|  |
| --- |
| **GUIDANCE & INSTRUCTIONS[[1]](#endnote-1):**  The investigator must demonstrate that the study is consistent with sound scientific design and that the design is sufficient to achieve the study objectives. The protocol must provide sufficient details to provide the IRB with a basis for its decisions. HSPP staff will perform an administrative pre-review of submissions and may request additional information, changes, and/or clarifications to ensure the submission is complete. The IRB cannot approve studies that provide insufficient information.  Below are instructions and guidance to assist you in developing your protocol.   * Visit the HSPP website to access and review guidance documents, standard operating procedures (SOPs), templates, worksheets, etc. * The purpose of this template is to prepare a protocol document for **investigator-initiated clinical research**. * If you are using this template for a Quality Improvement (QI) project, then use the term “project” rather than “research” or “study” since those terms are used to describe research. The QI proposal must explain why the project is QI rather than research, including whether the information learned may contribute to generalizable knowledge. The IRB does not approve how privacy, data storage, and confidentiality procedures are implemented for QI projects, nor are they responsible for making consenting and HIPAA determinations for QI projects. Review the “Differences Between Research and Quality Improvement Activities” guidance document. * Some sections may not apply to your research. If so, keep the heading and state “N/A.” * Delete these instructions and remove all directional/informational text/boxes (blue and red) so they are not included in the final version of the protocol. * Insert the CHLA IRB number and version date of the document in the footer. * Keep the final IRB-approved version of this protocol in your study records. If you need to amend the research, access the most current approved version of the protocol via the IRB application. * It is suggested that you add a revision history table/section at the end of the protocol to track changes made to it. |

**PROTOCOL TITLE:** Include the full protocol title. This title must match the full title within the IRB application.

**PRINCIPAL INVESTIGATOR:**

Name

Department

Telephone Number

Email Address

**STUDY ABSTRACT**

Provide a lay summary of the research by briefly explaining each of the following in 1 to 2 sentences: (1) rationale; (2) intervention; (3) objectives or purpose; (4) study population(s); (5) study methodology; (6) study endpoints or outcomes; and (7) the data analysis plan. In addition, describe whether this is a multi-site study. The abstract should be concise, not exceeding 250 characters, yet detailed enough to extend beyond just a few sentences for clarity and completeness.

# OBJECTIVES/SPECIFIC AIMS/PURPOSE/HYPOTHESIS

* Objective(s): Clearly state the main goal(s) of the research. This could involve testing a hypothesis, evaluating the efficacy of an intervention, or exploring the relationship between variables. Outline any additional goals the study will address which are secondary to the main research questions. These can include exploring side effects, understanding mechanisms, or examining associations between secondary variables.
* Specific Aim(s): Detail the specific aims that will guide the research activities. These may be more detailed objectives that contribute to achieving the primary and secondary objectives, often phrased as measurable outcomes.
* Purpose: Describe in lay terms the goal(s) of the study and what the study seeks to accomplish.
* Hypothesis: If applicable, include the hypothesis or hypotheses that the study is designed to test.

**BACKGROUND**

* Summarize relevant research findings related to the study topic. This should highlight key studies, summarize current knowledge, describe any relevant preliminary data, and identify gaps or inconsistencies in the literature.
* Provide the rationale for and significance of the research based on existing literature and how it will add to existing knowledge.
* Elaborate on the significance of the problem and the expected impact of the study’s results. Discuss how the research could advance understanding, influence practice, or inform policy in the relevant field.
* List relevant reference citations at the end of the protocol.

**STUDY POPULATION**

Describe the criteria that define who will be included or excluded in the study (such as age range, race, ethnicity, gender, language, diagnoses, lab values, etc.). For each subject cohort/group (e.g., diseased group, control group, parent subjects, etc.), separate inclusion and exclusion criteria should be listed.

For studies where the parent/legal guardian is enrolled, describe whether the parent/legal guardian must participate in the research for their child to participate.

Indicate specifically whether you will include or exclude the following populations:

* Cognitively impaired adults
* Individuals who are not yet adults (infants, children, teenagers)
* Non-English-Speaking Subjects or Subjects with Limited English Proficiency
* Pregnant women/Human fetuses
* Prisoners/Detainees
* Wards
* CHLA employees/students
* Healthy volunteers undergoing clinical/medical procedures for research purposes. **NOTE**: If you enroll this population and the research involves clinical/medical procedures (e.g., MRI), provide the rationale for including this population.

