

**National Clinical and Translational Research Capability
Strategic Goal Committee (SGC) #1
January 21, 2009
Meeting Summary**

Strategic Goal Committee #1

Time: 3:00 – 4:00 PM ET

Attendees: Dan Ford, Johns Hopkins (Co-Chair); Etta Pisano, North Carolina (Co-Chair); Renee Joskow, NCRN (NIH Coordinator); Dan Rosenblum, NCRN (NIH Coordinator); Paul Appelbaum, Columbia; Brian Athey, Michigan; Susan Autry, UCSF; Robin Brey, UT-San Antonio; Lisa Guay-Woodford, Alabama-Birmingham; Anthony Hayward, NCRN; Ken Holroyd, Vanderbilt; Clay Johnston, UCSF; Walter Koroshetz, NINDS; Rhonda Kost, Rockefeller; Dan Masys, Vanderbilt; Rebbecca Moen, Duke; Harold Pincus, Columbia; Bonnie Ramsey, Univ. of Washington Deborah Roth, Duke; Jody Sachs, NCRN; Mary Samuels, OHSU; Anantha Shekhar, Indiana; Kim Toussant, Ohio State

I. Welcome and Introductions

Dr. Ford introduced members of SGC #1 – National Clinical and Translational Research Capability – as well as the Chairs and Co-Chairs of the Key Function Committees (KFCs) to the meeting. He shared that during the first SGC #1 call on November 18, 2008, members decided to form subgroups based on the sub-goals that were determined at the October 6-7 CTSA Steering Committee meeting. The three subgroups had an opportunity to clarify concepts and determine priorities and have since consolidated. The SGC #1 is in the process of preparing for a presentation at the SGC Face-to-Face on January 26-27 in which it will offer short- and long-term priorities. The purpose of this teleconference is to allow KFCs an opportunity to indicate how they can help SGC #1 achieve its goals and to avoid overlap across the Consortium.

He offered a revised version of the mission statement for SGC #1, which goes as follows:

“The National Clinical and Translational Research Capability Strategic Goal Committee (SGC #1) builds CTSA Consortium support for clinical and translational research by enhancing processes for streamlining pre-study regulatory requirements, supporting research networks, training research professionals who support principal investigators, and advocating for regulatory policies that enhance clinical and translational research.”

It was further noted that though not included, research subject retention and recruitment, a catalog of resources and phenotyping/genotyping are additional areas of interest.

II. Brief Description of Progress To Date

A. Clinical Research Management: Workshop, Pilots, Metrics, Publication, Groups on IRB, Contracts

To date, Clinical Research Management has had one workshop last June, is planning for another taking place this June, has its own Key Function Committee and strives to have publications by the end of 2009. The IRB and Contracts

Groups aim to kick off pilot projects in the near future and report metrics later in 2009.

B. Research Infrastructure

Members underlined the importance in determining what the NIH Institute and Center (IC) Directors would like to see. They also suggested the development of a CTSA site, disease-specific contact map for investigators with interest and readiness to respond to requests to develop new clinical trials with NIH IC partners.

The Informatics KFC indicated that they are aiming for a generalizable inventory. The Public-Private Partnerships KFC shared that the Agreements and Aggregating Resources Groups may make contributions in this area.

Dr. Ford also pointed out that the recruitment and retention of research subjects is a key component for SGC #1, is not in the plans for SGC #4 and that they can carve out a special population.

C. Phenotyping

Dr. Guay-Woodford mentioned two major issues that were raised during the call of the Phenotyping subgroup. They include the importance of a clinical data warehouse and the contents within it, as well as the importance of a phenotyping protocol. She indicated the need to determine how to develop the phenotyping ontology, how to agree on data sharing pieces and how to determine where to obtain data sources. She stated that a proof of concept pilot on a small and targeted scale is more realistic than an overarching plan and would enable the SGC to address major issues. Dr. Masys noted that the existence of eMERGE (https://www.mc.vanderbilt.edu/victr/dcc/projects/acc/index.php/Main_Page), which is funded by NHGRI, and is a national consortium formed to develop, disseminate, and apply approaches to research that combine DNA Biorepositories with electronic medical record systems for large-scale, high-throughput genetic research. A list of the five participating members, all of which are associated with CTSA institutions can be found on the eMERGE website.

