Annual Check-In Form

Notice: The purpose of this annual check-in is to confirm the status of your project. The IRB must maintain accurate records of all active research projects. To facilitate this process, the IRB requests a response to the annual check-in for this project if the project will remain active beyond the expiration date notice sent via IRBNet. When the annual check-in is completed, the IRB will issue an acknowledgement letter via IRBNet to confirm receipt and acknowledge ongoing research activities.

If the project activities <u>will not</u> continue beyond the expiration date, no further action is required. The IRB will administratively close this project after the date indicated on the notice, meaning no other research activities beyond data analysis are permitted after this date.

Instructions: This form is only required for projects that were approved via Expedited Review at the initial review or the project was escalated to Expedited 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 Annual Check- In document(s) as a subsequent package to the approved project via IRBNet. If the project expires prior to receiving final approval for this Annual Check-In, all project activities must be suspended until final IRB approval for this project is issued via IRBNet.

1. Basic Information

Principal Investigator:	
CITI Member ID Number:	
Email:	
Estimated Project Completion Date:	
Approved Protocol Number:	
Approved Project Title	

2. Project Status

Have all participants completed the research activities? (Type "x" in one):	[] Yes [] No	
Have there been any participant complaints, withdraws, terminations or adverse events since the last check-in? (Type "x" in one):	[] Yes* [] No	
*If yes, describe the complaints, withdraws, terminations and/or adverse events:		
Are you requesting any new protocol Amendments	[] Yes* [] No	
at this time? (Type "x" in one)		
*If yes, please describe the requested protocol amendments:		
If yes, will the amendments affect the risk/benefit	[] Yes [] No	
ratio of the project? (Type "x" in one)		
*If yes, please describe how the changes will affect the risk/benefit ratio.		

3. Investigator's Assurance

As the Principal Investigator, certify and confirm the following are true and accurate (type "x" 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 <u>ORED-Compliance@csulb.edu</u>. 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: (<u>https://www.csulb.edu/office-of-research-and-economic-development/research-related-policies</u>).

[] I will continue to comply with the Department of Health and Human Services (HHS) policy and regulation: <u>https://www.hhs.gov/ohrp/regulations-and-policy/regulations/45-cfr-46/index.html</u>

Name:

Date: MM/DD/YYYY

IF YOU REQUESTED CHANGES TO YOUR PROJECT, INCLUDE A REVISED VERSION OF THE IRB APPLICATION AND ANY OTHER RELAVENT 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.