Submission Type: Initial Date: 1-28-2020

IRB #: 20-211
Title: Third Party Access to Existing Data Example Shell Protocol 1.28.20
Creation Date: 1-28-2020
Status: Awaiting Certification
Principal Investigator: Gwendolyn Parnell

CSUB *Cayuse IRB Protocol Instructions

California State University, Bakersfield
Human Subjects Institutional Review Board (HSIRB)
FWA00013908

Cayuse IRB Submission Form Instructions

- **Cayuse IRB is an interactive application system.**
- **As you answer the questions, new sections relevant to the type of research being conducted will appear on the left-hand side of the screen.**
- **Not all numbered sections may appear, depending on how you answer the questions.**
- **You do not have to finish the application in one sitting.**
- **When completing this form please note that an * indicates a REQUIRED FIELD**

- **In order to submit your protocol to the IRB for review, you must:**

1. Have a green checkmark by each section showing on the left-hand side of the screen,
2. Complete & Submit the protocol, and
3. Certify the submission

Use this Cayuse IRB form to submit a (an):

- Initial (new protocol submission)
- Legacy/Existing Protocol (pre-existing study submission)
- Modification/Amendment (including personnel changes)
- Continuing Review/Renewal (renewal of study)
- Withdrawal (withdraw study submission)

- Closure/Final Report (close study)
- Incident/Problem Report (reporting incidents/adverse events/problems)

To help you determine if your project constitutes human subjects research, please review the following:

- *Definition of Human Subjects Research: The CSUB definition of research with human subjects is from Title 45: Part 46, which has been adopted in the CSUB IRB Policies & Procedures. "Research is defined as a systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge" [CSUB Policies & Procedures].*

- *Definition of Human Subject from 46.102(e) (HHS 2017)*

- *Human subject means a living individual about whom an investigator (whether professional or student) conducting research: (i) Obtains information or biospecimens through intervention or interaction with the individual, and uses, studies, or analyzes the information or biospecimens; or (ii) Obtains, uses, studies, analyzes, or generates identifiable private information or identifiable biospecimens.*

- *The Code of Federal Regulations*
- *The Belmont Report*

******Regardless of the timeline or level of review, only proceed with your Human Subjects research activities when you have received an official authorization letter from the IRB.***

For assistance, please contact:

Mrs. Gwen Parnell, Research Compliance Analyst
(661) 654-6712
irb@csub.edu or

Dr. Isabel Sumaya, University Research Ethics Review Coordinator
(661) 654-2381
rerc@csub.edu

To begin your IRB protocol submission, please click on Section 1 at the left-hand side of the screen.

Section 1 *Research Study Personnel & Project Dates

Who is the Primary Contact person for this project?

1. *Please identify the primary contact for this project. This may or may not be the same person listed at the Principal Investigator.*

Name: Gwendolyn Parnell
Organization: Grants & Contracts Admin
Address: 9001 Stockdale Highway , Bakersfield, CA 93311-1022
Phone:
Email: gparnell@csub.edu

Who is the Lead or Primary Researcher/Principal Investigator on this project?

Please identify the Principal Investigator

If you are a student researcher, you will be asked to identify your faculty sponsor upon answering question 3

2.

- *Instructions for adding a Principal Investigator: Click on the FIND PEOPLE button, click on the Plus sign at the Right, click on the name and then click SAVE.*
- *Note: The People Finder Button is HR Connect driven. CSUB Faculty & Staff can be found & selected readily.*

- ***CSUB Students and External Investigators need to be added manually to the system in order to gain access.***
- ***Contact Gwen Parnell at gparnell@csub.edu or (661) 654-6712 for assistance.***

Name: Gwendolyn Parnell
Organization: Grants & Contracts Admin
Address: 9001 Stockdale Highway , Bakersfield, CA 93311-1022
Phone:
Email: gparnell@csub.edu

What is the Principal Investigator's status at CSUB?

3.

Note: Students filling out this form are required to have a faculty mentor; the faculty mentor listed will be required to certify this protocol prior to CSUB HSIRB review.

