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

Section 3.3
Criteria for Approval

Policy

In order to be approved, a project must meet the criteria for approval in this section. This is true of projects reviewed through a convened IRB or expedited review, and during both initial approval and annual (or more frequent) continuing reviews. Research cannot commence until fully approved by the IRB. The IRB approval occurs when the HRPP releases an approval letter containing the approval date.

Required Criteria

The following requirements must be satisfied in order for the IRB to approve proposed research:

1. Risks to subjects are minimized by using procedures which are consistent with sound research design and which do not unnecessarily expose subjects to risk, and whenever appropriate, by using procedures already being performed on the subjects for diagnostic or treatment purpose. Additional information to consider includes whether there is/are resources necessary to protect subjects; adequate time for the investigators to conduct and complete the research; adequate number of qualified staff; adequate facilities in which to conduct the research; access to population that will allow recruitment of the necessary number of subjects; and medical or psychosocial resources available that subjects may need as a consequence of the research.
2. Risks to subjects are reasonable in relation to anticipated benefits, if any, to subjects, and in relation to the importance of the knowledge that may be expected to result. In evaluating risks and benefits, the IRB will determine the level of risk of the research, (e.g., minimal, greater than minimal). The IRB will consider only those risks and benefits that may result from the research as distinguished from risks and benefits of therapies that subjects would receive even if not participating in the research. The IRB will not consider possible long-range effects of applying knowledge gained in the research (for example, the possible effects of the research on public policy) as among those research risks that fall within the purview of its responsibility.
3. Selection of subjects is equitable from various populations and sub-populations, as applicable. In making this assessment, the IRB will take into account the purposes of the research, the setting in which the research will be conducted, and the population from which subjects will be recruited. They will consider whether inclusion and exclusion criteria impose fair and equitable burdens and benefits. The IRB will be particularly cognizant of the special problems of research

involving vulnerable populations, such as children, pregnant women, mentally disabled persons, or economically or educationally disadvantaged persons.

4. Informed consent will be sought from each prospective subject or the subject's legally authorized representative, in accordance with, and to the extent required by federal and applicable state and local regulations.
5. Informed consent will be appropriately documented, in accordance with, and to the extent required by federal and applicable state and local regulations.
6. Where appropriate, the research plan makes adequate provision for monitoring the data collected, to ensure the safety of subjects.
7. There are adequate provisions to protect the privacy of subjects, and to maintain the confidentiality of data.
8. For studies supported by a commercial entity, the legal, contractual, and institutional risks have been found to be limited based upon review of the agreement between the institution and study sponsor.

Additional Criteria

The IRB will consider the following additional criteria, when appropriate:

1. The IRB will consider participant's privacy interests in reviewing the recruitment, consenting, and medical procedures described in the research plan. Research plans must include a description of how participant privacy will be protected. Investigators must disclose their process for ensuring that participants have control over access to their information when applicable. Some examples of the types of questions the IRB should ask about the research when determining the adequacy of managing participant's privacy concerns include the following:
    a) Where the participants will be recruited? Will recruitment take place in an open public area, a crowded waiting room, or other venue that would jeopardize participant privacy?
    b) Where will the participant be consented? Will the informed consent process take place in a private room, where participant can ask questions without feelings of embarrassment or discomfort?
    c) If the research involves a physical exam, will the patient be provided with a room or private space to undress and dress? Who will be in the exam room?
    d) For research involving young children, will the parent be allowed to be present if this makes the child more comfortable? For adolescents, will the participant be able to talk privately to the researcher without parental supervision or intrusion?
2. Where some or all of the subjects are likely to be vulnerable to coercion or undue influence, such as children, pregnant women, mentally disabled persons, or economically or educationally disadvantaged persons, appropriate additional safeguards have been included in the study to protect the rights and welfare of these subjects.
3. The soundness of research design and the scientific basis for the proposed research. The IRB will review the design and scientific basis to the extent that it relates to the risks to subjects and the benefits of the study, including the generalized knowledge to be gained.

