# Human Research Application Template

Instructions: Read carefully before completing the application.

Complete this document before opening the online Human Subjects application. The online application cannot be saved. If you sign out, you will have to start over.

Before you start, have your CITI certification, informed consent form, all surveys, and data collection tools, interview questions, letters of support, and/or recruitment materials

REQUIRED: Use the Exempt Research informed consent form templates on the [Resources](http://www.csus.edu/research/irb/resources.html) [page](http://www.csus.edu/research/irb/resources.html).

**IMPORTANT**

Please remember throughout the application, there is a **difference between anonymity and confidentiality**.

**Confidentiality**

Maintaining confidentiality of information collected from research participants means that only the investigator(s) or individuals of the research team can identify the responses of individual subjects; however, the researchers must make every effort to prevent anyone outside of the project from connecting individual subjects with their responses.

**Anonymity**

Providing anonymity of information collected from research participants means that either the project does not collect identifying information of individual subjects (e.g., name, address, Email address, etc.), or the project cannot link individual responses with participants’ identities. A study should not collect identifying information of research participants unless it is essential to the study protocol.

## Application Type

New Application Select if you are filling out a brand new application

Modifications Select if the Human Subjects Committee has requested minor modifications

Revise and Resubmit Select this if the committee has requires you to revise and resubmit your application.

For Official Use: Do not select this

Student Investigators Information

|  |  |
| --- | --- |
| Investigator 1 - Last Name |  |
| Investigator 1 - First Name |  |
| Investigator 1 - Email Address |  |
| Investigator 1 - College/Department/Division |  |

If there is only one student researcher, type NA in response to all questions about Investigator 2

|  |  |
| --- | --- |
| Investigator 2 - Last Name |  |
| Investigator 2 - First Name |  |
| Investigator 2 - Email Address |  |
| Investigator 2 - College/Department/Division |  |

Select one

-Undergraduate

-Master's Student

Select one

-Research

-Project

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| --- | --- |
| Project or Research Title |  |
| Faculty Advisor |  |
| Faculty Advisor Name |  |
| Faculty Advisor Email | be sure to enter this correctly so we can communicate with your advisor |

Does your thesis research or thesis project involve intervention or interaction with people?

Select one

-Yes

-No

Does your thesis research or thesis project involve obtaining private, individually identifiable information about living individuals?

Select one

-Yes

-No

NIH or CITI certification (Required)

-Yes Select yes

-No

Upload Certification for Investigator 1

If there is one student researcher, upload your certification when you fill out the application

Upload Certification for Investigator 2

If there are two student researchers, upload the second CITI certification. Otherwise skip this step.

How will you use the data collected in your study/project? Check ALL that apply.

-I am writing a thesis or project to submit to Sacramento State Office of Graduate Studies.

-I plan to present my research findings at a conference.

-I plan to publish my work in a journal or report that is available to the public.

-I will write a paper for my class and/or present my research findings in class.

-I will use my findings to improve my teaching practices.

If you indicated that you will be working with human participants, please indicate how you will be interacting these human participants. Answer this question

-I will be surveying, observing, and/or interviewing human subjects for thesis.

-I will be asking human subjects questions about the quality of my project.

-I will not be doing either of these things.

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| --- | --- |
| Anticipated Start Date (This cannot be before the approval date) |  |
| Duration of Study |  |

Are other institutions/agencies involved (i.e. campus, foundation, corp.)?

Select one

-Yes

-No

List name of institution(s)

Attach letter of support from the institution

Purpose and Objectives of the Research / Project

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Main Research Question or Hypothesis / Statement of the Problem

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Development of/Contribution to Generalizable Knowledge and Design of the Study (if applicable)

Generalizable knowledge means conclusions, facts, or principles derived from particulars that are applicable to or affect a whole category and enhance scientific or academic understanding.

Design refers to the purpose of the research (i.e. archive results for future research, compare results to other assessments, or draw conclusions and thus contribute to generalizable knowledge).

