

**EDUCATIONAL LEADERSHIP FOR  
SOCIAL JUSTICE**



**DOCTORATE OF EDUCATION  
IRB STUDENT HANDBOOK**



*This handbook is a guide to assist students in preparation for conducting research for the dissertation. It does not constitute a contract and is subject to change at the discretion of CSUEB Department of Educational Leadership.*

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*All CSU EAST BAY IRB forms are available for download from the website:*

<http://www.csueastbay.edu/orsp/forms-policies-procedures/irb/forms.html>

## **Acknowledgements**

**This 2016 printed IRB Manual was developed under the direction Program Director, Dr. Bradley Porfilio.**

## **Introduction**

### **The Institutional Review Board (IRB) Protocol**

**The purpose of this handbook is two-fold: to acquaint students with the IRB process and steps leading to the submission of the IRB application Protocol to the ELSJ Academic Coordinator; and the submission of a complete IRB application Protocol to the University IRB Committee for approval.**

**The University IRB Committee is a federally mandated body, the purpose of which is to ensure ethical treatment of participants on research projects. In compliance with The National Commission for the Protection of Human Subjects and the Code of Federal Regulations 45 CFR 46 principles, the mandates makes clear the conduct for research with human subjects. Thus, the IRB process: ensures the rights and welfare of research subjects are protected; assures research subjects' informed consent to research procedures is clearly stated, understood, and executed; and assures the ethical treatment of participants in all research projects.**

**Students wishing to conduct research at CSU East Bay are required to submit an IRB Protocol (application and all supporting documents) first, to the ELSJ IRB Coordinator for preliminary review. When the preliminary review (and any required revisions) is achieved, the ELSJ IRB Coordinator submits the student's IRB Protocol (application and all supporting documents) to the University IRB Committee for review and approval.**

**The University's IRB review and approval is needed prior to executing research and accessing or collecting data. Research cannot begin prior to receiving approval from the CSUEB's IRB Committee. Data collected or accessed prior to obtaining all IRB approval, may constitute grounds for dismissal from the program. (See ELSJ Student Handbook – Key University Policies)**

**After receiving University IRB approval, students can execute his/her research, including data collection and analyses under the guidance of their dissertation chair.**

## Steps: Application for Approval

|                      |  |
|----------------------|--|
| <p><b>STEP 1</b></p> | <ul style="list-style-type: none"> <li>• Student develops the Dissertation Proposal in Spring: EDLD 8086</li> <li>• Student refines Dissertation Proposal under the guidance of the Dissertation Chair (Summer Quarter)</li> </ul>   |
| <p><b>STEP 2</b></p> | <ul style="list-style-type: none"> <li>• Student registers to take CITI online (Summer Quarter)</li> <li>• Student receives CITI Training Completion Certificate</li> <li>• Certificate required with IRB application submission</li> </ul>  |
| <p><b>STEP 3</b></p> | <ul style="list-style-type: none"> <li>• Under TVHE guidance of the Dissertation chair, student completes the IRB Application and all supporting documents (Summer Quarter)</li> </ul>   |
| <p><b>STEP 4</b></p> | <ul style="list-style-type: none"> <li>• The Dissertation chair submits the IRB application and all supporting documents to the IRB Coordinator for preliminary review (Summer Quarter)</li> <li>• IRB Coordinator communicates with the Chair regarding the outcome of preliminary review</li> <li>• If revisions are deemed necessary, the Chair works with the student to revise the IRB application and supporting documents and re-submits to the IRB Coordinator (Additional revisions might be required)</li> </ul> |
| <p><b>STEP 5</b></p> | <ul style="list-style-type: none"> <li>• IRB Coordinator submits student's IRB application and all supporting documents to the CSUEB IRB Committee for University review and approval (Summer Quarter)</li> </ul>  |
| <p><b>STEP 6</b></p> | <ul style="list-style-type: none"> <li>• Upon receipt of University IRB approval, student can begin the research and data collection process under the guidance of the dissertation chair and committee members</li> </ul>   |





## University IRB Website

### Complete Protocol Package

<http://www20.csueastbay.edu/orsp/irb/index.html>

The following documents are required for EVERY research protocol submission:

- Protocol Approval Form (PAF)
- Protocol Statement
- Informed Consent Document(s)
- CITI Training Completion Certificate ([www.citiprogram.org](http://www.citiprogram.org))

Other documents may include:

- Recruiting script/text or recruiting flyers/letters/ads
- Final survey to be administered- Final questionnaire - Interview questions
- Permission letter to recruit and/or conduct research
- Photo Releases (if using photographs of participants)
- Video Releases (if videotaping participants)

*Most of the above forms are in the ELSJ IRB Handbook. However, you may go to the Office of Research and Sponsored Programs on the CSU East Bay website to obtain electronic copies. All of the above forms and templates can be found by clicking "Forms & Templates" link on the navigation menu.*

## **Human Subjects Research Training Course**

### **CITI**

All researchers doing non-exempt research using human subjects are required to pass the online research-training course offered by CITI. This includes the principal investigator, all co-investigators, research technicians, research assistants, and/or student assistants who have contact with the research subjects. However, researchers doing exempt research are also strongly encouraged to complete the training..

Within a week after submission of your research protocol, the IRB Committee will categorize your protocol as exempt or non-exempt and notify you. If non-exempt, you must then complete the training before approval may be granted. Therefore, it is recommended that all researchers take the CITI training course, in advance of your submission of your Research Protocol application.

The CITI course takes 2-3 hours to complete and offers tracks in social/ behavioral/educational or biomedical research. ELSJ students should complete the social/behavioral/educational track that is most appropriate for your field of research. You may also complete elective modules in other areas if you wish. The CITI course is online and available 24/7.

### **Instructions:**

- Go to the CITI website at <http://www.citiprogram.org>.
- Log on (if already registered) or click on “Register here” next to “New Users”.
- In Section 1, choose “California State University East Bay” from the “Participating Institutions” menu.
- In Section 2, choose a username and password.
- In Section 3, enter your name.
- In Section 4, enter your email address.
- Click on “Submit”.
- Fill out the required fields in the course registration.
- Under “What course do you plan to take?”, choose “Basic Human Subjects” — “Social and Behavioral Focus”. Then click on “Submit”.
- Now select your curriculum. In Section 2, Human Subjects Research.
  - Choose: Social and Behavioral Research Investigators.

- If you have already completed the training course in the past, choose “I have completed the Basic Course”.
- Click on “Submit.”
- Choose “No” when asked if you wish to affiliate with another institution.
- Click on the red “Enter” button under My Courses in order to begin the course modules.
- Click on the first course module, read the material, take the mini-test at the end and repeat until all course modules have been completed.
- From the Main Menu, under My Courses, click on “Print” under Completion Report in order to print out your completion report.
- You may then log out of the CITI site.

Note that you need not complete the entire course in one sitting. The CITI site will remember which modules you have completed and you may pick up where you left off.

Your initial training is valid for 3 years. Before the 3 years expire, you must complete the refresher course. For researchers completing the refresher course, choose “I have completed the Basic Course” in Section 2, and then the appropriate choice in Section 3.

You must achieve an 80% success rate in the module tests to complete the courses. You may retake tests until you have achieved the necessary success rate.

A course completion report will be issued upon completion of the course. The report must be printed out and submitted with the protocol materials. The Office of Research and Sponsored Programs will maintain a database listing investigators who have completed the training. The reports are valid for 3 years from the date of issue. Every 3 years, a refresher course, also offered through CITI, must be completed.

Note that you may choose additional study modules if desired as well as the optional courses in Good Clinical Practice (GCP) and Responsible Conduct of Research (RCR).

If you have completed a human subjects training course elsewhere, such as the NIH course, mail or bring the completion certificate to the ORSP, and it will be accepted.

# Protocol Approval Form

Type of review requested:  New  Continuation  Modification

## PROTOCOL APPROVAL FORM HUMAN SUBJECTS RESEARCH

*California State University East Bay*

All research involving human subjects proposed by faculty, staff, or students must be reviewed and approved by the CSUEB Institutional Review Board (IRB). The Protocol Approval Form (PAF) is required as the cover form for all research protocols.

In all cases, research must not proceed until approved by IRB. The total review process for non-exempt protocols, which require full committee review, can take up to 8 weeks. Protocols, which qualify for expedited review,

may take up to 4 weeks. Exempt protocols may take up to 2 weeks. Please leave adequate time for the revision cycle. Phone: (510) 885-4212 Fax: (510) 885-4618

The PAF must be filed with a complete protocol statement, informed consent(s), and any related documents. Please list an email address that you check regularly. Notice of requested revisions and final approval will be sent to that address.

