Protocol Outline Template

Guidance and Resources:

- Refer to the UI IRB Standard Operating Procedures and Researcher Guide to make sure the study protocol complies with UI IRB policies and guidance on the conduct of human subjects research.
- Additional information and guidance on the Human Subjects Office website:
  - Frequently Asked Questions
  - Education and Training
  - Resources for Faculty/Staff

Protocol Title:
Protocol Version:
Protocol Date:
Principal Investigator:
Research Team:

I. Abstract

Provide a summary of the study background, aims, and design.

II. Background and Significance/Preliminary Studies

Describe the current environment that is the basis for the proposed research, including a presentation of the problem (with references) and a review of current literature. Include a critical evaluation of current knowledge and preliminary studies related to the proposed research and describe how this proposal will enhance this knowledge.

III. Study Aims

Describe the purpose of the study, including identification of specific primary objectives/hypotheses. Secondary objectives/hypotheses should be described as necessary.

IV. Administrative Organization

Describe the participating units, including the name and location of other participating study sites, laboratories, data management center, and coordinating center, as applicable. Specify the role/responsibility of each unit.

V. Study Design

a. Experimental design of the study (e.g., single-blind, double-blind)
b. Study population general description
    i. Specify total number of adult subjects, age range and percent by gender.
    ii. Specify total number of minor subjects (less than 18 years of age), age range and percent by gender.
c. Sample size determination and power analyses
d. Study outcomes/endpoints

VI. Study Procedures

a. The data being collected should directly correspond with the study aims or hypotheses
b. Describe Subject selection procedures
    i. Describe the sampling plan including Inclusion/Exclusion criteria (subject and disease characteristics)
    ii. Indicate if the study plans to enroll non-English speaking subjects. If so, specify language(s), who will translate documents, who will serve as a translator. The IRB must review and approve all translated documents.
    iii. Indicate if the study will enroll subordinates of the PI or a member of the research team.
    iv. Indicate if the study will enroll pregnant women for research on fetuses and neonates
    v. Indicate if the study will enroll adult subjects who have cognitive impairment and are not able to provide legally effective informed consent. If so, specify how you will assess capacity to consent and whether you will enroll subjects who cannot consent for themselves. Describe the consent process with the Legally Authorized Representative.
    vi. Indicate if the study will enroll subjects whose capacity to consent may change during the study. If so, specify how you will assess capacity to consent and how you will obtain consent from subjects or their Legally Authorized Representative.
c. Describe all possible recruitment procedures
    i. Describe all recruitment methods and materials.
    ii. Specify if the researcher will use protected health information (PHI) to identify potential subjects – what data elements, why you couldn't recruit without accessing PHI, why you couldn't obtain patient permission, how you will protect identified PHI used for recruitment purposes, when you will remove identifiers OR justification for storing identifiers until the end of the recruitment period. You must agree to agree not to reuse or disclose this information.
    iii. Describe screening prior to consent
    iv. What recruitment materials will be provided to the potential participant (brochures/information sheets/video presentation)?
    v. Specify if you are discussing study in person or by phone prior to consent.
d. Describe the consent process, including all possible variations
    i. Indicate where and when consent be obtained
    ii. State who will conduct the consent process
    iii. Describe the steps of the consent process in detail.
    iv. Specify what documents will be used in the consent process (Informed Consent Document, Consent Letter or Information Sheet, Assent Document, Verbal/Phone Script, Exempt Information Sheet, Consent Summary, Other)
    v. Specify if the study requires a waiver of consent OR waiver of documentation of consent. If so, provide justification.
    vi. Specify how long subjects can consider whether to participate AND if they can consult with other people before deciding to participate.
    vii. Specify how long after subjects agree to participate before the study procedures begin.
e. Describe screening procedures
    i. Describe eligibility screening procedures before and/or after consent.

ii. Describe the screening schedule (number of visits, length of visits)
iii. Indicate whether screening tests/procedures are part of standard care or done for research purposes only
iv. Specify what happens with screen failures (including any data gathered during screening)

f. Describe randomization procedures (if applicable) – Specify the randomization scheme and process.
g. Describe study intervention(s)
    i. For Drug/device studies, describe:
        1. Active study agents
        2. Placebo study agents
        3. Blinding/labeling/preparation of agents
        4. Storage plans
        5. Administration
        6. Toxicities and guidelines for adjustments
    ii. For Other types of intervention studies, describe:
        1. Active intervention description
        2. Control group, if applicable
h. Describe all study assessments and activities
    i. Provide a thorough, detailed description
    ii. Provide a schedule of all study assessments and subject activities, including a tabular representation or timeline as applicable
i. Recontacting Subjects Lost to Follow Up – Indicate if the researcher will attempt to locate subjects if the research team is unable to reach them through the contact information they provided. Describe the procedures and justification for these efforts to locate subjects.
j. Subject Compensation
    i. Specify compensation method(s)
    ii. Describe the compensation plan, including amount per visit, total compensation amount, pro-rating for early withdrawal
    iii. Indicate whether the study will use the departmental cash handling plan or obtain approval from Accounting Services for a study-specific cash handling plan.

VII. Privacy and Confidentiality Protections

a. Describe privacy protections – collecting data in a private space, collecting the amount and type of information you need to answer your research question(s)
b. Describe plans and justification for collecting social security number (SSN)
c. Confidentiality / Data Security Plans – Refer to the Data Security Educational Tool and the Protecting Sensitive Data page of the UI ITS website. Specify plans for transmitting, transporting and/or storing:
    i. Paper records
    ii. Electronic records - Specify who is responsible for maintaining security. Researchers are advised to consult with the departmental IT representative to establish a data security plan that is appropriate to the level of security of the data being collected/stored for the project.
    iii. Biospecimens - Specify who is responsible for maintaining security.

d. Plans for sharing data or taking data outside the UI

VIII. Risks and Benefits

a. Describe all possible risks (physical, emotional or psychological, financial, legal or social risks).
b. Describe all steps to minimize any possible risk to subjects.
c. Describe all guaranteed direct benefits to subjects (do not include compensation or hypothesized results).
d. Describe potential benefits to society from the results of the research.

IX. Safety Monitoring Plan

a. Definition of adverse events, serious adverse events
b. Indicate who (list names and/or titles) will identify, document, and report adverse events
c. Describe procedures to monitor subject safety, such as review of aggregate data.
d. Specify who will conduct the safety monitoring. This could be a formal Data Safety Monitoring Board (DSMB) or a smaller committee that will review aggregate data on a regular basis. A smaller committee must consist of people who are not named on the research team.
e. Indicate the frequency for review of summarized safety information.
f. Describe the stopping rules with regard to efficacy and safety.

X. Data Analysis Plan

a. Describe statistical analysis methods as appropriate. Consult with a biostatistician, if appropriate. The analysis plan should correspond with the data collection described in the Study Procedures section. Describe plans for intent-to-treat methodology and any sample stratification.
b. Provide the rationale or power analysis to support the number of subjects proposed to complete the study.

XI. Literature Citations