**Inclusion Criteria for XX Cohort/Group**

* List all the inclusion criteria. **REMINDER**: Be sure to list the minimum and maximum age range of all subjects to be enrolled.

**Exclusion Criteria for XX Cohort/Group**

* List all the exclusion criteria.

Provide the rationale for excluding groups/individuals based on age, ethnicity, language, or gender, as applicable.

**NUMBER OF SUBJECTS**

* State the total number of all subjects to be accrued at CHLA. Account for screen failures, withdrawals, and dropouts/lost to follow-up. Remember, the study will be limited to the maximum number of subjects stated.
* Multiple cohorts/groups: Indicate the total number of all subjects to be accrued for each cohort/group (e.g., 100 patient subjects, 100 parent subjects, etc.).
* 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., the number of subjects excluding screen failures.)

**PROCEDURES INVOLVED**

This section must provide a thorough and detailed description of the procedures required with participation in the research. If the research involves multiple cohorts/groups, clearly identify which cohort(s)/group(s) are completing the research procedures.

If your study is a multi-center study, describe what research procedures are occurring at CHLA that are different from what is happening at the other sites.

The following should be provided in this section as applicable:

**Study Design**

Briefly describe and explain the research study design to indicate how the objective(s)/specific aim(s) will be achieved. Include the type of study (e.g., single center/multi-center, double-blind, randomized, crossover/parallel groups), the type of controls (placebo, active), specific treatment groups, and the method of subject assignment/randomization.

**Procedures**

* Describe **ALL** procedures required for the research including any procedures performed to monitor subjects for safety or to minimize risks. It is **recommended** that sub-headings for each procedure be used.
* Delineate procedures performed as part of routine care and those being done solely for research purposes. **NOTE:** The following are the CHLA IRB’s definitions of routine care and research procedures:
  + Routine care procedures: Procedures performed as part of the individual’s routine care regardless of participation in the research.
  + Research procedures: Procedures performed only because the individual is enrolled in the research OR the research protocol increases the duration and frequency, and/or modifies the technique of routine care procedures (clinical and/or diagnostic).
* Describe the duration (e.g., 10 minutes, etc.) and frequency of each procedure (e.g., one time, weekly, annually, etc.). This includes when the frequency of routine procedures changes because of participation in the research. It is **recommended** that a schedule of events table be used to illustrate when each procedure is being done.
* Describe:
  + Procedures performed to lessen the probability or magnitude of risks.
  + Source records and data that will be accessed/used to collect information from or about the subjects.
  + 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 and 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.

Below are some common research procedures with guidance on what information to include in the description **in addition** to the above (as applicable).

**Medical Record Review**

Describe:

* The source records to be reviewed to abstract information about the subject (e.g., KIDS, Cerner, Synapse, etc.). If using databases, identify the databases that will be used and specify whether the databases being accessed are clinical, research, publicly available, and/or QI databases and whether they are HIPAA protected.
* Identify whether the study team or CHLA Health Information Management will abstract the data from KIDS to create research data set(s).
* **Working with CHLA Health Information Management to obtain information from KIDS**:
  + Describe what information will be provided to HIM staff (e.g., ICD and/or CPT codes) and what information will be provided by HIM staff to the study team (e.g., patient names, MRNs). **NOTE:** **Do not** list the specific ICD and/or CPT codes or all the specific data points that will be used/collected. You may add a reference such as *“See the data collection tool within the IRB application for the specific data points to be collected.”*
* If you already have access to the datasets, explain why you already have access.
* If medical records will be requested from outside healthcare providers/other institutions (e.g., another institution such as Kaiser), describe how this will be done (e.g., subjects will be asked to sign a medical release, permission to contact the subjects outside healthcare provider, etc.).

