Administrative Initiatives Subcommittee Notes
Academic Planning and Budget Committee

April 28, 2015

The Campus Planning Subcommittee met on April 28, from 2:00pm – 3:00pm, in Rm MH-2104.

Associate Vice Chancellor of Clinical and Translational Research Jennifer Grandis and Associate Vice Chancellor of Ethics and Compliance Terri O’Lonergan provided the subcommittee with an overview of the work being done to address delays in coverage analysis and to develop a new simultaneous review process that will help expedite the review of studies.

Coverage Analysis
AVC Grandis thanked the subcommittee for invitation to attend. She started the conversation by informing the group that she is new to UCSF, arriving in November of 2014, and that she has been working to understand problems with coverage analysis. Over the past several months, her office has been evaluating the issues and several key problems have been identified. 1) There has been poor customer service; 2) There have been extended timelines for analysis which is currently estimated between 5 and 45 days depending on the complexity of the trial; 3) There has been a lack of communication between the investigator and the assisting analyst; 4) Departments are mandated to use the service center; and 5) For billing, there has been no connection between the office and the CHR and APEX.

To solve each problem, the campus has been working with the Medical Center to develop one complete service center. Once established, the goal is to turn around all studies within 10 business days. The new process will also include a face-to-face meeting between the analyst and the investigator. The campus and the Medical Center have also worked to create new charge masters. The reasoning is that there has been a lot confusion over what tests cost. The new charge master will be linked to industry-funded trials and NIH-funded trials. AVC Grandis hopes that the service center will be so great that investigators will use them; however, if investigators want to perform the coverage analysis on their own, they will be allowed to do so as long as they complete a training course. If the study is industry funded, there will be a fee. The goal is to make it free for everyone else. The hope is that if you have an under funded study, you will want to come to use UCSF’s resources.

CHR Coordination Efforts
AVC Grandis is also working with AVC O’Lonergan to streamline the review processes so that coverage analysis can occur at the same time as CHR review. This simultaneous review should help to expedite approvals. The goal is to work out a method that will not delay investigators. AVC O’Lonergan informed the subcommittee that to make improvements, her office is working on strengthening connections between CHR and Encore. In order to make changes, her office will have to implement new software programs. If there are any issues with compliance, she asked for faculty to contact her personally.

Opening Trials
AVC Grandis informed the subcommittee that she had recently reviewed Encore data that showed a significant number of opened trials do not enroll anyone. It costs money and resources to open trials, so all efforts need to be made to enroll patients. Subcommittee members acknowledged this issue, but noted that the delays in approval have been leading to the lack of enrollment. For example, by the time the study is approved, it may be too late for the investigator to find enrollees.
Consultant Report
AVC did inherent a consultant slide deck and she is willing to share this with the group.

Subcommittee Discussion:

• VA: Subcommittee member Steven Cheung asked how will the VA will integrate with UCSF on the study approval process. AVC Grandis responded that the VA controls all of its processes and UCSF is not involved. However, it is still important for UCSF to know what is going on at the VA. AVC Grandis and AVC O'Lonergan agreed that their offices will need to work on this issue. Staff will need gain some understanding of the VA rules and regulations on clinical trials to determine how our units could be helpful.

• Timeline for Coverage Analysis: APB Chair Sharmila Majumdar asked if there will be a timeline for coverage analysis. AVC Grandis informed the group that it should be 10 business days. The hope is to implement this new timeline by July or August.

• Simultaneous Review: Subcommittee Chair Marcelle Cedars asked for more details regarding the planned simultaneous reviews of proposals. In an ideal world, how long would it take to have a proposal go through Encore, CHR and Coverage Analysis? AVC Grandis stated that she wishes that she could state a number at this time, but it is still to difficult to say. The hope would be 30-days, however it depends on many different factors. For example, it depends on the experience of the investigator at writing protocols. AVC O’Lanergan added that an efficiency effort her office is leading is create more IRB alliance agreements and accept other IRB approvals. A new director will be hired who will work on this issue.

• Cancer Imaging: APB Chair Sharmila Majumdar asked if UCSF could have an opt-out option for patients willing to provide their images for research? AVC O’Lonergan noted this is something we could do if we compare it to bio-depositories. She will look more into this issue.

• Faculty Participation: Subcommittee Chair Marcelle Cedars asked what the best way for faculty to get involved in the clinical research reforms? What is the best way to get feedback to leadership? AVC O’Lonergan asked for all interested faculty to contact her directly. In addition, she is also looking for faculty to tell her how best they can provide feedback. She wants more participation in the review process from young researchers and academics that have been here awhile. AVC Grandis also added that she and AVC O’Lonergan will be holding office hours for faculty to meet with them and discuss.

• Accountability: Subcommittee member Flavio Vincenti informed the group that there needs to be more accountability for IRB and coverage analysis. Leadership needs to develop ridged timelines and stick to those timelines. This has not been here at UCSF. AVC O’Lonergan informed Flavio that CHR needs to be fully staffed before the office can start to develop predicable timelines.

• Committee on Research: Subcommittee member Steven Cheung asked if the Academic Senate’s Committee on Research has been involved in the discussions. AVC O’Lonergan informed the group that there will be a meeting with a research committee under AVC for Research Brian Smith, but that she was not aware of another research committees. Member Cheung detailed the role of the Academic Senate’s Research Committee and suggested that they attend. Both AVC Grandis and O’Lonergan agreed to attend.