***INSTRUCTIONS:***

* Use “TEMPLATE Protocol” to prepare a document with the information from following sections.
* As you are writing the protocol, remove all instructions in italics so that they are not contained in the final version of your protocol.
* Depending on the nature of your study, some sections may not be applicable to your research. If so, mark as “N/A”; do not remove the section headers. For retrospective chart reviews, enter “N/A” in sections denoted by \*.

**PROTOCOL TITLE:**

*Include the full protocol title.*

**PRINCIPAL INVESTIGATOR:**

*Name*

*Department*

*Telephone Number*

*Email Address*

**VERSION NUMBER:**

*Include the version number of this protocol.*

**VERSION DATE:**

*Include the version date of this protocol.*

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# Study Summary

|  |  |
| --- | --- |
| **Study Title** |  |
| **Study Design** | *(e.g., pre-post, case-control, cohort, case series, chart audit, randomization)* |
| **Primary Objective** |  |
| **Secondary Objective(s)** |  |
| **Research Intervention(s)** | *Briefly describe the study intervention or what you plan to evaluate* |
| **Study Population** | *Inclusion/exclusion criteria* |
| **Sample Size** |  |
| **Study Duration for individual participants** |  |
| **Study Specific Abbreviations/ Definitions** |  |
| **Keywords** |  |

# Objectives

* 1. Describe the purpose, specific aims, or objectives.
  2. State the hypotheses to be tested.

# Background

* 1. Describe the relevant prior experience and gaps in current knowledge.
  2. Describe any relevant preliminary data.
  3. Provide the scientific or scholarly background for, rationale for, and significance of the research based on the existing literature and how will it add to existing knowledge.

# Study Intervention

* 1. Description: *Describe the study intervention or what you plan to evaluate.*

# Procedures Involved

* 1. Describe and explain the study design.
  2. Provide a description of all research procedures being performed and when they are performed, including procedures being performed to monitor participants for safety or minimize risks.
  3. Describe procedures performed to lessen the probability or magnitude of risks.
  4. Describe the data will be collected during the study and how that data will be obtained.

# Sharing of Results with Participants

* 1. Describe whether results (study results or individual participant results) will be shared with participants or others (e.g., the participant’s primary care physicians) and if so, describe how the results will be shared.

# Study Timelines

* 1. Describe:
     + The duration of an individual’s participation in the study.
     + The duration anticipated to enroll all study participants.
     + The estimated date for the investigators to complete this study (complete primary analyses)

# Inclusion and Exclusion Criteria

* 1. Describe how individuals will be screened for eligibility. For chart reviews, describe how the sample population will be identified/scoped.
  2. Describe the criteria that define who will be included or excluded in your final study sample.
  3. Indicate specifically whether you will include or exclude each of the following special populations: (You may not include members of the below populations as participants in your research unless you indicate this in your inclusion criteria.)
     + Adults unable to consent
     + Individuals who are not yet adults (infants, children, teenagers)
     + Pregnant women
     + Prisoners

# Vulnerable Populations

* 1. If the research involves individuals who are vulnerable to coercion or undue influence, describe additional safeguards included to protect their rights and welfare.

# Local Number of Participants

* 1. Indicate the total number of participants to be accrued locally (e.g, at MGH).

# Recruitment Methods

* 1. Describe when, where, and how potential participants will be recruited.
  2. Describe the source of participants.
  3. Describe the methods that will be used to identify potential participants.
  4. Describe materials that will be used to recruit participants.
  5. Describe the amount and timing of any payments to participants.

# Withdrawal of Participants

* 1. Describe anticipated circumstances under which participants will be withdrawn from the research without their consent.
  2. Describe procedures that will be followed when participants withdraw from the research, including partial withdrawal from procedures with continued data collection.

# Risks to Participants

* 1. List the reasonably foreseeable risks, discomforts, hazards, or inconveniences to the participants related the participants’ participation in the research. Include as may be useful for the REB’s consideration, a description of the probability, magnitude, duration, and reversibility of the risks. Consider physical, psychological, social, legal, and economic risks.
  2. If applicable, indicate which procedures may have risks to the participants that are currently unforeseeable.
  3. If applicable, describe risks to others who are not participants.

# Potential Benefits to Participants

* 1. Describe the potential benefits that individual participants may experience from taking part in the research. Include as may be useful for the REB’s consideration, the probability, magnitude, and duration of the potential benefits.