Date: \_\_\_\_\_

Title of Research: \_\_\_\_\_

Name of Researcher: \_\_\_\_\_ Phone Number: \_\_\_\_\_  
Last Name First Name

Address: \_\_\_\_\_

E-mail Address: \_\_\_\_\_ Department: \_\_\_\_\_

Type of Research:

- Faculty/Staff    Funded? \_\_\_\_\_ By whom? \_\_\_\_\_  
 Student

*The PAF must be filed with a complete protocol statement, informed consent(s), related documents (questionnaires, surveys, interview questions) (see next page). A CITI course completion certificate will be*

required for non-exempt research. Document templates and samples may be found on the IRB website at: <http://www.csueastbay.edu/orsp/forms-policies-procedures/irb/forms.html>

**APPROVALS:**

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Signature of Researcher  
ID#

Graduate or Undergraduate/Student  
  
(Complete if researcher is a student)

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Signature of Faculty Advisor (if Researcher is a student)

Name and Academic Rank

Email: \_\_\_\_\_

**Directions for Completing Protocol Approval Form**

*Follow directions AND keep it simple, in direct style, and to the point*

- **Signatures:** Provide your signature and, if you are a student, your advisor’s signature. Your advisor’s signature signifies that she/he has reviewed and approved of the research as written. Review will not be initiated without appropriate signatures.
- **Template:** Follow the most current protocol template, which guides the investigator to provide required information (see page 8). The University’s web site may change so refer back to it frequently as opposed to using another researcher’s form. Retain this outline format for ease of review.

**Protocol Statement**

- **Complete protocol:** Submit a complete protocol, including all sections and attachments (all consents/assents, recruiting materials, questionnaires, interview questions, permission letters, training certificates, etc.).
- **Background:** Provide an explanation of anything needed for the committee to understand your protocol, e.g., if you are using dietary supplements we need to know all about them—studies, risks, benefits; if you are studying Youth Radio, tell us what it is. Be sure your literature review is related to the human subjects portion of your project. Define all terms and acronyms and avoid use of discipline-specific jargon.

- **Data analysis:** Include methods, not just “the data will be analyzed statistically”. Be sure that the data collected answer the stated research question.
- **Risks:** Be inclusive and specific. Realistically acknowledge possible risks.
- **Qualifications:** Include qualifications to conduct your specific research project, not just “I am a grad student”. Also, be sure you are qualified.
- **Proofread:** While minor errors can be tolerated in the protocol itself, the documents that go out to the public must be perfect.
- **Consistency:** Be sure you are consistent: 20 minutes for the survey in the protocol and 30 minutes in the consent form; changing between calling your activity a survey or interview; different ages of participants in different places will trigger a question from us.
- **Sample:** If you are using a sample protocol to help you with your submission, be sure it is the final, approved version, not an early draft that may have been extensively modified to secure approval.

#### **Attachments**

- **Consent/assent forms:** These need to be complete and concise and at an appropriate level for the intended audience.
- **Interview/survey questions:** We need to see the final version, not a draft or a general idea. For online surveys, we need to see the print-out for formatting.
- **Permission letters:** Be sure they cover the activities you are going to pursue.
- **Recruiting materials:** Include all scripts, flyers, emails, web postings, etc. in their final form.

#### **Follow-through: Once received by the University IRB Committee**

- **Receipt of documents:** We acknowledge receipt of all documents. If you haven’t heard from us, check.
- **Address IRB’s questions:** Either incorporate suggested changes or give justification for not doing so.
- **Timely response:** The more quickly you respond to our requests, the faster the process will go.

#### **Could this project be modified to be exempt?**

Sometimes making a minor change in research design could move a protocol into the “exempt” category, which generally does not require committee review.

**Your project may not require IRB review**

*The following activities may not require IRB review. Please contact the IRB to help determine if review is required.*

- **“Self Improvement” studies (for example, where someone reviews their own teaching methods with an eye to becoming a better teacher)**
- **Key Informant Interviews where the information presented is about the program and not the individual**
- **Curriculum Development where the curriculum is not being evaluated in the field**
- **Needs Assessments and Program Evaluation with the sole intent of sharing the results internally with the agency, organization, etc.**
- **Oral History where the information is merely reported, but not analyzed**
- **Web Design Evaluations, Product Design Assessments**
- **De-Identified Secondary/Existing Data**
- **Classroom projects: If a class project will not be published, it may not need IRB review. If, at a later time, a student wishes to, e.g., use these data in the Student Research Competition or for a thesis, this may be possible.**

# Protocol Application

## CALIFORNIA STATE UNIVERSITY EAST BAY HUMAN SUBJECTS RESEARCH PROTOCOL

Use of this template (outline) is suggested when submitting a research protocol to the IRB. Your responses should be in terms, which may be understood by a non-specialist.

