

**University of San Diego  
Institutional Review Board  
Checklist for an Initial Application under Exempt Review**

**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.

Cayuse IRB Application	Checklist
<b>Your Role</b>	<input type="checkbox"/> Select the category that reflects role with regard to the study (e.g., if you are USD faculty or staff but conducting a study to satisfy course or degree requirements, check “student”).
<b>Principal Investigator (PI)</b>	<input type="checkbox"/> List the student as the PI for student-led research. <input type="checkbox"/> Use only USD contact information (no personal email addresses or phone numbers). <input type="checkbox"/> Note that all researchers’ email addresses in their CITI training accounts under USD affiliation must match exactly with the email addresses used in their Cayuse IRB accounts.
<b>Secondary Contact</b>	<input type="checkbox"/> Students: List your faculty advisor as the Secondary Contact and <b>attach the faculty’s letter of support.</b> <input type="checkbox"/> Faculty or Staff: List your department chair or dean as person who may be contacted about the study. A second USD contact other than the faculty PI is required.
<b>Co-Investigator(s)</b>	<input type="checkbox"/> List co-investigators of the research project. <input type="checkbox"/> If the listed Secondary Contact is also a co-investigator in this project, their name must be listed under this section. If Secondary Contact is not listed here, it is interpreted that the Secondary Contact is only serving in the departmental contact role and is NOT part of the research team.
<b>Other Research Team Member(s)</b>	<input type="checkbox"/> List other investigators in the project, including both USD-affiliated and non-USD affiliated members. <input type="checkbox"/> Include their names, titles, current affiliations and roles in the project. <input type="checkbox"/> Note that research team members need to be included, regardless of whether or not they will interact with participants.
<b>Human Subjects Training Certificate(s)</b>	<input type="checkbox"/> For researchers listed under “Other Research Team Member(s)” category, <b>attach their current and valid CITI training certificates</b> for the appropriate Human Subjects Research training course. <input type="checkbox"/> USD-affiliated researchers must show University of San Diego as the official affiliation on their certificates. <input type="checkbox"/> CITI training records for USD-affiliated researchers listed as PI and co-PIs on the application are linked directly with Cayuse IRB, so there is no need to attach the certificate PDFs for these individuals.

<b>Reviewing IRB(s)</b>	<input type="checkbox"/> Select the appropriate IRB based on circumstances of project. <input type="checkbox"/> For “External IRB” review: <b>Attach study protocol and external IRB approval document.</b> <input type="checkbox"/> For “External IRB is IRB of Record”: <b>Attach multi-site cooperative agreement.</b> A template for “External IRB is IRB of Record document” is available on <a href="#">USD IRB website</a> .
<b>Review Category</b>	<input type="checkbox"/> Select appropriate review category for proposal. <input type="checkbox"/> Include a brief project description <input type="checkbox"/> Explain why this project qualifies for the selected Exempt category <input type="checkbox"/> Describe data collection/analysis methods and provide appropriate references to support the selected methodology. <input type="checkbox"/> <b>Attach documents supporting the study protocols</b> <input type="checkbox"/> <b>Attach recruitment documents and consent forms if the project is research and human subjects are involved in the study activities</b>
<b>Start Date</b>	<input type="checkbox"/> Enter a proposed start date for the study. Note that the IRB cannot approve studies retroactively per regulations. It may take more than 30 days for the review and processing of an IRB application, depending on how attentive the PI is in addressing the reviewers' feedback. <input type="checkbox"/> Research may not begin prior to IRB approval of study.
<b>Funding</b>	<input type="checkbox"/> Enter the enter the OSP funding application number (CayuseSP number) if the study is funded by an external sponsor.