**University of Southern California Medical Records and/or Specimens ONLY Protocol Template**

[Please click here for a welcome to the IRB Submission Process.](https://hrpp.usc.edu/wp-content/uploads/sites/3/2023/06/Welcome-to-the-IRB-Submission-Process.m4a)

### Who should use this protocol:

* Any investigator using medical records and/or Specimens **only.**

### Are the prompts in this protocol *also* in iStar?

* No, the prompts in this protocol are not in iStar. There are no duplicative prompts. Please address all the prompts in this protocol.

### How to complete this protocol:

* Please first review the entire protocol template. Please note there are links that will help you throughout the document. Taking the time to review the links and listen to the recordings will help you prepare your protocol.
* Please answer the prompts by providing all relevant information to each prompt below. **Answering the prompts is the “protocol.”**
* Please **do not** delete the prompts.
* If a **section is not applicable** to your study, please **include n/a in the section**.
* This protocol **must** be uploaded to Section 5.2 in the iStar application. Applications without this protocol in Section 5.2 *will* be returned without review.
* Please **do not** cut and paste information from grant proposals, research proposals, theses, dissertations, or dissertations in practice. Doing so *may* result in the return of the application.
* Please use lay language to describe the study. Please define all acronyms.

### Additional supplemental information that may be needed:

* If sharing or receiving data or materials/specimens please check with [USC Stevens Center](https://stevens.usc.edu/researchers/request-an-mta-dta-cda/) to determine if a Data Use Agreement is required. This does not to be reviewed by the IRB, however, it is the investigator’s responsibility to double check.
* Secondary Data Analysis **does not** require CIC review or approval. Please select NO in section 2.4 in the iStar application.

## [General Information](#_General_Information)

### Study Title:

### PI Name:

*If following the single IRB mandate OR collaborating with colleague/Institutions, please fill out the* [*Collaboration*](#_Collaboration) *section.*

## [Study Information](#_top)

[To hear from an IRB Analyst regarding this section, please click on this link.](https://hrpp.usc.edu/wp-content/uploads/sites/3/2023/06/Study-Information.m4a)

[Please click here if you would like to review transcripts of the recordings.](https://hrpp.usc.edu/wp-content/uploads/sites/3/2023/08/Transcripts-for-medical-record-template.docx)

### What is the general purpose of your study? What do you hope to learn? (Maximum 1–2 paragraphs of explanation).

### List the Research Questions.

## [Secondary/Archival/Existing Data/Specimens](#_top)

[To hear from the Policy Administrator about this section, click on this link.](https://hrpp.usc.edu/wp-content/uploads/sites/3/2023/08/Secondary-Data.m4a)

### 3) Please list the kind of data to be collected (e.g., demographic data, test scores, grades, academic records, data from social media platforms, medical records, specimens etc.).

* 1. If data are from multiple sites, please list what data will be collected at each site.

### 4) Will the data set include any identifiers? ([Please carefully review this information to determine if the data set contains identifiers.)](https://hrpp.usc.edu/wp-content/uploads/sites/3/2023/10/human_subject_data_classification_tool.pdf)

Tip: To check the boxes, please double click.

  No

Yes

If yes, will the data set contain any of the following? (Please check all that will apply.)

Information about abortion

Immigration status

Illegal or illicit behaviors (e.g., Illegal drug use, criminal records)

Suicidality

Abuse victim or perpetrator (e.g., Elder Abuse)

Other \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

### 5) Is your data set private or publicly available (Public: anyone can access the data without logging into a site)?

  Private. ([A data use agreement](https://hrpp.usc.edu/wp-content/uploads/sites/3/2021/09/Data-Use-Agreement.doc) may be needed. It’s the PI’s responsibility to check with the [USC Stevens Center for Innovation](file:///C:\Users\heathermiller\Documents\USC\SB%20protocol\USC%20Stevens%20Center%20for%20Innovation). If Single IRB is anticipated and USC is the IRB of record, study team may upload other contracts/agreements to iStar section 40.1)

Publicly Available. Paste below the links to the website(s) where you will download the data.

### 6) Will you be de-identifying data/specimens prior to analysis?

  Yes, I will de-identify (there are no links to the original data set) all data prior to data analysis.

  No, I will retain identifiers or there will be links to the original data set during analysis.

  No, Data/specimens are already de-identified.

### 7) I confirm that all data will be protected using best practices and securities with data storage including encrypting files, robust passwords, and following [all university practices and policy](https://hrpp.usc.edu/irb/privacy-confidentiality-and-anonymity-in-human-subjects-research/) for storage of data. I also understand that the IRB may audit this study, including how the data will be stored.

  I confirm that this study may be audited, and I will protect the data using most current practices.

## [Collaboration](#_General_Information)

Collaborating Investigator Name:

Role in the research study:

Collaborator Email Address:

Institution name:

If you are part of the [Single IRB Mandate](https://hrpp.usc.edu/research/requesting-usc-irb-to-act-as-the-sirb/) please review this information.

\*\*Students do not need to list their faculty advisors in this section, this section is specifically if you are working with investigators at another location and for any investigator part of the Single IRB Mandate\*\*