4. The selection of subjects should reflect the purposes of the research and the group that will benefit from the research outcome. The IRB will place special emphasis on the inclusion of minorities and both genders in study populations so that research findings can be applied to all persons at risk for the disease, disorder or condition under study. The proposed research should specify the gender and racial/ethnic composition of the subject population, if it differs from that of the general population, as well as justification for inclusion or exclusion of any subpopulation.
5. Where some or all of the subjects are likely to have reduced decision-making capacity or require surrogate consent, appropriate additional safeguards have been included in the study and the review process to protect the rights and welfare of these subjects.
6. The IRB will also consider the following criteria during initial review, as appropriate to the type of study being proposed. These criteria are assessed for each protocol using a checklist associated with each project and available to the IRB reviewer electronically:
    a) Whether the purpose of study is clear.
    b) Results of any related studies.
    c) The number of subjects and duration of participation is stated and appropriate.
    d) Duration of the study and frequency of activities are clear and appropriate.
    e) Wash-out period for medications is appropriate and safeguards are in place to assure subject's condition will be adequately monitored during that period.
    f) Use of placebo is appropriate.
    g) The setting in which research occurs is appropriate.
    h) Plan for recruiting subjects including recruitment and enrollment procedures and appropriateness of claims made in advertising.
    i) The nature or amount of the compensation offered to subjects for participation in research does not create undue influence, particularly for economically disadvantaged subjects.
    j) The risks of research activities are clearly distinguished from the risk of relevant standard healthcare.
    k) Physical, psychological, social and economic risks, including risks to privacy and the probability of occurrence posed by research design, interventions and procedures.
    l) When reviewing a research proposal with elements warranting special attention (e.g., placebo, challenge studies, radiation exposure, deviations from standards of care), the IRB will consider the appropriateness of, and rationale for, such elements and document such considerations.
    m) Attestation, when required, by the investigator as to whether the proposal, or one substantially similar to it, has been disapproved by another IRB.
    n) Process for monitoring and reporting adverse events.
    o) Presence of a Data Safety Monitoring Board (DSMB) if applicable.
    p) Information to be used for recruitment or to inform subjects or potential subjects about the nature of the research.

q) The investigator and research staff has appropriate scientific and human subject protection training to conduct the study.
r) Investigator potential financial conflicts.

7. If the sponsor or IRB requires a witness to the consenting process in addition to the witness to the participant's signature and if the same person needed to serve both capacities, a note to that effect must be placed under the witness's signature line.
8. A statement that a copy of the signed and dated consent document would be given to the person signing the consent document.

In general, IRB approval cannot occur unless the IRB is able to determine based on information presented that the investigator obtained the legally effective informed consent of the participant or the participant's legally authorized representative; the circumstances of the consent process provided the prospective participant or the legally authorized representative sufficient opportunity to consider whether to participate; the circumstances of the consent process minimized the possibility of coercion or undue influence; the individuals communicating information to the participant or the legally authorized representative during the consent process provided that information in language understandable to the participant or the representative; the information being communicated to the participant or the representative during the consent process did not include exculpatory language through which the participant or the legally authorized representative was made to waive or appear to waive any of the participant's legal rights. The informed consent process may be periodically reviewed for select studies by the IRB or designated reviewers, such as UCSD auditors. Findings will be shared with the IRB Steering Committee or as delegated.

Procedures

1. Reviewer(s) will assess risks, benefits and the adequacy of subject protections; determine whether approval criteria have been met; and make recommendations as to IRB action.
2. IRB members will discuss project in light of approval criteria and vote on approval.
3. IRB Administrator will document in the minutes that approval criteria have been met if approval has been granted and maintain reviewer written comments.

Applicable Regulations

21 CFR 812.2(b)(1)(ii)
21 CFR 812.66
21 CFR 56.108(a)(1-2)
45 CFR 46.109 (a-e)
45 CFR 46.111
ICH 3.1