

IRB Application for Continuing Review

Instructions: This form is only required for projects that were approved via Standard Review at the initial review or the project was escalated to Standard 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

Principal Investigator:	Click or tap here to enter text.
CITI Member ID Number:	Click or tap here to enter text.
Telephone:	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:	<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>	
Faculty Advisor Name:	Click or tap here to enter text.
Faculty Advisor:	Click or tap here to enter text.
List the name, email and CITI member ID number for all other individuals active on this project:	
Click or tap here to enter text.	

2. Project Status

Project Title:	
Click or tap here to enter text.	
Total number of subjects enrolled in the study:	Click or tap here to enter text.
Number of subjects withdrawn or lost to follow-up:	Click or tap here to enter text.
Number of subjects terminated by the investigator:	Click or tap here to enter text.
Have all enrolled subjects completed research related activities?	<input type="checkbox"/> Yes* <input type="checkbox"/> No
*If yes, do you want to close this project?	<input type="checkbox"/> Yes <input type="checkbox"/> No
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):	
Click or tap here to enter text.	

What is the estimated completion date for this project?	Click or tap to enter a date.
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3. Results

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

4. Amendments

Are you requesting any protocol amendments at this time?	<input type="checkbox"/> Yes* <input type="checkbox"/> No
*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.	
Click or tap here to enter text.	

5. Investigator’s Assurance

I, 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 Sponsored programs via ORSPCompliance@csulb.edu. I agree to report any adverse events to ORSP 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:
<http://web.csulb.edu/divisions/aa/research/compliance/humans/#CSULBPolicies>
- 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: Click or tap here to enter text.

Date: Click or tap to enter a date.

IF YOU REQUESTED CHANGES TO YOUR PROJECT, SUBMIT A REVISED VERSION OF THE IRB APPLICATION AND INCLUDE ANY OTHER DOCUMENTS RELEVANT TO THIS SUBMISSION VIA IRBNet. PLEASE HIGHLIGHT ANY CHANGES SO THE IRB CAN EASILY CONFIRM THE CHANGES.