California State University, Long Beach
Institutional Review Board (IRB)
Class/Program Specific Umbrella Protocol for Administrative Review

Please refer to the **CSULB IRB Guidance on Student Projects**. In brief,

A. If a student project falls within the scope of those projects specified in the Guidance Section III, there is no need for IRB submission/review.
B. If a student project falls within the scope of Human Subject Research (HSR) projects specified in Guidance Section IV, each student needs to submit a separate IRB Application Form.
C. As the class/program instructor/faculty adviser, you are submitting this Class/Program Specific Umbrella Protocol for Administrative Review. This is because this Class/Program Specific HSR Project meets the two key requirements as specified in the Guidance Section V, i.e., (1) to be conducted by more than one student but with a similar setting, instruments, informed consent forms, subject populations and methodology, and (2) not involve vulnerable populations, sensitive information/topics, or more than minimal risk to the subjects.

Instructions:

The Principal Investigator (PI) is responsible for all information in this form. The PI should fill out the form completely; incomplete forms will be returned. This form should be completed in Microsoft Word; any other word processing program may compromise the formatting of this document. Use as much space as necessary to answer each question adequately. Check boxes can be filled and unfilled by clicking once inside the box you intend to select or de-select. Please upload the completed application and all relevant appendices to IRBNet (www.irbnet.org).

IMPORTANT: NO ACTIVITY MAY BEGIN ON THIS PROJECT UNTIL THE CSULB IRB ISSUES FORMAL NOTIFICATION TO THE PI REGARDING PROJECT APPROVAL VIA IRBNet. In addition, the IRB will confirm that all individuals listed on this project have successfully completed the CITI online training for the Social & Behavioral Basic/Refresher course before issuing final approval (www.citiprogram.org).

Section I - Class/Program Instructor/Faculty Investigator Information

Full Name	Click or tap here to enter text.
CITI Member ID #	Click or tap here to enter text.
Telephone Number	Click or tap here to enter text.
Email Address	Click or tap here to enter text.
Department	Click or tap here to enter text.

Section II - Project Overview

1. **Class/Program/Lab Title/Course Number**

Click or tap here to enter text.

2. **Purpose/Abstract**

Describe the learning objective/purpose of the project. Provide background context by explaining how the findings of this project will contribute to generalizable knowledge, which groups/populations may benefit from the research. Define any acronyms used for the first time.
Click or tap here to enter text.

Section III- Subject Recruitment & Informed Consent

1. **Subject Population & Inclusion/Exclusion Criteria**

- **If your research population includes vulnerable populations specified in 45 CFR 46 Subparts B, C, D and those defined by CSULB, then this Class/Program Project Umbrella Protocol is not appropriate for this study.**

Total number of subjects (Include a range if applicable):	**Click or tap here to enter text.**
Define specific Inclusion/Exclusion Criteria of the subject populations (language requirements, enrollment or membership in any organization, job roles, students at institution, etc.). Insert charts if necessary or appropriate to show distribution and number of subjects for multiple subject groups.	
Click or tap here to enter text.	

2. Subject Recruitment

Select the method(s) of recruitment (Check all that apply):	
☐ Personal Network/Snowball Sampling	☐ Subject Pool (SONA or department pool)
☐ Flyers/Letters	☐ In Person
☐ Social Media Post	☐ Letter
☐ Telephone	☐ Other (Explain): Click or tap here to enter text.
Describe the step-by-step method of recruiting participants with each method selected above. Clearly define recruitment methods for different subject groups if the recruitment methods differ.	
Click or tap here to enter text.	

☐ I have attached all relevant recruitment material (flyers, email/phone/verbal announcement script, social media post, etc.) as an appendix to this project in IRBNet.

3. Informed Consent Documentation. Please check method(s) & justification(s):

METHOD OF CONSENT	JUSTIFICATION
☐ Written informed consent, with signature	☐ Normal circumstances
☐ Requesting a waiver of documentation of informed consent*	☐ The research presents no more than minimal risk of harm (procedures do not surpass normal everyday activities). "Implied consent" for online or anonymous surveys.
☐ Requesting a waiver of the informed consent process*	☐ The research cannot practicability be carried out without the waiver or alteration, *AND* the research will not adversely affect the rights and welfare of subjects, *AND* the research involves no more than minimal risk to subjects (all conditions must be met for this justification).
If *more than one method and more than one justification* is selected above, please provide an explanation below (e.g. different procedures for different subject groups).	

In cases where written informed consent will not be obtained, the IRB requires an informed notice to be issued or read to participants. Please attach the notice as an appendix to your project in IRBNet. The IRB will make the final determination whether to grant any waiver or alteration of the informed consent process.

4. Informed Consent Process

Describe the step-by-step process for obtaining informed consent or issuing an informed notice to subjects. For multiple subject groups, distinguish the methods for obtaining consent from each group. If the process is identical for each subject group, please state so. Do not include any data collecting steps in this section since data collection should not be conducted prior to informed consent.

Click or tap here to enter text.

