



How to Write a Protocol

Investigators have responsibilities to provide complete and accurate information for reviewers to make informed decisions on the requirements for IRB review/approval. All supporting documents, such as approvals by other IRBs, letters of support, data collection forms, study tools, and informed consent documents should be submitted with the protocol for review.

Below is an example of a protocol outline that may be used. Depending on the complexity of the study, not every protocol needs to contain every element. Tailor the protocol to the complexity of the study.

General Outline of a Protocol

I. Overview

- *Cover page*: A project title should provide the main idea of the study. Include the version number and date.
- *Project summary*: Give a concise overview of the project. Describe the purpose of the study, including problem to be investigated and hypothesis(es) to be tested, the population, and the methods that will be used. Include the expected benefit of the study.
- *Investigators/collaborators*: include their roles, and responsibilities.

II. Background

- *Literature review/current state of knowledge about project topic*: Discuss relevant information about the subject of the project based on a review of the literature. Provide citation of the sources and include a reference in the appendix (if applicable).
- *Justification for study*: Explain the public health and scientific importance of the study.
- *Location(s)*: Identify the study location(s).
- *Intended/potential use of study findings*: Define the primary target audience(s) and discuss the expected applicability of study findings.
- *Goals/Objectives*: Clearly and concisely, list the goals and/or objectives that the project will address.
- *Hypotheses or questions (if applicable)*: Describe the question(s) that the study will answer. State the type of hypothesis(es) (if applicable) that will be explored or tested.



III. Methods

- *Study design/timeline*: Describe the methods to be used and the duration of participants' involvement.
 - (If applicable) Describe whether the approach used will be descriptive, exploratory (hypothesis-generating), confirmatory (hypothesis-testing), or developmental (focused on corrective action).
- *Study population(s)*: Describe the study population, number of participants, sampling frame, case definitions, inclusion/exclusion criteria, recruitment, and justification for involving vulnerable populations.
- *Study procedures*:
- *Data analysis*: Describe key variables that will be collected and how data will be analyzed, data storage, and quality assurance.
- *Data management plan*: Descriptions of how data will be collected/abstracted/cleaned/maintained;
 - ➤ How access will be provided to the data (including provisions for protection of privacy, confidentiality, security); If data will be de-identified, describe that process. Include the data collection instrument.
 - ➤ Plans for archival and long-term preservation of the data.
- *Dissemination/Reporting of Results*: Describe any plan for notifying participants and other stakeholders of study findings.

IV. Ethical considerations

- *Risks/Benefits*: Describe the potential risks (physical and mental) and benefits to study participants
- *Informed Consent/Assent/Permission*: Describe the informed consent/assent procedures, waiver of informed or written consent, assent of children, parental permission,
- *Other ethical considerations*: Describe confidentiality/privacy protection, autonomy, safeguard for vulnerable population, reporting of adverse events. Describe conflicts or potential conflicts of interest if any.
- *HIV Notification Policy*: If individuals will be consented and tested for HIV, describe the plan to inform individuals of their test results, including providing appropriate counseling according to HHS Policy -- <http://www.hhs.gov/ohrp/policy/hfdc88jun.html>.
- *References*: List of references cited.
- *Appendices*: Include all relevant materials, such as study tools, informed consent document, local IRB approval, confidentiality agreements, material/data transfer agreement, and other supporting documents.