

**CTSA Principal Investigator Steering Committee Meeting**  
**Tuesday, April 17, 2007**  
**8:30 a.m. - 3:00 p.m.**  
**Bethesda**  
**Democracy One - 9<sup>th</sup> Floor Conference Room**

**Meeting Summary**

Attendees: Rob Califf, Duke; Mike McCune, UCSF; Garret FitzGerald, U. Penn; David Guzik, U. Rochester; Bob Sherwin, Yale; Eric Orwoll, Oregon HSU; Barry Coller, Rockefeller U; Lars Berglund, UC Davis; Robert Rizza, Mayo Clinic; Frank Arnett, U. Texas, Houston; Steve Reis, U. Pittsburgh; Henry Ginsberg, Columbia U; Mike Joyner, Mayo; Sheila Olson, Mayo; Laurel Yasko, U. Pittsburgh; Deborah Roth, Duke; Jane Atkinson, NIDCR; Steffano Bertuzzi, NINDS; Elaine Collier, NCCR; Rosemarie Filart, NCCR; Mary Durham, OHSU, Greg Farber, NCCR; Brandy Fureman, NINDS; John Gallin, NIH; Geoffrey Ginsberg, Duke U.; Deborah Grady, UCSF; Emily Harris, NHGRI; John Heckler, NCCR; Bernard Talbot, NCCR; Laura Lee Johnson, NCCAM; Kameha Kidd, NCCR; Joyce McDonald, NCCR; Mary Ellen Michel, NIDA; Lori Mulligan, NCCR Iris Abrams, NCCR; Gail Pearson, NHLBI; Shelly Pollard, NCCR; Ann Puderbaugh, NCCR; Carol Romano, NCC; Andrea Sawczuk, NCCR; Mark Scheideler, NINDS; Doug Sheeley, NCCR; Jean Stanford, NCCR; David Timpane, NCCR; Dorothy West, NCCR, Iris Abrams, NCCR, David Wilde, NCCR, Carol Merchant, NCCR, Dennis O. Dixon, NIAID, Paul Wakim, NIDA; Linda Weiss, NCI

Phone/Breeze Participants: Mike Becich, U.Pitt; Ricardo Pietrobon, Duke U.; Ann Valverde, Duke U.; Rob Schuff, Oregon HSU; George Klee, Mayo Clinic College of Medicine, David Rubenson, Linda Schmandt, U.Pitt.; Carol Shreffler, NIEHS; William Hersh, Oregon HSU; Mara Kalter; Kameha Kidd, NCCR; Margaret Ames, NICHD; Laura Lee Johnson, NCCAM

**Introductions**

Dr. Coller, acting as Interim chair, opened the meeting at 9 am and, following introductions, Dr. Alving welcomed participants. The Nominating Committee had proposed two candidates to chair the PI Steering Committee and, following discussions with Dr. Coller, both candidates (Drs. Berglund and Califf) had agreed to serve as co-chairs. The morning session of the PI Steering Committee was chaired by Dr. Coller with the new co-chairs agreeing to chair the afternoon session.

**Budget issues**

Initial discussions focused on CTSA budgeting issues and the handling of requests for carryovers for pilot project and KL2 support. Dr. Alving responded to a letter from the PIs and Irene Grissom, head of NCCR's Office of Grants Management answered additional questions.

**KL2 issue**

CTSA PIs were concerned that some NIH Institutes might not allow KL2 scholars to compete for, or be awarded, K23 awards for the number of years requested. K awards are usually capped at 5 years and scholars who have already received 2 years of KL2 support may be denied more

than 3 further years of K23. This policy conflicts with the practice at some awardee sites to require institutional K scholars (K12 and KL2) to apply for a K23 within 2 years of starting their support. The issue will be referred to the CTSA Research Education Steering Committee to collect data that would support a case for any changes that might be requested. Cataloging and sharing educational programs and materials was another topic for this committee to address.

