**University of Southern California Social Behavioral and/or Secondary Research 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)

[Please click here for a transcript of all the recordings in this document.](https://hrpp.usc.edu/wp-content/uploads/sites/3/2023/08/Transcripts-of-the-voice-recordings-for-the-SB_Secondary-protocol.docx)

### Who should use this protocol:

* Any investigator interacting with and collecting data from human participants.
* Any investigator interacting with human participants and collecting data from human participants *and* collecting secondary/archival/existing data.
* **Any investigator collecting or using secondary/archival/existing data only. Please fill out the following sections *only:*** [General Information](#_General_Information), [Study Information](#_Study_Information), [Secondary/Archival/Existing Data](#_Secondary/Archival/Existing_Data) and if applicable, [Collaboration.](#_Collaboration_1)

### 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 your study is exempt and you are conducting an interview or focus group with participants, submit an [information sheet](https://hrpp.usc.edu/wp-content/uploads/sites/3/2023/08/Information-Sheet-8.9.2023.docx) and [recruitment document(s)](https://hrpp.usc.edu/irb/forms-and-templates/) to section 40.1. [This is common in student research].
* If working with American Indian/Alaska Native or other Indigenous Populations [this additional supplemental form must be attached to iStar Section 40.](https://hrpp.usc.edu/wp-content/uploads/sites/3/2023/07/AI_AN-Supplemental_form7.17.2023.docx)
* If conducting a full board study, [please include this additional supplemental information in iStar Section 40.](https://hrpp.usc.edu/wp-content/uploads/sites/3/2023/07/Supplemental-Information-for-SB-Full-Board-studies.7.31.2023.docx)
* If compensating participants, [please review this guidance to supplement iStar Question 25.2.](https://hrpp.usc.edu/wp-content/uploads/sites/3/2023/06/Compensation-guidance-for-SB-protocol.docx) This guide is meant to help you respond to iStar prompt 25.2.
* 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.
* If it is a reasonable expectation that you will have even a single research participant that lives in the European Union, please review the form titled “Consent to Collect and Process Personal Data from the European Union” on the website under “Other Forms and Templates” on our “[Forms and Templates](https://hrpp.usc.edu/irb/forms-and-templates/)” page. If applicable attach to iStar section 40.
* 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:

### Is this study federally funded: Yes No

1. **Will there be non-USC people involved in this study?  Yes  No**

If yes, fill out the questions in the [Collaboration](#_Collaboration_1) section of this protocol.

1. **Will there be non-USC locations involved in this study? Virtual meeting spaces such as Zoom are not considered a study location.  Yes  No**

If yes, please list locations below.

If yes to questions 1 and either 2 or 3 above: [1) please review the single IRB information on the HRPP Website and](https://hrpp.usc.edu/research/requesting-usc-irb-to-act-as-the-sirb/) 2) contact the reliance team at [reliance@usc.edu](mailto:reliance@usc.edu).

If no to questions 1-3 above,please move to the [Study Information](#_Study_Information) section of this protocol.

## Collaboration

Please check the box if this section is *not applicable* to your study.

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

If you are working with non-USC people, please address the following prompts below. Please be sure that all study activities are included for each collaborator. Each collaborator should be listed separately below.

Collaborating Investigator Name:

List the study activities conducted by the collaborator (for example, consenting, recruiting, data analysis, etc.):

Collaborator Email Address:

Institution name:

Collaborating Investigator Name:

List the study activities conducted by the collaborator (for example, consenting, recruiting, data analysis, etc.):

Collaborator Email Address:

Institution name:

## [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)

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

### List the Research Questions.

## Inclusion & Exclusion Criteria

Please check the box if this section is *not applicable* to your study.

[To hear from an IRB Analyst regarding this section please click on this link.](https://drive.google.com/file/d/1ditAKMVtua-9_D5Y7H85zts5p6sgWmuH/view?usp=sharing)

### Describe the inclusion *and* exclusion criteria for enrollment.

### Provide justification for the population you are including.

## Where will Recruitment occur?

Please check the box if this section is *not applicable* to your study.

[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/Where-will-recruitment-occur.m4a)

### List all sites or locations where you will recruit participants (e.g., on USC campus, your place of employment, a specific elementary school, Amazon Turk, Qualtrics panel, specific groups within Facebook, Instagram, etc. Provide exact locations and/or weblinks as applicable).

### Are you *specifically* seeking any participants physically present in a country outside of the United States?

Tip: To check the boxes, please double click.

No

  Yes If yes, please answer the *additional* questions regarding [International Research](#_International_Research).

## How will Recruitment happen?

Please check the box if this section is *not applicable* to your study.

