Reviewer Checklist

Completed By: [redacted]

[redacted]

Initial Submission

CSUB IRB Protocol Reviewer Checklist

Human Subjects Research Protocol Reviewer Checklist

Check the Regulations!

45 CFR 46.111 Criteria for IRB Approval of Research

- **a1: Minimization of risks**
- **a2: Risk-benefit relationship**
- **a3: Equitable selection**
- **a4: Consent process**
- **a5: Consent documentation**
- **a6: Data monitoring**
- **a7: Privacy/confidentiality**
- **a8: Broad consent (*option not utilized by CSUB*)**
- **b: Vulnerable population/subjects**

When finished completing the Reviewer Checklist, please remember to click on the green save button at the bottom.

Date Please select today's date below:

SECTION 1: RESEARCH STUDY PERSONNEL & PROJECT DATES

Q1-4 Do you have any concerns pertaining to the items listed below?

- **the Principal Investigator,**
- **the Principal Investigator status, and/or,**
- **the Faculty Sponsor (where applicable),**
- **the Faculty Sponsor status.**

Select one radio button from below:

Q5 Are there any concerns regarding the Project Start and End Dates?

Select one radio button from below:

Q6 Are the qualifications of the investigator(s) appropriate for the proposed research?

Principal Investigator's professional qualifications to do the proposed research

- **Degree type**
- **Degree field**
- **Years in the field**
- **Publications**
- **Presentations**
- **Other certifications**
- **Experience related to the proposed research**
- **If a student, the courses taken related to area of study and research**

Select one radio button from below:

Q7 Are the qualifications of the Co-investigator(s) appropriate for the proposed research?

Key personnel are the principal investigator and any other people -- co-investigators and research assistants -- who would interact with human subjects in data collection or obtaining informed consent, or have access to data with personal identifiers.

Q8 Are there any concerns regarding the additional personnel?

Key personnel are the principal investigator and any other people -- co-investigators and research assistants -- who would interact with human subjects in data collection or obtaining informed consent, or have access to data with personal identifiers.

Select one from below:

Q9 Is this is a Classroom Project or Culminating Project?

Select one radio button from below:

SECTION 2: IS MY PROJECT HUMAN SUBJECTS RESEARCH?

*****This section is not required, however, it can provide helpful educational information to students and serve as a useful administrative tool for the analysts as well.**

Q1-3 Activities of the research may result in:

PI may select from the different options below:

- a classroom project, for example, a Research Methods course project
- an undergraduate senior thesis

- a master's thesis that will be filed in the library
- a dissertation
- a presentation at a scholarly professional meeting, current or future
- a publication, current or future
- a culminating project for a master's thesis that does**NOT** meet the definition of Human Subjects Research.
- a program review or program evaluation or quality improvement activities
- a program evaluation project for a culminating course

SECTION 3: PROJECT BACKGROUND & STUDY DETAILS

Note: Depending on how the PI has answered the questions, some of the sections may not be relevant and not all numbered sections will appear.

Q1 Is the Literature Review Section adequately completed?
Select one answer from the options below:

Q2 Is the purpose of the research study clear?

- Are the aims of the project clear?
- Are the research questions clear?

Q3 Does the PI adequately describe how the research could add to the field of study?
Does the PI explain the gap that they are trying to fill?

Q4 Is there an adequate explanation of how the research would benefit the study participants?
Select one from the options below:

Q5-8 Is the study design clear and appropriate?

See 45 CFR 46.104(a)(1)
Select one from below:

Information Security

With respect to data collection, handling, storage, reporting, and destruction of research data and consent forms; when answering these questions, the PI should be sure to spell out the specific steps that will be taken to enhance confidentiality and protect the privacy of the subjects.

Q9 Are the procedures for Information Security clear and adequate for data collection?
Select one from below:

Q10 Are the procedures for Information Security clear and adequate for data handling?
Select one from below:

Q11 **Are the procedures for Information Security clear and adequate for data storage?**
The PI should explain the procedures for data storage in detail.