**Interview(s)/Focus Group(s)**

Describe:

* The topic(s) that will be discussed.
* The location of the interview(s)/focus group(s) (e.g., in person, virtually, etc.).
* Whether the interview(s)/focus group(s) will be audio and/or video recorded; and if so, explain why it is necessary to audio and/or video record the interview(s)/focus group(s).
* Whether the audio and/or video recordings will be transcribed, and if so, who is transcribing them (e.g., the study team or a 3rd party vendor). **NOTE**: You **do not** need to identify the 3rd party vendor.
* If the interview(s)/focus group(s) will be video recorded, explain whether the subject’s entire face can be seen on the recording(s) and describe what steps will be taken to protect the subject’s privacy if it is essential to record their entire face (e.g., put a black bar over their eyes, etc.). If it is necessary to video record the subject’s full face and the recording(s) cannot be anonymized, then provide a rationale for why this cannot be done.
* How and where the audio and/or video recording(s) will be stored, including who may have access to the recording(s), and if and when the recording(s) will be destroyed (e.g., the recordings will be destroyed once the transcription is completed).
* Whether the recording(s) will be shared outside of CHLA and if so, explain the purpose of sharing them.

**Survey(s)/Questionnaire(s)/Psychological Assessment(s)**

Describe the survey(s)/questionnaire(s)/assessment(s) that will be used, including, as applicable, validation, the age range for which the measures are validated, and how each will be completed (e.g., online via an email link, interview with a member of the study team, paper version, etc.). **NOTE:** If these tools include placeholders to record direct identifiers (e.g., names, etc.), then ensure that they are removed (if possible) or describe how the investigator will ensure that direct identifiers are not recorded. If it is necessary to record direct identifiers on these tools, please provide the rationale.

**Specimen/Material Collection**

* Identify all the types of specimen(s)/material(s) to be collected.
* State the amount or volume of each specimen/material to be collected (e.g., 2 teaspoons of blood).
* For each specimen/material type (as applicable), state if the specimen/material is (a) leftover from routine procedures and would otherwise be discarded, (b) being collected solely for research purposes, (c) if extra (additional) is being collected during a routine procedure (e.g., 1mL of additional CSF will be collected during the subject’s routine spinal tap), (d) if extra (additional) is being collected during a research only visit because the subject is not having this collected during a routine procedure at the timepoint indicated for this study, and/or (e) obtained from a research repository and if yes, identify the source (e.g., CHLA-XX-XXXX, etc.).
* Describe how each specimen/material will be collected as applicable. For example, urine collection techniques differ for infants than for older children.
* Blood samples: Identify all the methods used to obtain research blood specimens from the following list: venipuncture (needle stick for single blood collection), venipuncture (starting a peripheral line for multiple draws), central venous catheter (use of an existing central line), central venous catheter (placement of a central line), dried newborn blood spots, finger stick, heel stick, or arterial stick. In addition, and if applicable, state whether the existing central line will be accessed solely for research purposes and/or if the research blood specimen(s) will be collected while the line is accessed for routine blood collection. If accessing a central line for research purposes, provide the rationale for doing this.
* **NOTE**: Review the *“Acceptable Blood Draw Volumes for Children in Research”* guidance document on the HSPP website. If the investigator intends to draw more research blood than is allowed under this policy, then also provide the following information in this section: (a) scientific justification that the amount of research blood is necessary and (b) the safety plans in place for monitoring subjects during the period in which the local CHLA blood volume limits will be exceeded (for risks associated with blood loss).
* Nasal, vaginal, and rectal swabs: State whether the swabs will go beyond the nares (for nasal swabs), beyond the cervical os (for vaginal swabs), or beyond the rectum (for rectal swabs).
* Describe the type of **research laboratory testing** being conducted with each specimen/material and whether this testing involves whole genome/exome sequencing. **Do not** describe testing being performed as part of routine care.

**Imaging (MRI, Ultrasound, X-rays, CT scans, DEXA, etc.)**

Describe:

* The type of research imaging to be performed (e.g., MRI) and identify which parts of the body research imaging will be performed on.
* How the research imaging will be performed in lay terms.
* The screening procedures that will be followed to ensure that it is safe for the subjects to undergo the research imaging (e.g., asked questions about whether they are wearing any metal objects such as piercings, pacemakers, screws in their bodies, etc.).
* Whether sedation/anesthesia/contrasting agent(s) will be used to obtain the research images. If yes, identify the drug(s)/agent(s) that will be used. If infants will not receive sedation/anesthesia but will be swaddled during the scan, then be sure to state this.
* For the subjects that have imaging done as part of their routine care, specify the amount of time the imaging will be ***extended*** to obtain the research images (e.g., 15 minutes, etc.). In addition, and if applicable, specify whether the research component will require ***additional*** sedation/anesthesia or if the sedation/anesthesia period for the standard of care imaging will be ***extended*** to accommodate the research imaging. If yes, state by how much will sedation/anesthesia be extended.
* **NOTE**: Review and approval from the CHLA Radiation Safety Committee (RSC) is required if the study involves the use of ionizing radiation for research purposes (i.e., outside or in addition to routine care). The “Clinical Radiation Safety Committee Application (Instructions)” is available on the HSPP website.

