EXPEDITED/FULL APPLICATION

*See page 9 for instructions.*

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| **Section 1: PROTOCOL FULL TITLE** |
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| **Section 2: PROJECT PERSONNEL** | | | |
| **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: AGENCY/ORGANIZATION** |  |
| **Name:** | **Address:** |
| **Website:** | **Type: *(Higher ed, for-profit, non-profit)*** |
| **Contact Person:** | **Email Address:** |

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| **Section 4: VERSION DATE** *(mm/dd/yyyy):* |

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| **Section 5: GENERAL INFORMATION** |
| 1. **Has this project previously been considered by the IRB or by a peer review committee?** |
| * Yes If yes, give approximate date of review *(mm/dd/yyyy)*: * No |
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| 1. **Anticipated beginning and ending dates of human subject contact?** |
| **Beginning date *(mm/dd/yyyy)*:** |
| **Ending date *(mm/dd/yyyy)*:** |

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| **Section 6: ABSTRACT (Limit 350 words)** |
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| **Section 7: STUDY SUMMARY** | | | |
| **Type of Research** | Clinical  Social-Behavioral | | |
| **Clinical Research** | **List investigational agent(s), device(s)**  **FDA-Approved**  Yes  No  **List Biospecimen(s):** | | |
| **Indicate**  **Special Population(s)** | **Categorically Vulnerable Populations** as designated in45 CFR 46 Subparts B, C, & D.(Check all that apply):  Adults unable to consent due to mental, cognitive, or communicative disability  Economically and/or educationally disadvantaged  Minor children  Neonates of uncertain viability  Pregnant persons  Prisoners (or other detained/paroled individuals)  **Contextually Vulnerable Populations** as designated by the Declaration of Helsinki and The President's Council on Bioethics. (Check all that apply):  Immigrants and/or refugees  Indigenous/tribal peoples  LBGTQIA+ Community  Persons with medically or physically compromised  Persons over 70  Marginalized/Minority Population  Neonates of Uncertain Viability  Military Personnel and/or Military Families  Students/Employees  Unhoused persons or persons near to no housing | | |
| **Funding Source** | Federal | Corporation | University |
| Self | Nonprofit | Other: |
| **Indicate the type of consent to be obtained** | Written  Verbal/Waiver of Documentation of Informed Consent  Waiver of HIPAA Authorization  Waiver/Alteration of Consent Process | | |
| **Site(s)** |  | | |
| **Research Related Radiation Exposure** | Yes  No | | |

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| **Section 8: FEDERAL FUNDING** | |
| **Funding Agency:** |  |
| **Sponsored Research ID#:** |  |
| **Does the grant indicate that covered activities will include Human Research?** | (Yes / No / Unknown) |
| **Prime Award Recipient** |  |
| **Sub-Award Recipients** |  |

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| **Section 9: RESEARCH QUESTION, HYPOTHESIS, OBJECTIVES, and OUTCOMES** |
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| **Section 10: BACKGROUND** |
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| **Section 11: Study Intervention(s) / Investigational Agent(s)** |
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| **Section 12: Procedures InvolveD** |
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| **Section 13: DATA AND SPECIMEN BANKING** |
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| **Section 14: SHARING RESULTS WITH PARTICIPANTS** |
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| **Section 15: STUDY TIMELINES** |
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| **Section 16: INCLUSION AND EXCLUSION CRITERIA** |
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| **Section 17: Participant Population(s)** | | | | |
| **Accrual Number** | | **Recruited** | **Maximum Consented** | **Enrolled** |
| **Pilot** | Vulnerable Populations |  |  |  |
| Other |  |  |  |
| **Study-wide** | Vulnerable Populations |  |  |  |
| Other |  |  |  |
| **Total** | Vulnerable Populations |  |  |  |
| Other |  |  |  |