### **Report on Steering Committees and CTSA Governance**

Dr. Hersh from Oregon Health & Science University presented the report from the Informatics Steering Committee. Ms. Mulligan provided a status report for the CTSA Evaluation Steering Committee, announcing that Dr. Harold Pincus from Columbia is now serving as the Interim Chair. She then explained the interface between the CTSA self-evaluation process and the national consortium evaluation feasibility study being conducted by The Madrillon Group (TMG). Dr. Jack Scott from TMG answered specific questions that the CTSA PIs had regarding the overall vision for the evaluation and the process for developing common indicators, definitions, and baselines. A total of 8 CTSA topic-specific Steering Committees have met and summary reports from the others were provided.

Dr. Hayward presented a proposal to reduce the number of CTSA topic-specific Steering Committees from the 14 projected when the program was started to a total of 7. These would be: Clinical Informatics, Translational, Public-Private Partnerships, Evaluation, Education and Career Development, Community Outreach and 'Clinical.' The latter would serve as an umbrella for several currently active committees: Participant and Clinical Interactions, Biostatistics, Epidemiology and Research Design, Ethics and others as necessary. The Pediatric Steering Committee had expressed a wish to be represented on each of the topic-specific Steering Committees – but this is not yet fully accomplished. There was some discussion that the Pediatrics Steering Committee should be renamed Special Populations but consensus was not reached and the group decided that further discussion about pediatrics is necessary before making a decision. Several of the Steering Committees that would be included under the 'Clinical' umbrella have already met and identified issues to be addressed and would continue to address these issues as Topic Workgroups. The PI Steering Committee would continue as the central coordinating committee to which all the topic-specific committees report.

Discussion focused on the reporting structure for the Steering Committees, and the role that the PIs should have in setting their agendas. There was a consensus that the PIs needed a mechanism to charge the committees with actionable agenda items and all agreed that function should determine steering committee structure. Dr. Hayward explained that each PI had been supplied with a summary of topics raised at Steering Committee meetings. He will follow up with members of the PI Steering Committee to identify those topics that should be assigned the highest priority, in the expectation that Topic Workgroups would continue to meet to address these issues.

The group asked whether NIH will provide additional resources to support Steering committee activities and projects. Dr. Hayward provided an update on the CTSA Support Center contract that has been advertised that will help support steering committee activities. However, the contract is not designed to fund Steering Committee projects. Members expressed enthusiasm for

the limited competition for supplements to CTSA's to plan for pilot projects for community engagement activities.

Dr. Alving also mentioned that the CTSA members should also consider convening thematic workshops around specific topics as another way to work together and with the research community at large.

### **CTSA purchasing**

The PIs will follow this topic up by e-mail.

### **Sharing information about patients with rare disorders who may wish to participate in clinical studies**

Dr. Ginsberg suggested that consideration be given to starting a searchable database.

### **Potential for CTSA- Wide Data Collection and Management System**

There was some consensus that the CTSA's would examine National informatics organizations to review and set standards for data systems, since many informatics standards efforts are already funded.

Dr. Reis presented the Pittsburgh experience with methodology (Hochin Evaluation) and results of the Pittsburgh CTSI Retreat/Strategic Plan meeting.

### **Experience with External Advisory Boards**

PIs had generally had very positive experiences with their External Advisory Boards.

### **CTSA Collaboration**

PIs discussed their strategies for collaboration within their respective CTSA development. Discussions also involved plans to collaborate among the CTSA's in topic specific areas such as IT networks. Initial integration strategies were discussed for upcoming new CTSA awardees. FDA officials offered their assistance in the CTSA development and the PIs were receptive.

### **Action Items**

- The CTSA PIs will draft a vision statement that highlights the top three goals/priorities for the CTSA Consortium. The PIs agreed that "People" and "Collaborations" were two definite goals and they would need to decide on a third after the meeting. Dr. FitzGerald will draft the first statement on "People" and distribute for comment.
- CTSA PI Steering Committee teleconferences will continue to convene every 6 weeks with NIH staff. (Post-meeting update. The Pediatrics Steering Committee presented to the CTSA PI Steering Committee on May 8<sup>th</sup> and the recording is available at <https://webmeeting.nih.gov/p68872359/>. The Ethics and Participant Interactions Steering Committees will present on May 18, 12 noon – 1 pm ET).
- Discuss communication strategies at next face-to-face CTSA PI meeting. (Post meeting update. The next face-to-face meeting will be on October 3 in Rm 10, Bldg 31C on the NIH campus from 9 am to 3 pm. The FY2007 awardees will be invited to this meeting)