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| **Thesis research**: the goal of your work is to gather information from a sample, and then generalize to a larger population.  **Project**: the goal of your work is NOT to generalize findings to a larger population. The goal of your work is to evaluate a program or product you are creating.  Sample language: The purpose of this project is to develop and implement a parent education workshop about children’s self-regulation. Participating parents will be asked to provide feedback on how to improve the workshop [notice that the purpose is not about influencing psychological/behavioral change – it’s only about evaluating a product]. The project does not contribute to generalizable knowledge.  For some Graduate Programs, your work includes a combination of both. For example, you may be gathering data from participants to then create a product to disseminate. Please be clear in describing the aspects of your work that is intended to gather information from human participants and how that information will inform the creation of a product you will disseminate. |

Who are the subject groups?

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|  |

How are they recruited? (you will upload a flyer or email if advertising for subjects, later)

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| --- |
|  |

Maximum enrollment:

|  |
| --- |
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Criteria for selection:

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| --- |
| Be as specific as possible |

Criteria for exclusion:

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| --- |
| Must be everything NOT specified in the criteria for selection above |

Will any special population be included?

Select only if you will include a special population. Otherwise, skip this step.

-Children (under 18)

-Prisoners

-Pregnant women

-Fetuses Neonates

Those who involve special populations OR undocumented individuals (e.g., DACA), must apply directly to the University IRB: <https://www.csus.edu/compliance/research-integrity-compliance/human-subjects-research.html>

Are the children students in a class you teach?

Select one

-Yes

-No

Explain If you are testing a teaching practice in your classroom, select yes, and explain here.

Is an incentive offered?

This includes gift cards and extra credit. If you offer extra credit, a separate option must be available for students who do not wish to participate in your research. If you plan to conduct a drawing, see the information about California Law in this [document.](https://www.csus.edu/compliance/research-integrity-compliance/_internal/_documents/cayuse-irb-application-question1.pdf)

-Yes

-No

Describe

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How will real or perceived conflicts of interest be avoided? (e.g. asking your students to participate in your study)

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| The term “conflict of interest in research” refers to situations in which financial or other personal considerations may compromise or have the appearance of compromising a researcher's professional judgment in conducting or reporting research. See: <https://coi.ucsf.edu/>  Also, conflicts of interest arise when there is an unbalanced power dynamic between investigators and potential participants.  Sample: The researcher is recruiting through the district, and is currently employed with an agency that contracts with the district; the researcher is choosing to exclude aides that have had previous working relationships with. The researcher is also choosing not to work with teachers with preexisting working relationships.  Sample: I am a teacher at the research site. I know the families that will potentially participate. However, I have no power to change their children’s status in the school program if they choose/do not choose to participate. |

How long will participation take?

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| Example: Will subjects participate one time for a period of 1 hour, will they participate 2 hours a week for 10 weeks? |

Where will the study be conducted?

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| Check the University site for current policies regarding research participation and Covid-19 |

From the participant’s perspective, describe what their participation entails from consent process to completion of participation.

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| Must detail the steps from the consent process to the completion of data collection. Think about detailing your study/project procedures here.    For those using **audio recordings**, here is a recommendation for how to obtain consent:  The researcher will  introduce the study, and then review the consent form with the participant. During the consent form they will be reminded of what the study entails, the risk and benefit, permission to audio record and that they can stop participation at any time. After reading the form together they will be asked if they have any questions. After they have asked any questions regarding the study and their participation, they will be asked if they consent to participate and to choose pseudonym. **Once consent has been obtained verbally the researcher will start the recording and ask the participant to identify themselves using their pseudonym and to then repeat the statement of consent so that it is recorded.**  **For Zoom recordings turn off the camera and have participant change their name to a pseudonym before beginning.** |

Research materials to be disseminated to participants. E.g. surveys.

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| Describe here – you will upload materials later. |

How will data be recorded (notebook, computer files, audio tapes, online or paper surveys and questionnaires, etc.)?

