**PROTOCOL TITLE:**

*Include the full protocol title.*

**PRINCIPAL INVESTIGATOR:**

*Name*

*Department*

*Telephone Number*

*Email Address*

**VERSION NUMBER/DATE:**

*Include the version number and date of this protocol.*

**REVISION HISTORY**

|  |  |  |  |
| --- | --- | --- | --- |
| **Revision #** | **Version Date** | **Summary of Changes** | **Consent Change?** |
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# Study Summary

|  |  |
| --- | --- |
| **Protocol Information** | **Description** |
| **Study Title** |  |
| **Study Design** |  |
| **Primary Objective** |  |
| **Secondary Objective(s)** |  |
| **Research Intervention(s)/ Investigational Agent(s)** |  |
| **IND/IDE #** |  |
| **Study Population** |  |
| **Sample Size** |  |
| **Study Duration for individual participants** |  |
| **Study Specific Abbreviations/ Definitions** |  |

# Objectives\*

## *Describe the purpose, specific aims, or objectives.*

## *State the hypotheses to be tested.*

# Background\*

## *Describe the relevant prior experience and gaps in current knowledge.*

## *Describe any relevant preliminary data.*

## *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.*

## *Include references, as appropriate*

# Study Endpoints\*

## *Describe the primary and secondary study endpoints.*

## *Describe any primary or secondary safety endpoints.*

# Study Intervention/Investigational Agent

## Description: *Describe the study intervention and/or investigational agent (e.g., drug, device) that is being evaluated.*

## Drug/Device Handling: *If the research involves drugs or device, 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.*

* + - If the control of the drugs or devices used in this protocol will be accomplished by following an established, approved organizational SOP (e.g., Research Pharmacy SOP for the Control of Investigational Drugs, etc.), please reference that SOP in this section.

## *If the drug is investigational (has an IND) or the device has an IDE or a claim of abbreviated IDE (non-significant risk device), include the following information:*

* + - Identify the holder of the IND/IDE/Abbreviated IDE.
    - Explain procedures followed to comply with sponsor requirements for FDA regulated research for the following:

# Procedures Involved\*

## *Describe and explain the study design.*

## *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.*

## 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 that will be used to collect data about subjects. (Attach all surveys, scripts, and data collection forms.)

## *What data will be collected during the study and how that data will be obtained.* *Specify each type of data file (data only, audio, video, image including photos, CT, MRI, x-ray or other)*

## *If there are plans for long-term follow-up (once all research related procedures are complete), what data will be collected during this period.*

## *HIPAA Tracking technologies: Will a website, mobile application, or other tracking device (i.e., wearable) be created or used? If yes, please elaborate on all tracking technologies to be used, including third party tracking technologies (i.e., Google Analytics).*

## *For Humanitarian Use Device (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\*

## *If data or specimens will be banked for future use, describe where the specimens will be stored, how long they will be stored, how the specimens will be accessed, and who will have access to the specimens.*

## *List the data to be stored or associated with each specimen.*

## *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.*

# Sharing of Results with Subjects\*

# *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 the results will be shared.*

# Study Timelines\*

## 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).

# Inclusion and Exclusion Criteria\*

## *Describe how individuals will be screened for eligibility.*

## *Describe the criteria that define who will be included or excluded in your final study sample.*

## *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

# Vulnerable Populations\*

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

* + - If the research involves pregnant women, review HRP-412 - CHECKLIST - Pregnant Women to ensure that you have provided sufficient information.
    - If the research involves neonates of uncertain viability or non-viable neonates, review HRP-413 - CHECKLIST - Non-Viable Neonates or HRP-414 - CHECKLIST - Neonates of Uncertain Viability to ensure that you have provided sufficient information.
    - If the research involves prisoners, review HRP-415 - CHECKLIST - Prisoners to ensure that you have provided sufficient information.
    - If the research involves persons who have not attained the legal age for consent to treatments or procedures involved in the research (“children”), review the HRP-416 - CHECKLIST - Children to ensure that you have provided sufficient information.
    - If the research involves cognitively impaired adults, review HRP-417 - CHECKLIST - Cognitively Impaired Adults to ensure that you have provided sufficient information.

# Local Number of Subjects

## *Indicate the total number of subjects to be accrued locally.*

## *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.)*

# Recruitment Methods

## *Describe when, where, and how potential subjects will be recruited. If applicable, describe procedures for oral or written communication with the prospective subject or legally authorized representative that will be done for purposes of screening, recruiting, or determining eligibility.*

## *Describe the source of subjects.*

* + - Describe the methods that will be used to identify potential subjects. If applicable, describe procedures for accessing records or stored identifiable biospecimens for purposes of screening, recruiting, or determining eligibility.

