**Exemption Review Application**

**SECTION 1:**

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| **Protocol Title:** |
| **Research Organization:** |
| **Address:**  |
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**SECTION 2: Project Personnel**

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| **Principal Investigator (Project Director)**  |
| Last Name: | First Name: | Title/Degree: |
| Phone: | Email: |
| If student, list faculty sponsor |
| Last Name: | First Name: | Title/Degree: |
| Phone: | Email: |
| If additional personnel need to be listed, please attach an addendum with that information. |
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**SECTION 3: Funding Information**

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| **Has your research been funded, or is a funding decision pending?** Yes No Pending |
| **What is the funding agency?** |
| Please include a copy of the funding proposal with this application. |
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**SECTION 4: Research Overview**

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| **Briefly summarize the objectives of the research:** |
| **What forms of data will the research use?** (check all that apply)* Primary Data (Data you collected for this specific project)
* Qualitative
* Quantitative
* Secondary Data (Data collected for purposes other than this specific project)
 |
| **Where will the research be taking place?** (check all that apply)* Community/Public Center
* Clinic/Medical Center
* Public Education Institution
* Private Education Institution
* Faith-Based Organization
* Virtual
* Other For-Profit Entity
* Other Non-Profit Entity
 |

**SECTION 5: Participants & Recruitment**

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| **What is the estimated number of participants?** |
| **Age of populations that will be recruited?** (check all that apply):* Specific Age Range (Please Indicate):
* Adults (18-65 yrs.)
* Elderly (65+ yrs.)
* Children (≤17 yrs.)
 |
| **Vulnerable Populations as designated in** 45 CFR 46 Subparts B, C, and D.(check all that apply):* Pregnant Women
* Persons with mental disabilities
* Prisoners
* Economically and educationally disadvantaged persons
 |
| **Underserved Populations:**  |
| * Military personnel
* Families of military personnel
* Immigrants
* Persons homeless or near homeless
 | * LBGTQIA+
* Medically compromised
* Indigenous/tribal peoples
* Other specific race/ethnicity (Indicate):
 |
| **Ethical Use:** If seeking cultural knowledge that is considered sacred or revered by the target population (e.g. indigenous/tribal knowledge), how will the investigators and research assure good stewardship and respect of the acquired information? Explain:  |
|  **Gender:*** No specific gender will be targeted
* Female
* Male
* Other (Please Indicate):
 |
| **Priority population,** e.g., youth in foster care (Please Indicate): |
| **Beneficence:** Are harms minimized and benefits maximized?* Yes
* No

Explain:  |
| **What methods of recruitment will be used?** (check all that apply)* Email
* Flyers
* Online Advertisement
* Social Media
* Website
* Other (Please specify):
* Print Advertisements
* Television Advertisements
* USPS Mail
* Verbal Announcements
* Student Subject Pool (Please specify):
* Other (Please specify):
* Not Applicable (Secondary Data)
 |
| **Describe the details of the recruitment process (if varies by group, detail them separately):** |
| **Will participants receive compensation at any point?** * No
* Yes (Please explain):
 |
| **What is the duration of participants’ involvement?**  |
| **How many times will participants engage in research activities?**  |

**SECTION 6: Procedures & Methodology**

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| **What research methods will be used?** (check all that apply)* Field Work
* Focus Groups
* Intervention or Experimental Manipulation
* Interviews
* Recordings (audio, video, or photographic)
* Standardized Tests
* Surveys
* Paper Survey
* Online Survey
* Telephone Survey
* HIPAA Data
* Existing Materials (Please specify):
* Other (Please specify):
 |
| **Please list all research instruments that will be used in this research:**  |
| Please attach copies of drafts or final copies of these materials. If published, attach abstracts.  |
| **What is the approximate timeline of the research?**  |
| If not included in the Funding Proposal, please attach research procedures. |

**SECTION 7: Confidentiality**

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| **How are participants’ data identified when collected?** (e.g., SSN, Name, Date of Birth, Contact Info, Address, Recordings, etc.)* No identifiers are collected
* Direct identifiers are collected
* Indirect identifiers are used (codes, aliases)

 If indirect identifiers are used, do researchers have access to the code key? * No
* Yes (Please explain privacy safeguards)
 |
| **What methods are used to safeguard records?** (check all that apply)* Consent forms are stored separately from data
* Data is collected and given to researchers without identifiers
* Data is recorded by researchers without identifiers
* Direct identifiers are removed from collected data as soon as possible
* Direct identifiers are deleted as soon as possible and no key exists
* Codes/aliases are used on all data; the key is stored separately
* Electronic data is stored in a secure location
* Hard-copy data is stored in a secure location
* Other (Please specify):
 |
| **How long will data be stored?** |
| **Please describe any other provisions that will be used to protect the privacy of subjects:** |
| **Describe the training and experience of all persons who will collect or have access to the data:** |

