IRB #: CSUEB-IRB-2020-8
Title: Sample Study
Creation Date: 4-17-2020

Initial Submission

1. POLICIES

Investigator(s) Assurance: By certifying this project submission, the principal investigator affirms they will take full responsibility for the conduct of the research for themselves and any/all co-investigators (faculty, students, key personnel, and others), for oversight of this study and other investigators named in this study. The principal investigator also affirms they will follow CSUEB IRB policy and federal regulatory guidelines in the protection of human subjects in research and the responsible conduct of research, and that all research personnel (faculty, students, key personnel, and others) have completed the required human subjects training requirements (CITI online human subjects training.)

Faculty advisors acting as Principal Investigators on student-led projects further affirm that they have reviewed the accuracy of this submission and accept responsibility for the ethical conduct of research, student supervision, and documentation maintenance.

Investigator Responsibilities: Investigators or researchers are required to notify the IRB of substantive changes to the research protocol, unanticipated, adverse, or serious events experienced by participants, and project completion. In these cases, please submit a modification request, adverse event request, or project closure request respectively.

Projects which have been assigned approval expiration dates must be renewed if research activities are to extend beyond the approval expiration date. Please submit a renewal/continuation request before the expiration date in these cases.

Failure to follow CSUEB IRB policy may result in disciplinary action. Completed consent forms and data must be kept at least three years after the study ends.

Training Policy: All Investigators and research assistants involved with a non-exempt category protocol must complete the CITI Course in Human Subjects Online Training before submitting an IRB application (see policy at https://www.csueastbay.edu/orsp/compliance/irb/training.html). Please attach a completed copy of your CITI Training Completion Report(s) with the IRB Application by uploading the report(s) in Section 2.

Cayuse Electronic IRB Application System: CSUEB faculty and student profiles must be entered into the Cayuse IRB system before submitting an IRB application. Once entered,

faculty and student(s) will have direct access to the online application. When specifying investigators and other research personnel, please use the Find People tool, which allows you to search for faculty and/or students by entering their names and automatically populates the investigator/researcher information into the application. Off campus researchers unaffiliated with CSUEB may not be entered into the system and may not be provided access to this application.

Communications with the IRB: For general questions, investigators may email the IRB at irb@csueastbay.edu. For questions or to provide more information regarding this protocol submission, a text box is available in the last section of this submission which both the investigator and IRB staff may update.

Communications between faculty advisors and student researchers: A text box is available in the last section of this submission which faculty advisors and student researchers may use if they wish to maintain all communications regarding the submission in one place.

Instructions: Please continue to the next section to begin the application.

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2. INVESTIGATOR(S)

Please note: Non-CSUEB campus community members cannot be added to the Cayuse IRB System. Non-CSUEB investigators, key personnel, and others must be added in the related text box area below.

Are you faculty, staff, or a student?

- Faculty
- Staff
- Student

Principal Investigator on Research Study

Phone # (if not listed above)

510-885-4007

If not indicated above please enter your college below (i.e. College of Business and Economics, College of Education and Allied Studies, College of Letters, Arts, and Social Sciences, College of Science, University Library.)

CSCI

Add additional CSUEB affiliated Co-Principal investigators) using the Find People function below as needed.

Student investigators, add yourself as the Co-Principal Investigator here.

Is this a multi-institution project?

Answer yes if either of the following two statements is true:

1) Non-CSUEB research members will complete portions of this project.
(Example: SF State professors will gather and analyze information from the students in their classes.)

2) CSUEB researchers will perform research activities on another institution's site.
(Example: CSUEB students will travel to SF State and conduct interviews with staff.)

Please note: This section should only be completed if the external organizations maintain their own IRBs. Typically, only four-year universities and hospitals maintain their own IRBs.

Yes

No

Unsure at this time

Training Documentation

Human subjects training reports must be provided for ALL personnel involved in non-exempt category studies (e.g., faculty advisers, students, principal investigators, co-principal investigators, key personnel, and evaluators).

CSUEB has contracted with CITI to provide Training Completion Reports directly to this application. If you select the **"Trainings"** tab next to the listed personnel above, the training reports we have on file will be shown.

If reports are not shown for study personnel, please attach CITI Online Human Subjects Training Completion Report(s) here.

3. DATA COLLECTION

Enter the proposed start date of your study allowing sufficient time for the IRB to review your application

Exempt (Limited)

- The study start date should be at least 15 days from the day you submit your IRB application.

Expedited Review

- The study start date should be at least 30 days from the day you submit your IRB application.

Full Board Review

- The study start date should be at least 90 days from the day you submit your IRB application.

Proposed Start Date of Study:

04/30/2020

Proposed End Date of Study:

12/16/2020

Number of Participants

Indicate the number of participants proposed for your study.
300

Demographic Information

Subject Ages

Select all that apply.

- 0 to 6 years
- 7 to 12 years
- 13 to 17 years
- 18 to 64 years
- 65+ years

Gender

Select all that apply.

- Female
- Male
- Other (For individuals who do not identify as male or female)

Special Populations

Describe any populations you hope to s rib = to s

Economically or educationally disadvantaged persons

Other

None of the above

C.

-
-
-

-
-
-
-

Data Analysis

G. Describe how you will analyze the data.

For example: Describe if your analyses will be qualitative, quantitative, or mixed methods or use any specific software.

Both quantitative analysis, using SAS and qualitative analysis, searching for dominant themes will be done.