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| **Section 18: RECRUITMENT METHODS** |
| **Recruitment Protocol:** |
| **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: |
| **Note**: Before recruitment begins, the IRB must review and approve all methods and materials used to contact and recruit potential participants, including letters, flyers, emails, etc. |

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| **Section 19: Compensation for Participation in Research Activities** |
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| **Section 20: WITHDRAWAL OF PARTICIPANTS** |
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| **Section 21: RISKS TO PARTICIPANTS** |
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| **Section 22: POTENTIAL BENEFITS TO PARTICIPANTS** |
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| **Section 23: Provisions to Monitor Data to Ensure the Safety of Participants** |
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| **Section 24: Provisions to PROTECT THE PRIVACY INTERESTS of Participants** |
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| **Section 25: ECONOMIC BURDEN TO PARTICIPANTS** |
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| **Section 26: CONSENT PROCESS** |
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| **Section 27: NON-ENGLISH-SPEAKING Participants** |
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| **Section 28: Waiver or Alteration of Consent Process** |
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| **Section 29: Protected Health Information (PHI and HIPAA)** |
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| **Section 30: Qualifications to Conduct Research and Resources Available** |
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| **Section 31: 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 study.** |
| 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.** |
| 1. **Training Verification** |
| 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 |
| **List each researcher, source of training, date, and course.** |
| 1. **Certifications** |
| As principal investigator, 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 principal investigator, 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 principal investigator, 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**  **X**  **FACULTY SPONSOR DATE** |

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| **Section 34: ATTACHMENTS CHECKLIST:** |
| Did you submit:   1. Survey or questionnaires?   0 Yes 0 Not Applicable   1. Interview questions?   0 Yes 0 Not Applicable   1. Recruitment email, announcement, or script?   0 Yes 0 Not Applicable   1. Informed consent form?   0 Yes 0 Not Applicable   1. CV of Principal Investigator   0 Yes   1. List of additional personnel (include degree, role, affiliation, and email)   0 Yes 0 Not Applicable |

**EXPEDITED/FULL APPLICATION**

**INSTRUCTIONS**

* *Depending on the nature of what your research, some sections may not be applicable. If a section or subsection is not applicable, do not delete or leave it blank. Write “Not Applicable" to subsections that are not applicable.*
* *Add the Version Date to the document footer.*
* *When you save and upload this document, add the protocol version date to the document title.*
* *Keep an electronic copy of this document for your files. You will need to modify this copy when making changes.*

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| **Section 4: VERSION DATE** *(mm/dd/yyyy):* |

*Include the version date in the document footer also*

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| **Section 6: ABSTRACT (Limit 350 words)** |

*Briefly summarize your project using non-technical, jargon-free language that can be understood by non-scientists. Include:*

* *a statement of the research question and related theory supporting the reasons for, and importance of, the research*
* *the ages and characteristics of your proposed subjects and how you will recruit them*
* *the research design; and*
* *a description of the procedure(s) subjects will undergo. Limit to 350 words.*

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| **Section 7: STUDY SUMMARY** |

*Complete the matrix.*

**Special Populations***: Even if the vulnerable population is not your target subject, indicate all that may be a member of your subject pool.*

**Site(s)**

* *Describe the site(s) or location(s) where your research team will conduct the research.*
* *Describe the composition and involvement of any community advisory board.*
* *For research conducted outside of the organization and its affiliates describe:*
* *Site-specific regulations or customs affecting the research for research outside the organization.*
* *Local scientific and ethical review structure outside the organization*.

**Note:**

* Lead Coordinating Center:*A lead coordinating center is defined as a site that provides the administrative, clinical, and technical expertise and leadership in the design and coordination of the multi-site collaborative research for a multi-center trial.*
* Data Coordinating Center: *A data coordinating center is defined as a site that is responsible only for the collection and storage of data collected from all sites involved in a multi-site trial.*
* *The principal investigator will be responsible for all site monitoring and for the coordination of participant recruitment, screening, enrollment and retention, data and safety monitoring, data collection and analysis, adherence to the protocol-directed procedures and guidelines, and the prompt review, reporting and resolution of adverse events*.

