Department of Medicine  
RSA Monthly Meeting  
September 16, 2010  
8:30 to 10:00 AM, Laurel Heights 416

Present: Connie Archea, Ross Beard, Michele Benjamin, Michele Carter, Hung Dao, Margie Dere, Lidia Espino, Elizabeth Flora, Raymond Fong, Olive Giovannetti, Lynn Ha, Cherie Habayeb, Kathy Judd, Calvin Kwok, Susan Lau, Victoria Lee, Paul Luong, Rashaan Lyons, Christine Mok, Marianna Murch, Solat Navab, Wendy Ng, Eric Ormsby, William Rypcinski, Suzanne Sutton, Susan Szeto, Kapo Tam, Yvette Villicana, Tanjira Wilawanchit, Joseph Wilson, Pat Wirattigowit, Eric Wu, Samantha Yee.

Announcements
• New Staff: Pat Wirattigowit has joined the Division of General Internal Medicine (DGIM) as a Research Services Analyst (RSA).
• Overdraft Reporting: with the end of furloughs comes the return of monthly overdraft reporting. Overdraft reports are due to Suzanne Sutton by the 20th of each month.
• Next RSA Townhall Meeting: October 28, 9:00 – 11:00, Cole Hall

Suzanne Sutton  
Research Director

Update on Operational Excellence Initiative
There are five subgroups within the OE Research Workgroup (OERW). The subgroups are Approvals, Award Set-up, PI Portfolio Management and Reporting, Funding Opportunities, and Training/Certifications. Some proposals that are on the table:

• Approvals: streamline the signature process for proposals and administrative requests that are handled by C&G. The subgroup interviewed representatives from all 4 schools and 14 departments about current processes and proposed changes. The subgroup proposes to limit signatures on proposals to the PI and Chair or his/her delegate; to eliminate Dean’s Office signature for PI waivers and fund advances and to delegate the authority to the chairs; and to eliminate chair signature on carry-forward and NCE requests. Campus Policy 400-14 on PI eligibility in the VC for Academic Affairs would need to be revised to allow the Deans to delegate the PI Waiver authority to departments.
• PI Portfolios: group has just begun to meet, but responsible for post-award issues.
• Funding Opportunities: use Community of Science (COS).
• Award Set-up: DPA is assigned at the point of the proposal by the Cluster, thereby eliminating a step in the award set-up.
• **Training and Certification:** using existing material from UCSD, UNC, and UCSF, the subgroup completed its task of drafting the training presentation materials. A complementary handbook will need to be developed (likely from DOM’s handbook) but is being handed to the 3 prospective trainers hired by C&G to develop. For certifications, the subgroup proposes signature authority as follows:
  a. Tier 1 (Federal R's, K's, F's), Certification A: RSM signature authority up to $500K (direct costs/yr).
  b. Tier 2 (Federal T's, P's, U's; Non-Profit Fellowships; Non-Profit Grants with standard terms and conditions), Certification B: to be eligible for this certification, RSM needs to have passed Cert. A, and also needs field experience in preparing R's, K's, and F's (or equivalent); not based on amount of length of experience, but rather, on the # of grants prepared.
  c. Tier 3 (CDC, HIRSA, Federal Contracts, Difficult Non-Profit Grant): Certification C: RSM can prepare, but C&G signs.
  d. Tier 4 (Industry Contracts): Not in the Cluster - Certification "XX" (TBD by C&G)
  e. Based on the above, should someone who enters the University without any prior res admin experience be limited to the Admin Asst position only (or some other title)? Candidates with higher degrees who can specifically benefit the res admin mission e.g., someone with a JD, would never apply to an entry-level position. How can we account for individuals with specific expertise but no prior knowledge/experience to able to sign on behalf of the institution? We suggested that the candidates without prior experience can be hired at any cert level based on the recommendation/appeal of the Cluster or Dept manager(s), but this creates exceptions driven by subjective measures. We propose to separate classification from the certification as a solution to this.