**Pregnancy Testing**

Describe how pregnancy testing will be performed (e.g., urine sample, blood sample, both).

|  |
| --- |
| **REMINDER:** Upload finalized and clean copies of the following documents within the IRB application (as applicable):   * Data collection tools (e.g., REDCap CRFs, excel spreadsheets. The data collection tools must include all the data points required to achieve the objectives of the study. **Do not** upload the key to the code. * Interview/Focus group scripts. * Survey(s)/Questionnaire(s)/Psychological Assessment(s). * Suicidal ideation SOP. This is required if suicidal ideation may be revealed during research procedures (e.g., interview, surveys, etc.). * Other documents that subjects may be asked to use/complete for research purposes (e.g., diaries, medication tracking logs, etc.). |

**STUDY INTERVENTION / INVESTIGATIONAL TEST ARTICLE**

* Describe the study intervention(s) and/or investigational test article (e.g., drug, device) used in the study and state whether the safety and/or effectiveness of the drug/device is being evaluated in the study.
* If the drug or device is investigational (has an IND or IDE), include the following information:
  + Name of the drug(s)/device(s) being investigated in the study, including active and placebo drugs.
  + The status of the drug/device being investigated (i.e., investigational – IND/IND Exempt, IDE/IDE exempt, new use of an FDA-approved/cleared drug/device, legally marketed in the US, or used as FDA-approved/cleared).
  + Identify the holder of the IND/IDE/Abbreviated IDE.
  + Provide the IND/IDE number or justifications for IND/IDE exemption.
  + 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 drugs or devices used in this protocol will be controlled 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.

|  |
| --- |
| **REMINDER**: Upload copies of the following (as applicable) within the IRB application if your study involves the use of investigational drug(s)/device(s): investigator brochure(s), package insert(s), user manuals, and evidence reflecting the FDA status of the drug(s)/device(s) (e.g., PMA letter, 510(k) letter, HDE letter, Class I/II exemption category, IDE, etc.). |

**STUDY TIMELINES**

Describe the total duration of an individual subject’s participation in the study. This refers to the length of time each participant will be actively involved in the study. It includes all aspects of their participation, from initial enrollment through any treatments/interventions, follow-ups, and data collection processes (including the collection of information from medical records).

**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, etc.) and if so, describe how the results will be shared. In addition, state whether study results or individual subjects’ results will be placed in the subject’s medical record. If study results are not shared, then please provide the rationale for not providing them.

**RECRUITMENT METHODS**

**REVIEW:** The *“Identification and Recruitment of Research Participants”* guidance document.

**Recruitment Strategies**

Describe the approach to recruiting all potential subjects. Include the following in the description as applicable:

* Where potential subjects will be recruited (e.g., clinic visits, etc.).
* Who is approaching/contacting potential subjects. If the potential subjects are not patients of the investigator, who will first approach/contact the potential subjects and by what method (e.g., in person, via mail, via telephone contact, etc.). **NOTE**: Remember, “cold calling” should be avoided. Cold calling is unsolicited contact by a person/group with which the subject is unfamiliar or does not have an existing relationship. If you plan to use cold calling as a method, provide the rationale for why this is necessary.
* The methods used to identify potential subjects (e.g., review of medical records, review appointment schedule, etc.).
* The materials used to recruit subjects (e.g., flyers, etc.) and how the materials will be used (e.g., a flyer will be posted in clinics, etc.).
* Subject/Participant Pools: Provide the details of how potential subjects gave their permission to be contacted for participation in future research. Include the CHLA IRB # from which the subject/participant pool(s) were created.
* CHLA Employees/Students: Describe how you will minimize the potential for employees/students to feel obligated/pressured to participate and how the potential confusion in roles will be addressed.

