**Directions for completing a Saint Leo University IRB Application**

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| **Part 1** | Unless asked to enter text, mark your answers with an X on the appropriate lines.  If you check off an item marked with an asterisk, you will be required to fill out **Part 2** of the application. |
| **1** | The Principal Investigator is the person conducting the majority of the research. In a group project, this would be the primary contact for the group. Full legal first and last name must be used. |
| **2** | Organization the PI is affiliated with for the purposes of this research.  Applicants employed at Saint Leo, but performing research to obtain a degree with another university, need to name this other university as their organization, NOT Saint Leo. |
| **3** | Department the PI is affiliated with within the organization named under item 2. If none, state so. |
| **4** | Name of the academic program the PI is affiliated with within the organization named under item 2. If none, state so. |
| **5** | Level of study of the program named in item 4. |
| **6** | Professional email address where the PI may be contacted by the IRB for all electronic correspondence.  Please note that Saint Leo students are required to provide and use their Saint Leo student email.  The IRB discourages the use of personal email addresses, which are sometimes rejected by the Saint Leo server and cause delays in the processing of applications. |
| **7** | Best number to reach the PI, in case electronic communication fails. Professional numbers are preferred. |
| **8** | Any other researchers participating in the project. Co-PIs are not required to provide proof of ethics certification. The PI is held responsible for any ethical issue with the project. |
| **9** | Faculty advisor’s full legal name. There can only be one.  If none, state so. |
| **10** | Faculty advisor’s professional email address.  If none, state so. |
| **11** | Provide a simple and descriptive title that will give the IRB reviewer an idea of the focus of the research project.  This title is only for IRB purposes |
| **12** | Date when the PI anticipates starting data collection. This date cannot be anterior to the date of IRB approval. You may say “upon IRB approval.” |
| **13** | Date when the PI anticipates data collection and analysis will be complete. You may say “One year from IRB approval” since IRB approval is valid for only 1 year.  Multi-year projects will need to request an extension, (see webpage). |
| **14** | Should include any research the PI has been responsible for before the research that is the focus of this application.  If none, state so. |
| **15** | Any research where the PI was not responsible for the entire project, but collected data from human participants.  If none, state so. |
| **16** | Sentence or short paragraph describing what the PI intends to achieve or find out through this research. A research question or hypothesis may be stated within the sentence or paragraph. Full sentences are required.  Only projects involving risk greater than those of daily life will be required to elaborate, in the first question of Part 2 of the application. |
| **17** | The PI should clearly identify how the research will be conducted. Most projects only use one research method, but in case of a multi-method project, the PI should check all methods used. |
| **18** | Tools used to collect data and/or conduct research. A copy of all instruments listed here must be attached at the end of the application, in the exact same format as the documents the participants will be given. Any introductory statements, instructions, or debriefing statements to be provided along with the instrument must also be included in the application.  Research relying on observation notes may not include an instrument. |
| **19** | Reasonable estimation of the time the participants will need to complete the data collection procedures, such as filling out a questionnaire.  If an estimate cannot be given, the PI should provide an explanation.  If using existing data, state “Not applicable.” |
| **20** | Anticipated maximum number of participants in the research. A range is not acceptable.  Please note that adding participants to a project research constitutes a modification of the research plan that requires a request for modification to be submitted to the IRB. |
| **21** | Targeted types of participants. If recruiting among the general population, only check adults. Only check one of the other categories if they are explicitly used to design the recruitment and sampling strategy. |
| **22** | More specific characteristics of the potential research participants that the PI may be interested in, such as a specific age group, race, occupation, hobby, etc.  Any sensitive category should be described more specifically here by specifying the type of illness, mental disorder, etc. that the project focuses on. |
| **23** | Strategy(ies) the PI will use to draw the final sample. |
| **24** | Methods the PI will use to publicize the research in order to attract volunteers, or any other methods used to include specific individuals in the study.  If none, provide an explanation. |
| **25** | Name of the organization(s) through which participants will be selected and/or data will be collected, as well as any agency(ies) funding the research.  Proof of permission from any outside organization (i.e., any organization other than Saint Leo and the organization listed in item 2) used for data collection purposes must be attached at the end of the application. |
| **26** | All consent types used in the research. A template for each must be attached at the end of the application.  Template consent forms of various types are available on the Saint Leo IRB webpage.  Use of other templates is allowed, provided they include all the elements listed on the equivalent Saint Leo forms. |
| **27** | Methods the PI will use to record data.  Please note that a specific consent form template is available for audio and video recording. |
