STANDARD OPERATING PROCEDURES FOR THE PREPARATION, SUBMISSION AND REVIEW OF HUMAN SUBJECTS RESEARCH PROPOSALS

Determining Need for IRB Review

A) Investigator determination of applicability
   1) It is the responsibility of the principal investigator (PI) to determine if the proposed project is human subjects research as defined in the federal regulations.
      (a) **Research** is defined in 45 CFR §46.102(l) as "a systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge. Activities that meet this definition constitute research for purposes of this policy, whether or not they are conducted or supported under a program that is considered research for other purposes."
      (b) A **systematic investigation** is an activity that involves a prospective plan that incorporates data collection (quantitative or qualitative) and data analysis to answer a question. Activities are not research if they do not involve a systematic approach involving a predetermined method for studying a specific topic, answering a specific question, testing a specific hypothesis, or developing theory.
      (c) Activities intentionally designed to develop or contribute to **generalizable knowledge** are those designed to draw general conclusions, inform policy, or generalize findings beyond a single individual or an internal program (e.g., publication or presentation). The intent to develop or contribute to generalizable knowledge makes an activity research. Results do not have to be published or presented to qualify the activity as research.
      (d) **Human subject** is defined in 45 CFR §46.102(e)(1) as "a living individual about whom an investigator (whether professional or student) conducting research:
         (i) Obtains information or biospecimens through intervention or interaction with the individual, and uses, studies, or analyzes the information or biospecimens; or
         (ii) Obtains, uses, studies, analyzes, or generates identifiable private information or identifiable biospecimens."

B) Human subjects research proposals are subject to IRB review if they fall into one or more of seven categories listed in USD Policy 2.7.2, Part Two, Section I, subparts A-G. If an investigator is unsure of whether IRB review is required, they are strongly advised to consult with the IRB Coordinator or Administrator.

C) Research conducted by the University for the evaluation of its programs or to provide information for planning, policy formation, and decision making, is subject to the same criteria as any other research as defined in 45 CFR 46 (USD Policy 2.7.2).

D) Projects that fail to meet the definition of research or human subjects as defined by the federal regulations are excluded from IRB review. This is not the same as the "exempt from review" category (see II.A.3(a) of this document). Investigators can submit an application to the IRB in Cayuse to seek certification documented by letter that an activity **does not constitute human subjects research subject to IRB review**. This is an appropriate option for many evidence-based practice projects or action-research projects.

Determining Level of Review

A) Investigator's initial determination of the level of review

1) It is the responsibility of the PI to make an initial determination of the type of review that is appropriate to their project. Both the level of risk to the human subjects and the type of research being undertaken factor into this determination.
2) The level of risk in the research is assessed by using the definition of minimal risk found in 45 CFR §46.102(j)**:** **Minimal risk** means that the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.
3) Research proposals for human subjects research that poses no more than minimal risk may be categorized as **exempt from review** or may be reviewed using an **expedited** approach.
   (a) Research activities in which the only involvement of human subjects is in one or more of the categories defined in 45 CFR §46.104(d) may be categorized as exempt from review.
   (b) Human subjects research proposals that are subject to IRB jurisdiction that are in the "exempt from review" category must still be submitted to the IRB. The IRB makes the final determination that a proposal meets the requirements for the "exempt from review" category.
   (c) Research activities that (1) present no more than minimal risk to human subjects, and (2) involve only procedures listed in one or more of these categories, may be reviewed by the IRB through the expedited review procedure authorized by 45 CFR §46.110.
4) Human subjects research proposals that involve more than minimal risk to the subjects must be submitted for **full review** and must undergo annual renewal and **may be required to undergo more frequent review.**
5) Research activities that fall in the **"exempt"** category or the **"expedited"** category must undergo **annual renewal**.
6) Proposals that do not meet the federal definition of human subjects research may be designated as such to meet educational program requirements or for dissemination purposes. For a project to be designated as **"not human subjects research,"** the principal investigator must attest that the 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)]. For evidence-based practice projects or action research projects, to be designated as "not human subjects research," **ALL of the following must be true**:
   (a) Implementing the practice outlined in the project will not incur participant harm.
   (b) The practice change outlined in the project is not new or novel and has been published elsewhere.
   (c) The practice outlined in the project will be implemented in a single project location.
   (d) The project does not test issues or add questions that go beyond common practice.
   (e) The project will not randomize participants into different intervention groups.
   (f) The project will not deliberately delay interpretation of data.
   (g) The project will not deliberately delay or abbreviate feedback to those who would benefit from the findings in order to enhance likelihood of publication.
   (h) The project has no funding from an outside organization with a commercial interest in the use of the results.

7) Designation of a project as "not human subjects research" **does not impact the ability of the project team to disseminate internally or externally**, through presentation or publication of project results.

