Research Projects Qualifying for Expedited & Standard Review

Note: Before proceeding to the application on the next page, please confirm that your research activities satisfy one of the following criteria. Otherwise, your project may require qualify for Administrative or Limited Review.

You should only fill this form out if your project involves any of the following:

- Clinical trial involving a medical drug or device cleared for use by the FDA.
- Collection of blood samples by finger prick or venipuncture under the following conditions:
  - Healthy, non-pregnant adults weighing at least 110 pounds. Amount of blood collection cannot exceed 550 ml with 8 weeks (no more than two blood draws per week).
  - Other adults and children (with consideration for age, weight and overall health). Amount of blood collection cannot exceed 50 ml with 8 weeks (no more than two blood draws per week).
- Prospective collection of biological samples by non-invasive means.
- Collection of data by non-invasive means in a clinical setting with the use of FDA cleared/approved medical devices (excluding X-ray).
- Identifiable data collection of individuals via voice, video or image recordings made for research purposes and the data collection may place subjects at increased risk.
- Research on an individual or group characteristics or behavior (perception, cognition, motivation, identity, language, communication, cultural beliefs or practices and social behavior) that do not satisfy the Exempt category (research involving public officials, anonymous data collection or less than minimal risk posed to subjects would be considered Exempt).
- Research is greater than minimal risk, meaning the assessment or intervention involves more than what subjects would encounter in normal everyday activities or the data has the potential to pose additional physical, psychological, criminal or social harms.
- Research involving vulnerable populations (i.e. children, pregnant women, fetuses, prisoners, undocumented individuals and other populations deemed vulnerable by the IRB).

IRB Application for Expedited and Standard Review

Projects involving minimal or greater than minimal risk

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

Investigator Information

1. Basic Information

Principal Investigator (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	Click or tap here to enter text.
Department	Click or tap here to enter text.
Affiliation with CSULB	☐Student* ☐Faculty ☐Staff ☐External PI ☐Other:
***If you are a student, please fill out the information for you faculty advisor in the next section and attach a signed permission letter from your advisor as an appendix to your project in IRBNet.**	

2. PI Qualifications

Describe any training, certification, experience or expertise relevant to this research. Also, explain your relationship or affiliation with any organization, course or group involved in with the project.

Example: I am the 8th grade science teacher at Adams Middle School and all 8th grade students, including my own will participate in the research.

Click or tap here to enter text.

Faculty Advisor

3. Faculty Advisor Information

☐ Not Applicable. I am not a student.

Faculty Advisor (Name)	Click or tap here to enter text.
Email	Click or tap here to enter text.
Telephone Number	Click or tap here to enter text.

Additional Personnel

4. Co-Investigator

☐ Not Applicable

Co-Investigator (Name)	Click or tap here to enter text.
CITI Member ID	Click or tap here to enter text.
Email	Click or tap here to enter text.
Affiliation to CSULB	☐Student ☐Faculty ☐ Staff ☐ External PI ☐ Other

5. Research Assistants

☐ Not Applicable

List the name, CITI Member ID # and email for each research assistant or key personnel. Listing the faculty advisor is *not required*, unless s/he is involved in the research procedures.
Click or tap here to enter text.

Project Overview

6. Project Title

Click or tap here to enter text.

7. Purpose/Abstract

Describe the purpose of the project and the project aims. Provide background context to the project by explaining how the findings of this project will contribute to areas within research literature that are insufficient or detail, which groups/populations may benefit from the research. Define any acronyms used for the first time.
Click or tap here to enter text.
What body of knowledge will the results of this project contribute to? (Click all that apply):
☐ Thesis ☐ Dissertation ☐ Research Publication ☐ CSU Provost ☐ Agency Improvement ☐ Academic Department ☐ Personal Knowledge ☐ Other (Explain): Click or tap here to enter text.

8. Expected Project Duration

Estimated Start Date	Click or tap to enter a date.
Estimated End Date*	Click or tap to enter a date.

This field is important because this project may not require continuing review unless the risks are greater than minimal therefore; the IRB requires an estimated project duration to determine the project status on an annual basis.

