_\_\_ Focus Group(s)

\_\_\_ Participant observation

\_\_\_ Unobtrusive observation

\_\_\_ Experiment (attach description detailed in a protocol and any instruments used)

\_\_\_ Analysis of data that have already been collected (i.e., “archival” data)+

\_\_\_ Other, specify: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

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

*PLEASE NOTE:*

*1) For any research conducted within an organization, provide documentation 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.*

**18.** Type of instrument used:

\_\_\_ Paper questionnaire, Survey, interview guide

\_\_\_ Online questionnaire, Survey, interview guide

\_\_\_ Pre-post survey

\_\_\_ Experimental design (protocol must be attached)

\_\_\_ None (note-taking)

\_\_\_ Not applicable (use of existing data)

\_\_\_ Other, specify: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**19.** How long do you anticipate that it will take the participants to complete the research procedure(s)?

**20.** Number of participants:

**21.** Types of participants (Mark all that apply with an X):

\_\_\_ 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\*

\_\_\_ Incarcerated individuals\*

\_\_\_ Undocumented immigrants\*

\_\_\_ Convicted felons\*

\_\_\_ Other sensitive populations, specify\*: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

*+ Requires recruitment materials to be added to the application.*

*++ Requires additional permission from the VPAA after approval of the IRB. IRB approval does not guarantee approval by the appropriate Saint Leo administrators.*

**22.** Please briefly describe your participants, including the social categories you are drawing from or targeting (race/ethnicity, gender, occupation, age group, military status, etc.), or any other relevant characteristics of your sample:

**23.** Sampling strategy:

\_\_\_ Convenience/availability

\_\_\_ Random/probability

\_\_\_ Snow-ball

\_\_\_ Purposive/judgmental/theoretical

\_\_\_ Other, specify: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**24.** 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

\_\_\_ Other, specify: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**25.** Agencies involved with recruitment or data collection (indicate any funders or organizations from which you obtain participants or their data):

**26.** What type of consent process will you use? (Mark all that apply with an X)

\_\_\_ Implied consent (attach template implied consent statement)

\_\_\_ Consent form (attach template consent form)

\_\_\_ Assent (attach template consent form or statement)

\_\_\_ Not applicable (research on publicly available data)

\_\_\_ Other, specify: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

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

\_\_\_ Written (includes notes, participants filling out a paper questionnaire or survey)

\_\_\_ Electronic (online survey, email, blog, etc.)

\_\_\_ Audio

\_\_\_ Video\*

\_\_\_ Photo\*

\_\_\_ Other, specify: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

\_\_\_ Use of existing data

**28.** How long do you anticipate it will take you to collect all your data for this project?

**29.** 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\*

\_\_\_ No

**30.** For how long do you plan to keep your data?

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

\_\_\_ Locked file cabinet

\_\_\_ Password-protected computer

\_\_\_ Locked office

\_\_\_ Locked safe

\_\_\_ Other, specify:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

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

\_\_\_ Publication (including in professional journal)

\_\_\_ Public presentation (including at professional meeting or to an outside agency)

\_\_\_ Report for an outside organization

\_\_\_ Master’s thesis or dissertation

\_\_\_ Senior thesis project

\_\_\_ Class paper

\_\_\_ In-class presentation

\_\_\_ Other, specify:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

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

\_\_\_ Yes\*

\_\_\_ No

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

\_\_\_ Yes\*

\_\_\_ No

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

< <https://www.saintleo.edu/application-directions-and-forms>

View definition of minimal risk: <https://cdn2.hubspot.net/hubfs/206683/Resource%20PDFs%20and%20DOCs/IRB%20Institutional%20Review%20Board/Defining%20Minimal%20Risk.pdf?t=1534255440211> >

\_\_\_ 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\*: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**36.** 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 at** [**http://www.saintleo.edu/resources/collaborative-research-institute/institutional-review-board-(irb)/irb-application-directions-and-forms.aspx**](http://www.saintleo.edu/resources/collaborative-research-institute/institutional-review-board-%28irb%29/irb-application-directions-and-forms.aspx)**, including (check all that apply):**

\_\_\_ 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 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 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 have obtained the required ethics training certification, as described on the IRB webpage at <https://www.saintleo.edu/irb-research-ethics-certification>

\_\_\_ If a student, I have received guidance from my faculty advisor and obtained his/her signature

\_\_\_ If a first time undergraduate Principal Investigator, my research involves no risk greater than those encountered in daily life < <https://cdn2.hubspot.net/hubfs/206683/Resource%20PDFs%20and%20DOCs/IRB%20Institutional%20Review%20Board/Defining%20Minimal%20Risk.pdf?t=1534255440211> >

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

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

\_\_\_ Consent form template(s)

\_\_\_ Assent form template(s)

\_\_\_ Implied consent statement template(s)

\_\_\_ If using Saint Leo students and/or a vulnerable population marked with an asterisk in item 21, recruitment materials (email announcements, flyers, etc. to match the recruitment methods listed in item 24)

\_\_\_ Authorization 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

\_\_\_ Proof of completion of ethical training (see more information on the IRB webpage at

[<https://www.saintleo.edu/irb-research-ethics-certification>)](http://www.saintleo.edu/resources/collaborative-research-institute/institutional-review-board-%28irb%29/research-ethics-certification.aspx%29) with at least 6 months validity, to be renewed if the study extends beyond that date.

\_\_\_ If I am submitting this application as a student, proof of completion of ethical training for my faculty advisor (see more information on the IRB webpage at <https://www.saintleo.edu/irb-research-ethics-certification>)

**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: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ 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 at:

<https://www.saintleo.edu/irb-who-should-submit-an-application>

<https://www.saintleo.edu/application-directions-and-forms>

\_\_\_ I approve the research project as outline 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.

 <https://www.saintleo.edu/irb-research-ethics-certification>

\_\_\_ 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: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**Applicants NOT checking any of those items marked with an asterisk (\*), only fill out Part 1.**

<https://cdn2.hubspot.net/hubfs/206683/Resource%20PDFs%20and%20DOCs/IRB%20Institutional%20Review%20Board/Defining%20Minimal%20Risk.pdf?t=1534255440211>

**Applicants checking one or more items marked with an asterisk (\*) in part 1, MUST complete parts 1 and 2.**

**PART 2 – TO BE FILLED BY APPLICANTS WHO CHECKED ONE OR MORE BOX(ES) FOR ITEMS FOLLOWED BY AN ASTERISK (\*)**

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

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

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

**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.

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

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

**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.

**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.

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

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

**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.).

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

\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*

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

*Verification of ethics training certification*

 PI: ❑ Valid certification (Expiration date: / / ) ❑ Certification expired ❑ No certification

Faculty Advisor: ❑ N/A ❑ Valid certification (Expiration date: / /)

❑ Certification expired ❑ No certification

*Type of review:* ❑ Exempt ❑ Expedited ❑ Full

*Decision:* ❑ Approved

❑ Minor Revisions Required

Minor revisions required: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

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 ❑ Revise and resubmit

Revisions required: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

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 ❑ Not approved

Justification for non approval: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

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IRB representative’s signature: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

<<Start inserting required supplemental documents here, after deleting this statement>>