**OR** Indicate if there is no direct benefit. Do not include benefits to society or others.

# Data Management and Confidentiality

* 1. Describe the data analysis plan, including any statistical procedures or power analysis.
  2. Describe the steps that will be taken to secure the data (e.g., training, authorization of access, password protection, encryption, physical controls, certificates of confidentiality, and separation of identifiers and data) during storage, use, and transmission.
  3. Describe any procedures that will be used for quality control of collected data.
  4. Describe how data will be handled locally:
     + What information will be included in the data?
     + Where and how data will be stored?
     + How long data will be stored?
     + Who will have access to the data?
     + Who is responsible for receipt or transmission of the data?
     + If applicable, how data will be transported?
     + What type of data are being collected, stored, transmitted and shared?
* *Personal Health Information (PHI)*
* *Personal Information (PI)*
* *Identified and/or De-identified Data*
* *Data for vulnerable populations*

# Provisions to Monitor the Data to Ensure the Safety of Participants\*

This section is required when research involves more than Minimal Risk to participants.

* 1. Describe:
     + The plan to periodically evaluate the data collected regarding both harms and benefits to determine whether participants remain safe.
     + How the safety information will be collected (e.g., with case report forms, at study visits, by telephone calls with participants).
     + Who will review the data.
     + Any conditions that trigger an immediate suspension of the research.

# Provisions to Protect the Privacy Interests of Participants

* 1. Describe the steps that will be taken to protect participants’ privacy interests. “Privacy interest” refers to a person’s desire to place limits on whom they interact or whom they provide personal information.
  2. Describe what steps you will take to make the participants feel at ease with the research situation in terms of the questions being asked and the procedures being performed. “At ease” does not refer to physical discomfort, but the sense of intrusiveness a participant might experience in response to questions, examinations, and procedures.
  3. Indicate how the research team is permitted to access any sources of information about the participants.

# Economic Burden to Participants\*

* 1. Describe any costs that participants may be responsible for because of participation in the research.

# Consent Process\*

* 1. Indicate whether you will you be obtaining consent, if not, please enter “N/A”, if so describe:
     + Where will the consent process take place
     + Any waiting period available between informing the prospective participant and obtaining the consent.
     + Any process to ensure ongoing consent.
     + Whether you will be following “SOP008\_09: Informed Consent Process” If not, describe:
* *The research project team members involved in the consent process.*
* *The time that will be devoted to the consent discussion.*
* *Steps that will be taken to minimize the possibility of coercion or undue influence.*
* *Steps that will be taken to ensure the participants’ understanding.*

**Non-English Speaking Participants (include if applicable)**

* + - Indicate what language(s) other than English are understood by prospective participants or representatives.
    - If participants who do not speak English will be enrolled, describe the process to ensure that the oral and written information provided to those participants will be in that language. Indicate the language that will be used by those obtaining consent.

**Participants who are not yet adults (include if applicable)**

* + - Describe the criteria that will be used to determine whether a prospective child participant is able to consent to treatments or procedures involved in the research.
    - Describe whether parental permission will be obtained from:
* *Both parents unless one parent is deceased, unknown, incompetent, or not reasonably available, or when only one parent has legal responsibility for the care and custody of the child.*
* *One parent even if the other parent is alive, known, competent, reasonably available, and shares legal responsibility for the care and custody of the child.*
  + - Describe whether permission will be obtained from individuals other than parents, and if so, who will be allowed to provide permission. Describe the process used to determine these individuals’ authority to consent to each child’s general medical care.
    - Indicate whether assent will be obtained from all, some, or none of the children. If assent will be obtained from some children, indicate which children will be required to assent.
    - When assent of children is obtained describe whether and how it will be documented.

**Cognitively Impaired Adults (include if applicable)**

* + - Describe the process to determine whether an individual is capable of consent.

# Setting

* 1. Describe the sites or locations where your research team will conduct the research.
     + Identify where your research team will identify and recruit potential participants.
     + Identify where research procedures will be performed.
     + Describe the composition and involvement of any community advisors.

# Resources Available

* 1. Describe the resources available to conduct the research: For example, as appropriate:
     + Justify the feasibility of recruiting the required number of suitable participants within the agreed recruitment period. For example, how many potential participants do you have access to? What percentage of those potential participants do you need to recruit?
     + Describe the time that you will devote to conducting and completing the research.
     + Describe your facilities.
     + Describe the availability of medical or psychological resources that participants might need as a result of an anticipated consequences of the human research.
     + Describe your process to ensure that all persons assisting with the research are adequately informed about the protocol, the research procedures, and their duties and functions.

# Multi-Site Research

* 1. *Study-Wide Number of Participants*

*If this is a multicenter study, indicate the total number of participants to be accrued or charts accessed across all sites.*

* 1. If this is a multicenter study where you are a participating site/investigator, describe the local procedures for maintenance of confidentiality.
     + Where and how data will be stored by the recipient (e.g., Principal Investigator, Sponsor-Investigator)?
     + How long the data will be stored by the recipient?
     + Who will have access to the data once transferred to the recipient?