Human Subject Protection Program
Investigator Guidance
October 14, 2021

REQUESTING DATA FROM HEALTH INFORMATION MANAGEMENT (HIM) AND IRB REVIEW

Overview

- All data release requests made to HIM for research purposes must have prior IRB review and approval. It is the Principal Investigator's responsibility to ensure that the protocol states whether HIM will be used, what information will be provided to HIM (e.g. ICD and/or CPT codes), what information HIM will provide back to the study team (e.g. patient names, MRN), the specific data points in the data collection sheets and/or case report forms (CRFs), the date range of when the data will exist, and any personnel who will be accessing the data have been added to the study and have undergone IRB review and approval PRIOR to requesting any data from HIM. This guidance assists investigators with their HIM data requests and reduces the need for duplicative review.

    - **IMPORTANT NOTE:** CHLA IRB review and approval, certification of exemption, research and/or human subject determinations must be obtained prior to any contact, intervention, interaction with human subjects, or any use of specimens, records, or data. The CHLA IRB does not grant retroactive approvals, exemptions, or determinations for activities that have already been performed.

- Use this guidance for completing the DATA REQUEST ATTESTATION FORM when the data parameters requested, including dates, are the same (this can be fewer data points than what is in the original IRB approved data collection form, but not additional) and person(s) requesting the data from HIM are listed as study personnel in the currently approved iStar application for the study.
    - For Example, if you have an IRB approved study with a data collection sheet that lists 10 diagnostic codes, and an additional data collection sheet that lists 5 demographic points, and are now requesting a "new" list with fewer diagnostic codes and fewer demographic points as approved, then this "new" data request has already been reviewed and approved by the IRB, and you do not need to submit an amendment to the IRB. You will need to submit the DATA REQUEST ATTESTATION FORM to HIM, with a copy of your IRB Approval letter.

- If you are requesting additional data parameters that have not gone through prior IRB review and approval, please submit an amendment through iStar and include the new data collection sheet/s that are different than what is currently approved. Once the amendment has been reviewed and approved by the IRB, then use the DATA REQUEST ATTESTATION FORM to request the data from HIM.

- ❑ **IMPORTANT NOTE:** There may be MANY data collection sheets included in a study. Please verify that the data you are requesting are within the parameters of ALL data collection sheets, especially as a new data collection sheet MAY include data from a number of data collection forms, that have been reviewed and approved by the IRB.

Purpose

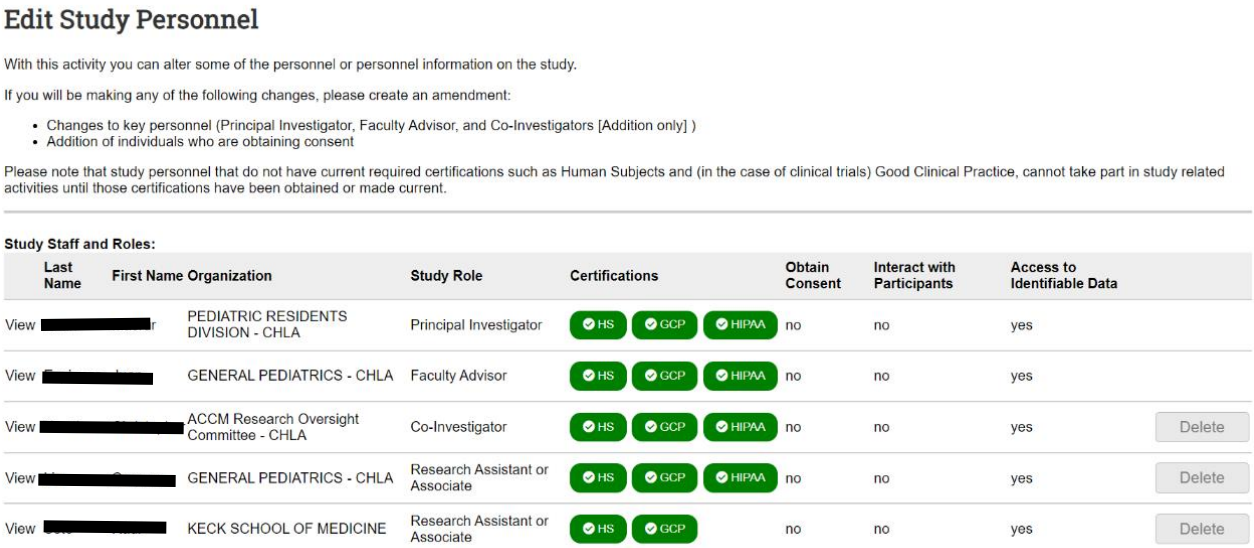
- ➢ The purpose of this DATA REQUEST ATTESTATION FORM is to have the PI verify that the IRB has reviewed and approved the data being requested and that the individuals accessing the data are approved study personnel.