**Mora Mattingly & Kent Iwamiya**  
**Industry Contract Officers**  
**Clinical Trial Agreements:**  
**Industry Sponsored vs. PI-initiated vs. Registry Studies**

**Presentation Attached**

**Supplemental discussion notes:**
- Whose idea is it? The PI's or Industry's?
- Is this a New or Standard Treatment?
- Registry Studies: new or standard treatment or device. It isn’t a protocol. The outcomes are registered.
- Clinical Trial: when trying determine, look for Phase I, II, III, or IV, or if it involves a device.
• Holdbacks: only agree to 5% or 10% at most. Otherwise, you may go into deficit while waiting on payment.
• Emergency or Compassionate Use: this is not sponsored research, and usually needs to move quickly. Bruce Flynn in Risk Management can turn these around quickly.
• Protocol and Informed Consent: industry contract officers look for subject injury language.
• Contract Issues: UC will never budge on Publication rights. They are non-negotiable. Confidentiality cannot affect publication ability.

**Upcoming RSA Meetings**

*RSA Meeting on October 21, 2010 at 8:30-10 am in TBD (Wendy Ng)*
*RSA Meeting on November 18, 2010 at 8:30-10 am in TBD (Kathy Judd)*
*RSA Holiday Party on December 16, 2010 at 8:30-10 am in TBD*
*RSA Meeting on January 20, 2011 at 8:30-10 am in TBD (Suzanne Sutton)*
*RSA Meeting on February 17, 2011 at 8:30-10am in TBD (Joseph Wilson)*
*RSA Meeting on March 17, 2011 at 8:30-10am in TBD (Wendy Ng)*
*RSA Meeting on April 21, 2011 at 8:30-10am in TBD (Kathy Judd)*
*RSA Meeting on May 19, 2011 at 8:30-10am in TBD (Joseph Wilson)*
*RSA Staff Retreat on June 16, 2011*
Industry Contracts Division
Office of Sponsored Research

Clinical Trial Agreements:
Industry Sponsored vs. PI-initiated vs. Registry Studies

Kent Iwamiya, Industry Contracts Officer
Mora Mattingly, Industry Contracts Officer
September 16, 2010
Discuss & Compare

• Industry-sponsored Clinical Trial
• PI-initiated Clinical Trial
• Registry Study
• Emergency/Compassionate Use

Including …
• Contract Issues
• Overhead
• Holdbacks
Website

http://research.ucsf.edu/icd
Clinical Trial

**UCSF definition:**

1. The controlled, clinical testing of either:
   - Investigational New Drugs (INDs), or
   - Investigational Devices (IDEs)
   using either a
   - Sponsor, or
   - investigator
   developed protocol under either a
   - FDA Phase I, II, III, or IV drug study, or
   - FDA-regulated medical device study; or

2. The controlled, clinical testing of a protocol performed under the sponsorship of an approved national cooperative consortium for clinical trial services.

3. Ancillary studies at UCSF that support an FDA-approved clinical trial being performed at an outside agency, or under a clinical trial sponsored under the direction of an approved national cooperative consortium, can be classified as a clinical trial.
Sponsored Research

• If the protocol does not meet the above definition, it will be treated as Sponsored Research.

• The indirect cost rate for Sponsored Research is 54.5%
Investigator-Initiated Trials

- UCSF PI developed the protocol
- May include a sponsor’s drug and funding
- Contractual issues include:
  - Intellectual Property
  - Indemnification
  - Subject Injury
  - Ownership and use of data
Registry Studies

- Sponsor-initiated studies where the sponsor is seeking additional information about their drug or device by asking the PI to fill out Case Report Forms (CRF)

OR

- If the Study is not an FDA Phase IV clinical trial, then it is Sponsored Research and the indirect cost rate is 54.5%
Emergency or Compassionate Use

- Industry Contracts Division does not handle these types of agreements – they are not research

- For all Emergency or Compassionate Use studies, please contact Bruce Flynn, Director of Risk Management and Insurance Services
What paperwork is needed?

