

University of California, San Diego  
Human Research Protections Program  
Institutional Review Board  
Standard Operating Policies and Procedures

Section 3.1  
Initial Screening

***Policy***

Applications will be screened by HRPP program staff. Those qualifying for “expedited review” as established by the Secretary, DHHS, (see Expedited Review) will be sent to the appropriate IRB Chair or designee(s) for review. Those qualifying for “exemption from IRB review” as established by the Secretary, DHHS, (see Exemption from IRB Review) will be sent to the appropriate IRB Chair or HRPP Director for review.

Individuals with any question about whether an activity represents “human subjects research” are to provide the IRB with a written description of the activity and request a determination. IRB staff will use the checklist “Determining Whether a Proposed Activity is Human Research According to DHHS or FDA Regulatory Definitions.” The determination as to whether an activity represents human subjects research will be made by the IRB Chair or the Chair’s designee. The criteria to make the determination include the following:

1. The activity involves human participants
2. The activity is a systematic investigation including research development, testing and evaluation.
3. The activity is designed to develop or contribute to generalizable knowledge.

If a project is determined to not meet the criteria, the individual will be informed of this determination either via telephone, e-mail or written document.

Applications that meet DHHS, FDA, or UCSD HRPP definitions of “human subjects” and “research” must be approved by an IRB unless the research has been determined to be exempt from IRB review.

Applications that meet the definition of “research involving human subjects” according to DHHS and FDA will be assigned a primary and a secondary reviewer from the members of the IRB based on reviewer expertise (and any other relevant consideration, such as individual background and experience) for all protocols requiring convened IRB review. Should there not be at least one person present who is knowledgeable about or experienced in working with a specific field or population, or available as a consultant for a specific IRB meeting, the protocol will be “re-assigned” to another IRB or to a subsequent meeting of that IRB where such expertise is present. These evaluations, assignments and determinations are initially done by an HRPP analyst with review and approval by the IRB Chair, the HRPP Director, or an HRPP Associate Director. If the protocol to be reviewed involves a commercially sponsored drug, device or biologic study, at minimum, copies of the sponsor’s master

protocol, investigator's brochure and the UCSD protocol and consent document(s) will be available to the IRB for review.

### ***Procedures***

1. Initial submissions will be screened to determine whether the study qualifies as human subjects research or a clinical investigation based on the DHHS, FDA, or UCSD HRPP definition of "research involving human subjects" and if necessary will use the worksheet "Determining Whether a Proposed Activity is Human Research."
2. If the activity is not "human subjects research" as defined by DHHS, FDA, or UCSD HRPP definitions, it does not require review by the IRB. Investigators will be notified in writing if their application does not meet criteria for human research and therefore would not require IRB review.
3. Prior to full IRB review, initial submission applications will be screened by HRPP staff using a checklist, "Initial Submission Screening Checklist," to determine whether appropriate documents has been provided and whether criteria for expedited review or exempt from IRB review are satisfied. For applications not providing appropriate documents, HRPP staff will notify the PI of any deficiencies in an attempt to rectify the deficiency prior to submitting the application for consideration by a convened IRB. Those meeting expedited criteria, will be assigned to the appropriate HRPP analyst for expedited review. Those applications that appear to meet exempt criteria will be assigned to an IRB Chair or the HRPP Director.
4. For applications that meet the definition of "research involving human subjects" and require convened Committee review, a primary and a secondary reviewer will be assigned from the members of the IRB based on reviewer expertise (and any other relevant consideration, such as individual background and experience). Should there not be at least one person present who is knowledgeable about or experienced in working with a specific field or population, or available as a consultant for a specific IRB meeting, the protocol will be "re-assigned" to another IRB or to a subsequent meeting of that IRB where such expertise is present. These evaluations, assignments and determinations are initially done by an HRPP analyst with review and approval by the IRB Chair, the HRPP Director, or an HRPP Associate Director.
5. HRPP designated staff will ensure documents associated with the IRB meeting are available and ready for review.

### ***Applicable Regulations***

[45 CFR 46.101](#)

[45 CFR 46.108](#)

[45 CFR 46.109](#)

[45 CFR 46.110](#)

[45 CFR 46.116\(d\)](#)