

# Administrative & Limited Review Research Projects

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 Expedited or Standard Review. *If your project involves the use of identifiable secondary or existing data, please complete the IRB Application for Existing & Secondary Data.*

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

- Normal educational practices in an educational setting. The research activities cannot adversely affect students' opportunity to learn required educational content OR adversely affect the instructors who provide instruction.

**Example:** Comparing multi-media lesson plans in Fall Semester to paper-based lesson plans in Spring semester. The same educational material is covered, only the teaching technique varies.

- Surveys, interviews, observation, educational test or behavioral interventions where the data collection is verbal, in writing or recorded (audio or video) and *MUST* satisfy one of the following:
  - Anonymous data collection (no links to identifiers such as names)
  - Data collected does not place subjects at risk or harm
  - Data that are identifiable, but protections are provided for confidentiality

*Data collection involving children (under 18) or other vulnerable populations requires Expedited Review and submission via the IRB Application for Expedited and Standard Review.*

**Example 1:** Qualtrics survey to collect data on CSULB students' study habits during finals for the purpose of a senior thesis; whether data are collected anonymously or confidentially.

**Example 2:** Interviews with transgender women to understand the harassment they endure in the workplace. No names, employers or company names are used. Pseudonyms used instead. Interviews will be audio recorded with permission in the consent form prior to the interview.

- Benign behavioral interventions involving authorized deception (subjects must consent to deception prior to the research procedures). *The use of concealed deception or manipulation requires Expedited Review and submission via the IRB Application for Expedited and Standard Review.*

**Example:** Group activity involving a white woman in scenario 1 and a black man in scenario 2 who both demonstrate an anger problem and subjects are surveyed to determine underlying gender and racial bias. Subjects were consented to participate in a puzzle competition that involved an element of deception that the PI agrees to reveal at the conclusion of the experiment.

- Public benefit and service programs that are federally funded or conducted by the federal government.

**Example:** An assessment of emergency room wait times in a Veterans Affairs hospital.

- Taste and food quality tests involving ingredients the FDA determines safe for consumption.

**Example:** A marketing taste test evaluation of a chocolate chip cookie compared to a nutrition bar flavored like a chocolate chip cookie. Participants will submit surveys to determine whether the healthy nutrition bar is a tasty substitute for real chocolate chip cookies

# IRB Application for Administrative & Limited Review

## Projects involving less than minimal risk

**Instructions:** Complete all questions regarding the proposed project. Use as much space as necessary and be specific. Refer to the end of the document for term definitions. Check boxes can be filled in by clicking inside the box once.

**IMPORTANT:** NO ACTIVITY MAY BEGIN ON THIS PROJECT UNTIL THE PRINCIPAL INVESTIGATOR HAS RECEIVED FORMAL NOTIFICATION FROM THE CSULB IRB THAT THE PROJECT HAS BEEN ACKNOWLEDGED AS A QUALITY ASSESSMENT/QUALITY IMPROVEMENT PROJECT UNDER ADMINISTRATIVE REVIEW.

### 1. BASIC INFORMATION

<b>PI's Name</b> (Last, First, Degree)	Click or tap here to enter text.
<b>Telephone Number</b>	Click or tap here to enter text.
<b>Email</b>	Click or tap here to enter text.
<b>CITI Member ID #</b>	Click or tap here to enter text.
<b>Completion of CITI Social &amp; Behavioral Basic/Refresher Course (Check one)</b>	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Not Sure
<b>Department</b>	Click or tap here to enter text.
<b>Affiliation</b>	<input type="checkbox"/> Student* <input type="checkbox"/> Staff <input type="checkbox"/> Faculty <input type="checkbox"/> Other
<b>*If you are a student, please complete the information below for your Faculty Advisor:</b>	
<b>Faculty Advisor Name</b>	Click or tap here to enter text.
<b>Email</b>	Click or tap here to enter text.
<b>Telephone Number</b>	Click or tap here to enter text.
<input type="checkbox"/> I have attached a signed and completed letter from my faculty advisor as an appendix to this project in IRBNet.	

### 2. PROJECT SUMMARY

<b>Title of Project</b>	
Click or tap here to enter text.	
<b>Describe the purpose of the project. Provide context to the importance of the research and explain how the results of this study will contribute to the field of study or specific population.</b>	
Click or tap here to enter text.	
<b>Total number of subjects anticipated:</b>	Click or tap here to enter text.

