DPH IRB - Protocol Template

IMPORTANT: Remove all text in red font before submitting your protocol to the IRB.

A protocol is a document that provides important information about your project including: the background of the topic your project is addressing, the public health importance of the project, the methods you are using to accomplish your project's objectives, how consent will be obtained from participants, a description of the risks and benefits (including how vulnerable populations will be adequately protected), how privacy and confidentiality will be ensured, and how the community will be engaged. Please follow the template below when submitting an application for IRB review.

****If you are conducting a needs assessment, evaluation, or Quality Assurance/Quality Improvement project, some items may not be applicable and do not need to be included. These items are indicated with an asterisk *.***

Protocol Title: Title of your project

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

Co-Principal Investigator (Co-PI) [if applicable]: Include the name of the co-PI; 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 project should designate no more than one co-PI; include primary affiliation, degree(s) and title, as applicable.

Key personnel: Include the name(s) of all other personnel who will assist in carrying out the 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.

Program Director: Include the name of the program director (for projects external to the County, the liaison can also be listed as the program director)

Division(s)/Program(s)/Organization(s): Include the names of the division(s)/program(s) involved in the project as well as the names of any external organizations/partners involved.

DPH/DHS liaison [if applicable]: If the Principal Investigator/Project lead and Co-PI are not affiliated with the County (e.g., if they are from an organization that is external to the County such as a university), a permanent DPH/DHS staff member will need to be designated as DPH/DHS liaison on the IRB application and listed in the protocol.

Key terms: Please provide definitions of any key terms and/or acronyms that the reader might find helpful. Inclusion of key terms is recommended but not required.

I. Background/Objectives

Provide a brief description of the scope of the problem/issue being investigated and the project objectives as they relate to the issue of interest. Include a rationale for why the 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 (references can be included at the end of the background section, as footnotes, or at the end of the protocol document).

II. Study Design/Methods

This section should contain a detailed description of the activities that will be undertaken to accomplish the project objectives. This section should include the following:

A. Hypothesis or hypotheses that will be tested*

B. Description of the target population, including:

- Inclusion and exclusion criteria, including justification for any exclusions
  - Include a description of the sampling methods that will be utilized such as oversampling, snowball sampling, convenience sampling, etc.
  - 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.)
- How participants will be recruited
  - Include where and when recruitment will occur as well as who will conduct recruitment
- Total number of target participants for each project activity
- The process for obtaining documentation of written 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

C. Data-collection methods (e.g., surveys, focus groups, interview/focus group scripts, accessing secondary datasets, etc.), including the following:
    - Duration and location of project activities
    - A description of and rationale for the data-collection methods to be used
        - Describe whether any Protected Health Informatoin (PHI) will be collected and why
    - The length of participation (e.g., how long a survey will take to complete, whether pre- and post-measures will be collected and with what frequency, etc.)
    - Describe any data sources that will be used or accessed including how they will be accessed and by whom
    - Describe any incentives that will be provided to participants
    - Include a list of any software (and version) that will be used and how each will be used; make sure to note if any software will be used to collect, store, transfer, or analyze any PHI or Personally Identifying Information (PII).
    - List experimental procedures to be employed, if any*

D. Data Analysis Plan
    - Describe how the data will be organized and analyzed including the variables and relationships that will be explored as well as the type of statistical analyses that will be performed; include the period of time for data analyses

E. Reading Ease and Reading Grade Level
    - 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). Please refer to our website for assistance with obtaining the scores using Microsoft Word.

III. Risks and Benefits

Describe the known/anticipated risks and benefits (direct and indirect) associated with participation in the project. 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. Administrative Organization

Describe the roles of the various partners involved in the project.

V. Privacy of Individuals and Confidentiality of Data

Provide a detailed description of the steps that will be taken to ensure the privacy of individuals and the confidentiality of any data collected as part of the 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.

VI. Community Engagement and Sensitivity

Describe any steps that will be or have already been taken to engage the community/target population throughout any project activities, e.g., hosting a town hall meeting to solicit community input before beginning data collection. If the community has not been and will not be engaged throughout the project, provide a justification for why that is the case.

VII. Health Equity

Describe how your project will address health equity, or, if your project will not address health equity, provide a justification for why that is the case. Include a description of any data your project will collect that is related to health equity, diversity, and inclusion, such as social determinants of health, and other participant characteristics defined socially, economically, demographically and/or geographically. Please refer to the IRB's Health Equity in Research and Related Activities policy (available on the IRB website or IRB intranet page [for DPH staff only]) for more information. Include a description of steps your project will take to track any progress toward adherence to the health equity-related responsibilities outlined in the aforementioned policy.

VIII. Reporting/Dissemination of Findings

Include a description of how your 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. If there will be any follow-up engagement with participants and/or the community, describe that here.

Note about data sharing agreements: If your project has a Data Use Agreement (DUA) that is pending, it is still possible to obtain IRB approval; a copy of the final DUA will need to be submitted to the IRB when it is available.

IX. Attachments

Include a list of any supporting documents/appendices that will be included with your IRB submission, such as data collection tools, budget documents, MOUs, etc. These documents will still need to be uploaded separately to your IRB application. 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 elsewhere in the protocol, please include the title of the document so that it is clear which document is being referenced.