



IRB

Cal State University East Bay
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ORSP

BEFORE WE GET STARTED

IRB QUESTIONS

Quick Review

WHAT IS IRB?

- IRB is an acronym for Institutional Review Board
 - The committee or body that is delegated the authority to provide oversight of human subjects research

WHAT IS RESEARCH, AS DEFINED BY IRB REGULATIONS?

- A systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge.
- At CSUEB, the IRB considers any research intended for publication to be research. This includes journal articles, conference presentations or masters theses. In general, class projects are not considered research (unless they may be published).
- Human subject research is research that involves humans as research subjects by collecting data from them, performing experiments on them or with them, and may include observing humans.

BEFORE WE GET STARTED

WHEN DO I NEED TO SUBMIT AN IRB PROTOCOL?

When your research includes the use of Human Subjects.

- Collecting information and biospecimens from humans - surveys, questionnaires, blood samples, hair samples, dna. “obtaining, using, studying, analyzing, or generating identifiable private information or identifiable biospecimens (46.102[e][1][ii]”
- Performing experiments on humans or with humans - tests, drugs, observations on identified individuals whether or not influenced/manipulated.
- In a few instances research may be Exempt from full review, **but the IRB Protocol must still be submitted** so that the designated IRB representative can review the project and make the determination.
- Journalism, certain scholarly activities such as oral history, public health surveillance, criminal justice or criminal investigative activities, and activities in support of intelligence, homeland security, defense, or other national security missionse][1][ii] have been deemed not to be research.
- **Goal is to protect human subjects, their privacy, and confidentiality.**

IRB Review Categories - Non-exempt Research (Full Committee Review)

Exempt Research (Administrative Review)

Expedited Review of Non-Exempt Research (without an IRB meeting)

Normal Educational Practices Considered Exempt from Full Committee Review.

OUR RESEARCH SHOWS THAT, COMPARED TO THE OVERALL POPULATION, PEOPLE WHO AGREE TO PARTICIPATE IN SCIENTIFIC STUDIES ARE SIGNIFICANTLY LESS LIKELY TO CALL THE POLICE TO RESCUE THEM FROM OUR LAB.



1999 Explain XKCD

USING CAYUSE IRB TO SUBMIT AND MANAGE IRB PROTOCOLS.

What?

- Cayuse IRB for Human Subjects Research **provides an online space for IRB protocol submission, IRB review and approval.**

Why?

- Use of Cayuse is **beneficial to all - efficient, effective, thorough.**
- Cayuse IRB **expedites** all phases of **protocol creation, submission, review, approval, and renewal, creates an online repository, and is integrated with the required CITI training.**

Who?

- **Faculty, students, staff, and administrators** will use **Cayuse.**
- Whose research are we talking about?
 - **Research conducted by CSUEB faculty, staff, or student investigators, and also research by investigators from other institutions or agencies who are working in conjunction with CSUEB in any capacity.** (Only the CSUEB team will use Cayuse IRB.)

When?*

- Effective **3/1/20** Cayuse is **required for use by faculty, staff, and administrators**
- Effective **6/1/20** Cayuse is **required for use by Student PIs**

*Cayuse has been available since January for early adopters.

CAYUSE IRB FOUND IN MANY LOCATIONS

CAYUSE IRB TRAINING SITE LINK (FOR PRACTICE ONLY)

<https://csueastbay-t.cayuse424.com/>

CSU EAST BAY CAYUSE WEB SITE (TO SUBMIT YOUR PROTOCOL)

- <https://csueastbay.cayuse424.com/>

ORSP CAYUSE WEB PAGE

- <https://www.csueastbay.edu/orsp/cayuse/>

ORSP COMPLIANCE TOOLS WEB PAGE

- <https://www.csueastbay.edu/orsp/compliance/tools.html>

CAYUSE IRB HOW TO

<https://www.csueastbay.edu/orsp/compliance/irb/protocol-submission.html>



Welcome to Cayuse IRB!



