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| **INSTRUCTIONS:**   * This template is for medical chart review research studies. * Some sections may not be applicable to your research. If so, keep the heading and indicate “NA”. * 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.

DATA RESOURCES

* Describe the source/location of the medical records to be reviewed.
* 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).
* Identify the specific variables/data points that will be recorded for research analysis.
* Include the data collection sheet with the IRB submission if one will be used to record information from KIDS. Assure the data sheet is consistent with the information described in this section.

STUDY POPULATION – INCLUSION/EXCLUSION CRITERIA

* Identify the study population.
* Indicate specifically whether you will include:
  + Adults unable to consent
  + Individuals who are not yet adults (infants, children, teenagers)
  + Pregnant women
  + Prisoners
* Describe the inclusion/exclusion criteria that determine which charts will be reviewed.
* Identify the date range(s) of records will be accessed.

STUDY TIMELINE AND DATA ANALYSIS

* Describe the data analysis plan.
* Describe any temporary identifiers, codes, or links used between the subject’s identity and the data being recorded, and why they are required to complete the data analysis.

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 de-identified/anonymized data/specimens may 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 will 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 the 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 this repository. If this is possible, it is recommended that the following statement is added: “*Data/specimens collected under other CHLA IRB research studies may be stored in this repository. Amendments will be submitted to add those CHLA IRB number 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#.

PRIVACY & CONFIDENTIALITY

* Describe whether the study will access, use and/or disclose subjects’ Protected Health Information (PHI). If the study involves PHI you must request a waiver of HIPAA authorization in the IRB submission form.
* Describe the steps that will be taken to secure the 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.
* Plans to either keep or destroy direct identifiers: Discuss whether direct identifiers will be kept separate from the data (e.g., replaced with a code), and whether a code key will be retained.

INFORMED CONSENT

* Most **chart review studies** qualify as exempt research and do not require consent from subjects.
  + A request for a waiver of consent is not required if the research is exempt.