  - ❑ **IMPORTANT NOTE:** CHLA investigators assume important regulatory responsibilities when they serve as the PI. By submitting an application to the CHLA HSPP for IRB review or clearance, and being named as the PI of that study, the PI agrees to assume the overall responsibility for the study conduct. The PI is responsible for knowing the research regulations and guidelines that apply to the study, and any additional requirements imposed by the funding agency and/or study sponsor. Please see the Principal Investigator Responsibilities under the Getting Started – Guidance for Investigators on the HSPP webpage for more information.

Guidance

Adding study personnel requesting data from HIM to your study

- ➢ PI's and/or designated study personnel may utilize the "Edit Study Personnel" function in iStar to add individuals to the study team at item 2.1 that have an iStar account, have completed the required training, that are accessing PHI, but are not consenting subjects and do not have the role of PI, Faculty Advisor, or Co-I. See screen shot example below:



Edit Study Personnel

With this activity you can alter some of the personnel or personnel information on the study.

If you will be making any of the following changes, please create an amendment:

- Changes to key personnel (Principal Investigator, Faculty Advisor, and Co-Investigators [Addition only])
- Addition of individuals who are obtaining consent

Please note that study personnel that do not have current required certifications such as Human Subjects and (in the case of clinical trials) Good Clinical Practice, cannot take part in study related activities until those certifications have been obtained or made current.

Study Staff and Roles:

	Last Name	First Name	Organization	Study Role	Certifications	Obtain Consent	Interact with Participants	Access to Identifiable Data	
View	[redacted]		PEDIATRIC RESIDENTS DIVISION - CHLA	Principal Investigator	HS GCP HIPAA	no	no	yes	
View	[redacted]		GENERAL PEDIATRICS - CHLA	Faculty Advisor	HS GCP HIPAA	no	no	yes	
View	[redacted]		ACCM Research Oversight Committee - CHLA	Co-Investigator	HS GCP HIPAA	no	no	yes	Delete
View	[redacted]		GENERAL PEDIATRICS - CHLA	Research Assistant or Associate	HS GCP HIPAA	no	no	yes	Delete
View	[redacted]		KECK SCHOOL OF MEDICINE	Research Assistant or Associate	HS GCP	no	no	yes	Delete

Examples of Data Requests that May or May Not Require an Amendment

Type of Data being requested by HIM	Amendment Needed?
Diagnostic Codes, Patient Health Information, Retrospective review of a patient's medical record with intent to document a specific situation or the experience of an individual without intent to form a research hypothesis, draw conclusions or generalize findings.	**NO –** *if limited to the parameters that have already been approved by the IRB.* **YES –** *if exceeds the parameters that have previously been approved by the IRB.*

FAQ's

- If I am requesting data points that are the exact same as those specified in my IRB approved study, do I need to submit a DATA REQUEST ATTESTATION FORM to HIM?
  - **Yes. The PI must attest to the fact that the data being requested are within the parameters and date range of the IRB approved study.**

- This seems like a burden to the PI-why is it required by HIM?
  - **HIM requires confirmation that the data points being requested have been approved by the IRB. HIM does not have access to iStar to make this determination, thus the Principal Investigator is required to make this attestation.**

- What if I want to add another person to the study who will access the data requested of HIM – Do I need to submit an Amendment in iStar?
  - **No. You may use the "Edit Study Personnel" function in iStar to add individuals to the study team at item 2.1 of the application. This is only for adding personnel that have an iStar account, have completed the required training, are/will be accessing PHI, but are not consenting subjects and do not have the role of PI, Faculty Advisor, or Co-I.**

DATA REQUEST ATTESTATION FORM

Name of Person Requesting Data from HIM:_____

Date:_____

Principal Investigator:_____

By submitting an electronic copy of your IRB approval letter for the requested data, you are attesting to the fact that the data being requested are within the parameters and date range of the following IRB approved study.

IRB #:_____

IRB Study Title:_____

Principal Investigator:_____

If you are requesting data that are different from the IRB approved parameters and date range, STOP completing this form and submit an Amendment in iStar. Upon receipt of IRB approval, complete this form and send a copy of your IRB approval letter to: HIMRequest@chla.usc.edu