**INSTRUCTIONS:**

* Use this template to prepare a document with the information from the following sections.
* Depending on the nature of what you are doing, some sections may not be applicable to your research. If so mark as “NA”. For example, a local single-site study would not require information in section 6.0. For subsections, like 1.x or 8.x, you can delete it if it’s not applicable.
* When you write a protocol, keep an electronic copy. You will need to modify this copy when making changes.
* As you are writing the protocol, remove all instructions in italics so that they are not contained in the final version of your protocol.

**PROTOCOL TITLE:**

*Include the full protocol title.*

**PRINCIPAL INVESTIGATOR:**

*Name*

*Department*

*Address*

*Telephone Number*

*Email Address*

**STUDY LOCATION(S):**

*List each location, name, department and address*

*Name of locations*

*Department*

*Address*

**VERSION NUMBER:**

*Include the version number of this protocol.*

**VERSION DATE:**

*Include the version date. This is the date this protocol version was finalized.*

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# 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.

# Inclusion and Exclusion Criteria

* 1. Describe how individuals will be screened for eligibility.
  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 above populations as subjects 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

# Study-Wide Number of Subjects

* 1. If this is a multicenter study for which you are the lead investigator, indicate the total number of subjects to be accrued across all sites.

# Study-Wide Recruitment Methods

If this is a multicenter study for which you are the lead investigator and subjects will be recruited by methods not under the control of the local site (e.g., call centers, national advertisements), describe those methods. Local recruitment methods for non-multicenter research are described later in the protocol.

* 1. Describe when, where, and how potential subjects will be recruited.
  2. Describe the methods that will be used to identify potential subjects.
  3. Describe materials that will be used to recruit subjects. (Attach copies of these documents with the application. For advertisements, attach the final copy of printed advertisements. When advertisements are taped for broadcast, attach the final audio/video tape. You may submit the wording of the advertisement prior to taping to preclude re-taping because of inappropriate wording, provided the IRB reviews the final audio/video tape.)

# Multi-Site Research

* 1. If this is a multi-site study where you are the lead investigator, describe the processes to ensure communication among sites, such as:
     + All sites have the most current version of the protocol, consent document, and HIPAA authorization.
     + All required approvals have been obtained at each site (including approval by the site’s IRB of record).
     + All modifications have been communicated to sites, and approved (including approval by the site’s IRB of record) before the modification is implemented.
     + All engaged participating sites will safeguard data as required by local information security policies.
     + All local site investigators conduct the study appropriately.
     + All non-compliance with the study protocol or applicable requirements will be reported in accordance with local policy.
  2. Describe the method for communicating to engaged participating sites:
     + Problems.
     + Interim results.
     + The closure of a study.

# Study Timelines

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

# Study Endpoints

* 1. Describe the primary and secondary study endpoints.
  2. Describe any primary or secondary safety endpoints.

# 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 subjects for safety or minimize risks.
  3. Describe:
     + Procedures performed to lessen the probability or magnitude of risks.
     + All drugs and devices used in the research and the purpose of their use, and their regulatory approval status.
     + The source records, including medical or educational records, that will be used to collect data about subjects. (Attach all surveys, scripts, and data collection forms.)
  4. What data will be collected, including long-term follow-up.
  5. For HUD uses provide a description of the device, a summary of how you propose to use the device, including a description of any screening procedures, the HUD procedure, and any patient follow-up visits, tests or procedures.

# Data and Specimen Banking

* 1. If data or specimens will be banked for future use, describe where the specimens will be stored, how long they will be stored, when they will be destroyed (if ever), how the specimens will be accessed, and who will have access to the specimens.
  2. List the data to be stored or associated with each specimen.
  3. Describe the procedures to release data or specimens, including: the process to request a release, approvals required for release, who can obtain data or specimens, and the data to be provided with specimens, including whether those data will be identifiable to others.

# Data and Specimen Management

* 1. Describe the data analysis plan, including any statistical procedures.
  2. Provide a power analysis, if necessary.
  3. Describe the steps that will be taken to secure the data to maintain confidentiality (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.
  4. Describe any procedures that will be used for quality control of collected data.
  5. Describe how data and specimens will be handled study-wide:
     + What information will be included in that data or associated with the specimens?
     + Where and how data or specimens will be stored?
     + How long the data or specimens will be stored?
     + Who (role on the study) will have access to the data or specimens?
     + Who (role on the study) is responsible for receipt or transmission of the data or specimens?
     + How data and specimens will be transported?