**Screening for Eligibility**

Describe how potential subjects will be screened to determine eligibility and when screening procedures will occur (e.g., before or after obtaining consent/assent for participation in the main study, etc.). Ensure that you clarify/describe the following:

* Identify and describe the screening procedures to be used.
* Identify what screening data will be collected, how long it will be stored, who will have access to it, and whether it will be retained or destroyed.
* Screen failures: Describe how and what screening data will be retained (if any), and when it will be destroyed, including whether identifiers are retained from those who screen fail and whether contact information is retained for future research. Provide a rationale for keeping data on screen failures.

|  |
| --- |
| **REMINDER:** Upload copies of all recruitment materials and screening tools within the IRB submission. All recruitment materials and screening tools must be reviewed and approved by the IRB before they are used. For advertisements (e.g., radio/TV announcements, etc.), the wording or script to be used must be approved by the IRB prior to taping to avoid having to re-tape because of inappropriate wording, etc. |

**CONSENT AND HIPAA AUTHORIZATION**

**REVIEW:** The guidance documents under the *“Recruitment, Consent, and Assent”* section on the HSPP website.

This section must describe your plans for obtaining consent/permission/assent and HIPAA authorization and/or requesting full waivers of consent/permission/assent and HIPAA authorization. This must be indicated for all parts of the study (e.g., screening, main study, etc.) and all cohorts/groups being enrolled. It is **recommended** that sub-headings be used for each part of the study and each cohort/group being enrolled.

Consider the following for specific populations being enrolled:

* Minor Subjects: Describe whether assent will be obtained from all, some, or none of the minor subjects. If some, indicate which minor subjects will and will not provide assent. If assent will not be obtained from some or all minor subjects, explain why not. Indicate whether permission from the parent(s)/legal guardian(s) will also be obtained.
* Minor Research Subjects Considered Adults: In California, certain minors may consent to participate in research without parental permission if they are emancipated, if the research involves specific types of medical treatment, or if they are living separate and apart (see *HRP-013-SOP: Legally Authorized Representatives, Children, and Guardians*).
* Minor Parent Subjects: In California, a parent who is under 18 years old and not legally emancipated or considered an adult (see *HRP-013-SOP: Legally Authorized Representatives, Children, and Guardians*) may provide parental permission for their own child to participate in the study and assent for themselves to participate in a study; however, permission from the minor parent’s parent/legal guardian must be obtained for the minor parent to participate in the study.
* Minor Subjects Who Reach the Age of Majority: Per CA Law, children that reach the age of majority (i.e., turn 18 years old, married, joined the armed forces, legal emancipation) during participation in a study must be re-consented as adults and sign a HIPAA authorization form (if applicable) before they may continue participation in the study. If the now adult subject cannot provide consent and HIPAA authorization for their continued participation (e.g., cognitive impairment, etc.), then surrogate consent and HIPAA authorization from a legally authorized representative (LAR) must be obtained per CA law.
* Subjects that may regain the capacity to consent/assent: Subjects who were unable to provide consent/assent at initial enrollment (e.g., sedated, cognitively impaired, intubated, etc.) but who may regain the capacity to consent/assent during participation should be consented/assented for their continuing participation in the study. If subjects will not regain the capacity to consent/assent during their participation, then explain why not.

Consider the following for screening:

* Under the New Common Rule, screening procedures without obtaining consent/permission/assent may be approved by the IRB if either of the following is met: (a) the investigator will obtain information through oral/written communication with the prospective subject/parent/legal guardian/LAR or (b) the investigator will obtain identifiable private information/biospecimens by accessing records or stored identifiable biospecimens.
  + Examples of when consent/permission/assent **may** be required: Collecting biological samples solely for research purposes to determine eligibility, administering questionnaires/surveys that are sensitive or increase the potential risks to prospective subjects (e.g., questionnaires/surveys where responses may place prospective subjects at risk of criminal/civil liability or may damage their employability/insurability/reputation, etc.), retaining private identifiable health/contact information collected during screening procedures, etc.
  + Examples of when consent/permission/assent **may not** be required: Accessing medical records/clinic logs, asking limited questions (e.g., age, gender, etc.), not retaining private identifiable health/contact information, etc.
* FDA-regulated research: Consent/permission/assent must be obtained for screening procedures being performed to determine eligibility in a study. However, if the screening procedures are minimal risk and do not involve procedures for which written consent is normally required outside the research context (e.g., survey/questionnaire with limited questions, etc.), then a waiver of documentation may be requested.
* HIPAA authorization: HIPAA regulations may apply to screening procedures depending on what type of information is being collected (e.g., identifiable health/contact information, sensitive information, etc.), whether the screening information will be retained, how screening information will be labeled if retained (e.g., identifiable, etc.), and the intended purpose of retaining screening information. When identifiable health/contact information is created and/or retained, written HIPAA authorization from individuals may be required.

