

# IRB Application for Continuing Review

**Instructions:** This form is only required for projects that were approved via Standard (Full Board) Review at the initial review or the project was escalated to Standard (Full Board) Review during subsequent reviews and whose protocol is set to expire according to the expiration date on the most recent protocol approval letter.

Submit the Continuing Review documents as a subsequent package to the approved project via IRBNet. If the project expires prior to receiving final approval for this Continuing Review, all project activities must be suspended until final IRB approval for this project is issued via IRBNet.

## 1. Background

<b>Principal Investigator:</b>	
<b>CITI Member ID #:</b>	
<b>Telephone:</b>	
<b>Email:</b>	
<b>Department:</b>	
<b>Affiliation with CSULB:</b>	<input type="checkbox"/> Student* <input type="checkbox"/> Faculty <input type="checkbox"/> Staff <input type="checkbox"/> Other
<i>*If you are a student, please complete the information below regarding your faculty advisor:</i>	
<b>Faculty Advisor Name:</b>	
<b>Faculty Advisor:</b>	
<b>CITI Member ID #</b>	
<b>List the name, CITI member ID number, and email for all other individuals active on this project:</b>	

## 2. Project Status

<b>Project Title:</b>	
<b>Total number of subjects enrolled in the study:</b>	
<b>Number of subjects withdrawn or lost to follow-up:</b>	
<b>Number of subjects terminated by the investigator:</b>	
<b>Have all enrolled subjects completed research related activities?</b>	<input type="checkbox"/> Yes* <input type="checkbox"/> No
<b>*If yes, do you want to close this project?</b>	<input type="checkbox"/> Yes <input type="checkbox"/> No
<b>Provide a summary of the project activities since the last IRB approval. Describe any positive accomplishments or the research and any unanticipated problems (use as much space needed to adequately answer the question):</b>	
<b>What is the estimated completion date for this project?</b>	

## 3. Results

<b>Have any results or preliminary findings been published for this project?</b>	<input type="checkbox"/> Yes* <input type="checkbox"/> No
<b>*If yes, please include a copy of the publication in this package submission via IRBNet.</b>	

#### 4. Amendments

<b>Are you requesting any protocol amendments at this time?</b>	<input type="checkbox"/> Yes* <input type="checkbox"/> No
<b>*If yes, outline the changes below and confirm that the planned changes are fully reflected in all relevant documents, such as a revised IRB Application, the Consent Notice, and recruitment material.</b>	

#### 5. Investigator's Assurance

**As the Principal Investigator, certify and confirm the following are true and accurate (check and sign below):**

- ☐ The risk/benefit ratio for this project has not changed since the last review.
- ☐ All adverse events (if any) have been reported to the Office of Research and Economic Development via [ORED-Compliance@csulb.edu](mailto:ORED-Compliance@csulb.edu). I agree to report any adverse events to ORED within 48 hours of being made aware of the events.
- ☐ CITI training for Social & Behavior Basic/Refresher course is valid for all individuals listed on this project.
- ☐ All data is maintained and stored in a secure location with access reserved only for designated.
- ☐ Research activities will continue as described in the approved version of the protocol.
- ☐ I will continue to comply with the CSULB IRB policies: (<https://www.csulb.edu/office-of-research-and-economic-development/research-related-policies>).
- ☐ I will continue to comply with the Department of Health and Human Services (HHS) policy and regulation: <https://www.hhs.gov/ohrp/regulations-and-policy/regulations/45-cfr-46/index.html>

Name:

Date: MM/DD/YYYY

**IF YOU REQUESTED CHANGES TO YOUR PROJECT, INCLUDE A REVISED VERSION OF THE IRB APPLICATION AND ANY OTHER RELEVANT DOCUMENTS TO THIS SUBMISSION VIA IRBNet.**

Please try to mark (e.g., highlight, font color, etc.) any changes on the application/document(s) so the IRB can easily confirm the changes.