Please complete all sections of this template. If any section is not applicable, list the heading and simply indicate “N/A”.

*Instructions are bracketed and in italics. Please remove instructions prior to submission.*

- I. PROJECT TITLE
- II. DATE OF SUBMISSION
- III. STARTING AND ENDING DATES OF PROJECT
- IV. INVESTIGATORS AND STAFFING

*[In the table below (add additional rows as needed), indicate: (1) key project personnel, (2) their qualifications, and (3) a brief description of their responsibilities.]*

**Primary Investigator:**

**Department:**

**Phone number:**

**Email address:**

**If P.I. is a student, then complete next line:**

**Advisor’s name:**

**Please list all personnel (including P.I.) who will assist in conducting research in the table below:**

| NAME OF INDIVIDUAL | QUALIFICATIONS | RESPONSIBILITIES |
|--------------------|----------------|------------------|
|                    |                |                  |
|                    |                |                  |
|                    |                |                  |



## **V. FUNDING SOURCES**

*[If receiving funding for this research, please identify the funding agency. If not funded, state “No funding.”]*

## **VI. INVOLVEMENT OF OTHER ORGANIZATIONS**

*[If research will be conducted through other organizations, e.g., elementary schools, please list the name of each organization, and the name of the gatekeeper of the organization, e.g., the principle of the elementary school. Attach a letter of approval from each gatekeeper.]*

## **VII. HYPOTHESIS**

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

## **VIII. RESEARCH METHOD AND DESIGN**

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

## **IX. HUMAN SUBJECTS INVOLVEMENT**

*[Please complete all sections of the Human Subjects Instructions. If section is not applicable, indicate “N/A”.]*

### **A. DESCRIPTION**

*[Provide a detailed description of the proposed involvement of human subjects in the work. Specifically, state:*

*The procedures the participants will take part in, in a step - by - step chronological manner.  
Where the research will take place.*

*How long the research will take for the participant (for each meeting and total).]*

## **B. SUBJECT POPULATION**

*[Describe the subject population in terms of sex, race, ethnicity, age, etc., including the number of participants. Describe your access to the population that will allow recruitment of the necessary number of participants. State any inclusion/exclusion criteria used to select participants. Explain the rationale for the involvement of vulnerable populations (e.g., children, the cognitively impaired, or prisoners).]*

## **C. RESEARCH MATERIAL**

*[Explain how information will be obtained from the subjects (e.g., interviews, surveys, observations, reviewing participants' work, using pre and post test results as data). Attach any surveys, interview questions, or the like. ]*

## **D. RECRUITMENT PLAN**

*[Describe plans for the recruitment of subjects. If you plan to involve special cases of subjects, such as children, the cognitively impaired, prisoners or others who are likely to be vulnerable, describe any special recruitment procedures for these populations. Attach any recruiting materials.]*

## **E. 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.]*

## **F. 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).]*

## **G. 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; or 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.]*

## **H. CONFIDENTIALITY**

*[Describe how the confidentiality of research data will be protected (e.g., physical controls on the data; access controls to the data; coding of data; legal controls, such as a Federal Certificate of Confidentiality; statistical methods; or reporting methods).]*

## **I. 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.]*

## **J. CONSENT ISSUES**

- 1. 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. Attach consent form(s).]*

2. **SPECIAL CONSENT PROVISIONS** — *[If some or all subjects will be cognitively impaired, or have language/hearing difficulties, describe how capacity for consent will be determined. If you anticipate the need to obtain informed consent from legally authorized representatives (LARs), please describe how you will identify an appropriate representative and ensure that their consent is obtained.]*
  
3. *[If request is being made to **WAIVE SOME OR ALL ELEMENTS OF INFORMED CONSENT FROM SUBJECTS OR PERMISSION FROM PARENTS**, explain why: (1) the research involves no more than minimal risk to the subjects, (2) the waiver or alteration will not adversely affect the rights and welfare of the subjects, (3) the research could not practicably be carried out without the waiver or alteration; AND (4) whether or not subjects will be debriefed after their participation.]*
  