**Obtaining Consent/Permission/Assent**

If you will obtain consent/permission/assent, describe the following:

* Where the consent process will take place (e.g., in person, in a private area, remotely, etc.). If the consent process takes place in a waiting room/open ward/group or public setting, provide the rationale for why it must occur in those areas and describe how the subject’s privacy will be protected.
* How consent will be documented (signed or no signatures).
* **NOTE:** 
  + Signed: Subjects will sign a consent document (wet or electronic signature).
  + No signatures: Subjects will not sign a consent document (e.g., verbal consent/permission/assent will be obtained, a box in the consent document agreeing to participate in the study will be checked, etc.). You will need to request a waiver of documentation, and justifications for the requested waiver must be provided within the IRB application so that the IRB may consider the request.
* The measures that will be taken to ensure that subjects have sufficient time to consider participation (e.g., they will be given an adequate amount of time to consider participation in the study relative to the initiation of study procedures, they will be allowed to take the informed consent document home to discuss participation with their family, friends, and/or others before making a definitive decision, etc.).
* The process for obtaining and documenting consent/permission/assent, and whether you will be following *“SOP: Informed Consent Process for Research (HRP-090)”* and *“SOP: Written Documentation of Consent (HRP-091).”*
* Any process to ensure ongoing consent.
* The role of the individuals listed in the IRB application as being involved in the consent process. **Do not** list the names of the individuals obtaining consent/permission/assent within this document (this information will be required within the IRB application).

**Remote Procedures (Consent Conference and/or Electronic Signatures)**

If you are obtaining consent/permission/assent and plan to use remote procedures:

* Describe the remote consent procedures that will be used to obtain and document informed consent/permission/assent and HIPAA authorization. **NOTE**: The sample statements in the *“Remote Consent for Research: Obtaining and Documenting Consent (Electronic Consent)”* can be used to describe the remote consent process and how electronic signatures will be obtained or modified for your study.
* Describe how subjects will have access to all the consent-related materials, including hyperlinks or other external documents, throughout the study’s lifespan.
* For FDA-regulated Clinical trials including children as research subjects, if the parent/legal guardian initially documents the child’s assent, describe the procedures that will be used to verify the child’s identity and assent when the child initially presents to the investigator.

**Full Waivers of Informed Consent/Permission/Assent**

Indicate if you are requesting full waivers of consent/permission/assent (i.e., subjects will not be asked to sign or be given a consent document). Justifications for the requested waivers must be provided within the IRB application so that the IRB may consider the request.

**Research HIPAA Authorization**

Indicate if you will be obtaining HIPAA authorization or requesting a complete waiver of HIPAA authorization. If you request a full waiver of HIPAA authorization, provide justifications for the requested waiver within the IRB application so that the IRB may consider the request. **NOTE**: See the *“HIPAA and Research”* section on the HSPP website. At CHLA, a partial waiver of HIPAA authorization is only necessary if non-CHLA personnel will access CHLA PHI to identify, screen, and/or recruit CHLA patients/records. In addition, HIPAA authorization should be obtained from the adult subject or the surrogate for adults incapable of providing authorization or from the parent/legal guardian for minor subjects.

|  |
| --- |
| **REMINDER**: Upload final and clean copies of the consent, assent, and addendum forms (as applicable) within the IRB application. The forms must be consistent with the protocol and IRB application. Template consent, assent, and addendum forms are available on the HSPP website as well as the *“CHLA Consent Form Standards and Sample Language”* guidance document. |

**RISKS TO SUBJECTS**

**REVIEW:** The “*Conducting Risk Assessments*” guidance document.

* List the reasonably foreseeable risks, discomforts, hazards, or inconveniences to the subjects related to the subject’s participation in the research. Include, as may be helpful in the IRB’s consideration, a description of the risks’ probability, magnitude, duration, and reversibility. 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 (e.g., study personnel) who are not subjects.