Submitting a Proposal for Review

A) First time applications: All PIs must contact the USD IRB prior to initiating their first IRB application to the USD IRB. The investigator's information will be entered into the Cayuse and CITI (human ethics) training data bases.
B) Researchers are strongly encouraged to contact their unit IRB representative when preparing an IRB application. Students must also consult with their faculty advisor for the project.
C) All IRB applications are submitted through the Cayuse Human Ethics Application located under Applications & Tools on the MySanDiego portal. Instructions for completing the IRB application are found on the USD IRB website under the Apply tab.
D) For applications that request review by the **USD IRB only**, **investigators must use the forms and templates provided on the USD IRB website** under the Forms tab.
E) Students must attach a letter from their faculty advisor approving the IRB application and attesting to supervision of the project. The **signed letter**, **dated within 90 ninety days of the application**, **must include the title of the study and must match the title of the study listed on the IRB application**.
F) A USD faculty member may continue with their own research during their sabbatical, but they may not oversee the work of any students unless this is specifically indicated per the terms of their sabbatical letter. If not included in the terms of the sabbatical, a new faculty advisor must be assigned to oversee the project.
G) All attachments to the IRB application must be in pdf. All acronyms must be spelled out for clarity.
H) Investigators should **allow a minimum of 30 days for the processing of an application**, regardless of type of application. Approval of an application may take longer than 30 days if changes are required by the IRB.
I) There are no deadlines for submission of an application for not human subjects certification or submission for exempt or expedited review.
J) Projects for full review must be submitted by the deadlines found on the IRB website.
K) If an investigator anticipates that the application will require a **FULL review**, the investigator must contact their unit IRB Representative ***before*** initiating an application.

Managing an Approved Project

A) Instructions for managing a project approved by the IRB are found on the USD IRB website under the Education / Resources tab.
B) Principal Investigators must submit a **Modification** application in Cayuse for **any change in the study protocol**, including but not limited to faculty advisor, primary contact, members of the researcher team, purpose and significance, participants (inclusion or exclusion criteria), recruitment, methodology, consent, and/or procedures to maintain confidentiality. Changes in the study protocol may not be implemented prior to IRB approval of the application for modification of the study.
C) Principal Investigators are required to submit a **Renewal** application in Cayuse, annually, on or before the anniversary of the approval date of the initial study as long as research or

data is still being collected or where the remaining research activities are limited to data analysis.

D) It is the responsibility of the PI to verify that IRB training certificates are **current** for all research team members and to attach updated (renewed) certificates when needed. The IRB will not renew an application if certificates are not current and all research activities must stop if the approval has expired.

E) Principal Investigators are required to submit a **Closure** application in Cayuse when:
   1) Data collection has concluded and all use of identifiable data has been completed; or
   2) A previously approved study was not and will not be initiated; or
   3) A previously approved study was discontinued prior to its completion

F) Once a study is closed, it cannot be reopened. A PI must submit a new application if they wish to continue the study.

G) Principal Investigators may **Withdraw** an unsubmitted application in Cayuse at any time, especially if an application has been started, but not submitted within 90 days, or not approved, or if it is decided that research will not take place.

H) Principal Investigators may **Delete** an application in Cayuse any time prior to application approval.

I) The IRB Administrator may **Administratively Withdraw** applications when there is no response from the Principal Investigator for more than 90 days.

J) When an unanticipated problem involving risk to subjects or another unexpected event occurs, the Principal Investigators must contact the IRB Administrator as soon as possible and submit an **Incident Report** in Cayuse.

Required Training in the Protection of Human Subjects for the Research Team

A) All investigators and all study team members who will engage in human subjects research must undergo training in the ethics and regulations for the protection of human subjects research participants. This includes research team members who will not have contact with human subjects and students serving as research assistants.

B) This training is to be obtained through the on-line program called the Collaborative Institutional Training Initiative (CITI Program) prior to conducting any human subject research.

C) Training must be **renewed every 3 years** to continue conducting human subject research and proof of training (certificate) is required at time of initial IRB application and at renewal.

Not Human Subjects Research	Exempt	Expedited	Full
A proposal may be designated by the IRB as "not human subjects research," if the principal investigator attests that the project does not meet the federal definition of human subjects research. For evidence-based practice projects or action research projects, ALL of the following must apply: • Implementing the practice outlined in the project will not incur participant harm. • The practice change outlined in the project is not new or novel and has been published elsewhere. • The practice outlined in the project will be implemented in a single project location. • The project does not test issues or add questions that go beyond common practice. • The project will not randomize participants into different intervention groups. • The project will not deliberately delay interpretation of data. • The project will not deliberately delay or abbreviate feedback to those who would benefit from the findings in order to enhance likelihood of publication. • The project has no funding from an outside organization with a commercial interest in the use of the results.	The proposed research and all proposal procedures fit into one or more of the categories meeting exempt status as defined by the federal regulations.	The proposed research poses no more than minimal risk and all proposal procedures fit into one or more of the categories for expedited review as defined by the federal regulations.	All human subjects research proposals that do not fall under exempt or expedited review categories must be reviewed at a convened meeting of the IRB where a quorum of the Board is present.