Compliance Corner

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A Message from the Associate Vice Chancellor

I am pleased to bring you this inaugural issue of the Compliance Corner newsletter and I look forward to providing you with quarterly updates, news, and articles on interesting topics in the ethics & compliance field. Please pass this along to your colleagues and let us know if there are any topics you would enjoy reading about in an upcoming issue. If you miss an issue, don’t worry, the newsletters will be posted on the Ethics & Compliance website.

Elizabeth A. Boyd, PhD

HRPP Implements Time-Saving Changes

The Human Research Protection Program (HRPP) implemented some major changes this spring that should lead to less work for investigators. The most radical change is that the HRPP can now grant 3-year approvals for minimal risk research projects that have no federal oversight. These studies will continue to have the same post-approval submission requirements, but annual continuing review is no longer required.

The HRPP also lifted some restrictions on research that can qualify as exempt, and no longer requires investigators to submit minor changes for approval for exempt studies. In addition, the HRPP responded to feedback from researchers and published 11 exempt consent templates, which make it easy to create a short (e.g., half-page) and acceptable consent document for an exempt study.

Finally, the UCSF HRPP is instituting a process to accept reviews by Western IRB for some industry-funded clinical research. Detailed information about which studies qualify will be available soon on the HRPP website.

The HRPP always welcomes your ideas on ways we can improve the review process.

... the HRPP can now grant 3-year approvals for minimal risk research projects that have no federal oversight
Hello from your UCSF ClinicalTrials.gov administrators. We sit in the UCSF Office of Ethics and Compliance and are available to assist you with any ClinicalTrials.gov problems. Listed below are some of the latest information from UCSF and ClinicalTrials.gov.

**ClinicalTrials.gov Responsible Party Change:** As of August 18, 2011, ClinicalTrials.gov has changed their requirements for Sponsor-Investigators. Designated staff may continue to update and edit protocol records. However, Clinicaltrials.gov is now requiring sponsor investigators deemed as the “Responsible Party” to review the final protocol record and release it into the system. At UCSF, this will require all PIs of IND/IDE sponsor-investigator initiated protocols registered to clinicaltrials.gov to establish an account and be listed as the Responsible Party. About Responsible Party Change

**Results Reporting Efforts at UCSF:**
There is good news on the horizon for those of you who have spent hours and hours attempting to resolve results reporting errors in ClinicalTrials.gov. In collaboration with the Data Coordinating Center (DCC), development is almost completed for a set of computer data analysis programs (SAS macros) which can produce tables in the format of the ClinicalTrials.gov sample tables for minimal Basic Results reporting. Such programs will assist investigators in being compliant with FDAAA legal requirements.

Tables produced include:
- Participant Flow Summary Form
- Baseline Age, Gender, Race, Ethnicity, and Region Forms (combined)
- Outcome Measure Summary Form
- Serious Adverse Event Summary Form
- Other (Not Including Serious) Adverse Event Form

Users will need to have SAS datasets recording the relevant information and indicate variable names to produce the tables formatted to facilitate FDAAA reporting requirements. The race and ethnicity reporting use NIH/OMB categories. The adverse events and serious adverse events will require the users to categorize the events by term and organ system. We hope to have the tables available June 2012.

**Updating ClinicalTrials.gov Protocol Records:** Please note that protocol records should be updated every 6 months and final results should be entered within 1 year of the conclusion of the trial if the protocol qualifies per U.S. Public Law 110-85 FDAAA requirements.

**Recent ClinicalTrials.gov Articles of Interest:**
1. Characteristics of Clinical Trials Registered in ClinicalTrials.gov, 2007-2010
2. Compliance with mandatory reporting of clinical trial results on ClinicalTrials.gov: cross sectional study
3. The Evolution of Trial Registries and Their Use to Assess the Clinical Trial Enterprise
4. ClinicalTrials.gov Turns 10!