**PROVISIONS TO MONITOR THE DATA TO ENSURE THE SAFETY OF SUBJECTS**

This section is required when research is **more than Minimal Risk** to subjects. Describe the following:

* 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 the committee’s 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.
* Statistical tests that will be used to analyze the safety data to determine whether harm is occurring.
* Any conditions that trigger an immediate suspension of the research.

**POTENTIAL BENEFITS TO SUBJECTS/SOCIETY**

* Describe any direct benefits individual subjects may experience from participating in the research. Include the probability, magnitude, and duration of the potential benefits that may be useful for the IRB’s consideration OR state that there are no direct benefits to individual subjects. **REMINDER**: Payment for participation is not a benefit to participation.
* You may include indirect benefits to society or others.

**COMPENSATION & REIMBURSEMENT**

**REVIEW:** The *“Payment for Participation”* guidance document.

**Payment for Participation**

Describe the following:

* The amount of any payments to subjects and any relevant information, such as pro-rating if a person does not complete the study or bonus payments at the end of the study.
* Howpaymentswill be provided to subjects (e.g., prepaid debit card, ClinCard, cash, check, gift cards, toys, iPads, backpacks, other objects, etc.). Provide the estimated market value for non-monetary items.
* When payments will be made (e.g., immediately after the interview, etc.), including if payments will be provided in person, emailed, or mailed to subjects. Include a payment schedule, if appropriate.
* Who will receive the payment (e.g., the subject, etc.). When enrolling children, describe whether payment will be provided directly to the child or if it will be provided to the parent(s)/legal guardian(s) on behalf of the child.
* Commercial product(s): If the investigator thinks that using of data or specimens obtained for the study could be part of or lead to the development of a commercial product(s), indicate whether the subject(s) will have any rights to compensation or ownership interest in the product(s).

**Reimbursement for Expenses**

Indicate whether subjects will be reimbursed for **additional** costs (e.g., parking, transportation, meals, etc.) incurred because of participation. If yes, describe the plans, including the following details, as applicable:

* What subjects will be reimbursed for (e.g., parking, transportation, meals, etc.).
* How reimbursement will be made (e.g., prepaid debit card, cash, check, etc.).
* When subjects will be reimbursed (e.g., immediately after the interview, approximately 6 weeks after the study’s, etc.). Include a reimbursement schedule, if appropriate.
* Whether subjects need to submit receipts to be reimbursed.
* Whether subjects need to provide any personal information (e.g., name, date of birth, address, social security number, etc.) to receive reimbursements.

**COSTS TO SUBJECTS**

Describe any **additional** costs that subjects may be responsible for because of participation in the research and that they will not be reimbursed for (e.g., parking fees, transportation, etc.). **Do not** provide an actual dollar amount for the additional costs.

**PRIVACY PROTECTIONS**

**REVIEW:** The “*Privacy and Confidentiality in Research”* guidance document.

Describe the steps that will be taken to protect subjects’ privacy interests (e.g., interviewing participants in a private room/setting rather than in a public place, conducting the study visits in a private room, etc.). “Privacy interest” refers to a person’s desire to limit whom they interact with or provide personal information to.

Describe what steps you will take to make the subjects feel at ease with the research situation, including 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.

**DATA MANAGEMENT AND CONFIDENTIALITY**

Confidentiality refers to a subject’s understanding of how their identifiable information/specimen will be collected, stored, and shared. Describe the following for all parts of the study (e.g., screening, main study, sub-studies, etc.) and all cohorts/groups being enrolled:

* How will the research data/specimens be labeled (e.g., identifiable, coded, anonymous, etc.). If labeling the research data/specimens with direct identifiers (e.g., name, MRN, etc.), provide the rationale for doing this. **NOTE**: Below are the CHLA IRB’s definitions for identifiable, coded, de-identified/anonymized, and anonymous.
  + Identifiable: Data/specimens are directly labeled with a subject’s identifying information (e.g., names, SSN, MRN, etc.) so that they can be readily connected to a specific subject. This also includes audio/video recordings and full facial images/photographs containing identifiable features (e.g., birthmarks, tattoos, etc.).
  + Coded: Data/specimens are labeled with a unique number/code (e.g., Study ID), and there is a separate link (key) that connects the ID number to a direct identifier (e.g., name, etc.). As long as a link exists, data/specimens are considered indirectly identifiable and not anonymous or de-identified/anonymized.
  + De-identified/Anonymized: A record and/or specimen from which identifying information (e.g., Study ID, name, MRN) is removed. For a data set or specimen to be considered de-identified, a key code must not exist, and/or the data/specimen must be stripped of any indirect identifiers (study ID) or direct identifiers.
  + Anonymous: Identifiers were not collected at any point in the research and cannot be retrieved by the investigator.
* The steps that will be taken to secure the research data/specimens (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/shipment.
* Where and how research data/specimens will be stored.
* How long the research data/specimens will be stored. **NOTE**: Data must be retained for a minimum of 6 years after IRB closure of the study to maintain compliance with the CHLA record retention policy. Direct and indirect identifiers should be destroyed as soon as no longer needed.
* Who will have access to the research data/specimens.
* Who is responsible for receipt and/or transmission/transport of the research data/specimens.
* How research data/specimens will be transmitted/transported.
* What identifiable information will be included or associated with the data/specimens.
* What will happen to the research data/specimens at the conclusion of the study (e.g., destroy the key to the code, etc.).

