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| **INSTRUCTIONS:**   * This template can be used to prepare a protocol document with the information requested in the sections below. This template is intended for investigator-initiated clinical research. * Some sections may not be applicable to your research. If so, mark as “NA”. For subsections, you can delete them if they are not applicable. * Delete these instructions and remove all directional text so they are not included in the final version of the protocol. * Change the header/footer to reflect the study title and version date of the document. * Keep the final IRB approved version of this protocol in your study records. Access the most current approved version of the protocol via iSTAR if you need to make an amendment to change the research. |

**PROTOCOL TITLE:**

Include the full protocol title.

**PRINCIPAL INVESTIGATOR:**

Name

Department

Telephone Number

Email Address

**STUDY ABSTRACT**

* Provide a summary of the research (more than 250 characters).

# 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.

**STUDY ENDPOINTS**

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

**STUDY INTERVENTION / INVESTIGATIONAL TEST ARTICLE**

* Describe the study intervention(s) and/or investigational test article (e.g., drug, device) that is being evaluated.
* If the drug or device is investigational (has an IND or IDE) 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
* Drug/Device Handling: 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.
  + 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.

**PROCEDURES INVOLVED**

* Describe and explain the research study design.
* Provide a description of all procedures required for the research and when they are performed, including any procedures performed to monitor subjects for safety or to minimize risks.
* For studies that collect blood samples, describe the procedures for blood sampling and the volume of blood collected.
* 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 FDA regulatory approval status.
  + Source records and data that will be accessed/used to collect information from or about the subjects. (Include all surveys, scripts, and data collection forms with the IRB submission.)
  + What data will be collected during the study and how that data will be obtained.
* If there are plans for long-term follow-up (once all research related procedures are complete), what data will be collected during this period.
* For Humanitarian Use Device (HUD) protocols 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.

**FUTURE USE OF DATA/SPECIMENS**

State whether data/specimens collected in this study may be used in future research.

*The below sections may be deleted if anonymous and/or deidentified/anonymized data/specimens will be used in future research.*

If creating a repository under this protocol, describe:

* The intended uses of the data/specimens (e.g., studies related to condition X, undefined purposes, etc.).
* List the data to be stored or associated with each specimen.
* Restrictions on uses of data/specimens (e.g., genetic testing, etc.).
* How long the data/specimens may be stored (e.g., indefinitely, etc.).
* Who can use the data/specimens (e.g., the investigators for this study, other investigators at CHLA or elsewhere, etc.).
* The procedures to release data/specimens, including:
  + The process to request a release of data/specimens (e.g., email, application, etc.).
  + Procedures for reviewing the requests (e.g., reviewed by repository manager/gatekeeper, repository committee, etc.).
  + Documents/agreements required for release of data/specimens (e.g., protocol, IRB/Ethics board approval/determination letter, MTA, DUA etc.).
  + Procedures for tracking data/specimens released/removed from the repository (e.g., spreadsheet, tracking log, etc.).
* Whether data/specimens from other CHLA IRB approved studies may be stored in the repository being created under this protocol. If this is possible, it is recommended that the following statement is added: *“Data/specimens collected under other approved CHLA research studies may be stored in this repository. Amendments will be submitted to add those CHLA IRB numbers to this protocol in the future.”*
  + This protocol will need to be amended to include the CHLA IRB number(s) that will store data/specimens in this repository. The approved CHLA IRB number(s) may be listed in this section of the protocol **OR** a separate tracking document (e.g., excel spreadsheet) may be created and upload it at item 15.2 in iStar with the following statement added in this section: *“See the tracking log in iStar for a list of the approved CHLA IRB studies submitting data/specimens into this repository.”*

If submitting data/specimens to an existing repository:Identify the existing repository(ies). If at CHLA, provide the CHLA IRB#.

**Sharing of Testing 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 the criteria that define who will be included or excluded in the study.
* Describe how individuals will be screened for eligibility.
* Indicate specifically whether you will include or exclude the following populations:
  + Adults unable to consent
  + Individuals who are not yet adults (infants, children, teenagers)
  + Non-English-Speaking Subjects or Subjects with Limited English Proficiency
  + Pregnant women
  + Prisoners

**Number of Subjects**

* Indicate the total number of subjects to be accrued at CHLA.
* 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.
* 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 IRB submission).
* 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 any direct 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.
* If the study has no direct benefit to subjects, state such. You may include indirect 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 identifiable information will be included or associated with the data or specimens
  + Where and how data or specimens will be stored
  + 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

**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.

**Costs to Subjects**

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

**Consent Process**

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.
* The process for obtaining consent, and whether you will be following “SOP: Informed Consent Process for Research (HRP-090).”
* Any process to ensure ongoing consent.
* 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.

**Process to Document Consent in Writing**

Describe the process for documenting consent and/or how consent of the subject will be documented in writing. Indicate whether you will be following “SOP: Written Documentation of Consent (HRP-091).”

**Setting**

* Describe the sites or locations where your research team will conduct the research.
* 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.

Examples:

* 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 the facilities available to conduct the research.
* Describe the availability of medical or psychological resources that subjects might need, when applicable to the 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.