[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/How-will-recruitment-happen.m4a)

Note: If using a paid panel (e.g., MTurk, Qualtrics Panel, Survey Monkey Panel, etc.,) please do not fill out this section.

### What format(s) will you use to advertise (find) potential participants (e.g., Listservs, personal emails, public email, flyer, letter, phone call, social media post (e.g., Facebook, Twitter, Instagram)?

### Who will distribute the recruitment material, and how will it be distributed (e.g., Will somebody be helping you share the material? or are you posting in a specific group or place within social media? Will you be working with a moderator, etc.?)

Please see guidance on creating recruitment materials on our [Forms and Templates page](https://hrpp.usc.edu/irb/forms-and-templates/).

*Please note: For full board and expedited studies all referenced materials should be uploaded to iStar section 24.2. For exempt studies upload to section 40.1.*

## Role of the Investigator/Research Staff

Please check the box if this section is *not applicable* to your study.

[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/Role-of-the-InvestigatorResearch-Staff.m4a)

### ) Will the primary investigator or research staff know any research participants, or have a past or present relationship with *participants* (e.g., supervisors, principals, any kind of authority or influence over the participants)?

No

Yes: If yes, please explain the relationship.

### Will the primary investigator or research staff have a relationship with the *data collection site* (e.g., Are you an employee, consultant)? Please explain.

No

Yes: If yes, please explain the relationship.

### If you have answered yes to either prompt 10 or 11, please explain how can you ensure that research participants will not feel forced to be in your study?

### Provide the IRB with your relevant experience and background and/or that of research staff as it pertains to supporting and understanding the participants in the study.

Additional Explanation for question 13: If you are with working teachers and you are also a licensed teacher, or if you were studying a mental health condition and you are mental health professional/therapist, or if you are targeting non-English speakers you have experience working with them and can (or cannot) understand the language, or if you are working with participants with a specific medical condition, or if you/study team members have experienced this condition yourself, what is your experience, etc..

*Please note if you marked “yes” to any of the prompts above, include information about how people will not be forced or feel obligated to participate in the “Risk” section of the Informed consent (expedited or full board studies only).*

## Screening of Participants

Please check the box if this section is *not applicable* to your study.

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

*Please note: If you are keeping the screening data, even if a participant fails the screening, a* [*screening consent form*](https://hrpp.usc.edu/irb/forms-and-templates/) *will be required for expedited and full board studies. If you are* ***not*** *keeping the data, you do not need to have a consent form.*

### Will you be screening participants?

No: [Please skip to Research Activities](#_Research_Activities).

Yes: Please continue to #15.

### Will you be screening participants *and keeping the screening data*?

  No: [Please skip to Research Activities](#_Research_Activities).

  Yes: Please confirm that you will consent all participants prior to keeping data.

I confirm that I will consent all participants (or provide an [information sheet](https://hrpp.usc.edu/irb/forms-and-templates/)) prior to screening.

### Please choose one option if you answered “yes” to question 15:

The study will have one informed consent form for the screening *and* one consent form for the main part of the study (please upload both consent forms iStar section 24.7). If the study is exempt and you are using an [information sheet](https://hrpp.usc.edu/irb/forms-and-templates/), upload to iStar section 40.1.

The study will have only one main informed consent form that will cover *both* the screening and the main part of the study (please upload the single informed consent form to 24.7, or if an exempt study, upload the [information sheet](https://hrpp.usc.edu/irb/forms-and-templates/) to iStar section 40.1).

*Please note: All* [*informed consent forms*](https://hrpp.usc.edu/irb/forms-and-templates/) *must contain direct language that outlines what will happen with the participants’ data if not eligible to participate in the study (i.e., screen fail).*

*Please note: Attach interview or focus group screening questions to iStar section 19.1. Attach screening survey instruments to iStar section 21.2.*

## Research Activities

Please check the box if this section is *not applicable* to your study.

[To hear from an IRB analyst about this section please click on the link.](https://drive.google.com/file/d/1SlwmwUvqQsQFF1eaYAvw930ZJTykzJxO/view?usp=sharing)

### 17) List all activities (i.e., interviews, focus groups, surveys, interventions etc.) participants will be asked to perform and how long each activity will take. For studies with multiple populations, for each activity, specify which population is doing which activity. Additionally, indicate whether participants will be observed, whether the researcher is actively involved in these activities, and if the researcher’s role is disclosed to the participants.

* 1. If applicable and research activities will be happening at multiple sites, please include what activities are happening at what site(s).

### 18) Where will you meet with participants for each listed activity?

### 19) How many times will you meet with each participant for each activity listed?

### 20) Are you using survey instruments, interview/focus group questions, interview guides, etc., to collect data.

No

Yes: Please upload all information to iStar (surveys are uploaded to iStar section 21.2 and Interview questions are uploaded iStar section 19.1).

