Date: 4-17-2020

IRB #: CSUEB-IRB-2020-8
Title: Sample Study
Creation Date: 4-17-2020
End Date:
Status: Unsubmitted
Principal Investigator: Kevin Brown
Review Board:
Sponsor:

Study History

Submission Type	Review Type	Decision
Initial	Unassigned	

Key Study Contacts

Member Kevin Brown	Role Principal Investigator	Contact importantdatesorsp@csueastbay.edu
Member Kevin Brown	Role Primary Contact	Contact importantdatesorsp@csueastbay.edu

Initial Submission

1. POLICIES

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

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

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

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

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

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

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

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

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

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

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

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2. INVESTIGATOR(S)

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

Are you faculty, staff, or a student?

- ✓ Faculty
- Staff
- Student

Principal Investigator on Research Study

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)

Name: Kevin Brown
Organization: Computer Science
Address: 25800 Carlos Bee Blvd SF 568, Hayward, CA 94542-3000
Phone:
Email: importantdatesorsp@csueastbay.edu

Phone # (if not listed above)

510-885-4007

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

CSCI

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.

F**aculty** investigators should enter their own name as the primary contact.
S**tudent** investigators should enter their own name as the primary contact.
Name: Kevin Brown
Organization: Computer Science
Address: 25800 Carlos Bee Blvd SF 568, Hayward, CA 94542-3000
Phone:
Email: importantdatesorsp@csueastbay.edu

Co-Principal Investigator(s) if applicable

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

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

If you are unable to find the investigators and/or key personnel, it means they have not been added to the Cayuse IRB system. Please contact the CSUEB IRB at irb@csueastbay.edu to add them to the system and include the person's NETID and email address in the the request to add them.

Students, your faculty advisor/instructor must make a request on your behalf that you be added to the system.

Additional CSUEB Affiliated Study Personnel if applicable

Add additional CSUEB affiliated investigators and/or key personnel using the Find People function below as needed.

If you are unable to find the investigators and/or key personnel, it means they have not been added to the Cayuse IRB system. Please contact the CSUEB IRB at irb@csueastbay.edu to add them to the system and include the person's NetID and email in the the request to add them.

Non-CSUEB Affiliated Investigators, Co-Investigators, and Key Personnel

The text box below can be used for the following:

Adding Non-CSUEB affiliated investigators and/or key personnel such as evaluators, or external investigators as needed.
Please include their first and last name and contact information (email addresses and

phone numbers).

Adding multiple CSUEB student investigators, co-investigators, and key personnel. (For example: program managers, evaluators, technicians, and others.)

Non-CSUEB affiliated investigators may only be added in the text box area as they cannot be added to the Cayuse IRB system.

CSUEB Student 1
CSUEB Student 2

Involvement of other organizations

If research will be conducted through other organizations, e.g., elementary schools, counseling centers, religious organizations, please list the name of each organization, and the name of the gatekeeper of the organization, e.g., the principal of the the elementary school. Attach a letter of approval from each gatekeeper indicating permission to conduct research on/through their site.

Please note: This section should not be completed if the external organization has its own IRB. Typically, only four-year universities and hospitals maintain their own IRBs.

Dublin High School

Letter(s) of Permission

Attach letters of permission here.
Example Permission letter.pdf

Multi-Institution Projects

Is this a multi-institution project?

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

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

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

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

- Yes
- ✓ No
- Unsure at this time

Training Documentation

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

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

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

3. DATA COLLECTION

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

Exempt (Limited)

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

Expedited Review

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

Full Board Review

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

Proposed Start Date of Study:

04/30/2020

Proposed End Date of Study:

12/16/2020

Number of Participants

Indicate the number of participants proposed for your study.
300

Demographic Information

Subject Ages

Select all that apply.

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

Gender

Select all that apply.

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

Special Populations

Describe any populations you hope to study which may require special consideration.
Select all that apply.

- [x] Children/Minors (17 years of age or younger)
- [ ] Pregnant Women
- [ ] Cognitively-Impaired Adult Subjects
- [ ] Prisoners
- [ ] CSUEB Students
- [ ] Subjects unable to read, speak, or understand English

Economically or educationally disadvantaged persons

Other

None of the above

4. FUNDING

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

Is this study funded?

- Yes
- ✓ No

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.