- Faculty
- Doctoral Student
- Graduate Student
- Undergraduate Student
- Administrator
- ✓ Staff
- External Investigator
- Volunteer

Project Dates

5. *The Code of Federal Regulations: Title 45, Public Welfare, Part 46, Protection of Human Subjects, specifies that human subjects research may not begin until it has been authorized by the university IRB. This includes interacting with human subjects in data collection or obtaining informed consent, or accessing data with personal identifiers.*

Project Start Date

5a *You may indicate an estimated project start date.*

Note: This is the date you expect to be collecting data from human participants after receiving IRB authorization.

12/01/2020

Project End Date

5b

You may indicate an estimated project end date.

11/25/2022

What are the Principal Investigator's professional qualifications to do the proposed research?

Please list:

6.

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

Sample only

Will you be working with a Co-Investigator?

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.

7.

- A Co-investigator designation allows access to the protocol to review and make additions and edits.
- A Co-investigator must also "Certify" the protocol to forward it on for review by the IRB.

Yes

✓ No

Will there be additional personnel working on this study?

- 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.

8.

- You may add your Student Researchers, Research Assistants, and/or External Investigators in the Additional Personnel section.

- Tip: You can copy and paste a list of names in the Additional Personnel Section that is displayed on the left side of the screen when you select Yes. You may upload multiple CITI reports for the Additional Personnel in the HSPT Section.

Yes

✓ No, not at this time.

If you would like to add additional personnel down the road, after initial IRB approval, you will need to submit a request for a Modification.

Is this is a Classroom Project or Culminating Project ?

9. • *Does My Research Project or Class Project Require IRB Review? Flow Chart*

Select one radio button from below:

Yes

✓

9a **Does your project involve human subjects research/meet the criteria for human subjects research and is it designed/intended to contribute to generalizable knowledge?**

Select one radio button from below:

Yes

✓

- By selecting this option you will complete and submit a protocol to the IRB for review.
- Continue on to the next section and complete all required sections until they have a green checkmark next to it.

No

- By selecting this option you will only need to complete the Not Human Subjects Research Acknowledgment Form Section to submit a request to the IRB to obtain an NRRS (Not Regulated Research Status) Letter.

- The NRRS letter acknowledges the IRB has determined the project does not meet the criteria for IRB review.

- Tip: Only select 'No' if your research project is NOT designed or intended to contribute to generalizable knowledge and does NOT involve human subjects research nor meet the definition of human subjects research.

No or N/A

I am still not sure if my project meets the criteria for Human Subjects Research.

Section 2 *Is My Project Human Subjects Research?

***This section-Section 2, is not required, however, it can provide helpful educational information to students and serve as a useful administrative tool for the IRB Administrative Analyst/Research Compliance Analyst as well.

1. **What activities may result from the activities I am planning?**

Select all that may apply:

- [ ] a classroom project, for example, a Research Methods course project
- [ ] an Undergraduate Senior Thesis
- [x] a Master's Thesis that will be filed in the library, (All Master's Theses and Culminating Projects involving **human subjects** are considered contributions to generalizable knowledge and therefore must be submitted for IRB review).
- [ ] a Culminating Project for a Master's Thesis that does not meet the definition of Human Subjects Research. I would like to request a "Not Regulated Research Status (NRRS)" letter. *(Tip: If you selected this option, you would have selected 'Yes' for Section 1, Question 9 and 'No' to 9a)*
- [ ] a dissertation
- [x] a presentation at a scholarly professional meeting, current or future
- [x] a publication, current or future
- [ ] a program review *or* program evaluation or quality improvement
- [x] a program evaluation project for a culminating course

2. **Do you want to interview, survey, systematically observe, or collect other data from human subjects?**

For example, students in the educational setting.

Yes, *(If you selected this option, be sure to continue on to complete Sections 3-Project Background, the HSPT Section, & Section 4-Study Procedures).*

✓ No

Secondary Research Use/Third Party Access to Existing Data Protocol

Use the **"*Third-Party Access to Existing Data Protocol*" [3PA]** if you propose to access existing data about individual persons that have been collected by others and which contain personal identifiers, such as names or phone numbers. The protocol still applies *even if you do not intend to use or report the personal identifiers*.

