**Protocol Template**

 *A protocol is a description of your project that provides information about the background and current status of the issue, the public health importance of the project, methodology for accomplishing project goals, how consent will be obtained, description of the risks and benefits (including how vulnerable populations will be adequately protected), description of how privacy and confidentiality will be ensured, budget information, and description of efforts to involve the community in the project, including dissemination of findings. Your protocol should include the information noted in the template below; however, if you are conducting a needs assessment, evaluation, or QA/QI, some of the items below may not be applicable to your study/project and do not need to be included. These items are denoted with an asterisk \*.*

***Note: please remove/delete all text in red font before submitting your protocol to the IRB.***

**Protocol Title:** title of your research project

**Principal Investigator (PI)/Project Lead:** Include name of PI or project lead (for non-research); include primary affiliation, degree(s) and title, as applicable.

**Co-Principal Investigator (Co-PI):** Include name of co-PI (if applicable); a co-PI is a person who 1) has an equally shared responsibility with the PI for the conduct or a project; and/or 2) has delineated responsibilities such as being the local investigator for a site on a multi-site study. Each study/project should designate no more than one co-PI; include primary affiliation, degree(s) and title, as applicable.

**Key personnel:** Include name(s) of all personnel who will assist in carrying out the research protocol including activities such as consultation, data collection, analysis, and preparation of manuscripts; include degree(s) and titles, as applicable. All personnel listed in the protocol must be added to your IRB application as research personnel.

**Key terms:** Please provide definitions of any pertinent key terms and/or acronyms that the reader might find helpful (this information can be included as a separate attachment or at the end of the main protocol).

**I. Background/Objectives**

A brief description of the scope of the problem/issue being investigated and the study/project objectives as they relate to the issue of interest. Include a rationale for why this study/project is necessary and how it will contribute to a better understanding of the issue of interest. This section should not exceed 500 words and should include citations for any sources that are referenced.

**II. Study Design/Methods**

A description of the research activities that will be undertaken to accomplish the study/project objectives. This section should include the following:

1. Hypothesis or hypotheses that will be tested\*
2. Description of the target population, including:
	1. Eligibility criteria, including justification for any exclusions
		* Include a description of any oversampling or other such sampling methods that will be utilized
		* Describe if any mono-lingual speakers of languages other than English will be recruited and how they will be accommodated (i.e., translation of recruitment, consent, and data-collection materials, etc.)
	2. How participants will be recruited
		* Include where and when recruitment will occur as well as who will conduct recruitment
	3. Total number of expected participants for each project activity
	4. The process for obtaining informed consent or a justification for any alteration/waiver of informed consent requirements; include a description of steps you will take to ensure participant comprehension of the informed consent language
3. Duration and location of the project activities (a timeline is helpful but not necessary)
4. Data-collection methods (e.g., surveys, focus groups, interview/focus group scripts etc.), including the following:
	1. A description of and rationale for the data-collection methods to be used
		* Describe whether any PHI will be collected and why
	2. The length of participation (e.g., how long a survey will take to complete, will pre- and post-measures be collected, etc.)
	3. Describe any data sources that will be used or accessed including how they will be accessed and by whom
	4. Any incentives that will be provided to participants
	5. Include a list of any software that will be used and how each software will be used; make sure to note if any software will be used to collect, store, transfer, or analyze any PHI or PII.
	6. List of any experimental procedures to be employed\*
5. Data Analysis Plan
	1. Describe how the data will be organized and analyzed including the variables and relationships that will be explored as well as the statistical analyses that will be performed.
6. Reading Ease and Reading Grade Level

1. Include the Flesch Reading Ease and the Flesch-Kincaid Grade Level scores for your consent documents and any data collection/recruitment instruments. These scores help assess: 1) the ease with which a piece of text will be understood and engaged (Flesch Ease), and 2) the approximate reading grade level of a text (Flesch-Kincaid). These scores can be obtained in Microsoft Word. Please refer to the following link for assistance with obtaining the scores in Word:

<https://support.microsoft.com/en-us/office/get-your-document-s-readability-and-level-statistics-85b4969e-e80a-4777-8dd3-f7fc3c8b3fd2>

**III. Risks and Benefits**

Describe the known/anticipated risks and benefits associated with participation in the research study. Include any steps that will be taken to minimize risk and any measures that will be taken in the event of a negative or adverse reaction.

**IV. Privacy of Individuals and Confidentiality of Data**

A description of steps that will be taken to ensure the privacy of individuals and the confidentiality of any data collected as part of the research protocol. Include information about who will have access to data, how data will be stored and/or transferred, how long data will be retained and what will be done with it after it is no longer needed.

**V. Community Engagement and Sensitivity\***

Describe any steps that will be taken to engage the community/target population throughout any study/project activities e.g., hosting a town hall meeting to solicit community input before beginning data-collection.

**VI. Reporting/Dissemination of Findings**

A description of how your study/project results or findings will be reported back to the target population and/or community, including any summary reports that will be developed and how they will be shared, manuscripts that will be submitted for publication, etc. Include information about any data sharing agreements.

**VII.** **Attachments**

Include a list of any supporting documents/appendices that will be included with your IRB submission, including but not limited to the items below. Please make sure that all documents/appendices are clearly labeled with a title/heading at the top of the document. If you refer to any supporting documents/appendices in your protocol, please include the title of the document so that it is clear which document is being referenced.