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| If using audio recordings, direct and/or indirect identifiers will be collected. See below.  Online surveys should be completed on Qualtrics (supported by campus). When collecting data through Qualtrics, do NOT collect IP addresses.    **Data collection materials must be included with your application submission (e.g., copies of the online survey, interview questions, and/or observation protocols). Incomplete applications will NOT be reviewed.** |

Will direct or indirect identifiers be collected (i.e. name, address, audio/video, demographic information)? Even if you use pseudonyms in audio recordings, you are collecting identifiers.

Select one

-Yes

-No

If yes, is it likely that identification of one or more subjects is possible based on the demographic information collected and the size of your maximum enrollment? Can someone look at participant answers and figure out who some of them are? Even if you use pseudonyms in audio recordings, you are collecting identifiers.

Select one

-Yes

-No

Keep this in mind while completing Section G. Benefits and Risks below.

Who will have access to the raw data and how will confidentiality be maintained during collection and analysis? (videos should be erased after transcription, if possible; data should be stored on a University secure drive, such as the University OneDrive)

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| Sample: The data will only be accessible to the researcher and sponsor of the thesis. The audio recordings will be transferred as an audio file to a secure University drive (e.g., OneDrive). Once the audio recordings are transferred from the recording device to the University Drive, it will be deleted from the audio recording device. The audio recording will then be transcribed. Pseudonyms will be used in all interviews and subsequent transcriptions.   * For those using audio recordings, the Committee advises to obtain verbal consent on audio recording. Have participants read a consent form on recording. * Audio recordings should not be completed on a cell phone. Use a digital recorder or Zoom with the video turned off. |

How and when will data be maintained or destroyed after publication/presentation (If you save data, use a University secure drive, such as OneDrive, and public sharing should be turned off; shred documents; 3 years after completion)?

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| You may choose to keep data indefinitely for the purpose of publication and future presentations. However, you will need to explain how you will secure the data.  Sample: Data will be kept indefinitely with the possibility of publishing or presenting it. All data will be de-identified. Pseudonyms will be used in all interviews and subsequent transcriptions. |

Will medical records or other patient data be accessed?

Select one

-Yes

-No

Please upload any other supporting documents. You will upload your informed consent later. How many additional files you need to upload?

Upload supporting document here

Upload informed consent form, all surveys, and data collection tools, interview questions, and/or recruitment materials (anything that is needed to determine risk).

**Benefits and Risks.** If there is a significant probability of any one subject being identified based on the information collected and the maximum enrollment of this study, evaluate the below risks appropriately. See [FAQ’s](http://www.csus.edu/research/irb/faqs.html) for tips on safeguarding your subjects.

**REMINDER:**

Please remember throughout the application, there is a **difference between anonymity and confidentiality**.

**Confidentiality**

Maintaining confidentiality of information collected from research participants means that only the investigator(s) or individuals of the research team can identify the responses of individual subjects; however, the researchers must make every effort to prevent anyone outside of the project from connecting individual subjects with their responses.

**Anonymity**

Providing anonymity of information collected from research participants means that either the project does not collect identifying information of individual subjects (e.g., name, address, Email address, etc.), or the project cannot link individual responses with participants’ identities. A study should not collect identifying information of research participants unless it is essential to the study protocol.

Describe the benefits to the individual (if any) and to society:

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Physical Risk (i.e., devices, drugs, pharmaceuticals, exercise). This is TYPICALLY not applicable in educational/social sciences research.

Select one

-Not Applicable

-Minimal

-Greater than Minimal

Describe minimal or greater than minimal risk:

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Describe how this risk will be addressed/minimized:

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Psychological Risk (i.e., anxiety, stress, embarrassment). For most educational and social sciences research, this is MINIMAL.