**FUTURE USE OF DATA/SPECIMENS**

**REVIEW:** The *“Guidance for Future Use and Repositories”* guidance document.

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

If anonymous or de-identified/anonymized data/specimens will be used in future research, delete the sections below. **NOTE**: See the definitions for identifiable, coded, deidentified/anonymized, and anonymous under the DATA MANAGEMENT AND CONFIDENTIALITY section.

If creating a research repository under this protocol, describe the following:

* The intended uses of the research data/specimens (e.g., studies related to condition X, undefined purposes, etc.).
* List the research specimens to be stored.
* List the research data to be stored or associated with each specimen.
* Restrictions on the use of research data/specimens (e.g., genetic testing, etc.).
* How long the research data/specimens may be stored (e.g., indefinitely, etc.).
* Who can use the research data/specimens (e.g., the investigators for this study, other investigators at CHLA or elsewhere, etc.)
* The procedures to release research data/specimens including:
  + The process to request a release of research 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 research data/specimens (e.g., protocol, IRB/Ethics board approval/determination letter, MTA, DUA, etc.).
  + Procedures for tracking research data/specimens released/removed from the research repository (e.g., spreadsheet, tracking log, etc.).
* Whether research data/specimens from other CHLA IRB-approved studies may be stored in the research 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 research repository.”*

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

**WITHDRAWAL OF SUBJECTS**

* Describe anticipated circumstances under which subjects will be withdrawn from the research without their consent.
* Describe any procedures for orderly termination of participation in the study.
* Describe procedures that will be followed when subjects withdraw from the research, including partial withdrawal from procedures with continued data collection. **REMINDER:** Subjects and families may withdraw from participation in the entire study or partially withdraw from specific procedures either verbally or in writing.
* If participants withdraw from the study, describe if data collected up to that point will be retained or destroyed.
* Describe how participants can withdraw their research data/specimens from a research repository. If de-identified/anonymized or anonymous research data/specimens will be stored in a research repository, explain how withdrawal is impossible.

**SETTING**

* Describe the sites or locations where the research team will conduct the research and identify where research procedures will be performed.
* Describe the facilities available to conduct the research.
* If this is a multi-site study, identify what site is serving as the lead site/coordinating site.
* If applicable, 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 that affect the research when research is performed 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.
* Describe your process for ensuring that all persons assisting with the research are adequately informed about the protocol, the research procedures, and their duties and functions throughout the study’s lifespan.

**STUDY AND SAFETY ENDPOINTS**

* Study Endpoint(s): Clearly define the outcome measure(s) that the study aims to assess. They should be related to the hypothesis being tested and are usually the basis for calculating the study size. Describe any additional outcome measures that the study will evaluate. Study endpoints can explore other intervention effects, provide additional safety information, or investigate other research questions.
* Safety Endpoints: If applicable, identify any safety endpoints that will be monitored throughout the study, especially for clinical trials involving interventions. Safety endpoints are critical for assessing the adverse effects of the intervention.

**DATA ANALYSIS PLAN**

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

**REFERENCES**

List relevant reference citations.

1. This template satisfies AAHRPP elements 1.7.B, I.8.B, I-9, II.2.A, II.2.D, II.2.I, II.3.A, II.3.B, II.3.C, II.3.D, II.3.E, II.3.F, II.4.A, III.1.C, III.1.D, III.1.E, III.1.F [↑](#endnote-ref-1)