Cayuse Research Suite

3.8.1

Research Administration Modules

- Cayuse SP (Sponsored Projects)
- Cayuse 424
- Cayuse IRB (Human Studies Compliance)

System Administration Applications

- Backbone
- Research Contacts
- Workflow

Application Help

- Research Suite Support Center



Click on Cayuse IRB

<https://csueastbay.cayuse424.com/>

Training site password: CSUEBF%



- Click on [Cayuse IRB](#)

- **Dashboard** – Studies (IRBs), Tasks (Pending), Approved, Expiring, and Expired – and Submittals listed by whether they are Initial, Modifications, Renewals, have Incidents, were withdrawn, or closed.

The screenshot displays the Cayuse IRB dashboard for a user with the role of 'Researcher' (Jeanne Dittman). The dashboard is organized into several sections:

- Summary Cards:** A row of four cards showing counts for different study stages: In-Draft (1), Awaiting Authorization (0), Pre-Review (0), and Under Review (0). A '+ New Study' button is located in the top right corner of this section.
- My Studies:** A table listing the user's studies. One study is shown: 'Test 1' with ID 'CSUEB-IRB-2020-10'. A 'View All' link is at the bottom.
- My Tasks:** A table listing tasks. One task is shown: 'Complete Submission' with ID 'CSUEB-IRB-2020-10'. A 'View All' link is at the bottom.
- Submissions by Type:** A table summarizing the number of submissions for each type:

Submission Type	Count
Renewal	0
Initial	1
Modification	0
Incident	0
Withdrawal	0
Closure	0
Legacy	0
- Approved Studies:** A section indicating 'No Approved Studies' with a sad face icon.
- Studies Expiring in 30 days:** A section indicating 'No Expiring Studies' with a happy face icon.
- Expired Studies:** A section indicating 'No Expired Studies' with a happy face icon.

- Click on New Study button in Upper Right Hand Corner

[+ New Study](#)



0
In-Draft



1
Awaiting
Authorization



0
Pre-Review



0
Under Review

- Enter Your Protocol Title and Click the blue check mark on the right

Enter study title here



- Click on the blue button that now says “+ New Submission”

The screenshot displays the Cayuse IRB dashboard interface. At the top left is the Cayuse IRB logo. The top right corner shows a notification bell with a red '1' and a user profile for 'Jeanne Dittman'. Below the logo, there are navigation tabs for 'Dashboard', 'Studies', 'Submissions', and 'Tasks'. The main content area shows a breadcrumb trail 'Studies / Study Details' and a dark blue header for 'Study Details'. A red 'Unsubmitted' tab is visible. Below this, a table lists a study with ID 'CSUEB-IRB-2020-7' and title 'Test 3 IRB Cayuse Training'. A white notification box is overlaid on the right side of the screen, containing the text 'Begin Initial Submission' and 'You've created a study! Click here to begin your initial submission to the IRB.' To the right of the notification box is a blue button labeled '+ New Submission'.

cayuse IRB

Dashboard Studies Submissions Tasks

Studies / Study Details

Study Details

Unsubmitted

CSUEB-IRB-2020-7 Test 3 IRB Cayuse Training

Begin Initial Submission

You've created a study! Click here to begin your initial submission to the IRB.

+ New Submission

- Click “Initial” and on the right it will begin showing you tasks to complete under the Task bar. In this case, it says Assign PI.

The screenshot shows the Cayuse IRB interface. At the top left is the Cayuse IRB logo. At the top right, there is a notification bell with a red circle containing the number '1' and a user profile for 'Jeanne Dittman'. Below the header is a navigation bar with tabs for 'Dashboard', 'Studies', 'Submissions', and 'Tasks'. The main content area shows a submission workflow with four stages: 1. Submission is with researchers, 2. Submission is awaiting certification of approval, 3. Submission is being prepared for review, and 4. Submission is with reviewers. Below the workflow is a red 'Unsubmitted' tab. Underneath is the 'Initial' page for submission 'CSUEB-IRB-2020-7 - Test 3 IRB Cayuse Training'. This page has three buttons: 'Edit', 'PDF', and 'Delete'. Below the buttons is a table of submission details:

PI:	Current Analyst:	Decision:	Policy:	Required Tasks:
	N/A	N/A	Post-2018 Rule	<ul style="list-style-type: none">• Assign PI✓ Assign PC• Complete Submission
Review Type:	Review Board:	Meeting Date:		
N/A	N/A	N/A		

- Once you click on Assign PI you are taken to a new set of menus, through which you do all the rest of the completion steps.

