

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

Section 6.1
e-IRB Submissions and Review

Policy

The document management logistics of the IRB review and oversight process are a substantial burden to faculty investigators, to the Human Research Protections Program (HRPP) office, and to members of the IRBs who perform the essential task of reviewing proposed projects, amendments, and adverse event reports for their impact on the safety of human research participants. It is not uncommon for the reading materials associated with a single IRB meeting to comprise more than 1000 pages, which is both a challenge in terms of pounds of paper and a navigational challenge for quickly locating pertinent information among hundreds of documents.

The HRPP has undertaken an electronic document submission, distribution and archiving project named the “e-IRB” that uses paperless methods for acquiring documents from investigators, providing them to IRB reviewers, and archiving them in permanent form. These technologies are being developed, deployed and refined with the following goals:

1. To improve the efficiency and reduce the burden of the document review process performed by IRB members.
2. To compensate IRB members for their committee work.
3. To reduce the burden upon faculty investigators in the submission of materials necessary for IRB review and ongoing oversight of research projects.
4. To improve the systematic infrastructure of the HRPP office for creating, archiving and providing access to large numbers of research-related documents.
5. To improve the responsiveness of the HRPP office to inquiries and shared oversight issues arising from other organizational units, including research offices of the VA Medical Center, Veterans Medical Research Foundation, Rady Children’s Hospital – San Diego, and the federal Office of Human Research Protections.
6. To improve coordination among related administrative processes such as the School of Medicine clinical trials contracting, Office of Contracts and Grants, campus Conflict of Interest, and Institutional Biosafety/Radiation Safety review committees.

The electronic document management systems of the HRPP are based on acquiring and distributing both editable documents (e.g., consent forms in Microsoft Word or WordPerfect format) and non-editable archival forms (e.g., Adobe Portable Document Format PDF page images).

The creation and maintenance of archival documents will be compliant with the electronic signature and access control provisions of 12 CFR 11(c). Certification of system controls and original signatures will be submitted to the FDA Regional Office per the provisions of 21 CFR

11. As new staff members are employed and others depart, updated signature filings will be made to maintain currency of the FDA electronic document registration.

Procedures

1. IRB Administrator will maintain currency of FDA electronic signature documentation.

Applicable Regulation, and Link

[21 CFR 11 Subpart C](#)

<http://irb.ucsd.edu/e-IRBmenu.shtml>: e-IRB services link on the IRB website.