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**INSTITUTIONAL REVIEW BOARD**

# IRB SUBMISSION FORM

**\*\*You may not start the project until you receive IRB approval\*\***

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| **Instructions** | | |
| You should download this form and insert your responses directly below each question. Email the completed form with all necessary attachments in **a single Word document or a PDF**. The IRB will return submissions that have multiple attachments.  Send your submission at least two weeks before an IRB meeting to [irb@steu.edu](mailto:irb@steu.edu). Visit <https://www.steu.edu/irb> for IRB meeting dates. If you have any questions, contact Dr. Michele Yurecko, [myurecko@steu.edu](mailto:myurecko@steu.edu), 973-290-4036. | | |
| **Proposed Title** | | |
| Title of the proposed research: | | |
| **Dates** | | |
| Date of Application: | Approximate starting and ending dates for this research project: | |
| **Researcher Information** | | |
| Name/Affiliation of researcher 1: | Phone: | email: |
| Name/Affiliation of researcher 2: | Phone: | email: |
| Name/Affiliation of advisor 1: | Phone: | email: |
| Name/Affiliation of advisor 2: | Phone: | email: |
| Is this a student project?  Yes:  Undergraduate  Master’s  Doctoral  Thesis/Dissertation | | No:  Faculty/Staff |
| **\*You must use your @steu.edu email when communicating with participants\*** | | |

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| **Certification to protect human subjects agreement** |
| By submitting this form, you agree to comply with the SEU IRB policy for reporting adverse events and unanticipated problems and events within three business days. To report to the IRB, use Form 10 (Adverse Events).  Adverse events include but are not limited to death, injury, individuals’ loss of income, incurring expenses related to the research, and/or experiencing anxiety as a result of the research.  Unanticipated problems could include having a breach of security of your data. For example, if you misplaced your raw data or had your computer hacked, you might encounter a security breach.  Unanticipated events might include change in principal investigators or study site; additional time needed to complete your research; and/or any other alteration of the study subsequent to the IRB's approval of the initial proposal.   1. Have all investigators identified above completed **the CITI training** program? The certification is only good for three years. Please make sure your certification is up to date.   Yes  No   * 1. If No, complete the training program immediately and provide a copy of the training certificate to the IRB.   Note that the IRB will not approve this study until it receives all certifications. |
| **Protected Populations** |
| 1. If your research involves individuals/records from your place of employment:   Employer:  Job title:  Phone:  email:  Relationship among participants, researcher, and employer: |
| 1. Indicate with an X if you will collect data from or about any of the following protected populations:   Minors  Prisoners  Pregnant women  Fetuses  Institutionalized/diagnosed individuals (e.g., mentally disabled individuals residing in facilities or who exhibit psychiatric, cognitive, or developmental disorders)   * 1. If you answered yes, explain how you will protect this group:   For example, if you are collecting data from children, you must explain how you will obtain parental permission. The IRB recognizes that in some schools, parents give permission for their children to participate in surveys upon enrolling their student.  If this situation applies to your research project, you must explain.  For additional requirements regarding these categories of protected populations, consult the SEU IRB User’s Guidebook. |

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| **Purpose of Study** |
| Do not use pseudonyms. Note: IRB proposals are confidential. You may decide to use pseudonyms for your final report. Please use lay language. |
| 1. State briefly (less than 100 words) the purpose of the intended research. Please include:    1. What is to be learned?    2. What problems are addressed?    3. What are the specific objectives (or research questions)? |
| **Sampling Procedure** |
| 1. Describe in detail the **method** and **rationale** for selecting study participants: |
| * 1. State the number of people from whom you plan to collect data for each data source:   (For example, I plan to survey all 515 teachers within the district and then randomly select 30 teachers to interview.) |
| 1. If you are using a purposive (or judgment) sample, explain why these individuals are appropriate for your study:   (For example, I will invite only the ten senior dietitians to participate in the focus group, because these individuals have the most experience with palliative care.) |
| 1. Describe if and how participants will be compensated: |
| 1. Please report everything that you will tell participants about the study prior to participating in the research:   **Attach copies** of all recruitment flyers and emails **as appendices** |
| **INTRODUCTION OF STUDY TO PARTICIPANTS** |
| 1. For any interview, focus group or in-person survey that you will use, include the statement or “script” that you will use to introduce participants to the study:     Form 2 “Adult Consent Form Introduction” is a sample script you can use to model what you will tell participants.  (**Attach as an appendix**). |

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| **data collection** | |
| 1. Describe in detail how you will collect data: | |
| * 1. Location(s) where you will conduct your research: documentation that you have permission to collect data from off-campus sites, if applicable:   Email:  Fax: | * 1. Type of institution(s): |
| * 1. Provide documentation that you have permission to collect data from off-campus sites, if applicable.   (**Attach as an appendix**) | |
| * 1. Clarify your role in the organization where research is being conducted. Discuss any plans to protect the research from possible bias related to your position. | |