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| **Section 8: FEDERAL FUNDING** |

*Complete the following matrix if this study will be supported by federal funds. Add additional matrices for each unique funding source. Remove this section if the study will not be supported by federal funds.*

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| **Section 9: RESEARCH QUESTION, HYPOTHESIS, OBJECTIVES, and OUTCOMES** |

*Research Question: A focused and specific query that your study aims to answer.*

*Hypothesis: A statement about the expected outcome of the study.*

*Objectives: Statements that indicate the purpose for which the research was undertaken.*

*Outcomes: Expected benefits to subjects, research community, practitioners, science, and/or society.*

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| **Section 10: BACKGROUND** |

*Describe the relevant prior experience and gaps in current knowledge*.

*Provide the scientific or scholarly background for, rationale for, and significance of the research based on the existing literature and how it will add to existing knowledge*.

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| **Section 11: Study Intervention(s) / Investigational Agent(s)** |

*Describe the study intervention (e.g. research treatment, diagnostic or therapeutic procedure) and/or investigational agent (e.g., device) that is being evaluated.*

*Device Handling: If the research involves device(s), describe your plans to store, handle, and administer those devices so that they will be used only on participants and be used only by authorized investigators*.

* *If the control devices used in this protocol will be accomplished by following an established, approved organizational SOP, please reference that SOP in this section*.

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| **Section 12: Procedures InvolveD** |

*Describe and explain the study design*.

*Provide a description of all research procedures being performed and when they are performed, including procedures being performed to monitor participants for safety or minimize risks*.

*Describe:*

* *Procedures performed to lessen the probability or magnitude of risks.*
* *Delineate which procedures are considered standard of care and which are considered research related. (For example, if the frequency of CT scans is within standard of care, this should be indicated)*
* *All devices used in the research and the purpose of their use, and their regulatory approval status.*
* *The source records, including medical or educational records that will be used to collect data about participants. Attach all surveys, scripts, and data collection forms.*

*What data will be collected during the study and how will that data be obtained?*

* *If there are plans for long-term follow-up (once all research related procedures are complete), what data will be collected during this period*?

*Audio/Video Recording/Photography: If applicable, describe:*

* *The type of recording/photography being utilized*
* *Why the type of recording is necessary to the research*
* *How the recordings/photograph (s will be utilized in the research (e.g., data analysis only)*
* *How and where the recordings/photograph(s) are stored, who has access to them, and if/when they will be destroyed.*

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| **Section 13: DATA AND SPECIMEN BANKING** |

*If data or specimens will be banked for future use, describe*

* *Where the specimens will be stored,*
* *How long they will be stored,*
* *How the specimens will be accessed,*
* *Who will have access to the specimens, and*
* *The data to be stored or associated with each specimen*.

*Describe the procedures to release data or specimens, including: the process to request a release, approvals required for release, who can obtain data or specimens, and the data to be provided with specimens*.

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| **Section 14: SHARING RESULTS WITH PARTICIPANTS** |

*Describe if study results or individual participant results (such as results of investigational diagnostic tests, genetic tests, or incidental findings) will be shared with participants or anyone else (e.g., the participant’s primary care physician*).

*Describe how and when the results will be shared*.

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| **Section 15: STUDY TIMELINES** |

*Describe:*

* *The duration of an individual’s participation in the study,*
* *Approximately how long it will take to enroll all study participants, and*
* *The estimated date for the investigators to complete this study’s primary analyses*.