Hypothesis or Research Questions

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

Determine if high school students would rather start school at 10:00 am rather than 8:00 am.

Studies have shown that adolescents require more sleep, and performance in school will improve with later start dates. Often students have after-school activities or work responsibilities though. This study seeks to determine if students would approve of a later start time despite the impact on their extra-curricular activities.

Research Methodology and Design

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

A Qualtrics survey will be developed to assess student opinion. Dublin High School will provide email addresses for the parents of the students. The survey link will be sent to the parents.
In addition, a focus group will be held on campus with 10 students.

Human Subjects Involvement

C.

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 order.
- Where the research will take place.
- How long the research will take for the participant (for each meeting and total.

A 10 minute survey will be completed online through Qualtrics.
10 students will participate in a 45 minute focus group on the Dublin High School campus after school has ended.

Subject Population

D.

- Describe the subject population in terms of gender, 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 any vulnerable populations (e.g., children, the cognitively impaired).

The survey link will be sent to all students in the Junior class. Dublin High has a diverse community of students.

The principal of the school has agreed to provide access to email addresses and to allow a focus group to be held on campus.

The survey will only be available in English, so English language proficiency is required to participate.

Minors must be included in this study as we hope to ascertain the opinions of high school students.

Recruitment Plan

Describe plans for recruitment of subjects.

E. If you plan to involve special populations, such as children or the cognitively impaired, who may be likely to be easily coerced, describe any special recruitment procedures for these populations.

The principal of the school will forward a link to our survey to all parents of the school.

The survey will also ask for volunteers for the focus group.

Since the parents of the students will be contacted, we do not believe that the students will be coerced to participate against their will.

Recruitment Materials

Attach any recruitment materials here.

Example Recruitment.pdf

Research Material

F. 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.)

A 10 minute online survey will be conducted and a 45 minute in-person focus group held on Dublin High School grounds.

Surveys, interview questions, and similar documents

Attach any surveys, interview questions, and similar documents here.

Example Survey.pdf

Data Analysis

G. Describe how you will analyze the data.

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

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

Dissemination

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

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

We plan to submit results to a major journal.

6. CONFIDENTIALITY

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

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

7. RISKS AND BENEFITS

Potential Benefits

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

Note that excessive payments may be considered coercive. If students will receive extra credit or course credit, state the alternative method(s) of earning the credit that must be made available to those who do not wish to participate.
No benefits will be offered for completion of the survey activity.

Participants in focus group will be offered $5 via a Starbucks gift card. This is in compliance with ORSP policy on compensation to research subjects found here:
https://www.csueastbay.edu/orsp/files/docs/policy/...

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.
Students may become emotionally upset in learning that other students start school much later than they do.
A list of counseling resources will be provided.
In addition, PI is licensed counselor.

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.

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

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

Risk/Benefit

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

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

8. INFORMED CONSENT

Consent Process

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

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

Consent Forms

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

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

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

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

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.

Assent Forms

Assent is defined by the regulations as follows: Assent means a child's affirmative agreement to participate in research. Mere failure to object (i.e., absent of affirmative agreement) should not be construed as assent. (See federal regulation at 45 CFR 46.402 (b)

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

The child must actively show his or her willingness to participate in the research, rather than just complying with directions to participate and not resisting in any way. When judging whether children are capable of assent, the Institutional Review Board (IRB) is charged with taking into account the ages, maturity, and psychological state of the children involved. The IRB has the discretion to judge the child's capacity to assent for all the children involved in a proposed research activity, or on an individual basis. Assent forms must use age-appropriate language, and assent should be obtained verbally for children under the age of 8.

For an example Assent forms please refer to the CSUEB IRB website or click the following link:
Guidelines for Obtaining Assent from Minors

Attach your Assent form(s) here.

9. DEBRIEFING

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

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

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

Attach your debriefing form/statement here.

10. ATTACHMENTS

Letter(s) of Permission

Attach letters of permission here.
Example Permission letter.pdf

Multi-Institution Project Documents

Training Documentation

Recruitment Materials

Example Recruitment.pdf

Surveys, interview questions, debriefing forms, and similar documents

Example Survey.pdf

Consent Forms

Example Parental Consent.pdf

Assent Forms

Debriefing Form/Statement

Other Attachments

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

11. COMMUNICATIONS

Communications between Investigators and IRB staff

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

Communications between Faculty Advisors and Student Advisees

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