Subject Recruitment & Informed Consent

9. Subject Population & Inclusion/Exclusion Criteria

Total number of subjects (Describe subject groups or insert table to outline the subject population):	**Click or tap here to enter text.**
Select the general population group (Select all that apply):	

☐ Gender not relevant ☐ Males Only ☐ Females Only ☐ Transgender ☐ Binary Gender	☐ Seniors (over 65) ☐ Children (under 18) ☐ Non-English Speakers ☐ Vulnerable population (victims of crimes, homeless, cognitively impaired, disabled, prisoners, undocumented immigrants
Define any other characteristics of the subject populations (language requirements, enrollment or membership in any organization, job roles, students at institution, etc.). Insert charts if necessary.	
Click or tap here to enter text.	

10. Subject Recruitment

Select the method(s) of recruitment (Check all that apply):	
☐ Personal Network/Snowball Sampling ☐ Flyers ☐ Social Media Post ☐ Telephone	☐ Subject Pool (SONA or department pool) ☐ In Person ☐ Letter ☐ 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.

11. Informed Consent Documentation

Identify the process of obtaining informed consent (Please check ONE method & ONE justification):	
METHOD OF CONSENT	**JUSTIFICATION**
☐ Written informed consent, with signature (this also includes child assent)	☐ Normal circumstances
☐ Oral informed consent*****	☐ Rare and vulnerable populations (illiterate, minimal English speaking, culturally sensitive groups, etc.) ☐ Subject has a Legal Authorized Representative

☐ Requesting a waiver of documentation of informed consent*	☐ Linking the subject to the research via consent form will cause potential harm ☐ 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).

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.

12. 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.

Procedures & Methodology

13. 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) ☐ One-on-one ☐ Public area ☐ Focus Group Setting ☐ Virtual (Skype, Zoom, email)

	☐ Telephone ☐ Lab ☐ Classroom ☐Other (Explain): Click or tap here to enter text.
Is the research international (outside the U.S)?	☐ Yes * ☐ No
If yes, please describe any qualifications you have working in that country as a researcher and confirm that you will comply with the local research regulation. Attach any relevant permissions to conduct research in that country as an appendix to your project in IRBNet.	
Click or tap here to enter text.	

14. 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.	

15. Subject Compensation

Will subjects receive any form of compensation for participating in this project?	☐ Yes* ☐ No
***If yes*, what form of compensation will subjects receive?**	☐ Cash ☐ Gift Card ☐ mTurk credit ☐ Extra credit ☐ Course credit (required) ☐Other (explain): Click or tap here to enter text. **Total amount:** Click or tap here to enter text.

***If yes*, when will subjects be compensated?**	☐ After subjects completes *all* research activities ☐ After subjects complete *a portion* of research activities (define conditions): Click or tap here to enter text. ☐ Subjects' name is selected from a drawing/raffle ☐ Other (explain): Click or tap here to enter text.
***If yes*, describe any conditions that would deny/disqualify subjects from receiving compensation?**	
Click or tap here to enter text.	

Risks & Benefits

16. Potential Risks

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

17. 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.

18. 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). Subject compensation is addressed is Section 15. 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.

Data Management

19. Data Storage

List the location *AND* method of storage of raw data (consent forms, transcripts, recordings, etc.) for this project (Check all that apply):	
LOCATION	**METHOD OF STORAGE**
☐ PI's home ☐ PI's work office ☐ 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.

20. Data Access

List all individuals that will have access to the data for this project:
Click or tap here to enter text.

21. Data Destruction

Please certify your plan to maintain the raw data and records 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.

Collaboration and Funding

22. Collaboration

Is this project a collaboration with an external investigator or institution? (Select one):	☐ Yes* ☐ No

***If yes*, list the name(s) and institutional affiliation of the collaborator(s):**	
Click or tap here to enter text.	
Are you the lead investigator for this collaboration? (Select one):	☐ Yes ☐ No*
***If no*, please include a copy of the IRB Approval and or protocol from the other affiliate as an appendix to your project in IRBNet.**	

23. Funding

☐ This project is not funded

Grant/Funding Title:	Click or tap here to enter text.	
Funding Agency:	Click or tap here to enter text.	
Funding period:	**Start date:** Click or tap to enter a date.	**End date:** Click or tap to enter a date.

Appendices

List and label all appendices included with this initial submission (consent forms, permission letters, recruitment material, interview and survey questions, etc.):
Click or tap here to enter text.

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 personnel 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.