Select one

-Not Applicable

-Minimal

-Greater than Minimal

Describe minimal or greater than minimal risk:

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| Sample: Participants may feel uncomfortable/embarrassed answering some of the survey questions (e.g., they have had difficult experiences or situations or lack knowledge about the topic). |

Describe how this risk will be addressed/minimized:

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| Sample: The researcher will reiterate that participants can skip questions at any time or end participation at any time. The researcher will also keep information confidential so that others cannot find out what the participants have said. |

Sociological and Economic Risk (e.g., employability, reputation, financial standing, criminal prosecution) If someone can figure out who your participants are, is there potential for your participants to be hurt?

Select one

-Not Applicable

-Minimal

-Greater than Minimal

Describe minimal or greater than minimal risk:

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| Sample #1: As an employee of COMPANY, the researcher may have/have had children of participants in her classroom.  Sample #2: Participants may fear that colleagues could find out about what they reported in the interview and fear repercussions at work due to this |

Describe how this risk will be addressed/minimized:

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| Sample #1: This is addressed in the consent form by stating that children will not lose status in the classroom and parent/guardian information will remain confidential. None of their information will be provided to the center director.  Sample #2: The researcher will remind participants that the information they share will be kept confidential and that she will not disclose their individual responses. They will not lose employment status and their participation will not damage their reputation at work. |

Confidentiality Risk (i.e., collection of identifiable information, data maintenance, potential access to data from outside parties). Almost all studies/projects in the College of Education should check this as MINIMAL. Please remember the distinction between anonymous and confidential.

Select one

-Not Applicable

-Minimal

-Greater than Minimal

Describe minimal or greater than minimal risk:

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| Sample: Participants will be audio recorded during the semi-structured interviews. There will also be demographic information collected.  Also, consider protections for participants included in studies with small sample sizes. What protections will be included to prevent their identification? |

Describe how this risk will be addressed/minimized:

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| Sample: The researcher will never use real names to identify the participants. The researcher will have participants provide a pseudonym on the audio recording and will only be referred to using their pseudonym.  All information will be kept confidential [*notice that participants cannot be anonymous for interview studies*]. The researcher will also never disclose individual-level data. The audio recording will be deleted once transcription is completed. All data will be stored on a secure University drive.. |

Procedure for obtaining informed consent from subjects (see below for guidance): Use the Exempt Research informed consent form templates on the [Resources](http://www.csus.edu/research/irb/resources.html) [page](http://www.csus.edu/research/irb/resources.html).

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| Please describe your procedures. Attach your consent form – MUST USE THE UNIVERSITY TEMPLATES (<https://www.csus.edu/compliance/research-integrity-compliance/human-subjects-research.html>). Consent forms much include your contact information as well as your sponsor’s contact information. |

Attach a copy of the informed consent form, email, and/or script.

Exempt research must have an informed consent process, although there is flexibility as exempt research is not governed by the regulatory requirements. Below are examples of various ways to respect participant autonomy:

If identifiers will be collected, it is best to obtain signatures.

If you are conducting anonymous paper or online surveys in which identifiers are not collected, alter the informed consent form so signatures are not required. The collection of signatures in this case would be the only identifiers, thus placing them at risk for loss of confidentiality. Informed Consent forms can be kept by the participant as an information sheet and their participation serves as consent.

In some cases, verbal informed consent is the best option, although this is rare. Use the Exempt Research Template as a script and ask for a verbal “Yes” or “No” for participation. Scripts will also need to be submitted with this application.

Remember

Informed consent forms are the only document your participant will see regarding your study. Respect your participants by using common language and ensuring they have all the necessary information to make an informed decision to participate or not participate.

By typing my name below and by submitting this proposed project or research, I certify that:

I will conduct the activity involving human subjects as presented in the protocol and approved by the academic unit and faculty supervisor;

I will present any proposed modifications in the research to the department/college committee for review and approval prior to implementation;

I will report to the department/college committee any problems or injuries to subjects.

Type your name and date below. This will constitute your electronic signature.

|  |  |
| --- | --- |
| Your name Date |  |

When filling out the application online, you will confirm when you are ready to submit.