***Template instructional note:*** *The fillable fields on this template will show in shaded text boxes when your cursor hovers over the fields. Wherever template text does not apply, replace with N/A (or something equivalent.) If you have any issues with this template, contact the Office of IRE.*

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| **Research Project Overview:** |
| **Study/Project Title:**(Add your descriptive title for the nature/purpose of the research) | **Add your descriptive title for the nature/purpose of the research** |
| Principal Investigator: | **Name (First Last)**Email: xxx@xxx.xxxPhone: (xxx) xxx-xxxxRelation to Milligan: State from list below (Please state: Faculty, Graduate Student, Undergraduate Student, or Staff; if other, describe) |
| Faculty Advisor1: | **Name (First Last)**Email: xxx@xxx.xxxPhone: (xxx) xxx-xxxx |
| Research Assistant(s)/Co-Investigator(s): | Name(s): First LastEmail(s): xxx@xxx.xxx |
| Outside Collaborations:(If yes, describe names, addresses, emails, phone contacts, etc.) | <If yes, describe names, addresses, emails, phone contacts, etc.; otherwise, mark as N/A> |
| Proposed Study Start: | <Add proposed start date> |
| Proposed Study End: | <Add proposed end date> |
| Funding:(If yes, explain the sources of funding for the project. Specifically, that for:* **Federally** funded research projects
* Projects funded by **collaborating** organizations.)
 | <If yes, explain the sources of funding for the project, otherwise mark as N/A> |

1 For principal investigators who are students

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| **Study/Project Description:**(Please describe your research project. Tell us what you will be asking your participants to do in your study and elaborate on any measures/instruments/tests or activities they will complete as part of the study.) |
| <Describe your research project here.> |

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| **Research Methods:**(Identify the research methods to be employed for this study/project. Specify and describe the following as applicable:Experiment or Lab Observation; Anonymous Survey; Interview or Non-Anonymous Survey; Archival for Secondary Data Analysis; Field Observation; Pilot Study; Focus Group, Other methods – describe.) |
| <Identify/describe here the research methods to be employed for this study/project.> |

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| **Research Plan, Procedures, and Methods:**(Describe the overall plan, approach, and experimental design to be used for this research study. * Describe study procedures and estimate how long each procedure, survey, etc. will take, preferably as a bulleted list. Be clear about how many times data will be collected.
* For questionnaire/interview research, provide the full instrument along with the related cover letter and/or instructions.
* Describe if participants will be exposed to interventions or treatments intended to permanently change a participant’s physical or mental status or wellbeing.
* Describe if participants will be exposed to psychological interventions, such as deception or contrived social situations.
* In the case of biomedical or behavioral-health research, state whether there are any alternate procedures or course of treatment that might be advantageous to the research participant.
* Describe procedures for follow-up and/or debriefing, especially in studies involving deception or intervention.
* Describe procedures to address any adverse effects from participation in the study.
* For any research requiring permission from outside institutions or organizations (e.g., hospital, school), explain how the process to seek permission from the institution or organization (which has the responsibility for the participants) will be carried out **after** *initial* IRB approval. Be aware that the *final* *approval* is conditional on documentation from the outside institution or organization.)
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| <Describe here the overall plan, approach, and experimental design to be used for this research study.> |

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| **Study Participant Recruitment:**(Describe the inclusion criteria for participants in this study, to include:* The approximate number of participants to be recruited
* The age, gender, and other desired demographic
* Other relevant criteria
* How participants are to be recruited/selected for participation
* Describe any special populations to be recruited (i.e., children, prisoners, etc.)
* Describe the duration of their participation (i.e., one interaction vs. multiple)
* Any compensation/consideration (gifts, reimbursement, etc.) to be given in exchange for participation
* How that compensation/consideration will be received by the participants.)
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| <Describe here the inclusion criteria for participants in this study.> |

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| **Benefits:**(Identify and describe any benefits or potential benefits associated with this research project for either the participants, group of participants, or other general population. State whether or not these benefits are guaranteed. Describe any incentives you may use to encourage participation, e.g., extra credit, gift cards.) |
| <Describe benefits associated with this research project here.> |