The words "authorization" and "consent" are used as synonyms. The protocol outline is designed to elicit the information needed for the CSUB Institutional Review Board [IRB] to evaluate requests for *waiver of authorization by individuals* for use/disclosure of information about them for research purposes. The structure reflects the provisions of the federal Health Insurance Portability and Accountability Act [HIPAA] that regulates research access to protected health information. If the data requested contain protected health information, then the waiver documentation provided by the IRB will satisfy HIPAA requirements. However, at CSUB the same procedure is used to evaluate requests to waive authorization for use/disclosure of *any information* for research purposes, such as scores on standardized tests in the educational setting.

- **Use of this procedure is limited to *third-party access* to data, that is, for a researcher to seek access to existing data collected by another entity, for example, a school or public agency providing services to the individuals whose data are requested.**
- **Waiver of authorization will be granted only if the research participants are placed at *no greater that minimal risk*.**
- **If the individuals *have* consented that their data may be used for research purposes, then this request for waiver of authorization is not needed. However, if individuals have only consented that their data may used for purposes of program evaluation and/or providing of services, then this request for waiver of authorization is needed.**

Do you want to access Secondary Data?

3. *(If you selected 'Yes' for this option, be sure to continue on and complete Section 3, Project Background, the HSPT Section, and Section 5-Third Party Access to Existing Data protocol).*

✓ Yes, I want to access data about specific persons that have already been collected by others [such as test scores or demographic information].

3.1 Can those data can be linked to specific persons? *(Even if you do NOT intend to use or report the personal identifiers)*

Yes

✓ No

No

Section 3 *Project Background & Study Details

Title **Enter your project title here:**

Third-Party Access to Existing Data Protocol Sample Shell Only 1.28.20

Literature Review

What is known or unknown in this area of research?

1. *Tips:*

   - *Based on the previous literature, provide a brief review of the literature **(including citations)**.*
   - *The list of citations does not need to be exhaustive.*

Sample only

What is the purpose of your research?

2.

What are the aims of the project and/or what is your research question?
Sample only

What is the research intended to add to this field of study?

3.

What is the gap that you are trying to fill?
Sample only

4. **How would the research benefit the study participants?**

Sample only

Study Design

See 45 CFR 46.104(a)(1)

5. **Please provide a general overview of your proposed project in the text box below:**

Sample only

In detail, please explain the design of your project

6. Examples of some of the types of Research Design:

- Descriptive (e.g., case-study, naturalistic observation, survey)
- Correlational (e.g., case-control study, observational study)
- Semi-experimental (e.g., field experiment, quasi-experiment)
- Experimental (experiment with random assignment)
- Review (literature review, systematic review)
- Meta-analytic (meta-analysis)

Sample only

7. **What is your chosen research study design type?**

Select all that apply:

- Qualitative
- ✓ Quantitative
- Experimental
- Exploratory
- Correlation
- Longitudinal
- Other

8. **How is this design linked to your research question?**

Refer to "Purpose" question above as needed.
Sample only

Information Security

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

9. **How do you intend to collect information?**

Sample only

10. **How do you intend to handle the information once collected?**

Sample only

How & where will data/information be stored?

[Please explain in detail]

Authoritative Reference & Guidance:

11.

- 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 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.
- Where applicable, if the PI is a student and will graduate prior to the end of the 3 year period, the faculty sponsor will keep the signed Informed Consent form documents.

Sample only

How will information be reported?

12.

Select all that apply:

- Annual Performance Report
- Manuscript
- ✓ Presentation
- Symposium
- Classroom ONLY, no off campus visitors or attendees
- Other

When and how will research data be destroyed?

13.

This is a separate question from how long the signed Informed Consent documents are retained which is determined by 45 CFR 46.115(b).

Sample only

Does this Project have a funding source?

14.

Select one radio button from below:

- Yes, funding has been secured. (*Please complete the **Funding** section that appears on the left-hand side of the screen).*
- Funding is anticipated. (*Please complete the **Funding** section that appears on the left-hand side of the screen).*

✓ No

15. **Will CSUB be engaging in research with another institution through collaborative/cooperative research?**

OHRP Guidance: Determining When Institutions are Engaged in Research (January 13, 2009)

Yes. (*Please complete the Cooperative Research section that appears on the left-hand side of the screen).*

✓ No

16. **Are you 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, or data that is not publicly available.

