***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.xxx  Phone: (xxx) xxx-xxxx  Relation 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.xxx  Phone: (xxx) xxx-xxxx |
| Research Assistant(s)/Co-Investigator(s): | Name(s): First Last  Email(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> |

1 For principal investigators who are students

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| **Study Participants:** |
| Are any of the potential participants in this study children under the age of 18?  No  Yes |

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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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| **No More than Minimal Risks:**  (Please explain how your participants are at no more than minimal risk.) |
| <Explain here how your participants are at no more than minimal risk> |

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| **Participant Confidentiality:**  (Explain how you will maintain confidentiality of your participants. Explain if there is any risk to them if their responses are inadvertently made known?) |
| <Explain here how you will maintain confidentiality of your participants. Explain if there is any risk to them if their responses are inadvertently made known?> |

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| **Exempt Status Rationale:**  (Using the **“Is It Exempt?”** worksheet below as a reference, provide the rationale for any exemptions you believe apply to this study. On the worksheet, select all relevant exemptions that apply.) |
| <Add your exempt status rationale here> |

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| **Investigator Statement:** | |
| My printed name below indicates that:   * I have completed the training requirements on Milligan’s *Human Research Protections Program*. * I understand my responsibilities as an Investigator. * I have used Milligan’s *Research Study Plan and Informed Consent* template to help evaluate my proposed human research for allowable exemptions per the **“Is It Exempt?”** worksheet below. * As applicable to the requested exemption, **my Study Plan is attached** for IRB Limited Review. * I acknowledge and agree that if I find the need to change my study plan in ways that affect my exemption status after having been approved for exemption, I will be required to submit a new application. * *For students only*. I have evaluated my research in collaboration with my faculty advisor. My faculty advisor has approved my study plan. | |
| **Printed Name:** | <Type your first and last name here> |

***Submit this completed evaluation to IRB@Milligan.edu.***

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| **“Is it Exempt?” Worksheet** |

To be completed by the **Principal Investigator** for the **Exempt Status Rationale** statement required above**.**

**Column 1:** Based on the scope of your proposed research, identify the exemptions that might apply to your research.

**Column 2:** For each identified exemption that may apply, work through the decision-tree boxes. Mark the boxes that apply to your research.

