# Protocol

### A complete protocol of the proposed research project that addresses all the elements listed below must be submitted. A checklist is provided to assure all required documents are included for review. All documents must be received before the IRB will begin review of application.

##### INTRODUCTION

1. Describe the **BACKGROUND RATIONALE** for the study. Include the **PUBLIC HEALTH BENEFITS** to society.

1. List the **SPECIFIC AIMS AND HYPOTHESES** of the study (research questions).

# METHOD

1. Describe the **EXPECTED GROUP (S)** (control, experimental, geographic areas, or time periods, etc.) that will comprise the study populations. Include the number of subjects and/or records to be studied in each group. Describe the method of **ASSIGNMENT** to each group (randomization technique, sequential assignment, etc.)

1. Outline the **INCLUSION and EXCLUSION CRITERIA** for group membership. Justify the inclusion of records for any special groups, e.g., minors, pregnant women, etc. Justify exclusion criteria, where appropriate (e.g. women of child-bearing age).

1. Explain how **SUBJECT** **RECRUITMENT** is to be carried out. Provide copies of media ads, posters, announcements and clinic or hospital recruitment procedures, referrals, etc. If subject recruitment incentives are to be offered or payment to subjects is to be made, describe and justify.

1. Describe in detail the **ROLE OF SUBJECTS** in the investigation (questionnaires, observations, interviews, the use of body fluids, follow-up visits/tests, etc.)

1. Describe the **TIME FRAMES** for the phases of the study, e.g. number of months for recruitment, data collection, analysis etc.

1. Describe the **PARAMETERS/VARIABLES TO BE MEASURED**. Include how and when these measurements will be made. Attach copies of research instruments, (e.g. questionnaires) and include information supporting the validity and reliability of the instruments. If requesting data from DHSS, list name of file and the data items to be used.

1. Describe how **DATA ANALYSIS** will be performed (statistical tests, method for evaluating data) and indicate the smallest group/unit for which separate reporting will occur.

#### **RISK/BENEFIT ASSESSMENT**

10. Describe any foreseeable **RISKS TO THE SUBJECTS** that could arise from being in the study, particularly any risks from loss of confidentiality or anonymity. Include an assessment of each risk and indicate the steps to be taken to minimize each risk.

11. Describe the **POSSIBLE BENEFITS TO SUBJECTS** and **POSSIBLE BENEFITS TO SOCIETY** beyond those listed in response to item 1.

12. Describe any accepted **ALTERNATIVE PROCEDURES/THERAPIES** that are available to the participants in this research project, including the alternative of nonparticipation. If this is clinical research, include the alternative of standard therapy and describe.

13. Describe how **ANONYMITY OR CONFIDENTIALITY** will be maintained. Indicate measures employed to protect identity of the participants (collection of unidentifiable data or use of code numbers, master code sheet, etc.), how data will be secured and who will have access to the data (such as FDA, {named} drug company, co-investigators).

### SUBJECT CONSENT

14. Explain how **INFORMED CONSENT** will be obtained, i.e. who will discuss risks, benefits and alternatives with the subjects and when and where the discussion will occur.

**NOTE:** A copy of the **CONSENT FORM must be sent with this application.**  Consent forms should include enough information in everyday language about the purpose and procedures so that the subject will adequately comprehend of the hazards and benefits of being in the study. The statements of rights and alternatives assure the voluntariness of consent and participation. See “Informed Consent Guidelines” for more detail.

15. If there will be no consent form, or if not all elements of informed consent are to be addressed, explain/justify in detail, addressing the requirements of 45 CFR 46.116-117.

## BIBLIOGRAPHY

1. List the references that form the background/basis for the research project.

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