# Provisions to Monitor the Data to Ensure the Safety of Subjects

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

* 1. Describe:
     + The plan to periodically evaluate the data collected regarding both harms and benefits to determine whether subjects remain safe. The plan might include establishing a data monitoring committee and a plan for reporting data monitoring committee findings to the IRB and the sponsor.
     + What data are reviewed, including safety data, untoward events, and efficacy data.
     + How the safety information will be collected (e.g., with case report forms, at study visits, by telephone calls with participants).
     + The frequency of data collection, including when safety data collection starts.
     + Who will review the data.
     + The frequency or periodicity of review of cumulative data.
     + The statistical tests for analyzing the safety data to determine whether harm is occurring.
     + Any conditions that trigger an immediate suspension of the research.

# Withdrawal of Subjects\*

* 1. Describe anticipated circumstances under which subjects will be withdrawn from the research without their consent, including stopping participation for safety reasons.
  2. Describe any procedures for orderly termination.
  3. Describe procedures that will be followed when subjects withdraw from the research, including partial withdrawal from procedures with continued data collection.

# Risks to Subjects\*

* 1. List the reasonably foreseeable risks, discomforts, hazards, or inconveniences to the subjects related the subjects’ participation in the research. Include as may be useful for the IRB’s consideration, describe 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 subjects that are currently unforeseeable.
  3. If applicable, indicate which procedures may have risks to an embryo or fetus should the subject be or become pregnant.
  4. If applicable, describe risks to others who are not subjects, e.g., risks to ethnic or cultural groups, risks to sexual partners of subjects, etc.

# Potential Benefits to Subjects

* 1. Describe the potential benefits that individual subjects may experience from taking part in the research. Include as may be useful for the IRB’s consideration, the probability, magnitude, and duration of the potential benefits.
  2. Indicate if there is no direct benefit. Do not include benefits to society or others.

# 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.

# Community-Based Participatory Research

* 1. Describe involvement of the community in the design and conduct of the research.

Note: “Community-based Participatory Research” is a collaborative approach to research that equitably involves all partners in the research process and recognizes the unique strengths that each brings. Community-based Participatory Research begins with a research topic of importance to the community, has the aim of combining knowledge with action and achieving social change to improve health outcomes and eliminate health disparities.

# Sharing of Results with Subjects

* 1. Describe whether results (study results or individual subject results, such as results of investigational diagnostic tests, genetic tests, or incidental findings) will be shared with subjects or others (e.g., the subject’s primary care physicians) and if so, describe how it will be shared.

# 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 subjects.
     + Identify where research procedures will be performed.
     + Describe the composition and involvement of any community advisory board.
     + For research conducted outside of the institution and its affiliates describe:
       - Site-specific regulations or customs affecting the research for research outside the institution.
       - Local scientific and ethical review structure outside the institution.

# Resources Available

* 1. Describe other resources available to conduct the research: For example, as appropriate:
     + Justify the feasibility of recruiting the required number of suitable subjects within the agreed recruitment period. For example, how many potential subjects do you have access to? What percentage of those potential subjects do you need to recruit?
     + Describe the time that you will devote to conducting and completing the research. (Note: This description is intended to provide the IRB with information relative to conduct of the study as relevant for the protection of research subjects, not for effort reporting.)
     + Describe your facilities. (Note: This description is intended to provide the IRB with information relative to conduct of the study as relevant for the protection of research subjects, not for Facilities and Administration considerations.)
     + Describe the availability of medical or psychological resources that subjects 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.

# Recruitment Methods

* 1. Describe when, where, and how potential subjects will be recruited.
  2. Describe the source of subjects.
  3. Describe the methods that will be used to identify potential subjects.
  4. Describe materials that will be used to recruit subjects. (Attach copies of these documents with the application. For advertisements, attach the final copy of printed advertisements. When advertisements are taped for broadcast, attach the final audio/video file. You may submit the wording of the advertisement prior to taping to preclude re-taping because of inappropriate wording, provided the IRB reviews the final audio/video file.)
  5. Describe the amount, timing, and method of any payments to subjects. (E.g., Gift card, ClinCard, check.)

# Local Number of Subjects

* 1. Indicate the total number of subjects to be accrued locally.
  2. If applicable, include a break-down of subjects by study location or procedure group.
  3. If applicable, distinguish between the number of subjects who are expected to be enrolled and screened, and the number of subjects needed to complete the research procedures (i.e., numbers of subjects excluding screen failures.)

# Confidentiality

* 1. If this is a multicenter study, describe the local procedures for maintenance of confidentiality.
     + Where and how data or specimens will be stored locally?
     + How long the data or specimens will be stored locally?
     + Who will have access to the data or specimens locally?
     + Who is responsible for receipt or transmission of the data or specimens locally?
     + How data and specimens will be transported locally?