- The regulations do not dictate how long researchers must keep the data collected, however, the regulations **do** dictate how long the signed Informed Consent forms must be kept.
- As per 45 CFR 46.115(b), please include the following statement in both your protocol (in the section below) as well as in your Informed Consent form that you will be providing to your participants:
- **"The Researcher will keep the signed Informed Consent forms for a period of at least 3 years which can be destroyed after completion of the research".**
- *This language/verbiage needs to be included in both the Informed Consent form as well as the protocol itself. In other words, the information in the Protocol will match the information in the Informed Consent form*

Q12 **Are the procedures for Information Security clear and adequate for data reporting?**
Select one from below:

Q13 **Are the procedures for Information Security clear and adequate for data destruction?**
Select one from below:

Q14 **Does this project have a funding source?**

Authoritative References & Guidance:

- **An institution with a DHHS approved Federal Wide Assurance typically agrees to apply DHHS regulations to all research regardless of the funding source, including research that is internally funded and collaborative research across institutions.**
- **During the IRB review process the Board will consider whether the funds create a conflict of interest for the researcher. Some funding sources can present a conflict of interest for a participant group and the board may require that the PI provides full disclosure to the participants regarding the funding source for the study.**
- **The IRB may require that additional information be given to subjects "when in the IRB's judgment the information would meaningfully add to protection of the rights and welfare of subjects" (45 CFR 46.109(b), 21 CFR 56.109(b)).**

Select one from below:

Q15 **Will CSUB be engaging in research with another institution through collaborative/cooperative research in this study?**

Determining When Institutions are Engaged in Research (January 13, 2009)
Select one radio button from below:

Q16 Is the PI requesting access to Existing Data?

Examples: School attendance records, restricted online datasets, or secondary data that was collected from some other primary source or study, data that is not publicly available.
Select one radio button from below:

Q17 Does the Principal Investigator want to conduct interviews, distribute surveys, systematically observe, or collect other data from human subjects?
Select one radio button from below:

Section 4 - Study Procedures

Q1 Are the criteria for subject selection equitable?
45 CFR 46.111 (a)(3)

Equitable selection

Selection of subjects is equitable. In making this assessment the IRB should take into account the purposes of the research and the setting in which the research will be conducted. The IRB should be particularly cognizant of the special problems of research that involves a category of subjects who are vulnerable to coercion or undue influence, such as children, prisoners, individuals with impaired decision-making capacity, or economically or educationally disadvantaged persons.

Q2 Is the participant or target population clear and appropriate?
Select one radio button from below:

Q3 Is the number of participants adequate?
Select one radio button from below:

Q4 Are the criteria for subject rejection equitable in terms of the purpose of the proposed research?
Select one radio button from below:

Q5 Does the PI provide a clear and appropriate description of the recruitment procedures?
Select one radio button from below:

Q6 Is the person(s) who will be recruiting the participants for this study appropriate/qualified?
Select one radio button from below:

Q7 Is the location of the recruitment of participants appropriate?
Select one radio button from below:

Q8 Are the research subjects from any of the following vulnerable populations?

Children and minors (under 18 years of age)
Incarcerated persons
Institutionalized or hospitalized persons
Pregnant women, See 45 CFR 46 Subpart B
Mentally-disabled or cognitively-impaired persons
Elderly/aged persons
Economically- or educationally-disadvantaged persons
Students in the classroom
Ethnic/racial minority persons
Employees in their workplace
Other _____

Select one radio button from below:

Understanding the Research Participant's Perspective

Q9 The PI should answer the questions below in concise detail.

a. Focusing on the experiences of the subjects/participants in the research study, how do you intend to collect data?
b. How will human subjects be involved in the proposed research?
c. What are the procedures you will be using from the participant's point of view and what can they expect?

Select one radio button from below:

Benign Behavioral Intervention

Benign behavioral intervention" is described in 46.104(d)(3) as behavioral (not biomedical) "interventions in conjunction with collecting information from an adult subject through oral or written responses (including data entry) or audiovisual recording if the subject prospectively agrees to the intervention and information collection and certain conditions are met" (HHS 2017). The new exemption is for the research activities that pose little risk of harm to subjects.

Authoritative Reference & Guidance:

- See 45 CFR 46.104
- Attachment B- Recommendations on Benign Behavioral Intervention, SACHRP Recommendation Approved July 26, 2017, A Guidance and Educational Tool for Benign Behavioral Interventions

The regulations at 46.104(d)(3)(ii) (HHS 2017) also adds that benign behavioral interventions are:

- Brief in duration
- Harmless
- Painless
- Not physically invasive

- Not likely to have a significant adverse lasting effect on the subjects
- Not likely to be offensive or embarrassing to subjects

The preamble gives the following examples of benign behavioral interventions (HHS 2017):

- Having the subjects play an online game
- Having the subjects solve puzzles under various noise conditions
- Comparing test performance of test takers in quiet or noisy surroundings
- Having subjects decide how to allocate a nominal amount of received cash between themselves and someone else

Note: The Final Rule includes three of the above examples in the regulatory language. (CITI Program 2019)

Q10 Does the PI provide an adequate and appropriate description of the Benign Behavioral Intervention?

Select one radio button from below:

Research Involving Deception

Q11 Does the study involve deception or providing incomplete information to participants initially?