III. Expectations for January 26-27 Meeting

The following items below include the expected objectives and outcomes for the January 26-27 SGC Face-to-Face Meeting in Bethesda.

- A. Agree on direction of CTSA Strategic Plan
- B. Review of "mapping" – review relationships of KFCs and workgroups of SGC – reason for inviting KFC Chairs to meeting
- C. Discuss challenges, opportunities and deliverables from each SGC (1-4)
- D. Review hierarchy of deliverables – SGC #1 will be expected to say what it wants to do first, second and third, what the milestones will be, and when the SGC expects to produce deliverables. Other items discussed will include administrative supplements, resources, new members and other business.

IV. Review of Short- and Long-Term Goals

Prior to the meeting, Dr. Ford sent a draft list of short- and long-term goals for KFC Chairs and Co-Chairs to discuss and add how their committees can contribute to achieving these goals. Dr. Masys noted that the Informatics KFC has developed a Project Concept sheet, which may be reusable by other groups and is posted on the Wiki.

Short-term Goals

1. Develop metrics for study initiation (IRB, contracting) by CTSA institution and institute a quality improvement program to improve efficiency (work to develop a model contract agreement?)
 - The Regulatory Knowledge KFC is working on three white papers relevant to Clinical Research Management that go beyond contracts and IRB. They are interested in studying outcome measures, which goes beyond reporting an inventory of practices.
 - Members expressed the need for a measure of quality that gauges how much IRBs protect human subjects.
2. Survey research coordinators, IRB staff/members, contracting/grants management staff about needs for uniform training to help support master agreements and multicenter trials
 - Dr. Ford shared that SGC #2 – Training and Career Development of Clinical/Translational Scientists – is not addressing training issues relevant to non-investigators who are critical to the clinical research enterprise.
 - The Participant and Clinical Interactions Resources (PCIR) KFC asked whether there is an ongoing effort to certify research nurses and noted that there is a largely invisible research infrastructure that exists in the old GCRCs and the current PCIRs, which consist of research nurses and bionutritionists. There is a group within the KFC that is developing standardized training and materials, but are not resourced and have thus proceeded with caution.
 - SGC #1 members expressed favor in pursuing this short-term goal, because it is critical to the retention of subjects. Dr. Brey indicated that there is a certification process for all research staff at every level at UT-San Antonio.
3. Identify one policy issue related to support of clinical and translational research (research support by CMS and other insurers?)
 - There was difference of opinion on whether the Community Engagement KFC (and SGC #4 – Enhancing the Health of Our Communities and the Nation) aims to address this. Dr. Ford stated that he will bring this up at the SGC Face-to-Face Meeting to further determine whether this is a desired goal for SGC #4.
4. Create a research agenda and collection of best practices related to recruitment and retention of research participants
 - Dr. Ford stated that SGC #4 is not addressing this area.
 - Members felt strongly that this was the most important of the short-term goals because it affects all research that is done.
 - The Clinical Research Ethics and the Regulatory Knowledge KFCs indicated an interest in achieving this goal. Dr. Kost mentioned that

access and research diversity are useful to the Research Subject Advocate Group of the Regulatory Knowledge KFC.

- There are ongoing efforts at Vanderbilt that may assist (e.g. potential registry of research participants).

Long-term Goals

1. Create a website for public posting of metrics on study initiation
2. Develop materials or support a course to promote uniform training of research support professionals
3. Support a work group to create a model genotyping-phenotyping research program

V. Next Meeting

Following the SGC Face-to-Face Meeting, the SGC #1 will determine future meeting dates.

The meeting adjourned at 4:00 PM ET.