Section IV - Procedures & Methodology

1. Location of Research Activities

List the location(s) and setting(s) of the research activities	
Location (i.e. names of schools, non-profit or government agencies, businesses, hospitals, parks, etc.)	Click or tap here to enter text.
Setting(s) (Check all that apply):	☐ Online (Qualtrics, Survey Monkey, Google Survey, etc.) ☐ One-on-one ☐ Public area ☐ Focus Group Setting ☐ Virtual (Skype, Zoom, email) ☐ Telephone ☐ Lab ☐ Classroom ☐Other (Explain): Click or tap here to enter text.

2. Research Methodology

List all assessments used in the research (Check all that apply):	
☐ Paper-based survey ☐ Wearable devices/sensors ☐ Secondary data analysis ☐ Public observation ☐ Classroom observation ☐ Taste Test ☐ Video recording ☐ Audio recording ☐ Blood draw ☐ Review of course assignments ☐ Salvia test	☐ Online survey ☐ Interview ☐ Focus group ☐ Weight lifting (minimal) ☐ Weight lifting (maximum) ☐ Running/Walking ☐ Vital signs ☐ Review/access to educational records ☐ Other (Explain): Click or tap here to enter text.
Describe the step-by-step process for research activities *AFTER* informed consent is obtained. Use as much space necessary to thoroughly describe all research activities. Include the URL to any online survey, video or online activity in this section.	

Click or tap here to enter text.	
Do the research activities involve deception or manipulation?	☐ Yes* ☐ No
***If yes*, describe whether you will reveal the deception or manipulation in a debriefing to subjects.**	
Click or tap here to enter text.	

Section V - Risks & Benefits

1. Potential Risks

Describe the potential risks, harms, discomfort or inconvenience associated with the research activities. Number each risk (Risk #1, Risk #2, etc.) It is unacceptable to state "there is no risk" or leave it blank.
Click or tap here to enter text.

2. Mitigation of Potential Risks

Describe the methods of mitigation (protection against risk and harm) for each potential risk listed above. Each mitigation should correspond to the numbered potential risk above (Mitigation for Risk #1, Mitigation for Risk #2, etc.). In the event of injury or emotional distress, outline a plan to refer subjects to appropriate medical/professional services and a plan for reporting adverse events to the IRB.
Click or tap here to enter text.

3. Potential Benefits

List any direct benefits subjects can anticipate from participating in the research (do not list any forms of compensation because compensation is not a benefit). If there are not direct benefits to subjects, please state so.

Click or tap here to enter text.
List any potential benefits or contributions to the field of study, existing body of research or society the results of this may generate. Stating there are no benefits is not acceptable; otherwise, this project has no merit.
Click or tap here to enter text.

Section VI- Data Management

1. Data Storage

List the location *AND* method of storage of raw data to be published (consent forms, transcripts, recordings, etc.) for this project (Check all that apply):	
LOCATION	**METHOD OF STORAGE**
☐ Faculty home ☐ Faculty office at CSULB ☐ Other (explain): Click or tap here to enter text.	☐ Locked file cabinet ☐ Password protected computer ☐ External hard drive ☐ Cloud-based storage ☐ Other (explain): Click or tap here to enter text.

2. Data Destruction

Please certify your plan to maintain the raw data and records to be published for this project for 3 years (IRB policy) or state your alternative and/or provide a valid justification. (Check one):
☐ I certify that I will maintain the raw data and records for this project in a secure location and destroy the data after 3 years. ☐ I will not maintain and store the raw data and records for this project for 3 years. Please find my justification and plan to store and destroy the project data and records: Click or tap here to enter text.

Section VII - Appendices

List and label all appendices included with this initial submission (Class Syllabus, Informed Consent Forms, interview/survey questions, recruitment material, permission letters, etc.):

Appendix A – Class Syllabus
Appendix B – When census data becomes available by the fourth week of each semester, Roster of only those students who want to take part in the potential of publication
Appendix C – Informed Consent Form
Appendix D – Interview/Survey Questions
Appendix E – Recruitment Materials
Appendix F – Permission Letter

Section VIII Investigator Assurance

I, the Principal Investigator (PI) for this project certify the following (please check and confirm all):

☐ All subjects in this project will be afforded the same rights and protections.

☐ All provisions to maintain subject confidentiality and protect subject data will be upheld.

☐ The CITI online training is complete for myself and all students listed. Training will remain valid for the duration of research activity.

☐ Research activities will be conducted as described in the approved version of this application.

☐ Any modifications, including personnel changes to this project will be submitted, reviewed and approved by the CSULB IRB prior to implementation.

☐ All adverse events will be reported to the CSULB IRB within 48 hours of being made aware of the event.

☐ Will comply with the CSULB IRB research policies (http://web.csulb.edu/divisions/aa/research/compliance/humans/#CSULBPolicies)

☐ Will comply with the Department of Health and Human Services (HHS) research policy and regulation (https://www.hhs.gov/ohrp/regulations-and-policy/regulations/45-cfr-46/index.html).

Name: Click or tap here to enter text. Date: Click or tap to enter a date.

Appendix A – Class Syllabus

Appendix B – Students' Information & Their Specific Projects' Titles

List the name, CITI Member ID # and email address and specific project title for each student who will have access to *identifiable personal private* information.

Student Full Name	CITI member ID#	Email Address	Specific Project Title