Select one radio button from below:

✓ Yes. (*Please complete the **Third-Party Access to Existing Data** section that appears on the left-hand side of the screen).*

16a **Are there personal identifiers in the data to be accessed?** *(**Even if you are not reporting them, select 'Yes').*

Select one radio button from below:

Yes

No

✓

No

Note: If you select 'NO' for both Questions 16 & Question 17, you need to complete the NRRS section only. [Please select 'Yes' for Question #9 in Section 1].

17. **Do you want to interview, survey, systematically observe or collect data from human participants?**

Select one radio button from below:

Yes. (*Please complete the **Study Procedures** section that appears at the left-hand side of the screen).*

No

✓ *Note: If you select 'NO' for both Questions 16 & Question 17, you need to complete the NRRS section only.* [Please select 'Yes' for Question #9 in Section 1].

Section 4 *Study Procedures

Participant Selection Criteria, Recruitment Procedures, & the Informed Consent Process

What are your inclusion criteria for the selection of participants for this study?

1. *Be sure to specify the age or age range, gender, & ethnicity o*f your participants. For further guidance, click on the question mark at the top right corner of this box to reveal helpful information.

Sample only

2. **What is your your participant population?** Explicitly state what your target population is.

Examples: Children, CSUB Students, Community Members, CSUB Athletes

Sample only

3. **Approximately how many participants will be involved in your study?**

Sample only

Participant Exclusion Criteria

4. Examples:

- unable to read and understand English
- unable to give written informed consent
- under 18 years of age

Sample only

5. **How are you going to recruit your participants?**

Be sure to attach your recruitment materials to the Additional Supporting Documents section of this protocol form for IRB review .

CSUB Psychology Department Participant Pool (SONA)

Notes:

- The use of the Participant Pool is restricted to the Psychology Department.
- Where appropriate, language regarding the authorization to use the Participant Pool will be included in the IRB approval letter.

Advertisements, flyers, notices, internet posting, or social media

Direct recruitment of potential study participants

Recruitment letters or E-mails

Snowball method

Recruitment databases such as MTurk

✓ Review of records, Investigators will request and justify a Waiver of Consent

Review of publicly available records

Other

6. **Who will be recruiting participants for this study?**

Sample only

7. **Where will the recruitment of participants take place?**

Sample only

8. **Are the research participants from any of the following vulnerable populations?**

Regulatory notes: The Final Rule's preamble (HHS 2017) states that the possibility of coercion or undue influence could affect the ability to make an informed decision about participating in research. Therefore, IRBs should consider vulnerability of the subjects in research studies "as a function of the possibility of coercion or undue influence" (HHS 2017). The assessment of the equitable selection of subjects, as noted at 46.111(a)(3), should include factors like societal marginalization or discrimination. The criterion at 46.111(a)(1) includes risks of harm that some might term "vulnerabilities," which are not covered by the regulatory term.

It is important to note that the updates to the Common Rule relating to vulnerability do not affect the applicability of Subpart B, (additional protections for pregnant women, human fetuses, and neonates), Subpart C, (additional protections for prisoners), or Subpart D, (additional protections for children).

Select all that apply:

- Children and Minors (under 18 years of age)
- Incarcerated Persons
- Institutionalized or hospitalized persons
- Pregnant women, See 45 CFR 46 Subpart B
- Individuals with impaired decision-making ability

Elderly/aged persons

Economically or educationally disadvantaged persons

Students in the Classroom

Ethnic/racial minority persons

Employees in the workplace

Other

✓ None of the above

Understanding the Research Participant's Perspective

9. 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?

Please answer the above questions in concise detail below:

Sample only

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)

Will you be using a Benign Behavioral Intervention in your study?

10.

Select one radio button from below:

Yes I will be using a Benign Behavioral Intervention in my study and this information is detailed in the Procedures section above.

✓ No, I will not be using a Benign Behavioral Intervention in my study.

Research Involving Deception

Authoritative Reference & Guidance:

- 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.

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

11. ---

Select one radio button from below:

Yes

✓ No

Risks and Adverse Reactions

12. ---

Please answer the required questions A-D below:

What are the potential risks/adverse reactions subjects may be exposed to by participating in this study?

A

Including but not limited to:

- *Physical reactions*
- *Emotional reactions*
- *Psychological harm*
- *Possible breaches of confidentiality*

Sample only

B **How will participants be protected?**

Sample only

C **What precautions will be taken to minimize risk?**

Sample only

D **How will adverse reactions be dealt with?**

Sample only

Will participants be compensated (paid or given anything of value) in return for their participation?