# Provisions to Protect the Privacy Interests of Subjects

* 1. Describe the steps that will be taken to protect subjects’ privacy interests. “Privacy interest” refers to a person’s desire to place limits on with whom they interact or to whom they provide personal information.
  2. Describe what steps you will take to make the subjects 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 subject 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 subjects. (E.g., What permission does the research staff have to access medical records or other sensitive information?)

# Compensation for Research-Related Injury

* 1. If the research involves more than Minimal Risk to subjects, describe the available compensation in the event of research-related injury.
  2. Provide a copy of contract language, if any, relevant to compensation for research-related injury.

# Economic Burden to Subjects

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

# Consent Process

* 1. Indicate whether you will you be obtaining consent, and if so describe:
     + Where will the consent process take place
     + Any waiting period available between informing the prospective subject and obtaining the consent.
     + Any process to ensure ongoing consent.
     + Describe:
       - The role of the individuals listed in the application as being 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 subjects’ understanding.

**Non-English Speaking Subjects**

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

**Waiver or Alteration of Consent Process (consent will not be obtained, required information will not be disclosed, or the research involves deception)**

* + - Ensure you have provided sufficient information for the IRB to make these determinations.
    - If the research involves a waiver of the consent process for planned emergency research, ensure you have provided sufficient information for the IRB to make these determinations.

**Subjects who are not yet adults (infants, children, teenagers)**

* + - Describe the criteria that will be used to determine whether a prospective subject has not attained the legal age for consent to treatments or procedures involved in the research under the applicable law of the jurisdiction in which the research will be conducted. (E.g., individuals under the age of 18 years.)
    - 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. The IRB allows the person obtaining assent to document assent on the consent document and does not routinely require separate assent documents and does not routinely require children to sign assent documents, although such option is available in the template consent document referenced in Section 29 below.

**Cognitively Impaired Adults**

* + - Describe the process to determine whether an individual is capable of consent. The IRB allows the person obtaining assent to document assent on the consent document and does not routinely require separate assent documents and does not routinely require cognitively impaired adults to sign assent documents, although such option is available in the template consent document referenced in Section 28 below.

**Adults Unable to Consent**

* + - List the individuals from whom permission will be obtained in order of priority. (E.g., durable power of attorney for health care, court appointed guardian for health care decisions, spouse, and adult child.)
    - Describe the process for assent of the subjects. Indicate whether:
      * Assent will be required of all, some, or none of the subjects. If some, indicate which subjects will be required to assent and which will not.
      * If assent will not be obtained from some or all subjects, an explanation of why not.
      * Describe whether assent of the subjects will be documented and the process to document assent. The IRB allows the person obtaining assent to document assent on the consent document and does not routinely require separate assent documents and does not routinely require subjects to sign assent documents, although such option is available in the template consent document referenced in Section 28 below.
    - Describe the process for obtaining consent from subjects who were previously unable to consent for themselves.

**Adults Unable to Consent**

* + - For HUD, uses provide a description of how the patient will be informed of the potential risks and benefits of the HUD and any procedures associated with its use.

# Process to Document Consent in Writing

* 1. Describe whether and how consent of the subject will be documented in writing.
  2. (If you will document consent in writing, attach a consent document in your application. If you will obtain consent, but not document consent in writing, attach a consent script in your application. You may use the consent form template to create the consent document or script.)

# Drugs or Devices

* 1. If the research involves drugs or devices, describe your plans to store, handle, and administer those drugs or devices so that they will be used only on subjects and be used only by authorized investigators.
  2. If the drug is investigational (has an IND) or the device has an IDE or a claim of an abbreviated IDE (non-significant risk device), include the following information:
     + Identify the holder of the IND/IDE/Abbreviated IDE.
     + Identify/List the National Clinical Trial Number (NCT)
     + Explain procedures followed to comply with USFDA sponsor requirements for the following:

|  |  |  |  |
| --- | --- | --- | --- |
|  | ***Applicable to:*** | | |
| ***USFDA Regulation*** | ***IND Studies*** | ***IDE studies*** | ***Abbreviated IDE studies*** |
| ***21 CFR 11*** | ***X*** | ***X*** |  |
| ***21 CFR 54*** | ***X*** | ***X*** |  |
| ***21 CFR 210*** | ***X*** |  |  |
| ***21 CFR 211*** | ***X*** |  |  |
| ***21 CFR 312*** | ***X*** |  |  |
| ***21 CFR 812*** |  | ***X*** | ***X*** |
| ***21 CFR 820*** |  | ***X*** |  |