The screenshot shows the Cayuse IRB web interface. At the top left is the Cayuse IRB logo. The top right shows a user profile for Jeanne Dittman with a notification bell icon containing the number 1. Below the logo is a navigation bar with links for Dashboard, Studies, Submissions, and Tasks. The main header area includes a back arrow, 'SUBMISSION DETAILS', the IRB number 'CSUEB-IRB-2020-7', and the submission title 'Test 3 IRB Cayuse Training - Initial'. To the right of the title are buttons for 'CREATE PDF', 'COMPARE', and 'SAVE', along with left and right navigation arrows. On the left side, there is a 'Sections' sidebar menu with a list of items: '1. POLICIES' (highlighted with a green checkmark), '2. INVESTIGATOR(S)', '3. DATA COLLECTION', '4. FUNDING', '5. PROJECT DESCRIPTION', '6. CONFIDENTIALITY', and '7. RISKS AND BENEFITS'. The main content area displays the '1. POLICIES' section, which includes text about 'Investigator(s) Assurance' and 'Investigator Responsibilities'.

Sections

- 1. POLICIES ✓
- 2. INVESTIGATOR(S)
- 3. DATA COLLECTION
- 4. FUNDING
- 5. PROJECT DESCRIPTION
- 6. CONFIDENTIALITY
- 7. RISKS AND BENEFITS

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

- Click on **New Study** in the upper right hand corner.
- The system is user friendly and will walk you through the steps.
- Enter your Study Title, then Click New Submission in the upper right hand corner.
- The remaining sections to complete are shown below.
- Click Edit



Sections	
1. POLICIES	✓
2. INVESTIGATOR(S)	
3. DATA COLLECTION	
4. FUNDING	
5. PROJECT DESCRIPTION	
6. CONFIDENTIALITY	
7. RISKS AND BENEFITS	
8. INFORMED CONSENT	
9. DEBRIEFING	✓
10. ATTACHMENTS	✓
11. COMMUNICATI...	✓

Policies: Example-

“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.”

- **After reading the Policy content carefully, Click on Investigators**
- Identify yourself, your **collaborators**, other **personnel**, and other **institutions involved**.

Sections

- 1. POLICIES ✓
- 2. INVESTIGATOR(S)
- 3. DATA COLLECTION
- 4. FUNDING
- 5. PROJECT DESCRIPTION
- 6. CONFIDENTIALITY
- 7. RISKS AND BENEFITS
- 8. INFORMED CONSENT
- 9. DEBRIEFING ✓
- 10. ATTACHMENTS ✓
- 11. COMMUNICAT... ✓

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

Faculty investigators should list themselves as the Principal Investigator and can add one or multiple Co-Principal Investigators as needed. Student investigators should list their faculty advisor/instructor as the Principal Investigator and list themselves as the Co-Principal Investigator.

• PI (Principal Investigator)

FIND PEOPLE

Phone # (if not listed above)

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.)

If not indicated above please enter your department below (i.e., Psychology, Teacher Education, Biology, English, etc.)

Primary Contact

The Primary Contact (PC) is the primary point of contact with the IRB staff for a study. The PC must have a CSUEB email account to be added to the Cayuse IRB System.

• Faculty investigators should enter their own name as the primary contact. Student investigators should enter their own name as the primary contact.

FIND PEOPLE

Name	Organization	Address	Phone	Email
Jeanne Dittman	Research & Sponsored Programs	, Hayward, CA 945423000		

• Next Click on Data Collection

- Complete the section by identifying your **study start and end dates**, **number of participants**, and **demographic information** about the study population.