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| **Risks:**(Identify and describe the risks associated with this research project.* Describe the reasonable, foreseeable risks or discomforts (physiological, psychological, social)
* Describe actions to be taken to minimize risks/discomforts
* Describe any additional costs to the research participants that may result from participation in the research.
* Describe any anticipated circumstances under which the participant’s participation may be terminated by the Principal Investigator without regard to the research participant’s consent.)
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| <Describe the risks associated with this research project here.> |

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| **Informed Consent**(Describe how research participants will be informed of the nature of their participation in this research study, their rights during and after the study, and how their personal information will be handled. Specifically highlight how informed consent will be obtained from any special populations. If informed consent is not necessary or feasible, provide the justification and rationale accordingly.) |
| Participation in this study is voluntary. <Describe here how research participants will be informed.> An *Informed Consent* form for this study:[ ]  Is described in **Appendix A**[ ]  Is not required *(NOTE: This selection is infrequent for research conducted at Milligan.)* |

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| **Privacy and Confidentiality of Data:**(Describe how the study participants’ privacy will be maintained before, during and after the study:* Describe if participants’ identity and related study data will be totally anonymous (like an anonymous survey link), or if the participants Personal Identifying Information (PII) will be collected and connected to their research data.
* Describe what PII will be collected, and how that PII will be maintained confidentially before, during and after the study.
* Describe how the research data will be used and reported to maintain the participants’ confidentiality.)
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| <Describe how the study participants’ privacy will be maintained here.>Research data shall be maintained at all times in a secure manner by the Principal Investigator on a password protected Milligan network drive, or Milligan account within research/archival software (such as Qualtrics, Sharepoint). The research data will be maintained by the Milligan Investigator (or designee) for 3 years, at which time the digital (and any related physical data) will be securely destroyed per the *Human Research Protections Program* policies. The culminating research report shall be archived in a central location on Sharepoint maintained by the IRB and the Office of Institutional Research and Effectiveness (IRE). The Principal Investigator will retain a personal copy of the culminating research report/document.The research data and/or specimens from this study:[ ]  Will not be used for any other studies[ ]  May be stored for use in secondary research (broad consent to store will be obtained)[ ]  May be used in secondary research (broad consent to use will be obtained) |

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| **Results and Reports:**(Describe the following:* how the results of the research study will be used.
* how the results will be disseminated outside of Milligan (i.e., professional publication, media, employers, etc.)
* how the results will be disseminated to research participants, should they request to be informed or have access to the findings.)
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| The findings from this research will be used and disseminated as follows:* <Describe the details here.>
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**Appendix A – Informed Consent Form**

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| **Invitation to Participate** |
| You are invited to participate in a Milligan University sponsored research study. This form is part of a process called “informed consent” to allow you to understand this study before deciding whether or not to participate.This research study is recruiting <describe the participants who meet the requirements for the study> to participate in this study. The expected duration for participation is <describe the best guess for total time commitment expected of the participants>. This study is being conducted by <researcher’s First Last Name> (the Principal Investigator). The Principal Investigator is associated with Milligan as <state researcher’s role at Milligan such as undergraduate or graduate student, faculty, or staff member. NOTE: If you are recruiting participants that may know you from another role, an additional statement is required: You may already know the researcher as a STATE ROLE, but this study is separate from that role.> |

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| **Research Objective/Purpose:** |
| The purpose of this research study is to <briefly describe the purpose of your study – avoid technical terms and jargon>. |

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| **Procedures:** |
| The procedures used for this research study are described below. * <Using a bulleted list, describe the procedures with a time estimate for each procedure or survey>