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| **Instrumentation** |
| 1. Provide all interview questions and focus group guides; questionnaires; rating/observation forms, and **attach copies as appendices**: |
| 1. Are you using data collection/consent forms in a language other than English?   Yes  No   * 1. If yes, please explain how you have ensured for the accuracy of the translations:   The IRB prefers that researchers use the “back-to-back” method where one person translates from English and another person uses the foreign translation and re-translates back into English. If you are having difficulty finding an independent party to assist in the back-to-back process, contact the IRB. |
| 1. Do you plan to transcribe interviews/focus group meetings?   Yes  No   * 1. If yes, please explain the relationship of the transcriber to you and include a signed confidentiality agreement:   See IRB website for a model confidentiality agreement. |
| 1. Does the proposed research involve deception, e.g., through provision of misinformation, withholding information, etc.?   Yes  No   * 1. If yes, explain why it is necessary to involve deception(s) in the research: |
| 1. Provide a full account of the debriefing procedures to be followed, if applicable:   If you plan to debrief, attach a copy of the written debriefing procedures. |

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| **Protecting Human Subjects** | | |
| 1. All studies have the potential to place individual participants in physical, legal, economic, social and/or psychological risk (or discomfort). Most social/behavioral research studies pose no greater than minimal risk. In a minimal risk study, participants respond to questions or engage in activities that are consistent with routine daily life. Keep in mind that what you think is routine may be different from what your participants think is routine. For this reason, it is important to consider the perspective of potential research participants.   Minimal risk  More than minimal risk | | |
| * 1. If your study poses no greater than minimal risk, clearly explain how the information you plan to ask participants and/or or the activities you plan for them are consistent with their routine experiences in their workplace/other situations: | | |
| * 1. If your study poses more than minimal risk, clearly explain how you will minimize risk: | | |
| 1. In a few sentences, please describe the benefits of the research, both to the participant and to society: | | |
| 1. Explain how any possible risks that may be involved in the research are justified by the potential benefits resulting from the research even though the risks may be minimal: | | |
| 1. Explain how you will report findings so that no individual can be identified: | | |
| 1. Will you conduct:   Interviews/Focus Groups/Face to Face Survey Administration/Archival Data  Anonymous Surveys  Please complete either question 21 ***or*** 22 | | |
| 1. If Interviews/Focus groups/Face to Face Survey Administration/Archival Data,    1. If you will interview/conduct a focus group with the research participants, you cannot say that this data collection is anonymous because you know the participants’ identities    2. You must explain how you will preserve confidentiality by specifying how you will protect participants’ privacy in reporting research findings. For example, you might use pseudonyms and report findings according to general themes so that no participant’s comments can be attributed to him or her:    3. If you are conducting observations of individuals, your data collection is not anonymous. Here you must explain how you will present findings so that no individual can be identified.    4. Give specific examples of how you will ensure that readers will not be likely to identify interviewees and focus group members:    5. If you are using archival data with identifying information about individuals, explain whether you know the individuals’ identity and how you will protect their confidentiality: | | |
| 1. If Anonymous Surveys,    1. If you will administer anonymous surveys (either online or in a public area or large staff meeting), you must explain how you will present findings so that no participant can be identified:    2. If you are using online surveys, you must state that you will not collect IP addresses:   (For Survey Monkey, click Collect Responses tab in the middle of the screen; click continue; on the left-hand menu, click Change Settings; within the Change Settings menu, click No in the Save IP Addresses in Results.) | | |
| 1. Explain how your analysis of survey results by demographic variables will protect confidentiality:   For example, if your study site employed fewer than ten male nurses, your survey to nurses cannot ask respondents’ gender, because if you analyzed survey results by gender, readers might be able to determine which male nurses responded in a certain way. Similarly, if only one or two teachers had doctoral degrees, a question about educational level would have to say “Masters or higher” rather than parse out master’s degree and doctoral degree. | | |
| 1. Explain how you will withhold demographic breakdowns if the number of individuals in the target population (not the number of respondents) is small (e.g., less than 10): | | |
| **Informed Consent and/or Assent** | |
| 1. Do you plan to obtain signed consent or assent from any study participants?   Yes  No   * 1. If you plan to use a consent or assent form, please complete the appropriate template on the IRB website and attach a copy for IRB review. Within the consent template, explain what individuals will do to participate in the study, e.g. participate in a one-hour interview/agree to be observed/agree to be recorded. **Attach the appropriate consent/assent forms as appendices.** | * 1. If not, please explain why: |
| **Data Storage** | | |
| All data must be stored securely and be accessible only to members of the research team certified to work with human subjects. In addition, signed Consent Forms must be stored securely and separately from completed questionnaires and the data and any key used to specify subjects with their study number.  Please respond to the following questions. | | |
| 1. Describe the procedures you will use to secure your data during the course of your study:   (E.g. locked files, pass-word protection) | | |
| 1. Explain how you will arrange for secure storage of consent forms separately from all other study materials: | | |
| 1. Explain who will have access to these materials | | |
| 1. Describe your plan for disposing or storing your data after you have concluded your study:   The IRB does not require that materials be destroyed within a specific period; the IRB wants to know how the researcher(s) will dispose of raw data in a responsible manner so that participants’ identities are protected. | | |