Sections <

- 1. POLICIES ✓
- 2. INVESTIGATOR(S)
- 3. DATA COLLECTION
- 4. FUNDING
- 5. PROJECT DESCRIPTION
- 6. CONFIDENTIALITY
- 7. RISKS AND BENEFITS
- 8. INFORMED CONSENT
- 9. DEBRIEFING ✓
- 10. ATTACHMENTS ✓
- 11. COMMUNICATI... ✓

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:

• Proposed End Date of Study:

• Number of Participants

Indicate the number of participants proposed for your study.

• 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 study which may require special consideration.

Select all that apply.

- Children/Minors (17 years of age or younger)
- Pregnant Women
- Cognitively-Impaired Adult Subjects

- **Next Click on Funding**
- If your project is funded by [Internal](#) or [External Funding](#) check, Yes.
- If you check yes, also complete the applicable sponsor information.

Sections <

- 1. POLICIES ✓
- 2. INVESTIGATOR(S)
- 3. DATA COLLECTION
- 4. FUNDING** ✓
- 5. PROJECT DESCRIPTION
- 6. CONFIDENTIALITY
- 7. RISKS AND BENEFITS
- 8. INFORMED CONSENT
- 9. DEBRIEFING ✓
- 10. ATTACHMENTS ✓
- 11. COMMUNICATI... ✓

4. FUNDING

Funding refers to internal or external grants specific to the research.

*** Is this study funded?**

Yes
 No

Internal Sponsor
Please provide name of internal sponsor.

External Sponsor
Please provide name of external sponsor.

FIND SPONSORS

Name
National Science Foundation - NSF

- **Next Click on Project Description**
- This is where you will put **important details for the basis of your protocol**

Sections <





- 1. POLICIES ✓
- 2. INVESTIGATOR(S)
- 3. DATA COLLECTION
- 4. FUNDING ✓
- 5. PROJECT DESCRIPTION
- 6. CONFIDENTIALITY
- 7. RISKS AND BENEFITS
- 8. INFORMED CONSENT
- 9. DEBRIEFING ✓
- 10. ATTACHMENTS ✓
- 11. COMMUNICAT... ✓

5. PROJECT DESCRIPTION

Briefly describe the objectives and methodology of your research (including hypothesis and/or research questions), data collection procedures, and features of the research design that involve specific procedures or special conditions for participants (including frequency, duration, and location of participation) in the provided spaces below.





*A. Hypothesis or Research Questions

Briefly state the problem, background, importance of research, and goals of the proposed project.

B I U    

*B. Research Methodology and Design

Include a brief description of the project design including the setting in which the research will be conducted and procedures.

B I U    

- **Project Description**

- *Protocol Details:*

- A. **Hypothesis or Research Questions**
- B. **Methodology and Design**
- C. **Human Subjects Involvement** – what procedures, where will they be performed, and for how long.
- D. **Subject Population** – number and categories, access or recruitment, inclusions/exclusions, rationale
- E. **Recruitment Plan**
- F. **Research Material** – How will information be obtained from the subjects – attach surveys or other collection or tracking documents
- G. **Data Analysis** – How will you analyze the data (qualitative, quantitative, methods)
- H. **Dissemination** – How do you plan to present and publish your research

• Next Click on Confidentiality

- Describe [how, what, when, and where you will store and secure data you have collected.](#)

Sections <

- 1. POLICIES ✓
- 2. INVESTIGATOR(S)
- 3. DATA COLLECTION
- 4. FUNDING ✓
- 5. PROJECT DESCRIPTION
- 6. CONFIDENTIALITY
- 7. RISKS AND BENEFITS
- 8. INFORMED CONSENT
- 9. DEBRIEFING ✓
- 10. ATTACHMENTS ✓
- 11. COMMUNICATL... ✓

6. CONFIDENTIALITY

* In this section, explain the how, what, when, and where you will store and secure the data you have collected. Clearly indicate specific procedures (e.g., coding of responses, aggregate reporting) to protect the confidentiality of participants and safeguard identifiable records and data. This includes safe and secure storage of the collected information and specifying when the data will be destroyed after the data collection process has been completed (if applicable). If not possible, state why.

