Avoiding Duplicative UC IRB Reviews

UC-Wide Biomedical Research Acceleration Initiative

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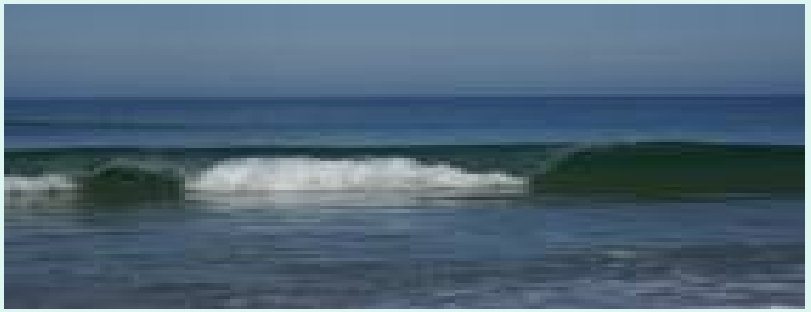
Waves of the Future



- Continued push to rely on other IRBs
  - OHRP
  - FDA
  - AAHRPP
  - CTSAs
  - Study Sponsors
  - Local Institutions
- What options do the UC IRBs have?

The Challenge for the UC IRB System

- **Challenge:** How can investigators avoid duplicate UC IRB reviews?

- **Choice of Models:**

Rely on one UC IRB review when same study is being conducted at more than one UC site

  - Creation of a New Single UC-Wide IRB
  - Use of a Commercial IRB

UC IRB Memorandum of Understanding

- Established UC MOU for Reliance on Other UC IRBs
  - 2006: Expedited and Exempt research only
  - 2006: Northern California (NorCal) MOU (UC Berkeley, UC Davis, UCSF, and LBNL) for all human research
  - 2009: Expanded overall UC IRB MOU to include Full Committee review, though not implemented beyond NorCal
- Used over 700 times since 2006
  - Used most often by NorCal IRBs
  - 30-40% currently full committee review

UC IRB MOU continued…

- Outlines responsibilities of
  - PIs
  - Reviewing IRBs and
  - Relying IRBs
- Describes need for "Notice of Intent to Rely" for PI from relying institution
- Does not provide implementation guidelines or procedures for each campus

Fundamental Premise #1 for Reliance on Another UC IRB

All UC IRBs are trustworthy and capable of conducting an IRB review that meets the federal, state and UC system-wide requirements for IRB approval.

UC Berkeley UC Davis UC Irvine UC San Diego UC San Francisco
Lawrence Berkeley National Lab
UC Merced UC Riverside UC Santa Barbara UC Santa Cruz

Fundamental Premise #2

Reviewing IRB

- assumes full responsibility as IRB of record
- reviews entire study
- assures local issues are identified and addressed

Relying IRB

- accepts determinations made by Reviewing IRB in their entirety

- has responsibility for ensuring that ancillary approvals (RSC, COI, IBC) are in place

NOTE: Model commonly used by commercial IRBs

Why MOU Works

- Strong cross-campus commitment
- Consensus to accept another IRB's template (with local contact information added)
- UCOP Policies in place for
  - Subject Injury policies
  - HIPAA rules (one covered hybrid entity)
  - Interpretation of state laws (surrogate consent, experimental subjects bill of rights, inclusion of minors)
- Same general requirements for ancillary reviews (RSC, COI, IBC, CCRC)

How MOU Works

Once Investigators confer with each other and Reviewing IRB

1. **Relying PI registers by completing on-line form and forwards to Reviewing PI**
2. **Reviewing PI submits IRB application and uploads completed registrations from Relying PIs**
3. **Reviewing IRB reviews entire study**
4. **Reviewing IRB sends IRB Approval Letter to Reviewing PI and Relying IRBs**
5. **Relying IRBs review local PI registration and if complete accepts reliance on Reviewing IRB**
6. **Relying IRB sends Acknowledgement Letters to Reviewing Campus, Relying PIs and Relying IRBs—automatically generated**

Challenges

- Developing and implementing a shared web-based UC IRB MOU registration tracking and submission system ("NOITR Website Clearinghouse")—in process
- Increased responsibilities for Reviewing PI
- Working with local affiliates
  - VA will allow review of local affiliate only
  - Children's Hospital? Kaiser?
- Working with local CTSI
- How best to determine which IRB is best suited to review

Decision Guide to Determine which IRB Reviews Multi-UC Site Study

- Primary Study Site
- PI home campus
- PI eligibility
- Recipient of prime award
- IRB expertise

Challenges continued…

- **Implementing Procedures for**
  - Assuring local ancillary reviews in place
  - Meeting local specific requirements (PI eligibility, investigator training)
  - Handling and coordination of post approval reporting requirements (reportable events, complaints)
  - Monitoring and assuring regulatory compliance
  - Protocol Modifications

Next Steps

- Develop system-wide submission clearinghouse (with UCOP)
- Beta test submission process
- Develop and post implementation guidelines at each site
- Disseminate information to researchers

Questions? Suggestions? Ideas?