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| **Section 16: INCLUSION AND EXCLUSION CRITERIA** |

*Describe:*

* *How individuals will be screened for eligibility,*
* *The criteria that define who will be included or excluded in your final study sample,*
* *Specify if you will include or exclude each of the following special populations (members of the populations below may not be included in your research unless you indicate this in your inclusion criteria):*
  + *Adults unable to consent*
  + *Individuals who are not yet adults (infants, children, teenagers)*
  + *Pregnant people*
  + *Prisoners*
  + *Marginalized/Minority/Vulnerable Populations*
* *If this study excludes certain populations, explain the rationale for the exclusion in detail.*

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| **Section 17: Participant Population(s)** |

*Complete the matrix with your planned number of subjects.*

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| **Section 18: RECRUITMENT METHODS** |

*Describe when, where, and how potential participants will be recruited. Your recruitment plan should incorporate methods that specifically address, and detail how potential participants from particular racial and ethnic groups/under-represented populations (with respect to the study) will be recruited. This is to ensure that the recruitment plan is inclusive and representative of the eligible population within the location at which the research is being conducted and considers the impact of the research on all such populations.*

*Describe the source of participants.*

*Describe the methods that will be used to identify potential participants.*

*Describe materials that will be used to recruit participants. (Attach copies of these documents with the application. For advertisements, attach the final copy of printed advertisements.)*

*When advertisements are taped for broadcast, attach the final audio/video file. You may submit the wording of the advertisement prior to taping to preclude re-taping because of inappropriate wording, provided the IRB reviews the final audio/video file.*

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| **Section 19: Compensation for Participation in Research Activities** |

*Describe the amount, timing, and method of any payments to participants. (e.g., gift card, monetary compensation*.)

*If payment is by check, you must request name, address and Social Security Number in order to issue a check for participation. Study payments are considered taxable income and are reportable to the IRS.*

*If the investigator believes that the biologic specimens obtained could be part of or lead to the development of a commercial product, indicate if the participant will have any right to compensation or ownership interest related to such development.*

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| **Section 20: WITHDRAWAL OF PARTICIPANTS** |

*Describe:*

* *Any anticipated circumstances under which participants will be withdrawn from the research without their consent,*
* *Any procedures for orderly termination,*
* *Procedures that will be followed when participants withdraw from the research, including partial withdrawal from procedures with continued data collection.*

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| **Section 21: RISKS TO PARTICIPANTS** |

*List the reasonably foreseeable risks, discomforts, hazards, or inconveniences to the participant related to participation in the research. Include, for the IRB’s consideration, a description of the probability, magnitude, duration, and reversibility of the risks*.

*Consider physical, psychological, social, legal, and economic risks*.

*If applicable, indicate:*

* *Which procedures may have risks to the participants that are currently unforeseeable.*
* *Which procedures may have risks to an embry/ fetus should the participant be/ become pregnant.*
* *Risks to others who are not participants*.

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| **Section 22: POTENTIAL BENEFITS TO PARTICIPANTS** |

*Describe the potential benefits that individual participants may experience from taking part in the research. Include, for the IRB’s consideration, the probability, magnitude, and duration of the potential benefits*.

*Indicate if there is no direct benefit and do not include benefits to society or others*. *Do not inflate benefits nor downplay risks.*

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| **Section 23: DATA PLAN** |

*Describe the data analysis plan, including any statistical procedures, power analysis, and a justification for your target enrollment number*.

*Describe the steps that will be taken to secure the data (e.g., training, authorization of access, password protection, encryption, physical controls, certificates of confidentiality, and separation of identifiers and data) during storage, use, and transmission*.

*Describe any procedures that will be used for quality control of collected data*.

*Describe how data or specimens will be handled study-wide:*

* *What information will be included in that data or associated with the specimens?*
* *Where and how data or specimens will be stored?*
* *How long the data or specimens will be stored?*
* *Who will have access to the data or specimens?*
* *Who is responsible for receipt or transmission of the data or specimens?*
* *How data or specimens will be transported?*

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| **Section 24: Provisions to Monitor Data to Ensure the Safety of Participants** |

*This section is required when research involves more than Minimal Risk to participants.*

