University of California (UC) IRB Reliance Registry: Facilitating Human Subject Review for Multi-campus Studies in the UC System

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UC MOU and the IRB Reliance Registry

In 2005, the University of California (UC) system, comprising 10 campuses including 7 Carnegie Research I universities, 6 medical schools and a national lab, established a Memorandum of Understanding (MOU) for IRB reliance when conducting multi-center research among its institutions. Registration of this reliance went online in 2012 for all participating institutions through the UC MOU IRB Reliance Registry. It does not cover collaborations with the VA, nor ancillary committee reviews that are still done locally.

Goals of the Online Registry

- Facilitate collaboration among researchers while fulfilling multi-campus IRB requirements
- Encourage collaborations amongst researchers on different UC campuses
- Decrease IRB workload and approval turnaround time
- Efficiently track IRB reliances for UC IRBs

Developing the Online Registry

- Envisioned by the IRB Directors
- Managed and funded by Univ. of California Office of the President (UCOP)/Research Policy Analysis and Coordination (RPAC)
- Developed by UCOP web-developers
- Tested by IRB staff and PIs
- Beta-launch: January 25, 2012
- Mandatory use by all campuses since July 1, 2012
- Version 1.1 released: August 1, 2012

Use of the MOU for Multi-Site Studies

As demonstrated by the graph above, the online registry system encouraged researchers to take advantage of the UC MOU and promoted IRB reliances, saving time for investigators and IRBs alike. Once researchers no longer had to get a paper form signed and PIs could log-in to the Registry remotely, use of the MOU quickly took off.

A Collaboration Among UC Campuses and UC Office of the President

One important result that came about directly from the MOU is a greater sense of trust across campuses and an agreement to rely on the other campuses’ reviews. The UC MOU was developed as a non-share model, where the reviewing IRB fulfills all IRB requirements. Some campus still perform their own “mini” reviews.

The UC campuses also adopted the same uniform instructions for investigators on how to use the Registry, saving campuses time creating instruction guides and lessening confusion among campus researchers.

Challenges for Future Development

- While the IRB Reliance Registry is currently used mainly for investigator-initiated federally-sponsored research, with modified workflow and functionality, it has potential to be used for industry-sponsored clinical trials
- Continue to harmonize local IRB processes and requirements
- Greater outreach to UC faculty who do not know the Registry exists

Version 2.0 of the Registry is in the testing phase by IRB staff as of Nov. 2014. Anticipated launch period is set for early 2015.

Goals of v2.0:
- Revise the workflow to reduce required steps for researchers
- Extend editing rights to all users
- Update the search function for use by all users

Want to Create your own Reliance System?

- Start with low-risk studies (i.e. exempt, expedited) to build trust in the review capabilities of partner IRBs
- Develop a process to efficiently monitor IRB reliances and share information (e.g., a registry bank)
- Allocate resources/funding to accommodate shifting needs in the collaboration and to handle technical issues/system updates

Other Options for Collaborative Review?

The IRBshare model where one IRB reviews the study at the full committee level then the relying sites use the full board review documentation to review the study at the expedited level at their local sites.