<b>Describe the subject population (Select all that apply):</b>		
<input type="checkbox"/> 18+ <input type="checkbox"/> 65 + <input type="checkbox"/> Other age range (Explain): Click or tap here to enter text.	<input type="checkbox"/> All genders <input type="checkbox"/> Females only <input type="checkbox"/> Males Only <input type="checkbox"/> Other (Explain): Click or tap here to enter text.	<input type="checkbox"/> Non-English Speakers <input type="checkbox"/> College Students <input type="checkbox"/> General public <input type="checkbox"/> Public officials <input type="checkbox"/> Agency/Institutional officials
<b>Provide any other subject characteristics for inclusion in your project:</b>		
Click or tap here to enter text.		
<b>List all methods of subject recruitment (Select all that apply):</b>		
<input type="checkbox"/> Flyers/letters <input type="checkbox"/> Emails <input type="checkbox"/> Telephone <input type="checkbox"/> In-class announcement	<input type="checkbox"/> Subject pool <input type="checkbox"/> Tabling in public <input type="checkbox"/> Personal network/Snowball sampling	<input type="checkbox"/> Passive recruitment <input type="checkbox"/> Social media post <input type="checkbox"/> Other (Explain): Click or tap here to enter text.
<b>Describe the step-by-step recruitment methods for each subject group (do not include any other project procedures in this section):</b>		
Click or tap here to enter text.		
<b>List the setting(s) of the research activities (Select all that apply):</b>		
<input type="checkbox"/> CSULB (in class) <input type="checkbox"/> CSULB (out of class) <input type="checkbox"/> CSULB (online) <input type="checkbox"/> Other College Campus <input type="checkbox"/> K-12 School <input type="checkbox"/> Lab	<input type="checkbox"/> Public setting <input type="checkbox"/> Nonprofit or Other Agency <input type="checkbox"/> Government Facility <input type="checkbox"/> Foreign Country <input type="checkbox"/> Subject's work/home <input type="checkbox"/> Prison/Jail	<input type="checkbox"/> Telephone <input type="checkbox"/> Email <input type="checkbox"/> Social media <input type="checkbox"/> Amazon mTurk <input type="checkbox"/> Online (general public) <input type="checkbox"/> Other
<b>List the location of the research activities (Agency/school names, city, county or social media site):</b>		
Click or tap here to enter text.		
<b>Do you have permission from the facility, institution or director of the organization to conduct your project? * If yes, please attach signed permission letter or data sharing agreement to this package.</b>		
<input type="checkbox"/> Yes* <input type="checkbox"/> No <input type="checkbox"/> In Progress		
<b>Is the project primarily for training purposes?</b>		
<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Other (Explain): Click or tap here to enter text.		
<b>List all methods of data collection (Select all that apply):</b>		
<input type="checkbox"/> Surveys/Questionnaires <input type="checkbox"/> Focus Groups <input type="checkbox"/> Educational Tests/Assessments <input type="checkbox"/> Accessing Public Records <input type="checkbox"/> Observation <input type="checkbox"/> Audio recording <input type="checkbox"/> Video recording	<input type="checkbox"/> One-on-One interviews <input type="checkbox"/> Data Mining <input type="checkbox"/> Digital media (videos, pictures, simulation) <input type="checkbox"/> Access to medical/academic records <input type="checkbox"/> Biospecimen Analysis <input type="checkbox"/> Experimental Controls <input type="checkbox"/> Other (Explain) Click or tap here to enter text.	
<b>Is there an experimental group compared to a control group?</b>		
<input type="checkbox"/> Yes <input type="checkbox"/> No		

**Describe the step-by-step procedures of your project beginning with the informed consent process and continuing with all other project activities (all project activities must occur *AFTER* IRB approval):**

Click or tap here to enter text.

**Will subjects be compensated for their participation? If monetary compensation is to be provided, please specify the amount and provide a justification for that amount that avoids potential coercion.**

No  
 Yes (Complete below):  
**Mode of compensation (Check one):**  Cash  Gift Card  Course credit  Other (Explain):  
 Click or tap here to enter text.  
**Total Amount per Subject:** Click or tap here to enter text.  
**Justification (Explain):** Click or tap here to enter text.

### 3. RISKS AND MITIGATIONS

**Describe any reasonable risks subjects may experience participating in this project (Ex. Risk #1: Loss of confidentiality, Risk #2: Discomfort answering questions, Risk #3: etc...):**

Click or tap here to enter text.

**Provide a reasonable mitigation to reduce each potential risk listed above. Each mitigation should directly correspond to each risk (Mitigation for Risk #1, Mitigation for Risk #2, etc.):**

Click or tap here to enter text.