If collecting your data through interviews or focus groups be specific as to the type of recordings (i.e., audio, video, photograph) and type of recording devices used (i.e., analog or digital). If transferring from analog (tape recordings) how will you transcribe the data and what will you do with the tape recordings after transcription? If you are destroying recordings, include how you will destroy them after transcription (e.g., demagnetize, shred).

If digital recordings are used, how will you be transferring the data from the digital recording device to a computer and what will be done with the data on the digital recording device after you have downloaded the data to the computer (e.g., data will be erased, deleted, overwritten)?

Note: A common mistake individuals make is confusing confidentiality with anonymity. For reference:
Anonymous data is data recorded so that the information can never be linked to the participant who supplied it.
Confidential data is data collected in a way that the participant could be identified from the data, but where that data is kept secure.

B I U G L B B O

• Next Click on Risks and Benefits

• Describe the

- Potential Benefits
- Potential Risks
- Risk Reduction techniques
- Risk/Benefits summary

Sections <

- 1. POLICIES ✓
- 2. INVESTIGATOR(S)
- 3. DATA COLLECTION
- 4. FUNDING ✓
- 5. PROJECT DESCRIPTION
- 6. CONFIDENTIALITY
- 7. RISKS AND BENEFITS
- 8. INFORMED CONSENT
- 9. DEBRIEFING ✓
- 10. ATTACHMENTS ✓
- 11. COMMUNICATI... ✓

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.

B I U S [List Bullets] [List Numbered] [Link] [Image]

* Potential Risks

Describe potential risks whether physical, psychological, social, legal, or other and assess their likelihood and seriousness. Example risks include physical injury, allergies to materials used in study, loss of privacy, and emotional discomfort (anxiety, stress, depression).

Please note that potential risks must be included in the consent form.

B I U S [List Bullets] [List Numbered] [Link] [Image]

• Risks and Benefits

- Describe the
 - Potential Benefits
 - Potential Risks
 - Risk Reduction techniques
 - Risk/Benefits summary

Sections <

- 1. POLICIES ✓
- 2. INVESTIGATOR(S)
- 3. DATA COLLECTION
- 4. FUNDING ✓
- 5. PROJECT DESCRIPTION
- 6. CONFIDENTIALITY
- 7. RISKS AND BENEFITS
- 8. INFORMED CONSENT
- 9. DEBRIEFING ✓
- 10. ATTACHMENTS ✓
- 11. COMMUNICATI... ✓

* Risk Reduction

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.

B I U ↺ ☰ ☷ ☹ 🖼

* 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.

B I U ↺ ☰ ☷ ☹ 🖼

• Informed Consent

• Describe the who, what, how, where, and when

- Who will provide consent, who will obtain consent
- How, Where, and When will the consent be obtained? Translation? Interpreters?
- Consent Forms – Attach copies of the Consent forms and waivers you will use. Follow the [CSUEB Standard Consent Form](#).

The screenshot shows a web application interface for creating informed consent forms. On the left is a dark sidebar with a 'Sections' menu containing 11 items, each with a green checkmark: 1. POLICIES, 2. INVESTIGATOR(S), 3. DATA COLLECTION, 4. FUNDING, 5. PROJECT DESCRIPTION, 6. CONFIDENTIALITY, 7. RISKS AND BENEFITS, 8. INFORMED CONSENT (highlighted in green), 9. DEBRIEFING, 10. ATTACHMENTS, and 11. COMMUNICATI... The main content area is titled '8. INFORMED CONSENT' and is divided into two sections: 'Consent Process' and 'Consent Forms'. The 'Consent Process' section contains a text area with a rich text editor toolbar (bold, italic, underline, link, unlink, list, list, link, image) and a large empty text box. The 'Consent Forms' section contains a text area with a rich text editor toolbar and a large empty text box. Below the text boxes are several paragraphs of text providing instructions and a list of 11 items to include in the consent statement.