Dissemination

H. Describe how you plan to present and/or publish your research.

For example: Will you present your research at a conference, publish in a scholarly journal, report in your thesis, or report in your dissertation?

We plan to submit results to a major journal.

6. CONFIDENTIALITY

In this section, explain the how, what, when, and where you will store and secure the data you have collected. Clearly indicate speci ca y

7. RISKS AND BENEFITS

Potential Benefits

Describe any direct or guaranteed benefit (e.g., cash payment, gift card, course credit, free treatment). If payments will be made, how will payment be received- cash or check, mailed or handed out?
Will payments affect confidentiality?

Note that excessive payments may be considered coercive. If students will receive extra credit or course credit, state the alternative method(s) of earning the credit that must be made available to those who do not wish to participate.

No benefits will be offered for completion of the survey activityT

Describe the procedures for protecting against or minimizing each potential risk listed above. For example, risk of loss of privacy may be reduced by storing all research material in a locked cabinet, by using codes rather than participant names on surveys, by conducting an anonymous study or other methods. If risk of emotional discomfort is high, provide the subjects with a list of referrals for counseling and attach to the informed consent document.

All data will be de-identified prior to analysis and stored on password protected computer on CSUEB campus.

Focus group attendees will be briefed prior to meeting about the importance of maintaining confidentiality.

Risk/Benefit

Discuss why the risks to subjects are reasonable in relation to the anticipated benefits to subjects and in relation to the importance of the knowledge that may reasonably be expected to result.

While benefits to subjects are minimal, risks are also extremely minimal.

8. INFORMED CONSENT

Consent Process

Indicate who will be asked to provide consent/assent, who will obtain consent/assent, what language (e.g., English, Spanish) will be used by those obtaining consent/assent, where and when will consent/assent be obtained, what steps will be taken to minimize the possibility of coercion or undue influence, and how much time will subjects be afforded to make a decision to participate. If a translator will be used, identify whether the translator will be a family member of the participant.

Consent for survey and focus group will be given by parent, with assent provided by child. Since subjects are in high school, they may sign the same consent form as the adults. Parents may have as long as they like to decide. No translation will be provided.

Consent Forms

Remember that the informed consent language should be written at the 6th to 8th grade reading level or lower if needed. Please follow the standard CSUEB consent form template unless there are specific reasons to use a non-standard format. If a non-standard format is used, the form must include the federal required sections below in items 1 through 11.

For an example Informed Consent form please refer to the CSUEB IRB website or click on the following link: Standard Consent Form

The IRB requires a text of the proposed statement to be used for oral or electronic consent. Like written consent, they should include:

1. Identification of the researcher(s)
2. The nature and purpose of the study
3. Expected duration of participant involvement
4. A description of the procedures to be followed
5. How confidentiality or anonymity will be maintained
6. The voluntary nature of participation
7.
8.

9. For more than minimal risk research, a statement as to whether compensation or
10.
11.

Example Parental Consent.pdf

) and OHRP questions and answers at http://answers.hhs.gov/ohrp/questions/7202.)

The child must actively show his or her willingness to participate in the research, rather than just complying with directions to participate and not resisting in any way. When judging whether children are capable of assent, the Institutional Review Board (IRB) is charged with taking into account the ages, maturity, and psychological state of the children involved. The IRB has the discretion to judge the child's capacity to assent for all the children involved in a proposed research activity, or on an individual basis. Assent forms must use age-appropriate language, and assent should be obtained verbally for ° iscret ʻ et ʻ et

9. DEBRIEFING

A debriefing statement is usually required only if any type of deception is used in the study. Participants may also be debriefed about their behavioral or emotional response(s) to the study. The two major goals of debriefing are de-hoaxing and de-sensitizing. Any undesirable influence the study may have on participants should be minimized or eliminated.

The debriefing statement should describe the reason(s) for conducting the research, how participants can obtain results of the study, and contact information for additional details or answers to questions. It would also be advisable, for methodological purposes, to request that participants not reveal the nature of the study to other potential participants. If you are a student researcher please check with your faculty advisor on whether you should include a debriefing statement.

Some researchers use an information form at the end of their studies to include relevant follow-up contact information of the faculty or student investigator(s). This may also include additional information for counseling services or emergency hotline numbers for those experiencing distress after a research/study procedure has ended and results in the participant recalling past instances of psychological or physical trauma.

Attach your debriefing form/statement here.

10. ATTACHMENTS

Letter(s) of Permission

Attach letters of permission here.
Example Permission letter.pdf

Multi-Institution Project Documents

Training Documentation

Recruitment Materials

Example Recruitment.pdf

Surveys, interview questions, debriefing forms, and similar documents

Example Survey.pdf

Consent Forms

Example Parental Consent.pdf

Assent Forms

Debriefing Form/Statement

Other Attachments

Please provide any other attachments necessary for your study that have not been previously requested.

11. COMMUNICATIONS

Communications between Investigators and IRB staff

Each item in the submission allows for comments to be entered. If you have comments or questions regarding the submission as a whole, you may use this text box to communicate with IRB staff. You may also email the IRB at irb@csueastbay.edu.

Communications between Faculty Advisors and Student Advisees

Faculty Advisors and their Student Advisees may use this text box for communication if they wish to maintain a record of those communications in the Cayuse system. While IRB staff may view this information, the intent is to provide a mechanism for Advisor/Advisee communication.