### 4. DATA ACCESS

<b>Who will have access to the data?</b>	Click or tap here to enter text.
<b>Where will the data be stored?</b>	Click or tap here to enter text.
<b>Will identifiable data be collected (names, student ID numbers, address, etc.)?</b>	<input type="checkbox"/> Yes* <input type="checkbox"/> No <input type="checkbox"/> Not Sure
<b>*If yes, why is it necessary for identifiable data to be collected?</b>	Click or tap here to enter text.
<b>Will you have access to external data i.e. medical charts, public records, proprietary information?</b>	<input type="checkbox"/> Yes* <input type="checkbox"/> No
<b>*If yes, please describe the additional data you will have access to:</b>	
Click or tap here to enter text.	
<b>Is it possible for the information collected to be traced back to identify the individual with subject master list or by other means?</b>	<input type="checkbox"/> Yes* <input type="checkbox"/> No
<b>*If yes, describe the method(s) to protect subject privacy and confidentiality:</b>	
Click or tap here to enter text.	

### 5. FUNDING

<b>Is the project funded?</b> (If no, skip to Section 5)		<input type="checkbox"/> Yes <input type="checkbox"/> No
<b>Name of Funding Agency:</b>		Click or tap here to enter text.
<b>Grant Title or Number:</b>		Click or tap here to enter text.
<b>Funding Dates:</b>	Start: Click or tap to enter a date.	End: Click or tap to enter a date.

### 6. RESULTS

<b>Will the results of this project be published?</b>	
<input type="checkbox"/> Yes* <input type="checkbox"/> No	
<b>*If yes, for what purpose will the results be published?</b> (Check all that apply)	
<input type="checkbox"/> Thesis <input type="checkbox"/> Dissertation <input type="checkbox"/> Research Journal/Article <input type="checkbox"/> Employee Manual <input type="checkbox"/> Pilot Data <input type="checkbox"/> Research Conference	<input type="checkbox"/> Course/Department Improvements <input type="checkbox"/> Course Assignments <input type="checkbox"/> Evidence Based Practice <input type="checkbox"/> Training <input type="checkbox"/> Other (Explain) <input type="checkbox"/> Click or tap here to enter text.
<b>What knowledge base will the results contribute to?</b>	
<input type="checkbox"/> Personal knowledge <input type="checkbox"/> Generalizable knowledge <input type="checkbox"/> Program Evaluation	

### 7. ADDITIONAL PERSONNEL

<b>List the name, email and CITI Member ID # for any additional research staff or assistants that will have access to the research data:</b>
Click or tap here to enter text.
<input type="checkbox"/> Not Applicable

### 8. 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.
- I will comply with the CSULB IRB research policies (<http://web.csulb.edu/divisions/aa/research/compliance/humans/#CSULBPolicies>)

I 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.

PLEASE ATTACH ALL OTHER RELEVANT DOCUMENTS SUCH AS FACULTY ADVISOR LETTER, PERMISSION LETTERS, CONSENT FORMS AND RECRUITMENT MATERIAL AS APPENDICIES TO THIS PACKAGE SUBMISSION IN IRBNet.

## DEFINITIONS

**Research:** A systematic investigation (including research development, testing and evaluation) designed to produce information to expand knowledge of a scientific discipline (Or other scholarly field of study) and contributes to generalizable knowledge.

**Human Subjects:** A living individual about whom an investigator conducting research obtains information or biospecimens through intervention or interaction with the individual and uses studies or analyzes the information or biospecimens or obtains, uses, studies or generates identifiable private information or identifiable biospecimens.

**QA/QI Projects:** Activities that are not designed to produce information that expands the knowledge base of a scientific discipline (or other scholarly field) and *does not constitute as research* when it is designed and implemented for internal knowledge/purposes. Some activities that qualify as QA/QI include: case management, internal course assignment assessments, patient care coordination, policy and guideline development, benchmarking activities and department procedural analyses.

**Generalizable Knowledge:** Information that contributes to a theoretical framework of an established body of knowledge. The results are expected to be generalized or applied to a larger population beyond the site of data collection or population studied. Results are intended to be replicated in other settings.

**Internal Knowledge:** Information that solely benefits the intended site or population investigated. The results are used to assess the quality of procedures, services or activities and used to improve the quality of those procedures, services or activities.

**Identifiable Data/Personal Information:** Private health information such as medical record numbers, social security numbers, address, diagnosis, etc. Alternatively, personal identifiable information such as name, student ID numbers, demographic information, etc.

For federal regulations regarding QA/QI activities, please visit the Department of Health and Human Services (DHHS) website: <https://www.hhs.gov/ohrp/regulations-and-policy/guidance/faq/quality-improvement-activities/index.html>