- OSR Approval Form (via Proposal Express)
- Form 700U (PI’s Statement of Economic Interests)
  NEED PAPER ORIGINAL!
- UCSF Policy 11 Compliance Form
- CHR Approval Letter
- Budget
- Protocol & Informed Consent Form
Contracts Issues to Watch For

- Publication
- Indemnification, Insurance & Subject Injury
- Confidentiality
- Data Ownership & Use of Data
- Intellectual Property
- Correct IDC Rate

For Clinical Trials, indirect costs are applied to ALL costs (NO CARVE-OUTS!) - Total Direct Costs
Publication

• UC Policy - A PI must have the freedom to publish or present his or her individual results of the study (subject only to minimal restrictions).
  
  - Consistent with university mission as an academic and research institution.
  
  - Policy is available on-line at: http://www.ucop.edu/raohome/cgmanual/chap01.html#1-400
Publication

• Sponsors often ask for restrictive language in order to prevent the publication of unfavorable or neutral results.
• Even if a PI does not intend to publish, the freedom to publish must be secured.
• Sponsors cannot have any editorial rights.
Indemnification

• UC Policy 95-05: Requires the sponsor to indemnify UCSF for all claims resulting from the performance of the Sponsor’s Clinical Trial Protocol (not just adverse reactions to the patient).
  – Why? Generally, UCSF is simply carrying out the specific instructions of a protocol authored by the sponsor. Thus, if an injury results, the sponsor should be responsible for the consequences.

• This is not required for PI-initiated clinical trials
Subject Injury

- UC Policy 95-05: For Sponsor-authored clinical trials, the Sponsor is responsible for all costs associated with the medical diagnosis and treatment of a research subject for injuries resulting from that patient’s participation in the study.
- This is not required for PI-initiated Clinical Trials
Subject Injury

The University is prohibited from:

• accepting language requiring third-party billing (e.g., patient’s medical insurance), or

• restricting participation of human subjects on the basis of medical insurance coverage.
Subject Injury

• For Committee on Human Research (CHR) guidelines regarding “Treatment and Compensation for Injury”, go to:

http://www.research.ucsf.edu/chr/Guide/chrH_Injury.asp
Confidentiality

• The University cannot conduct research in secret – our mission is teaching
  – Thus, UCSF cannot agree to keep the existence of a contract confidential.
    • UCSF’s status as a public institution prevents it from keeping the terms of a contract confidential because of the California Public Records Act.
    • UCSF is also subject to Freedom of Information Act (FOIA).
Confidentiality

• Sponsors often want the resulting data to be kept confidential.
  – UCSF cannot agree to this because the sponsor would then be able to prevent UCSF from disseminating the study results.

• Sponsors may review proposed publication or presentations and request that their Confidential Information be removed.
Data Ownership

• **UC Policy**
  - Sponsor owns all reports including Case Report Forms that are required to be delivered to the Sponsor as stated in the Protocol
  - UCSF owns all original records of work (including, but not limited to, laboratory notebooks and patient medical records).
  - UCSF must also retain the right to use the data for its internal research and academic purposes.
Intellectual Property

- **UC Policy**
  - Ownership of inventions resulting from the direct performance of the Sponsor’s Clinical Trial protocol belong to the Sponsor where:
    - the protocol is authored by the sponsor; and
    - the cost of the study is fully funded by the sponsor.
Intellectual Property

- What if the clinical trial is PI-initiated (i.e., the protocol is authored by the PI)?
  - Inventions made in the direct performance of the protocol remain the property of the University.
  - The sponsor may be given a first-right to negotiate an exclusive or non-exclusive license, depending on the level of sponsor funding.

- For more details and policy, go to: http://www.ucop.edu/raohome/cgmanual/chap11.html#11-340
What should you do when the sponsor contacts the PI to discuss the contract terms?

- Refer them to the Industry Contracts Division.
Thank you!

Industry Contracts Division
Office of Sponsored Research