



Implementation of the University of California System's IRB Memorandum of Understanding

Author: Rebecca D. Armstrong, DVM, PhD; Lisa Voss, MPH

Affiliation: UC Berkeley; UC San Francisco

Funding: None

Topic: IRB Operations

Problem/Issue Statement

As the number of collaborative multisite human research projects continues to increase, new models of IRB review are being explored. The University of California System and the Lawrence Berkeley National Laboratory have created a IRB Memorandum of Understanding with the goal of decreasing the number of UC IRBs that needed to review collaborative research taking place at multiple UC sites and thereby reducing the burden on principal investigators and increasing the speed of study implementation.

Description of Program

The possibility of a cooperative effort began with discussions amongst the IRB Directors of campuses with medical schools and with the assistance of the UC Office of the President in 2005 expanded to include the IRB Directors of all UC campuses and the Lawrence Berkeley National Lab IRB. After much discussion and negotiation, the proposed MOU allowing reliance on each others IRBs for new exempt and expedited studies was submitted to the Institutional Officials of each school for signature in March 2006. It was unanimously endorsed.

Program Description: The MOU delineates the responsibilities of the institutions and separates the IRBs into the Reviewing IRB or the Relying IRB but left out the details of how to implement the administrative processes. The IRB Directors reached consensus on a) documentation requirements; b) a MOU Application Form; and, c) a process flow chart. All three of these items have undergone changes and improvements as a result of our experiences. In 2008 the MOU was revised to include previously approved projects and in 2009 the MOU has been expanded to include full committee reviews along with implementing mandatory human subjects training for PIs to be able to submit protocols for review under the MOU.

Evaluation: Few objective measures exist of the success of the MOU other than the steadily increasing utilization of it by PIs. Systemwide there are approximately 100 Reviewing IRB projects; and, 125 Relying IRB projects however, UCSF estimates that the MOU saves their PIs approximately 137 hours in IRB preparation and review per project. An unanticipated benefit is an increased understanding of each others' policies, procedures and institutional climate – along with more cooperation between IRB offices.

Future Directions: We are just beginning to apply the MOU to full committee reviews systemwide although UCSF, UCB, UCD and LBNL had been piloting full committee reviews amongst their campuses for almost two years. We are also exploring expanding the MOU to include collaborations where institutions outside of the UC System are involved.

Additional Information

While this has been a UC Systemwide effort, Ms. Voss and Dr. Armstrong have spent an enormous amount of administrative time on this implementation and their institutions, UCSF and UCB respectively, are by far the biggest "users" of the MOU process.

PRIM&R Advancing Ethical Research Conference
2009 Navigating the Future Using the Belmont Compass

November 14-16, Nashville, TN | Pre-Conference Programs on November 13

