Protocol Format - Sociobehavioral

Title Page – Full title, Investigator's Names, Sponsor's Name if any, and Date

1. Background
   a. Specific aims [objectives, research questions, or hypotheses] of the study
   b. Preliminary studies in area that support this stage of the research
   c. Significance/justification for current study

2. Design
   a. Sample
      - Population (age range, county, region)
      - If vulnerable population (children, pregnant women, prisoners), describe safeguards
      - Inclusion criteria
      - Exclusion criteria

   b. Setting
      - Location of study procedures and/or data collection (e.g., telephone; respondent's home; research office, mall)
   c. Recruitment
      - Site of and/or procedures for recruitment
      - Description of recruitment methods (how will contact be made?)
      - Upload all verbal and written recruitment materials
      - Plans to monitor equitable recruitment of subjects
      - For a no-contact study (secondary data analysis, chart review, biobank) answer the following:
        1. Is the data publicly available?
        2. Is the data identifiable?
        3. Will any member of the study team have access to the code that links identifiers to subjects?
        4. Is privacy of existing data a concern (e.g., patients, people already in prior studies)? If you need to request a HIPAA waiver to access existing private data, make this clear.

   d. Procedures
      - Study design (survey, interview, focus group, experiment)
      - Procedures for subjects
        1. Data collection procedures
           a. Describe the nature of the interaction with the participant (e.g., survey, interview, group discussion, direct observation, computer administered self-interview, non-invasive tissue sampling, chart review)
           b. Describe other study related interactions (MRI, cognitive testing, experimental procedures)
        2. Describe total respondent burden (in hours)

e. Measures
   - Describe general scope of topic areas
   - Upload copies of surveys, interviews, focus group scripts, questionnaires

f. Risks to participation
   - Procedures to reduce risk

g. Benefits to subject or future benefits

h. Data analysis
   - Rationale for proposed number of subjects
   - Formal sample calculations, if applicable
   - Plans for data management and statistical analysis
   - Inclusion of stopping rules as appropriate

3. Training
   Description of training for research personnel

4. Plans for data management and monitoring
   a. Description of data safety and monitoring plan
   b. Inclusion of data safety and monitoring board, if applicable

5. Confidentiality
   a. Plans to protect privacy of subjects and confidentiality of data
      This applies to existing data used to identify participants (e.g., medical records) and identifiable and private data collected as part of the study (e.g., voice, photos, biomedical data with identifiers).
   b. Description of plans to link data to identifiers, if applicable
   c. Description of how linkage will be protected

6. Informed consent
   a. How and where will informed consent be obtained? Oral or written?

7. Plans to inform participants of new findings or research results that might affect health

8. References