## *HIPAA Waiver of Authorization for Screening*

* + - Review the HRP-441 - CHECKLIST – HIPAA Waiver of Authorization to ensure you have provided sufficient information for the IRB to make these determinations.
    - List the source(s) of PHI applicable to the waiver (e.g., EPIC, physician’s office records, clinical database, etc.). Be as specific as possible.
    - Describe the PHI that will be accessed (viewed) for the research under the waiver (e.g., medical record number, health history, diagnosis, test results, etc.).
    - Describe information that will be recorded. Be as specific as possible, including date ranges, when applicable. Spell out all abbreviations.
    - Provide a copy of the data collection form(s) used (e.g., Excel spreadsheet, etc.) to record the information above.
    - Explain why access to and/or use of the PHI is essential to conduct the research.
    - Explain how the PHI described above represents the minimum necessary information to accomplish the objectives of the research.
    - Explain how the access, use, or disclosure of PHI presents no more than a minimal risk to the privacy of the individual.
    - Describe your plan to protect identifiers and associated PHI (or links to identifiable data) from improper use or disclosure, including where PHI will be stored (include both building/room number and/or specific server information), what security measures will be applied, and who will have access to the information. Describe the safeguards used for electronic records, hard copy records, or both, as applicable.
    - Describe the plan to destroy the identifiers at the earliest opportunity consistent with the conduct of the research. Include when and how identifiers will be destroyed; OR Provide the legal, health, or research justification for retaining the identifiers. Legal justification should include a brief description/citation of the legal requirement.

## *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.)*

## *Describe the amount and timing of any payments to subjects.*

# Withdrawal of Subjects\*

## *Describe anticipated circumstances under which subjects will be withdrawn from the research without their consent.*

## *Describe any procedures for orderly termination.*

## *Describe procedures that will be followed when subjects withdraw from the research, including partial withdrawal from procedures with continued data collection.*

# Risks to Subjects\*

## *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, a description of the probability, magnitude, duration, and reversibility of the risks. Consider physical, psychological, social, legal, and economic risks.*

## *If applicable, indicate which procedures may have risks to the subjects that are currently unforeseeable.*

## *If applicable, indicate which procedures may have risks to an embryo or fetus should the subject be or become pregnant.*

## *If applicable, describe risks to others who are not subjects.*

# Potential Benefits to Subjects\*

## *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.*

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

# Data Management\* and Confidentiality

## *Describe the data analysis plan, including any statistical procedures or power analysis.*

## *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.*

## *Describe any procedures that will be used for quality control of collected data.*

## *Describe how data or specimens will be handled study-wide:*

* *What information will be included in that data or associated with the specimens?* *Identify if any data-source is a free-text fields. Include an Appendix of fields if necessary.*
* *Where and how data or specimens will be stored?* *Specify where each data file listed in Section 7.0 will be stored (Lifespan REDCap, Lifespan SQL Database, Lifespan SharePoint, Lifespan Departmental Server Share (“Network Drive”), Lifespan Home Directory, Lifespan IS Authorized cloud storage (Describe):, encrypted External Hard Drive, encrypted Portable Media (CD, DVD, flash, tape, audio recorder, handheld device, etc.), other internal or external storage location)*
* *Will any data or specimens leave the institution? Specify what data/specimens will leave the institution. Include an Appendix of fields if necessary.*
* *Will any data or specimens be received by the institution?*
* *How long the data or specimens will be stored?*
* *Who will have access to the data or specimens?*
* *Who is responsible for receipt or transmission of the data or specimens?*
* *How data or specimens will be transported?*
* *When and how will data or specimens be destroyed?*
* *Note: if there are multiple pathways of data/specimen movement, consider a table or separating into multiple sections for each direction and method of transfer. Include an Appendix if necessary.*

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

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

## 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.

# Provisions to Protect the Privacy Interests of Subjects

## *Describe the steps that will be taken to protect subjects’ privacy interests. “Privacy interest” refers to a person’s desire to place limits on whom they interact or whom they provide personal information.*

## *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.*

## *Indicate how the research team is permitted to access any sources of information about the subjects.*

# Compensation for Research-Related Injury

## *If the research involves more than Minimal Risk to subjects, describe the available compensation in the event of research related injury.*

## *Provide a copy of contract language, if any, relevant to compensation for research-related injury.*

# Economic Burden to Subjects

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

# Consent Process/HIPAA Authorization

## *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.
    - Whether you will be following HRP-090 - SOP - Informed Consent Process for Research. If not, 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 subject’s 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 that language. Indicate the language that will be used by those obtaining consent.
    - Review HRP-317 - WORKSHEET - Short Form of Consent Documentation to ensure you have provided sufficient information for the IRB to make these determinations.

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

* + - Review the HRP-410 - CHECKLIST - Waiver or Alteration of Consent Process to 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, please review the HRP-419 - CHECKLIST - Waiver of Consent Process for Emergency Research to ensure you have provided sufficient information for the IRB to make these determinations.