13.

Authoritative Reference & Guidance

- HHS regulations at 45 CFR 46.116
- Participant Compensation

Yes

✓ No

Informed Consent Process & Documentation

You must use one of the Informed Consent Form Templates which is compliant with the New Revised Common Rule regulations.

- **Informed Consent Form Template** Please remember to remove the instructions intended only for the PI/Researcher from the template before uploading your Informed Consent form to your protocol for IRB review.
- **Telephone Survey Consent Script and Procedures Template** Please remember to remove the instructions intended only for the PI/Researcher.
- **For online data collection, use the Information Sheet/Online Informed Consent Template.**
- **Additional templates and guidance 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

---

14. **What is your informed consent process & what are your informed consent documentation procedures?**

Select one radio button from below:

Face-to-face interviews or in-person surveys

ONLINE data collection

Face-to-face/in person interviews or surveys AND online data collection

Are you requesting a waiver of informed consent?

15. **For ONLINE SURVEY RESEARCH data collection, a waiver of the requirement for written informed consent may need to be requested.*

Select one radio button from below:

Yes, I want to request for a waiver of documentation of informed consent (to obtain a signature from the participant or the participant's legally authorized representative).

Waiver of Requirement for Signed Form--45 CFR 46.117

Yes, I want to request for a waiver of informed consent (waives the requirement to obtain informed consent or alters elements of informed consent).

✓ IRB Latitude to Approve a Consent Procedure that Alters or Waives some or all of the Elements of Consent--45 CFR 46.116

I want to request both a waiver of documentation of informed consent AND a waiver of informed consent or alteration of some or all of the elements of informed consent.

No

N/A

HSPT *Human Subjects Protection Training Section

Human Subjects Protection Training

The IRB accepts 3 types of Human Subject Protection training completion reports for the purposes of approving an IRB Protocol *(only one is required)*:

1. CITI-PI/Researcher SBE (Social, Behavioral, & Educational Research)
2. CITI- Students Conducting No More Than Minimal Risk Research
3. CITI-PI/Researcher Biomedical/Biomedical Data or Specimens

Learner Group Option #1: Human Subjects Protection Training for PI/Researchers (SBE) Social, Behavioral, & Educational Research
Learner Group Option #2: Human Subjects Protection Training for Students Conducting No More Than Minimal Risk Research
Learner Group Option #3: Human Subjects Protection Training for PI/Researchers for Biomedical Data or Specimens Research

If you have not completed one of the training courses listed below (*or a refresher within the last 4 years*) , please visit *CITI to complete the required training.*

Which Human Subjects Protection training has the PI (Principal Investigator) completed?

T1

- Only one Human Subjects Protection training course is required by the IRB.
- Note: If your/the training records don't automatically show up when clicking the **VIEW** link in the Training Section, please upload your completion report below.
- Screenshot Example of Training Link

Select one radio button from below:

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

CITI training certificate is attached.

Which Human Subjects Protection Training course has the Co-Investigator completed?

T2 *"Key personnel" in research projects involving human subjects or data containing personal identifiers must be certified in Human Subjects Protection Training (HSPT) for IRB authorization of their protocols.*

Select one radio button from below:

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

The CITI training certificate is attached.

✓ N/A

Which Human Subjects Protection Training course has the Faculty Sponsor completed?

T3

Select one radio button from below:

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

The CITI training certificate is attached.

✓ N/A

Which Human Subjects Protection Training course has the Additional Personnel completed?

T4 *"Key personnel" in research projects involving human subjects or data containing*

personal identifiers must be certified in Human Subjects Protection Training (HSPT) for IRB authorization of their protocols.

Select one radio button from below:

The CITI Training Records display automatically by clicking on the **VIEW** link (*CITI to Cayuse IRB Integration Function*) in Section 6.

The CITI training certificate is attached.

✓ N/A

Section 5 *Third Party Access to Existing Data

Authoritative References & Guidance

- Third-Party Access to Existing Data Protocol
- OHRP Guidance
- See also 45 CFR 46.104(d)(4)

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1. **Are you requesting access to pre-existing data from CSUB?**

Select one radio button from below:

✓ Yes, (*It is **not** necessary to attach an approval letter from the appropriate CSUB Department , CSUB Office or CSUB Program that you will request data from).*

No, I am requesting access to existing data from another organization or entity other than CSUB.