### 21) Are you doing research uncovering, or discovering information related to participant suicidality?

No

  Yes: Check this option in iStar *“The research includes the risk or disclosure that a participant may engage in self-harm or attempt suicide”* in 27.1, and then upload a suicide plan in iStar section 27.1.2.

*Please note: Upload all participant related materials for the IRB team, for example: surveys (iStar section 21.2), curriculum created specifically for this study and/or training materials, (iStar section 40.1) debriefing scripts (iStar section 16). If you are not sure where materials should be uploaded, please put them in section 40.1 and the IRB team will assist.*

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

Studies doing only Secondary Data Analysis **does not** require CIC review or approval. **Please select NO in section 2.4 in the iStar application.**

Please check the box if this section is *not applicable* to your study.

[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)

### 22) Will you be using any existing data and/or specimens?

Tip: To check the boxes, please double click.

  No: You are done with this section. Please skip to the International Research section of the application and fill in as applicable.

Yes: Please address all remaining prompts for the existing data sets.

### 23) Please list the kind of data and/or specimens to be collected (e.g., demographic data, test scores, grades, academic records, data from social media platforms, medical records, etc.). Include a link to the archive/data holder or a detailed description of the data and/or specimens you are requesting. Specify whether the data and/or specimens requested include “restricted data” or have any specific requirements for IRB approval and/or access.

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

### 24) Will the data and/or specimens 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)

* 1. No
  2. 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 \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

### 25) Is your data and/or specimens private or publicly available (Public: anyone can access the data and/or specimens 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.

### 26) Will you be de-identifying data and/or specimens prior to analysis?

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

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

  No, Data/specimens are already de-identified.

### 27) Are you linking any data and/or specimens?

Tip: To check the boxes, please double click.

  No

Yes

If yes, please answer the following:

1. Which will be linked?
2. What specific variables will be used to link?

**28)** **Are any artificial intelligence (AI) tools being used in the project (e.g., data being used to train and/or validate an AI tool)?**

  No: You are done with this section, please skip to #31 below.

Yes: Please answer question #29.

**29) Are you inputting patient data and/or specimen variables into an AI algorithm?**

  No: You are done with this section, please skip to #30 below.

Yes: Please answer question #30

**30) If yes, will you be de-identifying data and/or specimens (stripped of all 18 HIPAA elements) prior to inputting variables into the AI algorithm?**

Yes, I will de-identify all data/specimens [qualifies for Exempt determination]

  No, I will retain identifiers or there will be links to the original data set during analysis. [ You must update the iStar application section 5.1 to “Expedited Review”.]

If no, write a brief description (less than 2 paragraphs) of what will be retained and why?

### 31) I confirm that all data and/or specimens 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 methods.

## [International Research](#_Recruitment_Sites)

Please check the box if this section is *not applicable* to your study.

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

## If you plan for your research outside to take place outside of the United States, first review the [International Compilation of Research Standards](https://www.hhs.gov/ohrp/international/compilation-human-research-standards/index.html) for the country where the participants reside. This is section should specifically be filled out if you are intentionally and specifically recruiting participants in another country. The IRB will review all participant facing documentation *prior* to approval and translation. The IRB will request translated documents *after approval* of the English language versions.

### 32) Will you be in a country governed by privacy law, policy, or regulations? If yes, how will you address the regulations?

### 33) After reviewing the International Compilations of Research Standards, what regulations are applicable to the country where the research will take place?

### 34) How will you address the regulations?

### 35) How will culturally appropriate access/permissions to the community will be obtained?

### 36) Describe how cultural norms and/or laws differ between the host site and the United States.

### 37) What strategies will be used to mitigate cultural, political, or economic climate concerns that might increase risks for participants?

### 38) Are the participants fluent in English? If not, please describe the process for consent.

### 39) Are you or your co-investigator(s) fluent in the same language as your participants?

### 40) What is the experience of the PI and/or study team with the proposed participants?

### 41) Will local participant advocate will be available for participants? If yes, what is their specific role?

*Please note that if the researcher/investigators are on-the-ground, conducting research in countries outside of the US, even if they are residents of that country, all the above questions must be addressed. In addition, directives followed as per the International Compilation of Research Standards must be addressed.*

*If you will be collecting any data in the European Union regardless if you are engaging in research activities or a participant is that country please review the* [*Consent to Collect and Process Personal Data from the European Union*](https://hrpp.usc.edu/irb/forms-and-templates/) *(other IRB forms and templates), and if applicable attach the form to iStar section 40.*