4. *[If request is being made to **WAIVE DOCUMENTATION OF CONSENT**, provide a justification for waiver based on one of the following two elements AND include a description of the information that will be provided to participants: (1) the only record linking the subject and the research would be the consent document and the principal risk would be potential harm resulting from a breach of confidentiality. Subject will be asked whether they want documentation linking them with the research, and each subject's wishes will govern; or (2) the research presents no more than minimal risk of harm to subjects and involves no procedures for which written consent is normally required outside of the research context.]*
  
5. *[If applicable, explain the **ASSENT PROCESS** for children or decisionally impaired subjects. Attach assent form.]*

6. *[If request is being made to WAIVE THE REQUIREMENT TO OBTAIN ASSENT from children age 6 or higher, or decisionally impaired subjects, explain why: (1) why some or all of the individuals age 6 or higher will not be capable of providing assent based on their developmental status or impact of illness; (2) the research holds out a prospect of direct benefit not available outside of the research; AND/OR (3) [a] the research involves no more than minimal risk to the subjects, [b] the waiver or alteration will not adversely affect the rights and welfare of the subjects, [c] the research could not practicably be carried out without the waiver or alteration; AND [d] whether or not subjects will be debriefed after their participation.]*

**X. OTHER**

*[If there are issues which the board should consider which do not fall into any category above, please describe them here.]*

# Study Completion Form

## STUDY COMPLETION FORM

Institutional Review Board LI Room 2310  
California State University East Bay  
25800 Carlos Bee Blvd.  
Hayward, California 94542

PLEASE SUBMIT THIS FORM TO THE IRB  
AT THE CLOSE OF THE STUDY.  
Phone: (510) 885-4212 Fax: (510) 885-4618  
E-mail: [irb@csueastbay.edu](mailto:irb@csueastbay.edu)  
Website: [www.csueastbay.edu/orsp](http://www.csueastbay.edu/orsp)

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**Date:**

**Study Title:**

**Researcher's Name:**

**Initial Approval Date:**

**Completion/Closure Date:**

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|                                       |  |
|---------------------------------------|--|
| # Subjects Proposed for Study         |  |
| # Subjects Enrolled                   |  |
| # Subjects Withdrawn After Enrollment |  |
| # Subjects Completed                  |  |
| # Serious Adverse Events              |  |

**Reason for closure: (i.e., end of study, accrual met, etc.)**

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**Briefly describe any Serious Adverse Events (SAEs) or unanticipated risks encountered in this research. Use separate page if needed.**

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**IRB Response:**

⑨ **Final Report Received**

**Comments:** \_\_\_\_\_

**Signature:** \_\_\_\_\_ **Date:** \_\_\_\_\_

## Commonly Used Sample Forms

*[Delete all instructions in italics, like this one, before submitting the completed informed consent. You may also remove the section headers to save space. Use ordinary language so that ordinary people can understand this document. It's not written for academics.] (Once the italicized instructions have been removed, the consent document should be kept to 1 or 2 pages. You may delete double spaces between sections if necessary.]*

### CALIFORNIA STATE UNIVERSITY EAST BAY INFORMED CONSENT TO PARTICIPATE IN A RESEARCH STUDY (RESEARCH TITLE)

#### A. PURPOSE AND BACKGROUND

The purpose of this research study is to \_\_\_\_\_ (state in one or two sentences why the study is being conducted, for instance “to learn more about the effect of using math games in teaching sixth grade math.” Do not use academic or discipline-specific jargon.)

The researcher, \_\_\_\_\_, is a professor/ graduate student/staff member at California State University East Bay (conducting research for a master’s degree/honor’s thesis.)

You are being asked to participate in this study because you \_\_\_\_\_ (state here the reason for recruitment, e.g. “you are a student in the Psychology department.”). Be specific. Use the pronoun “you” throughout this document to refer to the research participant. Call yourself “the researcher.” Write at a 6th-grade level in lay language.

#### B. PROCEDURES

List all research activities for the participant. Be concise and clear. Adapt this to your own research, use only your own procedures.

*Sample:*

If you agree to participate in this research study, the following will occur:

- you will be interviewed for approximately thirty minutes about \_\_\_\_\_.