*Describe:*

* *The plan to periodically evaluate the data collected regarding both harms and benefits to determine whether participants remain safe. The plan might include establishing data monitoring committee (DSMB/DMC/IDMC) and a plan for reporting data monitoring committee findings to the IRB and the sponsor.*
* *The frequency of DSMB Meeting.*
* *What data are reviewed, including safety data, untoward events, and efficacy data.*
* *How the safety information will be collected (e.g., with case report forms, at study visits, by telephone calls with participants).*
* *The frequency of data collection, including when safety data collection starts.*
* *Who will review the data.*
* *The frequency or periodicity of review of cumulative data.*
* *The statistical tests for analyzing the safety data to determine whether harm is occurring.*
* *Any conditions that trigger an immediate suspension of the research*.

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| **Section 25: Provisions to PROTECT THE PRIVACY INTERESTS of Participants** |

*Describe the steps that will be taken to protect participants’ privacy interests. “Privacy interest” refers to a person’s desire to place limits on whom they interact or whom they provide personal information*.

*Describe what steps you will take to make the participants feel at ease with the research situation in terms of the questions being asked and the procedures being performed. “At ease” does not refer to physical discomfort, but the sense of intrusiveness a participant might experience in response to questions, examinations, and procedures*.

*Indicate how the research team is permitted to access any sources of information about the participants*.

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| **Section 26: ECONOMIC BURDEN TO PARTICIPANTS** |

*Describe any costs that participants may be responsible for because of participation in the research.*

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| **Section 27: INFORMED CONSENT PROCESS** |

***Indicate how you will be obtaining consent and describe:***

* *Where the consent process takes place.*
* *Any waiting period available between informing the prospective participant and obtaining the consent.*
* *Any process to ensure ongoing consent.*
* *The role of the individuals listed in the application as being involved in the consent process.*
* *The language used by those obtaining consent and the language understood by the prospective participant or the legally authorized representative.*
* *The time that will be devoted to the consent discussion.*
* *Steps that will be taken to minimize the possibility of coercion or undue influence.*
* *Steps that will be taken to ensure the participants’ understanding*.

**Special populations:**

***Minors (infants, children, teenagers)***

* + *Describe the criteria that will be used to determine whether a prospective participant has not attained the legal age for consent to treatments or procedures involved in the research under the applicable law of the jurisdiction in which the research will be conducted. (E.g., individuals under the age of 18 years.)*
  + *Describe whether parental permission will be obtained from:*
  + *Both parents unless one parent is deceased, unknown, incompetent, or not reasonably available, or when only one parent has legal responsibility for the care and custody of the child.*
  + *One parent, even if the other parent is alive, known, competent, reasonably available, and shares legal responsibility for the care and custody of the child.*
  + *Describe whether permission will be obtained from individuals other than parents, and if so, who will be allowed to provide permission. Describe the process used to determine these individuals’ authority to consent to each child’s general medical care.*
* *Indicate whether assent will be obtained from all, some, or none of the children. If assent will be obtained from some children, indicate which children will be required to assent.*
* *When assent of children is obtained describe whether and how it will be documented*.

**Adults unable to consent due to mental, cognitive, or communicative disability**

* *Describe the process to determine whether an individual is capable of consent.*
  + *List the individuals from whom permission will be obtained in order of priority. (E.g., durable power of attorney for health care, court appointed guardian for health care decisions, spouse, and adult child.)*
  + *For research conducted in the state, review “SOP: Legally Authorized Representatives, Children, and Guardians (HRP-013)” to be aware of which individuals in the state meet the definition of “legally authorized representative.”*
  + *Describe the process for assent of the adult participants. Indicate whether:*
* *Assent will be required of all, some, or none of the participants. If some, indicated, which participants will be required to assent and which will not.*
* *If assent will not be obtained from some or all participants, an explanation of why not.*
* *Describe whether assent of the participants will be documented and the process to document assent. The IRB allows the person obtaining assent to document assent on the consent document and does not routinely require assent documents and does not routinely require participants to sign assent documents*.