Contact Marlene Berro or Irene Broderick with questions or to create a clinicalTrials.gov account.
The Clinical Enterprise Compliance Program (“CECP”), under the new leadership of Eileen L. Kahaner, JD, Director – Clinical Compliance, has been actively re-introducing itself to the Clinical Enterprise. In order to achieve our goal of establishing an organizational culture of compliance with applicable laws, regulations, and rules, we need the participation and involvement of the entire organization. We encourage your collaboration and input.

In accordance with our Mission, the CECP regularly supports a dynamic group of Campus and Medical Center operational initiatives. We participate on several committees, such as APeX implementation related work groups, the Medical Center Medical Records committee, the Clinical Trials APeX Implementation Workgroup, and several UCOP system-wide compliance groups. We also consult with the School of Nursing on various clinical practice initiatives.

Currently, one of our main focus areas is responding to the increasing number of Government reimbursement audit initiatives, such as Recovery Audit Contractors (“RACs”) and Medicare Administrative Contractors (“MACs”). This work involves evaluating and coordinating the submission of requested medical record documentation to support clinical services billed to government payors, as well as appealing negative findings, as needed. Where errors are identified, we perform follow-up reviews to evaluate whether or not there may be systemic issues, and, if so, we work closely with leadership and department staff to correct them through training, operational tools, and subsequent monitoring.

In addition to fielding an increased number and variety of questions from faculty and staff regarding appropriate coding or regulatory interpretations, in March 2012, we issued a Teaching Physician Billing Compliance Policy intended to clarify UCSF requirements for billing physician services involving a resident or fellow. This is an evolving process, and we are developing additional guidance on appropriate billing for fellows who are not in ACGME or ABMS accredited programs.

With the recent additions to our staff: Juanita Villanueva, Operations Manager, Carol Yarbrough, Compliance Coordinator – Medical Center, and Jean Havel, Compliance Coordinator - Professional Services, we are pleased to be closer to achieving our staffing goals. In the coming months we will be hiring both Pro Fee and Medical Center Compliance Coordinators, as well as two new positions focused on Clinical Trial Billing Compliance.

Clinical Enterprise Compliance Program Has Moved to a New Location
The Clinical Enterprise Compliance Program has moved! You can now find them at Laurel Heights in Suite 216.
Three Quick Updates from the IACUC Program

In Fall 2012, UCSF will host the Association for the Assessment & Accreditation for Laboratory Animal Care, Intl. (AAALAC, Intl.) for their triennial site visit.

Updates and enhancements to RIO, the online database application used to manage research protocols, are in planning stages.

The NIH Office of Laboratory Animal Welfare recently approved a revised version of the Guide for the Care and Use of Animals, 8th Ed. IACUC and LARC are in the process of implementing changes that the new Guide is prescribing for animal research. Stay tuned for program modifications and they arise.

Regulatory Knowledge and Support Program

In February, Associate Vice Chancellor Elizabeth Boyd assumed the leadership of an important CTSI program, Regulatory Knowledge and Support (RKS). Funded by the NIH, the RKS is a program of the Clinical Translational Sciences Institute at UCSF. RKS supports researchers in navigating regulatory and compliance issues required to conduct clinical & translational research, and works with partners to advocate for improved efficiency of the regulatory approval process.

During Dr. Boyd’s brief tenure, she has set out an ambitious agenda for RKS which focuses on providing resources to researchers and developing processes to better facilitate research. Specific projects include developing a Global Health HUB and evaluating the feasibility of implementing an on-line tool to build consent forms. Options for automating Clinicaltrials.gov reporting will be researched. Additionally, a study of the association of the quality of CHR submission with time to approval will be performed and a rapid review process for retroactive chart review will be implemented. Faculty will be able to continue to receive consultations in Ethics, IND applications, and Clinicaltrials.gov reporting. If you would like a consultation from RKS, go to http://accelerate.ucsf.edu/. If you have questions about the RKS program, please contact Senior Program Manager Alice Fishman.