

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

Highlighted items indicate documents that will need to be attached to the Cayuse application. ALL documents attached to a Cayuse IRB application must be in PDF format.

Changes to a previously approved IRB study may not be implemented until the IRB approves the application for modification of the study.

Cayuse Application	Checklist
Modification section	<ul style="list-style-type: none"> <input type="checkbox"/> Select “Study created in Cayuse IRB”. The “Legacy study” option is reserved for studies that were originally submitted to USD IRB as paper hardcopy and has not been transferred into Cayuse IRB. <input type="checkbox"/> Depending on which sections of the previously approved application you wish to modify, check the appropriate boxes. <input type="checkbox"/> If changes are being made to section 1 - “General Information”, check the additional boxes under this section to specify the changes. Add descriptive text to explain the changes as needed.
General Information section	<ul style="list-style-type: none"> <input type="checkbox"/> Make sure the research team roster is still up to date and that ALL research team members’ human subjects research training is still valid. If not, have the respective researchers refresh their training and upload their training certificates if their names are listed under “Other Research Team Member(s)” category. <input type="checkbox"/> If changes are being made in this section, don’t forget to check the right boxes listed under the Modification section of the application.
Other sections of the application	<ul style="list-style-type: none"> <input type="checkbox"/> Update these sections of the application as needed. Ensure that ALL impacted sections/answers throughout the application are updated to consistently reflect the proposed changes. <input type="checkbox"/> If participant recruiting and consenting activities are still happening in the study and there has been a change in the research team roster, make necessary updates to the recruitment documents and consent/assent forms. <input type="checkbox"/> If new data collection sites are being added to the study, the PI needs to add comments to explain which site(s) have already completed with data collections and which site(s) are still ongoing to help with the review process. Attach new site permission letters as needed. <input type="checkbox"/> Do not remove any previously approved documents. Instead, add newly modified documents with a prefix “UPDATED ...” to assist the IRB in the review process.