1. IT IS REQUIRED to attach a letter of approval (on letterhead) from the organization granting you access to the data.
2. Note: Without the approval letter from the organization, IRB will not move forward on the review.
3. If accessing data from schools, the letter needs to be signed by the appropriate Superintendent of the School District.
4. The letter must also include explicit descriptions of the data being provided.

Both

I am requesting access to pre-existing data from CSUB as well as other organizations.

From where will you be accessing the data?

2. Information that is used for secondary research would generally be found by the investigator in the following types listed below.

Please select all that apply for your study:

- ✓ Records
- Information Systems
- Archives
- Databanks (in the case of information)
- Other

What is the existing data that you are requesting access to?

Please explicitly describe and identify these variables providing a complete list by numbering them as in the example below:

3. *Note: If using acronyms, please provide an initial definition*.

Example:

1. GPAs
2. Grades
3. Retention rates
4. Work absences
5. Rates of incarceration

Sample only

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.

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.

Are you able to certify that you have met the above requirements 1-4 for waiving informed consent as defined by Federal Regulations?

4.

Select one radio button below:

✓ Yes

No

Not applicable.

Do you know if those pre-existing data that you are requesting access to were collected by means of Informed Consent?

In some cases, during initial data collection, Informed Consent is gathered from participants.

5. *Guidance:*

- *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)*

Select one radio button from below:

Yes

✓ No/I don't know

6. **Does the data you wish to use for this research study include data that you have collected/will collect during the course of your regular job duties or employment?**

Select one radio button from below:

Yes

✓ No

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)

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7. **What is your plan to protect identifiers from misuse and to protect data storage?**

Sample only

8. **What is your plan to remove the identifiers at the earliest opportunity consistent with the research and law?**

Sample only

9. **Will the data you collect/use be disclosed to any other person or entity?**

Select one radio button from below:

✓ Yes

9a Please explain who the data will be disclosed to, how, and why here:

Sample only

No

Additional **Attach any additional documentation**

For example, authorization from agency

Section 6 *Additional Personnel

Who will be the additional personnel working on this project?

- *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.*

1.

- *Students and External Investigators must be added manually to the Cayuse IRB system and thus may not be found automatically using the People Finder button.*

- *If your Additional Personnel cannot be found using the People Finder button, please enter in their name(s) & information below in the text box:*

Sample only

1a You may use the People Finder button to select **CSUB faculty and/or staff**.

Additional Personnel

1b

Please include their First Name, Last Name, role(s), and Email address or alternately just their role and E-mail if using the People Finder button:

List You may use the Research Personnel Form below to upload a list of additional personnel and their information here:

Research Personnel Form

Do you need to add another person?

2.

Select one radio button from below:

- Yes
- No

Section 7 *Additional Supporting Documents

Attach additional supporting documents (where applicable) here:

Examples include:

1.
- 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

2. **Attach additional supporting documents (where applicable) here:**

Upload/Attach here:

3. Attach additional supporting documents here:

Upload/Attach here:

4. Attach additional supporting documents here:

Upload/Attach here:

5. Attach additional supporting documents here:

Upload/Attach here:

6. Attach additional supporting documents here:

Upload/Attach here:

7. Attach additional supporting documents here:

Upload/Attach here:

Submit Completed Protocol

Are you ready to submit your protocol now?

Final Step

- *If you are a student, your Faculty Sponsor will automatically receive an e-mail from the Cayuse IRB system indicating they need to review and Certify the protocol. This step is necessary for the protocol to advance on to the IRB for review.*

- *If you have a Co-Investigator, that person will automatically receive an e-mail from the Cayuse IRB system indicating they need to review/make changes and Certify the protocol. This step is necessary for the protocol to advance on to the IRB for review.*

Yes

✓

1. Complete the form by clicking on the **COMPLETE SUBMISSION** link at the left side of this page,
2. Click the green CONFIRM button,
3. Certify (sign) the protocol, click the blue **CERTIFY** button
4. Submit this form

No

Click the Green Save button and continue working on the protocol now or finish at a later time.