

**University of San Diego  
Institutional Review Board  
Checklist for Renewal of a Previously Approved Study**

ALL documents attached to a Cayuse IRB application must be in PDF format.

Principal Investigators must submit a Renewal application in Cayuse, annually, on or before the anniversary of the approval date of the initial study as long as data is still being collected or where the remaining research activities are limited to data analysis. If all research or data has been collected and analyzed, then a Closure application should be submitted.

Cayuse Application	Checklist
<b>Renewal</b>	
<b>Renewal</b>	<input type="checkbox"/> Verify whether any changes are required since the last submission to the IRB. <input type="checkbox"/> Submit a Modification application in addition to the application for Renewal if changes are needed. Changes may not be implemented until IRB approval of Modification application is approved.
<b>Original Review Level</b>	<input type="checkbox"/> Select the <u>approved review category</u> during the initial application. The Renewal application for a study originally approved under Full Review must be reviewed again if there has been an incident occurred during the study or if there are substantial modifications to the original study. Please contact <a href="mailto:irb@sandiego.edu">irb@sandiego.edu</a> for additional guidance.
<b>IRB Training Certificates</b>	<input type="checkbox"/> Attach new certificates in the event of expiration of certificates for the PI or research team members. If adding new team members, complete a Modification application concurrently with this renewal to update the research team roster and attach new member's certificate if they are listed under "Other Research Team Member(s)" section.
<b>Informed Consent Forms</b>	<input type="checkbox"/> Verify that signed consent forms are on file for all study participants enrolled in study as of the date of application for Renewal.
<b>Number of Study Participants</b>	<input type="checkbox"/> Enter the number of study participants enrolled in study as of the date of application for Renewal.
<b>Adverse Events</b>	<input type="checkbox"/> Address whether any adverse events or unanticipated problems associated with the study occurred. All adverse events or unanticipated problems must be reported to the IRB Administrator, <a href="mailto:irb@sandiego.edu">irb@sandiego.edu</a> , as soon as possible. <input type="checkbox"/> Submit an Incident Report with application for Renewal if not already on file.
<b>Funding</b>	<input type="checkbox"/> Indicate whether the study is supported by funding from an external (non-USD) source.