**Additional Vulnerable Populations**

* *Vulnerable populations include individuals who may be vulnerable to coercion or undue influence to participate in research projects, or who may be at greater risk when participating in research.*
* *Describe the process for assent of the adult participants.*
* *Describe process to safeguard subjects from coercion or undue influence.*
* *Describe how safeguards are tailored to the specific population.*
* *Describe how risks have been minimized to the greatest extent possible.*

***Process to Document ICP***

* *Describe how investigators will document informed consent of each participant**.*

**Note:** *If ICP needs to be altered to accommodate vulnerable participants, a separate form must be completed and approved by the IRB: Waiver/Alteration of Informed Consent*

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| **Section 28: NON-ENGLISH-SPEAKING Participants** |

*Indicate what language(s) other than English are understood by prospective participants or representatives*.

*If participants who do not speak English will be enrolled, describe the process to ensure that the oral and written information provided to those participants will be in that language. Indicate the language that will be used by those obtaining consent*.

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| **Section 29: Protected Health Information (PHI and HIPAA)** |

*HIPAA applies to Protected Health Information (PHI). PHI is individually identifiable health information that is created or maintained by a covered entity (health care providers, hospitals, physician offices, health care clearing houses, health care plans), or their business associate(s).  
  
If your research does not involve the use of medical record information maintained by a covered entity and if the information generated from research will not be placed into the medical record, then HIPAA does not apply.*

*Indicate the following:*

* *Does the study involve the creation, use, or disclosure of Protected Personal Health Information?*
* *Will a HIPAA Authorization be obtained from all or some participants?*
  + - *If HIPAA Authorization will not be obtained, indicate what alternatives will be used.*

*PHI examples:*

* *Names*
* *Geographic Subdivisions: All geographic subdivisions smaller than a state, including street address, city, county, precinct, ZIP code and their equivalent geographical codes, except for the initial three digits of a ZIP code if, according to the current publicly available data from the Bureau of the Census: (a) The geographic unit formed by combining all ZIP codes with the same three initial digits contains more than 20,000 people. (b) The initial three digits of a ZIP code for all geographic units containing 20,000 or fewer people are changed to 000.*
* *Dates and Age: All elements of dates (except year) for dates directly related to an individual, including birth date, admission date, discharge date, date of death; and all ages of 89 and all elements of dates (including year) indicative of such age, except that such ages and elements may be aggregated into a single category of age 90 or older.*
* *Telephone numbers*
* *FAX numbers*
* *Social Security Numbers*
* *Medical Record Numbers*
* *Health Plan Beneficiary Numbers*
* *Account Numbers*
* *Certificate/License Numbers*
* *Vehicle Identifiers and Serial Numbers, including License Plate Numbers*
* *Device Identifiers and Serial Numbers*
* *Web Universal Resource Locators (URLs)*
* *Internet Protocol (IP) Address Numbers*
* *Biometric Identifiers, including Fingerprints and Voiceprints*
* *Full-Face Photographic Images and any Comparable Images*
* *Any other Unique Identifying Number, Characteristic, or Code, unless otherwise permitted by the Privacy Rule for re-identification*

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| **Section 30: Qualifications to Conduct Research and Resources Available** |

*Describe the resources available to conduct the research: For example, as appropriate:*

* *Justify the feasibility of recruiting the required number of suitable participants within the agreed recruitment period. For example, how many potential participants do you have access to? What percentage of those potential participants do you need to recruit?*
* *Describe the time that you will devote to conducting and completing the research.*
* *Describe your facilities.*
* *Describe the availability of medical or psychological resources that participants might need as a result of anticipated consequences of the human research.*
* *Describe your process to ensure that all persons assisting with the research are adequately informed about the protocol, the research procedures, and their duties and functions.*
* *Study-Wide Number of Participants*
* *If this is a multicenter study, indicate the total number of participants to be accrued across all sites*.

***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.*