Sections

- 1. POLICIES ✓
- 2. INVESTIGATOR(S)
- 3. DATA COLLECTION
- 4. FUNDING ✓
- 5. PROJECT DESCRIPTION
- 6. CONFIDENTIALITY
- 7. RISKS AND BENEFITS
- 8. INFORMED CONSENT
- 9. DEBRIEFING ✓
- 10. ATTACHMENTS ✓
- 11. COMMUNICATI... ✓

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.

B I U L Link List List Link Image

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. Participants right to withdraw at any time without penalty
8. Information about foreseeable risks and benefits (or none)
9. For more than minimal risk research, a statement as to whether compensation or medical treatment is available in the event of injury
10. Contact information for questions or additional information including contact information for the IRB.
11. A statement regarding the additional use of de-identified private information or bio-specimens.

For non-English-speaking participants, be sure to include the translation in the appropriate language of the participants.

Attach the Informed Consent form(s) here.

• Informed Consent

- Regulations regarding consent forms are stringent and require specific information.

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
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For non-English-speaking participants, be sure to include the translation in the appropriate language of the participants.

Attach the Informed Consent form(s) here.

ATTACH

Consent/Assent waivers

- Documentation of consent
Documentation of consent is often provided via a signature on a consent form. For studies completed online or over the phone, or where anonymity is desired, a waiver of the requirement to document consent in writing may be granted. Please check this box if you would like to request a waiver of the requirement to document consent in writing.
- Additional consent provisions
Waivers of additional informed consent provisions may be granted under certain limited conditions. Any request for such should include an explicit justification.
- Assent waiver
Waivers of the assent requirement may be granted under certain limited conditions. Any request for such should include an explicit justification.
- Waivers of the assent requirement may be granted under certain limited conditions. Any request for such should include an explicit justification.

• Debriefing

- Attach a copy of your Debriefing Statement
 - When deception has been used in the study
 - When your design debriefs participants about their behavioral or emotional responses
 - When your design provides additional information, such as future contact info or emergency hotlines

Sections	
1. POLICIES	✓
2. INVESTIGATOR(S)	
3. DATA COLLECTION	
4. FUNDING	✓
5. PROJECT DESCRIPTION	
6. CONFIDENTIALITY	
7. RISKS AND BENEFITS	
8. INFORMED CONSENT	
9. DEBRIEFING	✓
10. ATTACHMENTS	✓
11. COMMUNICATI...	✓

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.

ATTACH

• Attachments

Sections	
1. POLICIES	✓
2. INVESTIGATOR(S)	
3. DATA COLLECTION	
4. FUNDING	✓
5. PROJECT DESCRIPTION	
6. CONFIDENTIALITY	
7. RISKS AND BENEFITS	
8. INFORMED CONSENT	
9. DEBRIEFING	✓
10. ATTACHMENTS	✓
11. COMMUNICATI...	✓

10. ATTACHMENTS

Letter(s) of Permission

Attach letters of permission here.

ATTACH

Multi-Institution Project Documents

ATTACH

Training Documentation

ATTACH

Recruitment Materials

ATTACH

Surveys, interview questions, debriefing forms, and similar documents

ATTACH

Consent Forms

ATTACH

Assent Forms

ATTACH

Debriefing Form/Statement

ATTACH

Other Attachments

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

ATTACH

• Communications

- You can use the [Communications](#) link at the bottom of the menu
 - [Communicate with the IRB Staff \(or email them at \[irb@csueastbay.edu\]\(mailto:irb@csueastbay.edu\)\)](#)
 - [Communications between Faculty Advisors and Student Advisees](#)

Sections <

- 1. POLICIES ✓
- 2. INVESTIGATOR(S)
- 3. DATA COLLECTION
- 4. FUNDING ✓
- 5. PROJECT DESCRIPTION
- 6. CONFIDENTIALITY
- 7. RISKS AND BENEFITS
- 8. INFORMED CONSENT
- 9. DEBRIEFING ✓
- 10. ATTACHMENTS ✓
- 11. COMMUNICATI... ✓

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.

