UC-Wide Biomedical Research Acceleration Initiative
IRB Working Group—September 2011 Report

Leads: Lars Berglund (UC Davis)

STRATEGIC GOALS

To more effectively implement the UC-Wide IRB Memorandum of Understanding (MOU), these issues must be addressed and resolved:

1. Reduce administrative burden and time required to execute processes related to notification, reporting and data searches related to IRB reviews in multi campus research under the MOU.

2. Ensure that responsibilities of each campus for adverse event reporting, noncompliance, and post approval monitoring and quality assurance/improvement (e.g., audits), as defined by the 2009 MOU, are well understood by research faculty and campus administrators.

3. Establish tracking and metrics to assess 2009 MOU effectiveness in human subject protection, increased administrative effectiveness in multi-site research monitoring and review, and promotion of multi-site research throughout UC.

4. Train researchers about the effective and appropriate use of the 2009 MOU process.

5. Establish a mechanism with Contracts and Grants to identify specific projects for which the MOU may be used (i.e., when a contract is written for multiple campuses, this is an opportunity to use the IRB UC MOU).

TACTICAL GOALS

1. Complete current UCOP-campus collaboration to develop an electronic clearinghouse to facilitate effective administration of MOU
Start: In Process Finish: December 2011

- IRB Working Group has met at least monthly.
- 80% completed. Target date is mid-November 2011. UCOP has taken the lead on completing programming of clearinghouse.
- Invite Informatics Group to provide input on metrics (see Goal #3).
- Pilot Phase & Go Live: January 2012 – June 2012

2. Define responsibilities of campuses for adverse event reporting, noncompliance, and post approval monitoring and quality assurance/improvement (e.g., audits)
Start: In Process Finish: November 2011

- Process developed, finalize standard operating procedures to share with all campuses.

3. Establish tracking and metrics to assess UC MOU effectiveness in human subject protection, increased administrative effectiveness in multi-site research monitoring and review, and promotion of multi-site research throughout UC.
Start: In Process Finish: November 2011

- Define set of metrics.

- Draft metrics proposal and distribute to stakeholders for feedback: consider PI satisfaction/feedback surveys.
- Incorporate metrics in scope of work as addressed above (e.g., approval time)
- Revise metrics/tracking as needed based on feedback
- Report status to broader UC-wide Biomedical Research Acceleration Initiative group
- Collect and track initial data using the pilot clearinghouse system

4. Effectively publicize process as an option to researchers
Start: January 2012 ***Finish: Ongoing as appropriate***

- Develop a training program proposal including both the curriculum and the model of delivery
- Identify and recruit training program mentors at the participating campuses
- Develop a pilot online training site
- Develop a training plan (e.g., a train the trainer model)
- Report out proposals and status to the UC-wide Biomedical Research Acceleration Initiative group

Potential Challenges

- Lack of a designated IRB project manager.
- Ease of applicability Industry v. NIH
- Communication
    - Marketing campaign to prospective sponsors
    - Faculty
    - How to utilize / Operational Challenges
        - PIs with off-campus IRB
        - IRB to IRB

Future

- Explore possibilities to link this database to Contracts and Grants