| **28** | Item 19 asked how long each participant would need to complete the research procedures. Item 26 refers to the time required for all the research data to be collected. For research using existing data, state “Not applicable.” |
| **29** | Identifying information may be collected on an instrument, or kept on a list that matches pseudonyms to the participants’ identity. Video recording is automatically considered identifying. |
| **30** | Stating a duration means that all data will be destroyed after that point.  Destroying data is not an IRB requirement, but may be advisable for project involving risk above those of daily life, or per outside agency protocols.  PIs using data owned by another entity should state so here. |
| **31** | Procedures put in place to protect the participants’ information for as long as the PI plans to keep the research data. |
| **32** | All methods used to communicate or disseminate the research findings.  The items listed here must be identical to the ones listed under Use of Information in the attached consent templates. |
| **33** | Deception should only be used when absolutely necessary to maintain the integrity of the research findings. For research that uses it, the need should be explained in detail in part 2 of the application. |
| **34** | Costs may occur if participants incur a monetary loss in order to participate in the research. This may include, for instance, having to pay a fee to access research materials, or losing income due to the amount of time required to complete the research procedures. |
| **35** | Risk must be reasonably assessed against those encountered in daily life, taking into account the population targeted in the study, the research topic, and the conditions under which data collection will take place. For more information, http://www.saintleo.edu/media/1154118/saint\_leo\_university\_irb\_defining\_minimal\_risk.pdf |
| **36** | The PI statement of responsibility is a series of items designed to ensure that the application if filled out properly, that all required additional documents are provided, and to attest that the PI understand his/her ethical responsibilities.  Failure to follow the guidelines provided in the statement of responsibility is likely to delay the review of the application.  **Signature:**  Because the submission process is entirely electronic, you may simply type in your name to serve as signature. |
| **37** | Student PIs are required to obtain their faculty advisor’s signature, to attest that they have fulfilled their own responsibilities. The faculty advisor is often the instructor in the course in which the PI is completing this application. S/he may also be a thesis supervisor or dissertation advisor.  The faculty advisor will be cced on any communication the IRB has with the PI regarding his/her IRB application. |
| **Part 2** | PIs who checked one or more item with an asterisk (\*) next to it are required to answer ALL questions fully in Part 2. The answers to Part 2 should expand on the answers to Part 1, NOT duplicate them, and pay particular attention to the asterisked items they checked in Part 1.  Please make sure to individualize your answers, meaning, make sure to address the elements stated in each questions without omitting any elements and without duplicating your answers. |
| **1** | Overall purpose and goal of the study, including variables, hypotheses (if applicable) or research questions. Explain how the study is unique and worth conducting. |
| **2** | Benefits to participants may include better understanding of themselves or others, clarifying goals; engaging in the creation of new knowledge.  Benefits to the academic community and/or society might include providing information; adding to the body of knowledge, training practitioners, etc.  Benefits should not be overstated. |
| **3** | Descriptions of demographics may include age, gender, ethnicity, or any individual characteristics that are relevant to the research or qualify the sample as being part of a sensitive population. PIs should provide sufficient details for the reviewer(s) to form a mental picture of the targeted population and its importance to the study. |
| **4** | Provide details that expand on the answers provided in Part 1 regarding the recruitment of participants. |
| **5** | Describe in detail the process used to provide the consent document and to ensure that the participants understand what is asked of them. |
| **6** | Provide details that expand on the answers provided in Part 1 regarding the collection and maintenance of the data. Describe the data collection setting and any introduction procedures. Describe how the data will be entered, stored, and retrieved. Do NOT discuss anonymity and confidentiality, which will be addressed in question 7. |
| **7** | Specify any procedures or technology which will be used to protect participant anonymity or confidentiality while collecting, recording, and storing data. Procedures may include taking steps to ensure anonymity, using private settings to conduct the research, keeping information in a locked file cabinet, using a password protected computer, minimizing the number of people with access to the data, and any other measures to protect participants' rights and privacy. Do NOT duplicate your answer to item 6. |
| **8** | Describe how many people will have access to the data, exactly who these people are, why they need to have access to the data, how long they will have access, and how they will use them. |
| **9** | Specify a date until which you plan to keep the project data, and if applicable, the participants' identifying information.  Please note that the IRB does not require that all data be destroyed, but this may be advisable depending on the nature of the project. |
| **10** | Address the risk(s) identified in part 1, item 35. This section should be reflected in your consent template(s). |
| **11** | Discuss in detail the measures you will take to minimize the risk(s) described in question 10. |