B I U

Communications between Faculty Advisors and Student Advisees

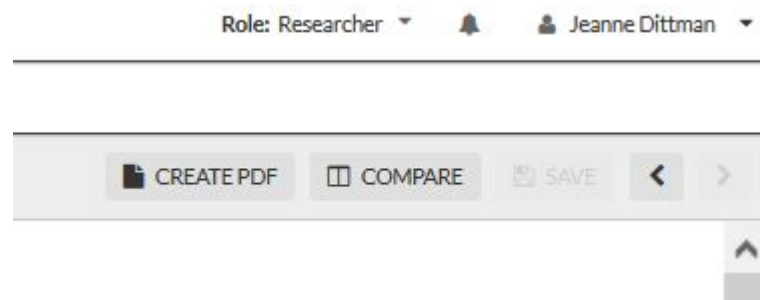
Faculty Advisors and their Student Advisees may use this text box for communication if they wish to maintain a record of those communications in the Cayuse system. While IRB staff may view this information, the intent is to provide a mechanism for Advisor/Advisee communication.

B I U

BEFORE YOU HIT SUBMIT

YOU CAN CREATE A PDF OF YOUR ENTIRE PACKAGE TO REVIEW WHAT YOU HAVE DONE.

- Click on “Create PDF” found at the top righthand of your screen.



Submission Type: Initial Date: 2-17-2020

IRB #: CSUEB-IRB-2020-10

Title: Test 1

Creation Date: 2-7-2020

Status: **Unsubmitted**

Principal Investigator:

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



Quick Meme

EDIT

YOU CAN STOP WHERE YOU ARE AT ANY TIME AND RETURN LATER TO EDIT YOUR PROTOCOL BEFORE SUBMITTAL.

- Go to the Dashboard
- Click on the Protocol Number or Title
- Click on the type listed in the Active column
- Click on Edit

cayuse IRB

Dashboard Studies Submissions Tasks Meetings Reporting More

Studies [Study Details](#) Submission Details

1 **In-Draft**
Submission is with researchers

2 **Awaiting Authorization**
Submission is awaiting certification or approval

3 **Pre-Review**
Submission is being prepared for review

4 **Under-Review**
Submission is with reviewers

Unsubmitted

Initial
CSUEB-IRB-2020-10 - Test 1

Edit PDF Delete

PI: N/A Current Analyst: N/A Decision: N/A Policy: Post-2018 Rule Required Tasks: [Assign PI](#)
Review Type: N/A Review Board: N/A Meeting Date: N/A [Assign PI](#)
[Complete Submission](#)

Approvals Task History Attachments

Research Team

Name	Role	Result	Date
No entries.			

SUBMIT

ONCE YOU HAVE COMPLETED ALL OF THE SECTIONS AND THEY ALL SHOW A GREEN CHECK YOU CAN SUBMIT YOUR PROTOCOL



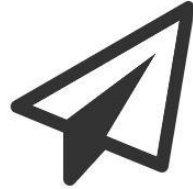
Certify

After Submittal Certify.

Go to the Dashboard

- See Tasks
- Click on Certify to Certify

Certify



I confirm that I have the proper training, expertise and resources to conduct this study. I understand and accept my responsibilities as the Principal Investigator and Primary Contact for this study. I confirm that I have no significant financial conflict of interest in this project or have disclosed a conflict per institutional policies and federal requirements. I confirm that the information provided in this application is true, complete, and accurate to the best of my knowledge; that any false, fictitious, or fraudulent statements or claims may subject me to criminal, civil, or administrative penalties; and agree to accept responsibility for the oversight and scientific conduct of the project.

Cancel

Confirm

Voila!



- You submitted an IRB protocol.
- The IRB will review the submittal.
- The initial reviewers may ask for additional information or move the submittal to the committee.
- You will receive notification of whether your project is approved.
- During the project as your protocol or project changes, you can use Cayuse IRB to modify your request.
- Renew your IRB every year using Cayuse IRB.



Questions?

Click here for [Answers](#)