**Columns 3 and 4**: Document your conclusion as to whether or not the research is Exempt or Non-Exempt.

| **Mark all that May Apply** | **Exemption Description and Evaluation** | **Exempt** | **Non-Exempt** |
| --- | --- | --- | --- |
|  | Special Population: 45 CFR 46 - **Subpart C** (Prisoner populations involved)   * **No exemptions** may be applied | N/A | ☒ |
|  | Special Population: 45 CFR 46 - **Subpart D** (Children populations involved)   * Exemptions 1, 4, 5, 6, 7, and 8 may be applied * Exemption 2(i) and 2(ii) may be applied. Exemption 2(iii) **may not** be applied. * Exemption 3 **may not** be applied |  |  |
|  | **Exemption 1 – Educational Settings and Practices**  Research is conducted in established or commonly accepted educational settings (e.g., classrooms, after-school programs, or online education settings), **AND**  Involves normal educational practices, **AND**  Is not likely to adversely impact students’ opportunity to learn required educational content, **AND**  Is not likely to adversely impact the assessment of educators who provide instruction. |  |  |
|  | **Exemption 2 – Educational Tests, Surveys, Interviews, and Observations of Public Behaviors**  Research *only includes interactions* (interventions are not allowed) involving educational tests (e.g., cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior (including visual or auditory recording), **AND**  The information obtained is recorded by the investigator in such a manner that the identity of the participants cannot readily be ascertained, directly or through identifiers linked to participants; **AND**  [If children are participants] Interactions ONLY involve educational tests or observations of public behavior, **AND**  [If children are participants] Investigator(s) does/do not participate in the activities being observed.  **OR**  Any disclosure of the participants’ responses outside the research would not reasonably place them at risk of criminal or civil liability or be damaging to their financial standing, employability, educational advancement, or reputation; **AND**  [If children are participants] Interactions ONLY involve educational tests or observations of public behavior, **AND**  [If children are participants] Investigator(s) does/do not participate in the activities being observed.  **OR**  The information obtained is recorded by the investigator in such a manner that the identity of the participants can readily be ascertained, directly or through identifiers linked to them, and an **IRB conducts a limited IRB review** to make the determination required by *§46.111(a)(7) for privacy/confidentiality*; **AND**  The research does not involve children. |  |  |
|  | **Exemption 3 - Benign “Behavioral” Interventions**:  The research involves a “behavioral” intervention (manipulation of one’s environment; Note: medical (physical) interventions – tests, procedures, devices – do not count for this exemption); **AND**  Data collection is through verbal or written responses or audiovisual recording; **AND**  Interventions are brief in duration (but can be repeated multiple times if the study warrants); **AND**  Interventions are harmless and painless; and are not physically invasive; **AND**  Interventions are not likely to have a significant adverse lasting impact on the participants; **AND**  Interventions are not likely to be offensive or embarrassing to the participant; **AND**  Only participants 18 years of age or older will be involved; **AND**  Participants must prospectively agree to the intervention and data collection; **AND**  **EITHER**  Information is recorded by the investigator in such a way that the identity of the participants cannot be ascertained, directly or through identifiers linked to participants, AND/OR  Any disclosure of the participant’s responses outside the research would not reasonably place them at risk of criminal or civil liability or be damaging to their financial standing, employability, educational advancement or reputation,  **OR**  The information obtained is recorded by the investigator in such a manner that the identity of participants can readily be ascertained, directly or through identifiers linked to participants, and **an IRB conducts a limited IRB review**.  [***Only mark if you plan to deceive participants about the nature of the study***] If research involves deceiving the participants about the nature of the study, participants must agree prospectively to such protocol (Informed Consent). In other words, you must tell them that deception may be part of the study before they can agree to participate. |  |  |
|  | **Exemption 4 – Secondary Research (Public/No Informed Consent)**  Identifiable private information or biospecimens are publicly available, **OR**  The identity of participants cannot readily be ascertained directly or indirectly through identifiers linked to them, the investigator does not contact the participants, and the investigator will not re-identify them, **OR**  [The HIPAA Exemptions] The research involves only information collection and analysis involving the investigator’s use of identifiable health information when that use is for the purposes of “health care operations,” “research,” or for “public health activities and purposes” as defined and regulated under 45 CFR parts 160 and 164; **OR**  The research is conducted by or on behalf of a federal department or agency as further described in 45 CFR 46.104(d)(4)(iv). |  |  |
|  | **Exemption 5 – Public Benefit**  Research is designed to study, evaluate, improve, or otherwise examine public benefit or service programs. |  |  |
|  | **Exemption 6 – Food/Taste/Acceptance**  Research involves consumption of wholesome foods without additives. **OR**  Food is consumed that contains a food ingredient at or below the level and for a use found to be safe, or agricultural chemical or environmental contaminant at or below the level found to be safe, by the Food and Drug Administration or approved by the Environmental Protection Agency for the Food Safety and Inspection Service of the U.S. Department of Agriculture. |  |  |
| **NOTE: Exemptions 7 and 8 are not currently being authorized by the IRB for Milligan research. Any desired proposals for secondary research will require a discussion with the IRB Chair before formally requesting these exemptions.** | | | |
|  | **Exemption 7 – Secondary Research (Broad Consent to Store/Maintain)**  Research involves the storage or maintenance of identifiable private information or biospecimens for potential secondary research use in a future study; **AND**  The IR**B conducts a limited IRB review** and makes the determinations required by §46.111(a)(8) *for broad consent.* |  |  |
|  | **Exemption 8 – Secondary Research (Broad Consent to Use)**  Broad consent for the storage, maintenance, and secondary research use of the identifiable private information or biospecimens was obtained in accordance with §46.116(a)(1) through (4), (a)(6) [Informed Consent] and §46.116(d) for Broad Consent for the earlier research; **AND**  Documentation of informed consent (or waiver of documentation of consent) was obtained in accordance with §46.117 for documentation of consent; **AND**  **The IRB conducts a limited IRB review** to make the determinations required by:  §46.111(a)(7) *for privacy/ confidentiality*; **AND**  §46.111(a)(8) for *broad consent and scope*; **AND**  The investigator does not include returning individual research results to participants as part of the study plan. |  |  |

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| **Principal Investigator Exempt Research Decision:** |
| This research **does not** **qualify** as Exempt Research. I will complete a***Non-Exempt Human Research Application***for IRB review and approval.  This research **potentially qualifies** as Exempt research according to (select all that apply):  Exemption 1 – Educational Settings/Practices  Exemption 2 – Educational Tests, Surveys, Interviews, and Observations of Public Behaviors  IRB Limited Review for *privacy/confidentiality* is necessary  IRB Limited Review is not necessary  Exemption 3 – Benign Behavioral Interventions  IRB Limited Review for *privacy/confidentiality* is necessary  IRB Limited Review is not necessary  Exemption 4 – Secondary Research (Public/Cannot be ascertained)  Exemption 5 – Public Benefit  Exemption 6 – Food/Taste/Acceptance |
| **Comments (IRB Use Only):**  Click or tap here to enter text. |

***Submit this completed evaluation to IRB@Milligan.edu.***