University of San Diego
Institutional Review Board
Checklist for an Initial Application under Expedited 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 Application	Checklist
Section 1. General Information	
Your Role	☐ 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").
Principal Investigator (PI)	☐ List the student as the PI for student-led research. ☐ Use only USD contact information (no personal email addresses or phone numbers). ☐ 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.
Secondary Contact	☐ Students: List your faculty advisor as the Secondary Contact and attach the faculty's letter of support. ☐ 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.
Co-Investigator(s)	☐ List co-investigators of the research project. ☐ 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.
Other Research Team Member(s)	☐ List other investigators in the project, including both USD-affiliated and non-USD affiliated members. ☐ Include their names, titles, current affiliations, and roles in the project. ☐ Note that research team members need to be included, regardless of whether or not they will interact with participants.
Human Subjects Training Certificate(s)	☐ For researchers listed under "Other Research Team Member(s)" category, attach their current and valid CITI training certificates for the appropriate Human Subjects Research training course. ☐ USD-affiliated researchers must show University of San Diego as the official affiliation on their certificates. ☐ 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.

Reviewing IRB(s)	☐ Select the appropriate IRB based on circumstances of project. ☐ For "External IRB" review: Attach study protocol and external IRB approval document. ☐ For "External IRB is IRB of Record": Attach multi-site cooperative agreement. A template for "External IRB is IRB of Record document" is available on USD IRB website.
Review Category	☐ Select appropriate review category for proposal. ☐ For Expedited review: Review the expedited categories and choose one expedited category number for your study.
Start Date	☐ 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. ☐ Research may not begin prior to IRB approval of study.
Funding	☐ Enter the enter the OSP funding application number (CayuseSP number) if the study is funded by an external sponsor.
Section 2. Purpose and Significance	
Purpose **Significance**	☐ Describe the purpose and significance of the study. ☐ Include research questions, specific aims, and/or hypotheses as appropriate.
Section 3. Study Participants	
Interaction with Participants	☐ Check "yes" or "no" as applicable and proceed.
If "No":	
Use of Data (existing)	☐ Provide the name of person / organization that owns or authorizes access to the existing data. ☐ Attach a letter of permission to use the data. Letter must be on the official institutional letterhead and signed and dated by person authorized to grant access to the data. Date of letter should be within 90 days of IRB application.
Data Set Description	☐ Describe indicators included in data set that will be analyzed.
If "Yes":	
Study Team Interaction with Participants	☐ List all research team members who will be interacting with the participants during the study period.
Number of participants	☐ Ensure that number of subjects is justified by the information provided in Section 2.
Participant Demographics	☐ Ensure that the participant demographic inclusion/exclusion criteria are supported by the information provided in Section 2.
Recruiting Participants	☐ Indicate method(s) of recruitment.
Recruitment Documents	☐ Attach recruitment documents must contain the following information, stated at 6th-8th grade reading level: • Purpose of the study (must make clear that it is a research study).

	• What is expected of the participant. • Time commitment (this must match application, consent/assent documents, etc.). • Location where the participant-involved activities will take place. • Whether activities will be audio or video recorded. • Whether participants will be compensated, and how, for their time and effort. • The PI's contact name with e-mail address; if student, also include faculty advisor (no personal contact information; USD office phone numbers only if messages are routinely checked, e.g., every 24 hours) ☐ Attach both a parental recruitment document and developmentally appropriate minor recruitment document for any study involving minors.
Section 4. Study Methodology	
Equipment	☐ Include all equipment used for study, including telephone, computers, audio and/or video recorders, etc.
Nature of Study Methodology	☐ Check applicable box and proceed.
If Experimental Manipulation(s) and/or Interventions:	☐ Describe the nature of the experimental manipulation and/or intervention. ☐ Provide detailed information about what will happen during the study.
Length of Participant Involvement	☐ Select one time interaction or multiple interactions expected with the participants.
Total Participant Time	☐ Ensure that length of participant involvement and total participant time is consistent across the application and all project documents (recruitment, consent, etc.).
Data Collection Methods	☐ Check all applicable methods that will be used to collect data. ☐ Attach a pdf copy of the survey, interview introduction script, focus group introduction script, etc., and the questions asked of the participants during the interviews/discussions.
Types of Data plus Measurement Tools or Interview Guides	☐ Describe each type of variable or data that will be measured or assessed in the study. ☐ For each variable or data, indicate the instruments to be used to collect that information. ☐ Ensure a pdf copy of the instrument is attached (no links to internet surveys).
Data Collection Sites	☐ Identify where the data will be collected. ☐ Enter street address if the data is to be collected at a specific site such as a clinic, a school or a community center. ☐ Attach a pdf copy of a letter of permission from site where data will be collected, on letterhead and signed by person with

	authority to grant permission (title and contact information included). ☐ Verify that site permission letter includes access to email addresses of participants if they are to be contacted via email.
Section 5. Informed Consent and Participant Confidentiality	
Obtaining Informed Consent	☐ Select response that is consistent with study purpose and significance and other information in application. ☐ Ensure alternate form of documentation that informed consent was obtained if a waiver of signed consent is requested, e.g., PI records consent obtained in study records.
Informed Consent Issues	☐ Answer all questions as applicable to study.
Additional Informed Consent Issues When Subjects Are Minors	☐ Answer all questions as applicable to study.
Consent and Assent Forms (Attachments)	☐ Attach USD approved template for consent and assent, with adult forms written at 6th-8th grade reading level. ☐ Attach parental consent and developmentally appropriate minor assent forms for any study involving minors. ☐ Attach Video Consent if participants will be video recorded *See consent and assent templates under "Forms" at: *If the PI is recruiting via electronic means (email, social media, etc.) for the purposes of collecting data exclusively by survey via the internet, PI may use USD approved template for "Email Solicitation Consent Form" under "Forms" on USD IRB website.
Section 6. Confidentiality, Risks, and Benefits	
Data Collection Tools **Deidentified Data** **Data Storage** **Research Team Access to Data**	☐ Answers should be consistent with study methodology and should be addressed as appropriate under Participant Risks (e.g., loss of privacy, etc.)
Length of Data Storage	☐ All records associated with the research must be secured and retained for 5 years per USD IRB policy.
Focus Group Confidentiality	☐ Measures used to ensure focus group confidentiality should be consistent with study methodology.
Video Recording	☐ If participants will be recorded on video, an additional video consent form must be attached in Section 5.
Deidentification In Video **Online Video Recording Access**	☐ Answers should be consistent with study methodology and should be addressed as appropriate under Participant Risks (e.g., loss of privacy, etc.)
Participant Risks	☐ PI must consider and address all types of risks to participants including physical harms, psychological harms, social and economic harms, privacy risks and breach of confidentiality risks.

	☐ Include Mental Health number if there is *any* risk, even a slight risk, of inducing anxiety or a chance of triggering past negative experiences.
Section 7. Attachments	
All of the attachments that have been previously entered are displayed here for the IRB reviewer's convenience. Nothing more is required of the submitter in this section.	