- See 45 CFR 46.104 (3)(iii)

- If the research involves deceiving the subjects regarding the nature or purposes of the research, the 45 CFR 46.104 (3)(iii) exemption is not applicable unless the subject authorizes the deception through a prospective agreement to participate in research in circumstances in which the subject is informed that he or she will be unaware of or misled regarding the nature or purposes of the research.

Select one radio button from below:

Risks and Adverse Reactions

Q12 Does the research protocol clearly describe the provisions for managing any adverse reactions, physical or emotional, as a result of the subject's participation in the research?

The PI is asked to answer Questions A-D listed below:
A. What are the potential risks/adverse reactions subjects may be exposed to by participating in this study?

Including but not limited to:

- *Physical reactions*
- *Emotional reactions*

- *Psychological harm*
- *Possible breaches of confidentiality*

B. **How will participants be protected?**
C. What precautions will be taken to minimize risk?
D. **How will adverse reactions be dealt with?**

Select one radio button below:

Q13 Will participants be compensated (paid or given anything of value) in return for their participation?
Authoritative Reference & Guidance

- HHS regulations at 45 CFR 46.116
- Participant Compensation
- CSUB Gift Card policy

Informed Consent Process & Documentation

Note: for online data collection see the next section below

The PI must use one of the Informed Consent Form Template which is compliant with the New Revised Common Rule regulations.

- *Additional templates can be found on the IRB Webpage, click here.*

Authoritative References & Guidance:

- *HHS regulations at 45 CFR 46.116 and 45 CFR 46.117 describe the informed consent requirements.*
- Informed Consent Tips (1993)
- Informed Consent FAQs
- Informed Consent Language For Confidentiality and Data Sharing
- The "Information Sheet" is what the online Informed Consent Form is called. Click on the link below:

  Information Sheet/Online Informed Consent Form Template 2019

  https://www.csub.edu/grasp/Research%20Compliance/I...

Q14 Do the informed consent process and informed consent documentation procedures meet the requirements?

Select one radio button from below:

Q15 Is the request for a waiver of informed consent appropriate?

Select one radio button from below:

HSPT Human Subjects Protection Training

The training records for the PI, Co-PI *(where applicable*), Additional Personnel *(where applicable)*, and Faculty Sponsor *(where applicable)* are verified in the Pre-Review phase of the protocol review, normally and routinely by the Research Compliance Analyst.

The CITI Training Records display automatically by clicking on the **VIEW** link (*CITI to Cayuse IRB Integration Function*) in Section 1.

Screenshot Example of Training Link

Cooperative Research Agreement Section

This section is to be used when CSUB will be engaged in research with another institution through collaborative research. If you have any questions, please contact Dr. Isabel Sumaya at (661) 654-2381 OR Gwen Parnell at (661) 654-6712. Both can be reached via email at irb.org@csub.edu

Authoritative Reference & Guidance:
The Revised Common Rule's Cooperative Research Provision (45 CFR 46.114)

CR1-9 Is this project a Cooperative Research Agreement request?

Select one radio button from below:

Funding Funding Section/Research Project Sponsorship

Select one from the options below:

Section 5 - Third-Party Access to Existing Data Protocol Section

OHRP Guidance

See also 45 CFR 46.104(d)(4)

Q1-3 Is the PI requesting access to existing data?

Select one radio button from below:

Waiving Informed Consent - Third Party Access to Existing Data

Given the answers above, you are requesting to waive the collection of Informed Consent from participants.

In certain cases, federal regulations allow the IRB to *waive the requirement to obtain any informed consent*. Most

waivers of consent involve studies in which there are minimal risks to subjects, and other limited circumstances. Federal regulation 45 CFR 46.116(d) and recent FDA Guidance establishes four criteria for waiving consent or altering the elements of consent in minimal risk studies.

- *SACHRP Recommendation on Compatibility of Secondary Use with Consent*
- *Guidance on HIPAA and Individual Authorization of Uses and Disclosures of Protected Health Information for Research*
- *Coded Private Information or Specimens Use in Research, Guidance (2008)*

Minimal Risk Studies

1. The research involves no more than minimal risk to the participants;
2. The waiver or alteration will not adversely affect the rights and welfare of the participants;
3. The research could not practicably be carried out without the waiver or alteration; and
4. Whenever appropriate, the participants will be provided with additional pertinent information after participation.

Q4-6 Has the PI met the above requirements for a request to waive informed consent?

