**Review date**:       **Reviewer’s Name**:

## **I. PROTOCOL INFORMATION**

1. **PROTOCOL #**:       **D.** **PRINCIPAL INVESTIGATOR**:

**B. PROTOCOL TITLE:**

**C. TYPE OF STUDY:**

*(i.e., observational, qualitative, interview, survey, experimental, quasi experimental)*

**E. RESEARCH CATEGORY:**

|  |  |  |
| --- | --- | --- |
| [ ]  Exempt | [ ]  Non-Exempt Minimal Risk | [ ]  Non-Exempt Greater Than Minimal Risk |

**F. REVIEW METHOD:**

|  |  |  |
| --- | --- | --- |
| [ ]  Expedited | [ ]  Full Board  |  |

## **II. Can the protocol and method of data analysis answer the** **research question?**

|  |  |  |
| --- | --- | --- |
| [ ]  **Yes** | [ ]  **No** | [ ]  **N/A** |

**Things to consider:**

**Research intent:** Are research questions or hypotheses clearly described?

**Research design and analysis plan:**  Is the research design likely to meet the research intent? Is the analysis plan likely to provide a clear answer to each research question or a clear test of each hypothesis?

**Instruments:** Are surveys, questionnaires, and interview checklists likely to meet the research intent? Are they attached?

**Participants:** Is the participant population suitable for the research intent? Are the Inclusion/Exclusion procedures adequate to exclude those who might be more susceptible to the risks posed by the study? Are there special physiological, psychological or social characteristics of the participant population that would pose special risks?

**Special populations:** Are some of the possible participants part of a special population likely to be particularly vulnerable to coercion? If so, is their participation necessary? If so, is the justification for their inclusion convincing. Are additional safeguards described? Are they sufficient?

**Note:**Special populations include children, prisoners, pregnant women, veterans, economically disadvantaged persons, individuals with diminished mental capacity, illiterate persons or persons for whom English is a second language, or individuals who are being questioned about a traumatic event (e.g., sexual assault).

**Comments, questions, or concerns (note if you feel unqualified to review a section of this checklist):**

## **III. ARE THE RISKS TO PARTICIPANTS REASONABLE RELATIVE TO THE BENEFITS?**

|  |  |  |
| --- | --- | --- |
| [ ]  **Yes** | [ ]  **No** | [ ]  **N/A** |

**Things to consider:**

* **Minimize risk:** Do procedures insure that participants are not exposed to unnecessary physical, psychological, legal, economic, and social risks?
* **Description of risks and benefits:** Are possible risks and anticipated benefits adequately and accurately described? Payment should not be listed as a benefit.
* **Incentives:** Based upon the complexity of the task and the inconvenience of participation, are incentives reasonable for the participant population? Is compensation or reimbursement appropriately prorated?

**Comments, questions, or concerns:**

## **IV. ARE RECRUITMENT/INFORMED CONSENT PROCESSES APPROPRIATELY DOCUMENTED?**

|  |  |  |
| --- | --- | --- |
| [ ]  **Yes** | [ ]  **No** | [ ]  **N/A** |

**Things to consider:**

* **Letter of support:** Are letters of support needed? If so, have they been provided by the appropriate authority? Are copies attached?
* **Recruitment materials:** Do recruitment materials accurately introduce possible participants to the research? Are they easily understood? Are they consistent with the protocol?
* **Informed consent materials:** Are consent materials provided for each participant? Are they consistent with the protocol? Do they include all necessary information about risks and benefits? Do they include information about the protection of privacy (confidentiality and anonymity)? Are they written to be understandable to all participants? Is consent given by the subject or the subject’s legal representative?
* **Deception (if used):**  Is deception essential for the study? If so, will deception place participants at significant financial, physical, psychological, or social risk? Is a debriefing checklist provided to fully inform participants of the nature and purpose of the deception?
* **Waivers**: Check below to indicate any waivers requested. Is each waiver justified? Is each justification valid?

|  |  |  |
| --- | --- | --- |
| [ ]  Informed Consent | [ ]  Assent | [ ]  Documentation of Informed Consent (signed ICF) |
| [ ]  HIPAA | [ ]  Other:       |

**Comments, questions, or concerns:**

## **V. ARE PROVISIONS ADEQUATE TO ENSURE THE PRIVACY AND SAFETY OF PARTICIPANTS?**

|  |  |  |
| --- | --- | --- |
| [ ]  **Yes** | [ ]  **No** | [ ]  **N/A** |

**Things to consider:**

* **Data monitoring:** Is data monitoring necessary? If so, is the procedure described sufficient to insure participant safety?
* **Adverse or unexpected results:** Are adverse or unexpected results likely enough to require a safety plan? If so, is the plan sufficient to insure participant safety? Does the plan include a requirement to inform the IRB?
* **Privacy**: Is the privacy of participants protected? Is confidentiality protected by limiting access to the data, or other appropriate methods? Is data destroyed after a specified period of time? Is anonymity protected by coding, destruction of identifying information, or other appropriate methods?

**Note**: The term confidentiality is used whenever the researcher has access to identifiable information. The term anonymity is used if the researcher cannot link data to a particular participant.

**Comments, questions, or concerns:**

## **VI. RECOMMENDATIONS FOR APPROVAL (TO THE PROTOCOL, ICF, OTHER FORMS, ETC.)**

|  |  |
| --- | --- |
| [ ]  **APPROVE AS IS** | [ ]  **MOVE TO FULL BOARD REVIEW** |

[ ]  **APPROVE WITH FOLLOWING CONDITIONS:**

**Any additional comments:**