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

Section 1.1
Responsibility and Authority

Policy

In accordance with federal policy on the Protection of Human Subjects (DHHS Policy 45 CFR Part 46, FDA Policy 21 CFR Parts 50 and 56), the University of California, San Diego (UCSD) is responsible for the protection of the rights and welfare of human subjects in research conducted by, or under the supervision of, UCSD faculty, staff or students. To conduct this responsibility effectively, the University supports Institutional Review Board (IRB) Committees that provide initial review and ongoing review and oversight of the ethical conduct and subject health and welfare for research protocols involving human subjects. It is the responsibility of the IRBs to 1) determine and certify that all projects reviewed by the IRBs conform to federal, state and institutional regulations and policies relevant to the health, welfare, safety, rights, and privileges of human subjects; and 2) assist investigators in complying with these regulations and policies.

The IRBs constituted in compliance with federal regulations and registered with the federal Office of Human Research Protections (OHRP) have the authority to perform the following:

1. Approve, require modifications to secure approval, and disapprove approve research protocols and proposed amendments based on consideration of the risks and potential benefits of the research, and whether or not the rights and welfare of human subjects are adequately protected.
2. Review, accept, or not accept reports, including adverse events, and require modifications to research protocols.
3. Require applications for study re-approval from investigators.
4. Oversee conduct of the study.
5. Observe or have a third party observe the consent process and the conduct of the research.
6. Suspend or terminate a study.
7. Place restrictions on a study.

In compliance with 45 CFR 46.112, research that has been approved by an IRB may be subject to further appropriate review and approval or disapproval by officials of the institution. However, those officials may not approve the research if it has not been approved by an IRB. Further, the institution, its officials, or other institutional committees may not override an IRB decision to disapprove a study. These policies and procedures apply to research involving human subjects conducted by UCSD faculty, staff, and students for research conducted completely or partially at UCSD, or approved off-site locations/facilities, regardless of funding source. These policies and procedures also apply to other institutions or investigators who may enter into

agreements with the Human Research Protections Program (HRPP) to review their human subjects research.

The IRB functions independently of, but in coordination with, other committees. The IRB makes its independent determination whether to approve or disapprove a protocol based upon whether or not human subjects are adequately protected.

Members of UCSD IRBs and HRPP administration/staff are encouraged to report any attempt to use or use of undue influence in the performance of their duties. "Undue influence" means attempting to interfere with the normal functioning and decision-making of the IRB or to influence an IRB member or HRPP administration/staff outside the established processes or normal accepted methods, in order to obtain a particular result, decision or action by the IRB or HRPP. Report of an attempt to use or use of undue influence should be made to the IRB Chair, Director of the HRPP, or UCSD Institutional Official (IO) for Human Research. The report may also be made using the UCOP Whistleblower Policy (http://www.ucop.edu/uc-whistleblower/). The IRB Chair, HRPP Director, IO and/or designated official will investigate the allegations and take appropriate actions including informing the IRB for review of allegations and possible suspension of research privileges.

To help preclude undue influence of IRB members, the HRPP preserves the anonymity of members. A list of IRB members that includes gender, scientist/non-scientist, primary scientific/non-scientific specialty, and institute affiliation is on file with the U.S. Department of Health and Human Services.

Section 103(a) of 45 CRF 46 requires that each institution engaged in federally supported human subject research file an "Assurance" of protection for human subjects. The Assurance formalizes the institution's commitment to protect human subjects. The University of California, San Diego, as part of its Federal Wide Assurance (FWA), FWA00004495, has agreed to protect the welfare of all human subjects involved in research, whether or not the research is conducted or supported by a federal department or agency. Therefore, the UCSD IRB has oversight over all human subject research conducted at these institutions, or by its faculty, students or staff, unless the research has been determined to be exempt from IRB review or the UCSD IRB has entered into an agreement with an "outside" IRB or non-UCSD institution to provide review such as a Review/Rely agreement.

The University of California, San Diego has five IRBs registered with the federal Office for Human Research Protections that have the authority to review, approve, disapprove, or require changes in research activities involving human subjects. Each of these IRBs has been established in accordance with the requirements of applicable federal rules. DHHS Registration numbers for the five IRBs include the following:

Committee A: IRB00000354
Committee B: IRB00000353
Committee C: IRB00002758
Committee D: IRB00005945
Committee S: IRB00000355

Procedures

1. UCSD Institutional Official
    a) Authorize and sign FWA
    b) Ensure ongoing authority of IRB to perform its function
    c) Investigate allegations of undue influence and take appropriate action(s)
2. HRPP Director
    a) Retain file copy of institutional FWA
    b) Investigate allegations of undue influence and take appropriate action(s)
3. IRB Chair
    a) Investigate allegations of undue influence and take appropriate action(s)

Applicable Regulations

21 CFR 50.20
21 CFR 56.109(a, f)
21 CFR 56.112
21 CFR 56.113
21 CFR 312.2
21 CFR Subpart D
21 CFR 312.80 to 88
45 CFR 46.101
45 CFR 46.109(a, e)
45 CFR 46.112
45 CFR 46.113
The Belmont Report
California Health and Safety Code 24170-24179.5

References Forms and Links

Federalwide Assurance, FWA0004495, available from HRPP office.
https://irb.ucsd.edu/about.shtml
http://ohrp.cit.nih.gov/search/search.aspx (use IORG number 0000210)