- the interview will be audiotaped to ensure accuracy in reporting your statements.
- the interview will take place in the researcher’s office at a time convenient for you. (or/ it will take place at a time and location convenient to you.).
- the researcher may contact you later to clarify your interview answers for approximately fifteen approximately forty-five minutes.
- total time commitment will be \_\_\_\_\_

*(Please state only those procedures that the participant will undergo. State where the research will take place, how long it will take, and when it will occur. Include the information you would like to have if you were going to participate in this project as a research subject. List the time each procedure will take, and also the total time commitment for the participant, not the researcher.)*

### C. RISKS

*Sample: There is a risk of loss of privacy. However, no names or identities will be used in any published reports of the research. Only the researcher will have access to the research data. (Add other risks if they exist, such as “There is a risk of discomfort or anxiety due to the nature of the questions asked; however, the participant can answer only those questions he/she chooses to answer, and can stop participation in the research at any time.*

*If you are conducting focus groups, see focus group consent under Forms and Templates for additional protections for participants in group discussions. If you are interviewing children or youth under the age of 18, see the Guidelines for Obtaining Minor Assent and sample assents; you will also need a Parental Permission for a Minor to Participate in Research, also found in Forms and Templates.*

### D. CONFIDENTIALITY

*Sample: The research data will be kept in a secure location (or/password protected program), and only the researcher will have access to the data. At the conclusion of the study, all identifying information will be removed and the data will be kept in a locked cabinet or office.*

*Describe where and how the data will be stored, and include the final disposition of the data, that is, what you will do with the data when the study is completed.*

*(If taping interviews and transcribing them for the content):* Audiotapes or videotapes will be destroyed at the end of the study.)

*(If keeping original tapes or digital data for future research, data may be used in the future only for research purposes consistent with the original purpose of the research stated in this consent. If the data is de-identified, ie. all identifiers have been removed including coding, the data will not need IRB review for future research use.*

#### **E. DIRECT BENEFITS**

*Sample:* There will be no direct benefits to the participant.

*(There is almost never a direct benefit, which generally applies to clinical trials in which a subject may get an experimental drug therapy, etc.)*

*(Any indirect benefits can only be anticipated, because you can't guarantee anything since you have no results yet. If you talk about anticipated benefits, do so briefly and use the conditional tense, as in "Benefits may include.....")*

#### **F. COSTS**

*Sample:* There will be no cost to you for participating in this research.

*(Or)* The only cost to participants will be transportation to the research site.

#### **G. COMPENSATION**

*Sample:* There will be no compensation for participating in this research. *(Or)* Compensation for participating in this research will be \$10.00.

#### **H. ALTERNATIVES**

*Sample:* Alternate therapies for this condition exist such as extended bed rest.

*(This section is typically used when a medical treatment is under investigation.)*

**I. QUESTIONS**

If you have any further questions about the study, you may contact the researcher by email at \_\_\_\_\_@\_\_\_\_\_ or phone at (510) 885-xxxx.

Questions about your rights as a study participant, or comments or complaints about the study, may also be addressed to the Office of Research and Sponsored Programs at (510) 885-4212.

**J. CONSENT**

You have been given a copy of this consent form to keep.

**PARTICIPATION IN THIS RESEARCH IS VOLUNTARY.** You are free to decline to participate in this research study, or to withdraw your participation at any point, without penalty. Your decision whether or not to participate in this research study will have no influence on your present or future status at California State University East Bay.

Signature \_\_\_\_\_  
Research Participant

Date \_\_\_\_\_

Signature \_\_\_\_\_  
Researcher

Date \_\_\_\_\_

*(Signature of researcher is optional.)*

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### Focus Group Consent

**(Directions: Focus groups require an additional layer of privacy protection, because the researcher cannot guarantee that the participants of the group will not reveal each other’s contributions to the group discussion once it has ended.**

**In addition to the usual warning about “loss of privacy is a potential risk,” the “Risks” section of the protocol and the informed consent should contain the “*focus group consent*” wording below, adapted to the individual research project.)**

**Also, because the focus groups include discussion of personal opinions, extra measures will be taken to protect each participant’s privacy. The researcher will begin the focus group by asking the participants to agree to the importance of keeping information discussed in the focus group confidential. She will then ask each participant to verbally agree to keep everything discussed in the room confidential, and will remind them at the end of the group not to discuss the material outside.**

**Only the researcher will have access to the data collected. Any tapes and transcripts of the focus group will be destroyed after one year or at the end of the study.**

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### Implied Consent to Participate in Research