**SECTION 8: Consent**

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| **Which of the following will be a part of the consent process?** (check all that apply)* Written informed consent
* Waiver of documentation of informed consent\*
* Online Consent Waiver
* Oral Consent Waiver
* Unsigned Information Sheet
* Waiver of informed consent\*\*
 |
| \***If indicated above, please specify why a Waiver of Documentation is necessary:** |
| **\*\*If indicated above, please specify why a waiver of informed consent is necessary:** |
| **What conflicting factors will influence the consent process?** (check all that apply)* No known conflicts
* Research involving students of a member of the research team
* Research involving employees of a member of the research team OR a member of the research team is the direct supervisor of participants
* Participants with a close relationship to a member of the research team
* Other (Please specify):
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| **In the case of a known conflict, how will the conflict be mitigated?** |
| Please attach a copy of all consent materials. |
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**SECTION 9: Dissemination**

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| **In what forms will the results of this research be disseminated?*** Conference presentation
* Industry sharing
* Journal article or academic paper
* Stakeholder presentation
* Other (Please specify):
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| **Will identifiers be published or shared in any way?** * No
* Yes

 **If yes, does the consent form explicitly request consent to publish?**  * Yes
* No
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| **Will de-identified data be included in published or shared data?** * No
* Yes

 **If yes, how will the data be de-identified?** |

**SECTION 10: Completion**

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| **When is the expected date of completion?**  |
| Exemption protocols are given a closure date 5 years after their initial approval. As the closure date approaches, a request for extension can be made. |

**SECTION 11: Attachments Checklist**

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| **Please ensure that the following materials are included:*** Copy of the Funding Proposal (as requested in §3) or Research Procedures (as requested in §6)
* Copy of Abstracts of Research Instruments (as requested in §6)
* Copy of Consent Materials (as requested in §8)
 |
| This application cannot be reviewed without the above materials included. |
| **If applicable, please ensure that the following are attached:*** Information for additional key personnel (as outlined in §2)
* Research procedures that are not present in the proposal or this application (as requested in §6)
 |

***Note:*** *Federal export control regulations may impact research activities, including international travel, hiring, collaborating with colleagues in other countries, and purchasing equipment and materials. The U.S.* export control regulations *have identified several countries under heavy embargo via the U.S.* [Office of Foreign Assets Control (OFAC).](https://home.treasury.gov/policy-issues/office-of-foreign-assets-control-sanctions-programs-and-information)

* *Embargoed countries include Cuba, Iran, North Korea, Syria, and certain regions in Ukraine (Crimea, Donetsk region, Luhansk region, Sevastopol region). These* countries change *over time.*
* *Military-end use countries include Belarus, Burma, Cambodia, China, Russia, and Venezuela. These countries change over time.*

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| **Section 12: Assurances** |
| 1. **Investigator Conflict of Interest/Financial Interest.**

(If there are no identified conflicts, please state that after *each* question). |
| 1. **Please provide a detailed disclosure of the financial interests that are related to this research. Your explanation must specify the nature and the monetary amount of the financial interest.**
 |
| 1. **Please explain the impact, if any, your financial interests may have on your conduct of this research study.**
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| 1. **Please describe your plan for managing the potential conflict of your financial and research interests in order to help ensure that the protection and rights of research subjects are maintained.**
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| 1. **Training Verification**
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| Within the past 3 years, each researcher must have completed one of the following. |
| **The Collaborative Institutional Training Initiative (CITI Program)** <https://about.citiprogram.org/> * One of the many offerings specific to human subject protections in research.

**Health and Human Services, Office for Human Protections** <https://www.hhs.gov/ohrp/education-and-outreach/human-research-protection-training/humanresearch-protection-foundational-training/index.html> * Human Research Protection Foundational Training

**National Institutes of Health** <https://researchethics.od.nih.gov/Introduction1.aspx> * NIH Research Ethics
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| **List each researcher, source of training, date, and course.** |

**As lead researcher, I** **\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ assure andcertify that the responses to the financial interest questions above are accurate and complete and that all responses constitute a full disclosure of any conflicting interests and activities that have the potential to affect the rights of human subjects involved in research, if any. I certify that I will disclose to The Institute for Evaluation and Research, LLC (TIER) any conflicts of interest that arise during the course of the study.**

**As lead researcher, I,\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ assure andcertify that all project researchers have completed the training(s) identified above within the past 3 years, understood the material, and will follow all SOPs and/or guidelines included in the training.**

**As lead researcher, I, \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ assure and certify that the project and research described in this application, to the best of my knowledge, is true, accurate, complete, and correct. I realize that changes to the project may alter the IRB status of this project, and as such agree to submit changes to the project to The Institute for Evaluation and Research, LLC (TIER) for review prior to implementation. In addition, I agree to provide a brief yearly update during implementation and a summary when the project is completed.**

**X**

 **PRINCIPAL INVESTIGATOR DATE**