

Glossary of USD IRB Terms

Administrative Closure

IRB Applications may *Administratively Withdrawn* when there is no response from the Principal Investigator For more than 90 days. (applications remain unsubmitted or incomplete)

Approved

Application has IRB approval and research may begin.

Assent

Permission from human subject minors agreeing to participate in research.

Audio Recording

Voice recording of research participants.

Authorization Agreement

Document required when another institution is approving IRB or relying on USD IRB approval. Also referred to as the IRB of Record.

Audio Recording

Voice recording of research participants.

Awaiting Certification

Application process is incomplete. The PI must log into the study and click on *complete submission, confirm* and *certify* to complete the submission process for the application to be reviewed.

Awaiting Org Approval

Application is awaiting review by the IRB Committee member from your department or unit.

Benefits

Positive results of research anticipated to increase generalizable knowledge.

Cayuse

Application software used by USD for all IRB submissions.

Certification

IRB Training Certification is required for all researchers, including persons who will not have contact with human subjects and students serving as research assistants. USD accepts CITI certification. Or, OHRP certification for non-affiliates of USD.

Certify

Term meaning to agree and approve of information submitted in Cayuse IRB application.

NOTE: Only the PI can certify applications in Cayuse.

CITI

Collaborative Institutional Training Initiative (CITI) IRB training certification. USD requires specific modules for Social & Behavioral Research Investigators OR Biomedical Research Investigators. Please confer with your faculty advisor or IRB Committee representative for clarification if you are uncertain as to which course applies to your research or role. CITI certificates are valid for three years. PDFs of the certificates must be attached in

the IRB application in Cayuse for research team members listed under the "Other Investigators" category, including both USD and non-USD members.

Closed

PI is required to submit a Closure application when data collection has concluded and all use of identifiable data has been completed. Studies expired more than 30 days are administratively closed. A closed study cannot be re-opened.

Compensation

Form of payment or recognition provided to all participants, even if they do not complete the research. (This included food and beverages.)

Consent

Permission from human subjects agreeing to participate in research. Parental consent is required for minors, in addition to Child Assent.

Co-PI

Co-Principal Investigator (Co-PI) shares in research and IRB application information. Co-PI is not authorized to submit the IRB application, nor make changes in the application.

Data

Information collected for research purposes.

De-identified Data

Collected information cleansed of any identifiers

Deferred

IRB submission review requiring the Principal Investigator to make application edits.

Delete

Principal Investigator may delete an application in Cayuse any time prior to application approval

Exempt

Study that falls within one of the defined exempt review categories. Typically, *non-human subject* research, which requires submission of an application, and certification of the exempt status by the IRB.

Expedited

Study that falls within one of the defined expedited seven review categories. Generally, studies that poses no more than **minimal risk** to human subjects and meet the 7 categories listed under USD policy 2.7.2, Part Two, section I.

External

Study that falls within one of the defined external review categories. An **external IRB** has already approved the protocol and USD's IRB approval for research involving USD faculty and/or students is required.

Faculty Advisor

USD faculty member who advises student researcher and provides letter of support.

Focus Group

Data collection from participants in a group setting.

Full

Study with more than minimal risk, requiring an IRB Committee review. Applications requiring a FULL review must be submitted at least two weeks prior to the scheduled IRB committee meeting. Meeting dates are on the USD IRB website. (IRB Committee does not meet in August.)

Funded

Money received by outside source to support research. (May require OSP application.)

Indirect Benefits

Positive results anticipated for research participants to increase generalizable knowledge.

IRB

Institutional Review Board comprised of USD administrators, faculty, staff, students and community members.

IRB Committee IRB Committee Representatives (Organizational Approver/Reviewer) from each USD academic unit available for consultation, application approval, and monthly meeting

IRB of Record Authorization Agreement document required when another institution is approving IRB or relying on USD IRB approval.

Incident

Unanticipated problems involving risk to subjects or others. Incidents MUST be reported to the IRB Administrator and an Incident Report must be submitted in Cayuse.

Modification

Any change in the initial study, which requires approval with a Modification application in Cayuse prior to implementation of changes.

New Submission

New information added to an EXISTING study. (Modification, Renewal, Incident, Closure)

Not Human Subjects Research

Project does not meet the federal definition of [human subjects research](#) [45 CFR 46.102(e)(1-7) and 45 CFR 46.102(l)(1-4)]

Org Approver

USD IRB Committee member from school or department who will consult/review/approve applications.

Other Investigators

Additional researchers, research assistants, researchers who will interact with human subjects or data.

Principal Investigator

Principal Investigator (PI) is the lead investigator on the study who submits application and edits in Cayuse.

Protocol

Draft of research procedures.

Recruitment

Solicitation of human subjects to participate in research.

Rejected

Term used in Cayuse when an application is returned to the Principal Investigator (PI) for edits.

Renewal

An application in Cayuse required for all IRB's, annually, on or before the approval date.

Reopened

Application has been reviewed and edits are pending from the PI. Refer to letters tab for required changes

Secondary Contact

Secondary Contact is a USD person, other than the PI, to contact about the study. USD IRB requires students to list their faculty advisor on the study is the Secondary Contact. Faculty may list their Co-PI, as long as they are at USD. Otherwise, faculty may list their Department Chair or Associate Dean as a Secondary Contact.

Site Letter of Permission

Letter of permission to collect data at a specific location, including permission to use email list where applicable, signed and dated by the appropriate authority on the sites letterhead.

Sponsor

USD faculty or staff member who acts as the Principal Investigator and submits the IRB application on behalf for an outside affiliate (non-USD member) who wishes to conduct research involving data collection at USD.

Start Date

Date *research* will begin, not the application date. IRB approval is required prior to start of research. Allow 30 days for edits and IRB review.

Study Number

Unique number assigned to IRB Initial application in Cayuse.

Video Recording

Film recording of research participants. PARTICPANT VIDEO CONSENT REQUIRED

Withdrawn

Application is no longer active. A new application will need to be submitted.

Unsubmitted

Application has not been submitted for review. Applications may *Administratively Withdrawn* when there is no response from the Principal Investigator for more than 90 days, or applications remain unsubmitted or incomplete in Cayuse.