**Research Title:**

**Researcher’s Name:**

*[Directions for Implied Consent for Surveys: Delete these before turning in your finished document. The following paragraph should go at the top of the survey you give/send out. It can be in a smaller font than the survey. Please adapt it to your own project, in terms of your department or college, what the research is and why these people have been asked to participate. If survey questions are sensitive in nature, i.e about drug/alcohol abuse or risky sexual behavior, the 2<sup>nd</sup> sentence in the 2<sup>nd</sup> paragraph should be changed to: There is a risk that you might feel some discomfort in answering these questions, but you may stop participating at any time or you may refuse to answer any question.”]*

**Data collected from this confidential survey will be used for completion of a master's degree in \_\_\_\_\_ at California State University East Bay. The information gathered will be used for research on \_\_\_\_\_.**

**The survey questions will be about \_\_\_\_\_.**

**You have been invited to participate because \_\_\_\_\_  
(insert inclusion criteria here).**

**You must be 18 years of age or older to participate. There are no risks or benefits to you in participating in this survey. You may choose to participate or not. You may answer only the questions you feel comfortable answering, and you may stop at any time. If you do not wish to participate, you may simply return the blank survey, with no penalty to yourself. If you do participate, completion and return of the survey indicates your consent to the above conditions.**

Please do not put your name on this form. The survey should take approximately \_\_\_ minutes to complete. Any questions or concerns should be directed to the principal investigator, \_\_\_\_\_, at \_\_\_\_\_@\_\_\_\_\_, the research advisor, Professor \_\_\_\_\_, at \_\_\_\_\_@\_\_\_\_\_, or the CSUEB Office of Research and Sponsored Programs at [irb@csueastbay.edu](mailto:irb@csueastbay.edu) or 510-885-4212.

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**Photo Release Form**

**Research Title:**

**Researcher's Name:**

**CALIFORNIA STATE UNIVERSITY EAST BAY  
PHOTOGRAPHIC RELEASE FORM**

As part of this project, we will be taking photographs. Please initial in the spaces below what uses of these photographs you consent to, and sign at the end of the release form. Photos will only be used in the ways you consent to. Your name will not be identified in these photos.

1. \_\_\_ Photographs can be reviewed by the research team.
2. \_\_\_ Photographs can be used for project illustration.
3. \_\_\_ Photographs can be used for promotional materials, such as brochures or fliers.
4. \_\_\_ Photographs can be used for classroom presentations.
5. \_\_\_ Photographs can be used for academic conference presentations.
6. \_\_\_ Photographs can be used for fundraising presentations/proposals.
7. \_\_\_ Photographs can be used for newspaper or magazine publication
8. \_\_\_ Photographs can be posted on a web site for promotional purposes.

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Name

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Signature

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Date

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**Video Release Form**

**Research Title:**

**Researcher's Name:**

*(Directions: Include this form in your protocol submission if you will be videotaping participants. If you are videotaping children, you will need to have their parents' permission. Please include only those uses of the video that you intend. All are included here to give you an idea of how you might want to use the video in the future. If you think that someday you might put this up on a web site, ask permission now, rather than having to go back to the participants later. If you have no intention of using it on a web site, don't include that option on this form. If you include #4, specify what level classroom—elementary/ middle/high school/college, and for what purpose. Delete these instructions before turning in your finished document.)*

**CALIFORNIA STATE UNIVERSITY  
VIDEO RELEASE FORM**

**As part of this project, I will be making videotape recordings of you (or your child) during your participation in the research. Please indicate what uses of these videotapes you are willing to permit, by putting your initials next to the uses you agree to, and signing the form at the end. This choice is completely up to you. I will only use the videotapes in ways that you agree to. In any use of the tapes, you (or your child) will not be identified by name.**

1. \_\_\_\_ The videotapes can be studied by the research team for use in the research project.
2. \_\_\_\_ The videotapes can be used for scientific publications.
3. \_\_\_\_ The videotapes can be shown at scientific conferences or meetings.
4. \_\_\_\_ The videotapes can be shown in classrooms to students.
5. \_\_\_\_ The videotapes can be shown in public presentations to non-scientific groups.
6. \_\_\_\_ The videotapes can be used on television or the audio portion can be used on radio.
7. \_\_\_\_ The videotapes can be posted to a web site.



**I have read the above descriptions and give my consent for the use of the videotapes as indicated by my initials above.**

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Name

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Signature

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Date

**Additional forms may be found on the CSU East Bay IRB website:**

**<http://www.csueastbay.edu/orsp/forms-policies-procedures/irb/forms.html>**