<**Additional Considerations**: When appropriate, including statements about the following:* A statement that a chosen procedure is “experimental” meaning, for instance, that you are not using a standard procedure widely adopted for diagnosis, treatment, research methods, or otherwise. “Experimental” here does not refer to experimental design.
* A statement that a particular treatment or procedure may involve risks thar are currently unforeseeable.
* Circumstances under which the participant’s involved in the research may be terminated without regard to the participant’s (or their legal representative’s) consent.
* Any additional costs to the participant that my result from their participation.
* The consequences of a participant’s decision to withdraw from the research.
* The approximate number of participants involved in the study; particularly if it could impact their anonymity (e.g., small number of participants) or otherwise impact their decision to participate.
* A statement regarding disclosure to participants about clinically relevant research results.>
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| **Voluntary Nature of the Study:** |
| Participation in this study is voluntary. Any decision not to participate in this study will have no penalty or loss of benefits to which you would otherwise be entitled if you were not invited to participate. Additionally, you may discontinue participation in this study at any time, without penalty or loss of benefits to which you would otherwise be entitled if you were not invited to participate. |
| **Risks and Benefits of Being in the Study:** |
| Risks: Participation in this research study involves the following risks or minimal risks.<Describe a bulleted list of risks as per the Research Proposal. Note: Some common risks to consider include those encountered in daily life, such as fatigue, stress or becoming upset.>Benefits: Participation in this research study involves the following benefits or potential benefits. These benefits, however, are not guaranteed.<Describe a bulleted list of benefits as per the Research Proposal. Do not overstate the possible benefits to the potential participants. Furthermore, if there are not specific benefits to the participant beyond their general role in research, you may state this to be the case.> |

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| **Compensation:** |
| This research study:[ ]  Does not involve any compensation.[ ]  Does involve compensation as described below:<Describe in detail any payment, gifts, or reimbursement you are providing to participants and how such compensation with be made available as per the Research Proposal.> |

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| **Privacy:** |
| By participating in this research study:[ ]  Your personal identifying information will be **maintained confidentially** and will not be used in association with any other research project. Your study-related research data will be used and reported as an aggregate only and will not be individually identifiable.[ ]  Your responses to the survey will be **completely anonymous** and no personal identifying information will be associated with your responses. Your survey responses will be used and reported as an aggregate only. [ ]  Your responses to the survey/interview will be **maintained confidentially** as follows: <Describe alternate criteria. For example, qualitative studies where some data is individualized but names and data are handled differently that the two options above.>Research data for this study will be maintained securely by the Milligan Investigator (or Milligan designee) for a period of 3 years, at which time it will be securely discarded. |

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| **Secondary Research**(NOTE: Research conducted by Milligan Investigators typically does not involve future, secondary research initiatives.) |
| This research study:[ ]  **Does not** **involve** storage or use of the research data (or specimens) for future, secondary research. [ ]  **May** **involve** storage and/or use of the research data (or specimens) for future, secondary research.* Your personal identifying information will be maintained as described in the “Privacy” section.
* Data/specimens will be stored and used within <#> years.
* The future, secondary research will be limited to <describe the type of research that is anticipated and permitted for this future, secondary research>.
* By initialing/dating in the space provided, you give broad consent to for the storage and/or future use of the studies research data and/or specimens: Initials:\_\_\_\_\_\_ Date:\_\_\_\_\_\_\_\_
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| **Research Participant’s Rights and Responsibilities** |
| As a research participant the following rights and responsibilities apply:* If applicable, significant new findings developed during the course of this research, which may relate to your willingness to continue participation in the study will be provided to you during the course of the study by the Principal Investigator.
* To withdrawal from the research study while it is still in-progress, contact the Principal Investigator to ensure orderly termination of your participation.
* For a summary of the findings or conclusions from this research study, you may contact the Principal Investigator.
* For questions about this research study, your rights and responsibilities, or a research-related injury, you may contact the Principal Investigator and/or Milligan’s Institutional Review Board.
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| **Contacts:** |
| **Principal Investigator:**First Last, Title@my.milligan.edu or @milligan.eduPhone number**Faculty Advisor:**First Last, Credential@milligan.eduPhone number | **Milligan Institutional Review Board:**IRB@Milligan.edu**Office of IRE:**IRE@milligan.edu423-461-8414 |

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| **Statement of Consent:** |
| I have read and understand the Informed Consent information presented for participation in this research study. [ ]  This study **does not** require written consent. As applicable to the study:* By clicking the provided **link or “I consent” button**, I am 18 years or older and I agree to participate in this research study.
* By **replying “I consent” via email** to the Investigator, I am 18 years or older and I agree to participate in this research study.

[ ]  This study **requires** written consent. By **signing below**, I (or my minor child) agree to participate in this research study. |
| Participant’s Name (Printed): |  |
| **Participant’s Signature:** |  | **Date:** |  |
|  |  |  |  |
| Parent/Guardian (Printed): |  |
| **Parent/Guardian Signature:** |  | **Date:** |  |