Select one radio button from below:

Research Data Protection Plan

Federal regulations require research to include adequate provisions to protect the privacy of subjects and maintain the confidentiality of data (Protection of Human Subjects 2017). Subjects [participants] should be informed during the consent process of the methods that will be used to maintain the confidentiality of their identifiable information and the possible risks of disclosure of this information outside of the research study.

Reference: CITI Program, Human Subjects Protection Online Training Course, Privacy and Confidentiality Module, December 10, 2019. https://www.citiprogram.org

Authoritative References & Guidance:

- Privacy and Confidentiality in Research
- Guidance Regarding Methods for De-identification of Protected Health Information in Accordance with the Health Insurance Portability and Accountability Act (HIPAA) Privacy Rule
- 45 CFR 164.514 - Other requirements relating to uses and disclosures of protected health information
- Attachment B -Recommendations on the Interpretation and Application of 45 CFR 46.104(d)(4) the HIPAA Exemption
- Certificates of Confidentiality -Privacy Protection for Research Subjects: OHRP Guidance (2003)

Q7-9 Do the details or components of the research data protection plan adequately address the following?

- Protection of identifiers
- Protection of data from misuse
- Protection of data storage

- Removal of identifiers at the earliest opportunity
- Disclosure of data to any other person or entity

Select one radio button from below:

Section 6 - Additional Personnel

Key personnel are the principal investigator and any other people -- co-investigators and research assistants -- who would interact with human subjects in data collection or obtaining informed consent, or have access to data with personal identifiers.

Q1-3 Are there any concerns regarding the additional personnel?

Select one radio button from below:

Section 7 - Additional Supporting Documents

Sect7 Are there any concerns regarding the additional supporting documents?

Examples include:

- Survey Instrument
- Survey Schedule
- Interview Questions
- Recruiting Materials
- Permission Letter from Superintendent of Schools
- Debriefing Documents
- Spanish Versions of Informed Consent Form
- Multiple Versions of Informed Consent Documents
- Multiple Versions of Information Sheet

Select one radio button below:

NRRSNot Regulated Research Status (NRRS)

This section is designed for programs that require a Not Regulated Research Status letter, the Student Principal Investigator will complete this section to obtain a letter from the IRB verifying the project does not meet the criteria for Human Subjects Research and does not fall under the purview of the IRB.

Culminating Project Checklist/Not Human Subjects Research Acknowledgement form

Risk Analysis Section

In this section the Reviewer is asked to provide a risk analysis for the research study being reviewed.

The different categories of potential risks to participants listed below are rated using these parameters: None, Minimal, Moderate, and Substantial.

1. Physical risk (injury, illness, etc.
2. Risk of criminal or civil liability if data disclosed
3. Financial or employment risk if data disclosed
4. Risk to family or personal reputation if data disclosed
5. Psychological or emotional risk (anxiety, frustration, stress)

R.A.1 Please rate the potential physical risk (injury, illness, etc.) to participants of the proposed research.

R.A.2 Please rate the potential risk to participants of the proposed research of criminal or civil liability if data disclosed.

R.A.3 Please rate the potential financial or employment risk to participants of the proposed research if data disclosed.

R.A.4 Please rate the potential risk of the proposed research to family or personal reputation if data disclosed.

R.A.5 Please rate the potential psychological or emotional risk (anxiety, frustration, stress) of the proposed research to participants .

R.A.6 Other risks

You may enter any other risks noted:

R.A.7 Summary of Risk Analysis

Select your overall risk category

Benefit Analysis Section

In this section the Reviewer is asked to provide a benefit analysis for the research study being reviewed.

The different categories of potential areas of benefits listed below are rated using these parameters: None,

Minimal, Moderate, and Substantial.

1. Potential benefits to the research participant him/herself
2. Potential benefits to the participant population as a generalized group
3. Potential benefits to scientific knowledge
4. Potential benefits to society of humankind in general

B.A.1 Potential benefits of the proposed research to the research participant him/herself

Select one radio button below:

B.A.2 Potential benefits of the proposed research to the participant population as a generalized group

Select one radio button below:

B.A.3 Potential benefits of the proposed research to scientific knowledge

Select one radio button from below:

B.A.4 Potential benefits of the proposed research to society of humankind in general

Select one radio button from below:

B.A.5 Other benefits

You may enter other benefits noted here:

B.A.6 Summary of Benefit Analysis

Select your overall Benefit Category

R/BSummary Select the statement that best summarizes your Risk/Benefit assessment:

Select one radio button from below:

Decision Recommended Action

Select one of the following options:

+COMMENTS Other Reviewer comments

You may enter your additional comments here:

NOTE: Reviewer comments directed to the PI/Research Team/Administrative Analysts can be entered/embedded in the Cayuse IRB protocol document itself for each question on the form.