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| **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 **medical chart review research studies** when consent is not required or full waivers of consent/permission/assent and HIPAA authorization (as applicable) for the entire study are requested.
* 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.
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**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) 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 that 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.

DATA RESOURCES

* Describe the source/location of the medical records to reviewed (e.g., KIDS, Cerner, Synapse, etc.). If using databases, identify the databases to 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 to be used in this study, explain why you already have access.

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| **REMINDER:** Upload finalized copies of the data collection tools (e.g., REDCap CRFs, excel spreadsheets, etc.) within the IRB application. The data collection tools must include all the data points required to achieve the objectives of the study. |

STUDY POPULATION – INCLUSION/EXCLUSION CRITERIA

Describe the criteria that define which charts 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.), there should be separate inclusion and exclusion criteria listed.

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 Populations or Subjects with Limited English Proficiency
* Pregnant women/human fetuses
* Prisoners/Detainees
* Wards
* CHLA employees/students

**Inclusion Criteria for XX Cohort/Group**

* List all the inclusion criteria.

**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.

Identify the date range(s) of the records that will be accessed.

PRIVACY & CONFIDENTIALITY

Describe the following:

* Whether the study will access, review, create, and/or disclose subjects’ Protected Health Information (PHI).
* How the research data will be labeled (i.e., coded, etc.). Provide the rationale for labeling the research data with direct identifiers (e.g., name, MRN, etc.) if applicable. **NOTE**: Below are the CHLA IRB’s definitions for identifiable, coded, de-identified/anonymized, and anonymous.
	+ Identifiable: Data 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.
	+ Coded: Data 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 are considered indirectly identifiable and not anonymous or de-identified/anonymized.
	+ De-identified/Anonymized: A record from which identifying information (e.g., Study ID, name, MRN) is removed. For a data set to be considered de-identified, a key code must not exist, and/or the data 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 and prevent a breach of confidentiality (e.g., training, limited team access, password protection, encryption, physical controls, and separation of identifiers and data) during storage, use, and transmission.
* Where the research data will be stored.
* If research data is being sent to or from CHLA, describe how the research data will be labeled (e.g., coded, etc.) and who will have access to the key code (if applicable).
* How the research data will be transmitted.
* How long the research data 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.
* What will happen to the research data at the conclusion of the study. Discuss plans to either keep or destroy direct identifiers, the key to the code, etc.

FUTURE USE OF DATA

State whether data 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 intended uses of the research data (e.g., studies related to condition X, undefined purposes, etc.).
* List the data to be stored.
* Restrictions on the use of the research data, if any.
* How long the research data will be stored (e.g., indefinitely, etc.).
* Who can use the research data (e.g., the investigators for this study, other investigators at CHLA or elsewhere, etc.)
* The procedures to release research data, including:
	+ The process to request a release of research data (e.g., email, application, etc.).
	+ Procedures for reviewing the requests (e.g., reviewed by the repository manager/gatekeeper, repository committee, etc.).
	+ Documents/agreements required for release of research data (e.g., protocol, IRB/Ethics Board approval/determination letter, MTA, DUA, etc.).
	+ Procedures for tracking research data released/removed from the research repository (e.g., spreadsheet, tracking log, etc.).
* Whether research data from other CHLA IRB-approved studies may be stored in this research repository. If this is possible, it is recommended that the following statement is added: “*Data collected under other CHLA IRB research studies may be stored in this research repository.”*

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

CONSENT AND HIPAA AUTHORIZATION

Most **chart review studies** may qualify as exempt research and if so, they do not require consent from subjects; however, HIPAA may apply. The investigator must describe their plans to either obtain HIPAA authorization or request a full waiver of HIPAA authorization if applicable. When requesting full waivers of consent/permission/assent and/or HIPAA authorization, provide justifications for the requested waiver(s) within the IRB application so that the HSPP/IRB may consider the request(s).

**SETTING**

* Describe the sites or locations where the research team will conduct the research and identify where the research procedures will be performed.
* If this is a multi-site study, identify what site is serving as the lead site/coordinating site.
* Describe the facilities available to conduct the research.

DATA ANALYSIS

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)