## *Waiver or Alteration of Authorization (authorization will not be obtained, required signature will not be obtained)*

* + - Review the HRP-441 - CHECKLIST - HIPAA Waiver of Authorization to ensure you have provided sufficient information for the IRB to make these determinations.
    - List the source(s) of PHI applicable to the waiver (e.g., EPIC, physician’s office records, clinical database, etc.). Be as specific as possible.
    - Describe the PHI that will be accessed (viewed) for the research under the waiver (e.g., medical record number, health history, diagnosis, test results, etc.).
    - Describe information that will be recorded. Be as specific as possible, including date ranges, when applicable. Spell out all abbreviations.
    - Provide a copy of the data collection form(s) used (e.g., Excel spreadsheet, etc.) to record the information above.
    - Explain why access to and/or use of the PHI is essential to conduct the research.
    - Explain how the PHI described above represents the minimum necessary information to accomplish the objectives of the research.
    - Explain how the access, use, or disclosure of PHI presents no more than a minimal risk to the privacy of the individual.
    - Describe your plan to protect identifiers and associated PHI (or links to identifiable data) from improper use or disclosure, including where PHI will be stored (include both building/room number and/or specific server information), what security measures will be applied, and who will have access to the information. Describe the safeguards used for electronic records, hard copy records, or both, as applicable.
    - Describe the plan to destroy the identifiers at the earliest opportunity consistent with the conduct of the research. Include when and how identifiers will be destroyed; OR Provide the legal, health, or research justification for retaining the identifiers. Legal justification should include a brief description/citation of the legal requirement.

## *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 assent documents and does not routinely require cognitively impaired adults to sign assent documents.
    - Review HRP-417 - CHECKLIST - Cognitively Impaired Adults to ensure you have provided sufficient information for the IRB to make these determinations.

## *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.)
      * For research conducted in the state, review HRP-013 - SOP - LARs, Children, and Guardians to be aware of which individuals in the state meet the definition of “legally authorized representative.”
      * For research conducted outside of the state, provide information that describes which individuals are authorized under applicable law to consent on behalf of a prospective subject to their participation in the procedure(s) involved in this research. One method of obtaining this information is to have a legal counsel or authority review your protocol along the definition of “legally authorized representative” in HRP-013 - SOP - LARs, Children, and Guardians.

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

* + - Describe the process for assent of the subjects. Indicate whether:
      * Assent will be required of all, some, or none of the subjects. If some, indicated, 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 assent documents and does not routinely require subjects to sign assent documents.

## *Humanitarian Use Device (HUD)*

* + - 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

## *Describe whether you will be following HRP-091 - SOP - Written Documentation of Consent. If not, describe whether and how consent of the subject will be documented in writing.*

## *If your research presents no more than minimal risk of harm to subjects and involves no procedures for which written documentation of consent is normally required outside of the research context, the IRB will generally waive the requirement to obtain written documentation of consent.*

## *(If you will document consent in writing, attach a consent document. If you will obtain consent, but not document consent in writing, attach a consent script. Review HRP-411 - CHECKLIST - Waiver of Written Documentation of Consent to ensure that you have provided sufficient information. You may use HRP-502 - TEMPLATE CONSENT DOCUMENT to create the consent document or script.)*

# Setting

## *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 organization and its affiliates describe:
      * Site-specific regulations or customs affecting the research for research outside the organization.
      * Local scientific and ethical review structure outside the organization.

# Resources Available

## *Describe the 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.
    - Describe your facilities.
    - Describe the availability of medical or psychological resources that subjects might need as a result of an anticipated consequence 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\*

## *Study-Wide Number of Subjects\**

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

## *Study-Wide Recruitment Methods\**

* + - If this is a multicenter study 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 are described later in the protocol.
    - Describe when, where, and how potential subjects will be recruited.
    - Describe the methods that will be used to identify potential subjects.
    - 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.)
    - If this is a multi-site study where you are the lead investigator, describe the processes to ensure communication among sites. See HRP-830 - WORKSHEET - Communication and Responsibilities. All sites have the most current version of the protocol, consent document, and HIPAA authorization.
    - All required approvals (initial, continuing review and modifications) 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, including secure transmission of data, as required by local information security policies.\
    - All local site investigators conduct the study in accordance with applicable federal regulations and local laws.
    - All non-compliance with the study protocol or applicable requirements will be reported in accordance with local policy.

## Describe the method for communicating to engaged participating sites *(see HRP-830 - WORKSHEET - Communication and Responsibilities):*

* + - Problems (inclusive of reportable events).
    - Interim results.
    - The closure of a study.

## *If this is a multicenter study where you are a participating site/investigator, describe the local procedures for maintenance of confidentiality. (See HRP-830 - WORKSHEET - Communication and Responsibilities.)*

* + - 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?

# Appendices

* *Include additional/supporting information such as tables, graphs, graphics*
* *Include a complete list of data fields to be collected under waiver of authorization, or transferred outside the institution etc.*