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 issue/topic your project is addressing, the public health importance of the project, the methods being used to accomplish the 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 drafting a protocol for inclusion with an IRB application. Following this template makes it easier for the IRB reviewer to get a clear understanding of your project and the risks that participants assume by taking part in it. The information should be presented in each section in a narrative style (prose); do not use bullet points for entire sections.

****If you are conducting a needs assessment, evaluation, or Quality Assurance (QA)/Quality Improvement (QI) project, some sections 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 (for research) or project lead; 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. A co-PI is not required and 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, obtaining informed consent, data collection, data analysis, and preparation of manuscripts; include degree(s) and titles, as applicable. In addition to being listed in the protocol, personnel must be added to your IRB application in the additional personnel section.

Program Director: Include the name of the director of the program where the project originates

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/collaborators involved.

DPH/DHS liaison [if applicable]: If the PI/Project lead and co-PI are not affiliated with Los Angeles County, a permanent DPH/DHS staff member will need to be designated as DPH/DHS liaison on the IRB application and also listed in the protocol. For projects external to Los Angeles County, the liaison can also be listed as the program director.

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

I. Background/Objectives

Provide a brief description of the topic/issue being investigated and the project objectives. Include a rationale for the project and how it will contribute to a better understanding of the topic/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 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.
- How participants will be recruited
  - Include where and when recruitment will occur as well as who will conduct recruitment
  - 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.)

- The process for obtaining informed consent or a justification for alteration/waiver of informed consent requirements; include a description of any steps taken to ensure participant comprehension of informed consent language.

C. Data-collection methods (e.g., surveys, focus groups, interviews, focus groups, accessing secondary datasets, etc.), including the following:
    - A description of, and rationale for, the proposed data-collection methods
        - Describe whether any Protected Health Information (PHI) will be collected and provide a justification for doing so.
    - The length and frequency of activities (e.g., how long a survey will take to complete, whether pre- and post-measures will be collected, whether there will be follow-up at 3 or 6 months, etc.)
    - Location of activities; include details relevant to the method of data collection (e.g., a survey will be administered in the patient waiting room of a clinic, etc.)
    - Total number of expected participants for each activity
    - Describe all secondary dataset(s) that will be accessed, if applicable
        - Include a description of the process through which project personnel will access the dataset(s)
        - Include the range of time that applies to the data being accessed (e.g., all clinic visits between Jan. 1 and Dec. 31, 2024, etc.)
    - Describe any incentives that will be provided to participants
    - Include a list of all software (include the 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; be explicit about the range of time

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 the IRB 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 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. Include information about who will have access to the data, who will have access to data that is PII or PHI, 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. If data will be deidentified, please explain who will be doing the deidentification and describe the steps that will be involved in the deidentification.

VI. Community Engagement and Sensitivity

Describe any steps that will be or have already been taken to engage the community/target population about this project (e.g., hosting a town hall meeting to solicit community input before beginning data collection, etc.). If the community has not been and will not be engaged, 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 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 for more information (available on the IRB website or IRB intranet [for DPH staff only]). Include a description of steps that will be taken 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 shared with the target population and/or community, including any reports/manuscripts that will be developed and how they will be disseminated, etc. Include information about any data sharing agreements. If there will be any follow-up engagement with participants and/or the community, describe 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 as separate files to your IRB application in their appropriate spaces. 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.