

**CTSA Evaluation Steering Committee Conference**  
**Meeting Summary**  
**February 8, 2008**

**8:00 A.M. - 3:30 P.M. EST**

Adobe WebConnect Recording URL:

<https://webmeeting.nih.gov/p85213847/> (Pre-lunch)

<https://webmeeting.nih.gov/p81613487/> (Post-lunch)

**Participants:**

**CTSA Representatives:**

Tabia Henry Akintobi (Emory)

Eric Bass (Johns Hopkins)

Phyllis Beemsterboer (OHSU)

Leonard Bickman (Vanderbilt)

Zeanid Breyer (UCSF)

Doug Brock (U Washington)

Sunday Clark (Pittsburgh)

Abigail Cohen (U Penn)

Ann Dozier (Rochester)

John Farrar (U Penn)

Mark Graham (Columbia)

Barbara Gulanski (Yale)

Brenda Hayes (Emory)

Patricia Higgins (Case Western)

Jan Hogle (UW-Madison)

James Huntzicker (OHSU)

Donna Jeffe (Washington U)

Stephen Johnson (Columbia)

Cath Kane (Cornell)

Stephen Lurie (Rochester)

Paul Moberg (UW-Madison)

Sheila Olson (Mayo)

Zoon Naqvi (Columbia)

Kelly Peck (Dallas)

Harold Pincus (Columbia, Chair)

Michael Quinn (Chicago)

Julie Rainwater (UC Davis)

Belinda Reininger (Texas)

Boyd Richards (Columbia)

Lynne Robins (U Washington)

Deborah Roth (Duke)

Doris Rubio (Pittsburgh)

Jodi Segal (Johns Hopkins)

John B. Serrecchia (Yale)

Iris Smith (Emory)

William Trochim (Cornell)

Christine Weston (Johns Hopkins)

Dena Wheaton (Dallas)

DuWayne Willett (Dallas)

Knut Wittkowski (Rockefeller)

Frederic Wolf (U Washington)

Donald Yarbrough (Iowa)

**NIH Representatives:**

Margaret Ames (NCI, NIH Co-chair)  
Sheryl Brining (NCRR)  
Elaine Collier (NCRR)  
Rosemarie Filart (NCRR)  
Anthony Hayward (NCRR)  
Karen Huss (NINR)  
Paul Johnson (NICHD)  
Kameha Kidd (NCRR)  
Carmela Lomonaco (NCI)  
Lori Mulligan (NCRR, NIH Co-chair)

Patricia Newman (NCRR)  
Iris Obrams (NCRR)  
Eugene Rich (NCRR)  
Melba Reed (NIAID)  
Eugene Rich (NCRR)  
Jody Sachs (NCRR)  
Andrea Sawczuk (NCRR)  
Bernard Talbot (NCRR)  
Brandie Taylor (NCI)  
Patrick Twomey (NCI)

**Booz Allen Hamilton Contractors:**

Erik Davis  
Paymon Hashemi

Lisa D. Jones  
Rajni Samavedam

**Welcome and Introductions**

Ms. L. Mulligan (NCRR) and Dr. H. Pincus (Columbia) welcomed everyone to the meeting. Dr. H. Pincus informed the Committee that the purpose of this Face-to-Face meeting is to maximize interaction among common interests, specifically sharing experiences, tools and lessons learned. He also briefly outlined the topics that will be addressed throughout the course of the meeting, which includes CTSA updates, National Evaluation updates, report from the Workgroup Chairs and round robin sessions on IRB and Evaluation, Role of the Evaluator and Measuring Indirect Benefits of the CTSA.

[refer to [http://www.ctsaweb.org/uploadedfiles/CTSA\\_Update.ppt](http://www.ctsaweb.org/uploadedfiles/CTSA_Update.ppt)]

Dr. A. Hayward (NCRR) reminded the Committee that the vision for CTSA should be considered as a 'home and career structure' for clinical research. Strengthening clinical research through a 'home and career structure' may prove useful to individual investigators to help them: write, approve and implement protocols; speed up the process in identifying scientific queries studied in a clinical environment; and disseminate information to the scientific community. Furthermore, the CTSA Program aims to change the clinical research culture, via collaboration, to advance research and to identify successful treatments faster.

The evolution of the CTSA presents a unique challenge due to the enormous diversity of the program, thus smaller, topic-specific committees were established to help support the objectives of the CTSA. The CTSA Program identified some immediate achievements, which include:

- Minority participation
- Research education and career development

- CTSA Informatics

## **National Evaluation Updates: Progress and Next Steps**

[refer to [http://www.ctsaweb.org/uploadedfiles/national\\_evaluation\\_updates\\_and\\_next\\_steps.ppt](http://www.ctsaweb.org/uploadedfiles/national_evaluation_updates_and_next_steps.ppt)]

Ms. L. Mulligan reiterated a similar message that the CTSA Consortium is a dynamic, complex program, whereby NIH seeks input from various communities and interfaces with them in order to fulfill objectives for a national evaluation. Such communities include CTSA Oversight and steering committees, CTSA Evaluation Steering Committee, external advisors and stakeholders and professional evaluators. In addition, she also reminded the Committee that the National CTSA Consortium Evaluation focuses on collective contributions of the Consortium as a whole.

Progress and next steps were presented to the Committee outlining three CTSA Evaluation phases. In the first CTSA Evaluation phase, Ms. L. Mulligan briefly reviewed the findings of the Madrillon Group feasibility study report, first presented in the November CTSA Evaluation Steering Committee Web Conference, for which they proposed the design for the National CTSA Consortium Evaluation into six sub-studies to concentrate on:

- Scholars and trainees' career pathways
- Public awareness
- Health practices
- CTSA implementation
- Clinical and translational science
- National evaluation questions

Currently, in the second CTSA Evaluation phase, NIH will review the feasibility study and will refine the design and issue a Request for Proposals late spring with the expectation of making an evaluation contract award by the end of the summer. The third CTSA Evaluation Phase will move toward looking at a National Consortium Outcomes Study.

The committee addressed a number of challenges and themes related to the National CTSA evaluation:

- Given that the Consortium is still in its critical stage of development Dr. W. Trochim (Cornell) suggested a logic model at the Consortium level should be developed and include how it will engage stakeholders. He also commented on the challenges that exist because the Consortium is a complex system with multiple levels.
- Dr. E. Bass (Johns Hopkins) introduced the notion of formative evaluation (which addresses improving processes) versus summative evaluation (which

assesses value and impact of programs). He stressed that formative evaluation should be emphasized in order to find success with evaluating the Consortium.

- A recommendation was posed to review the underlying theory (or model) developed of the CTSA Consortium, rather than first establishing objectives and measuring how objectives will be met.
- The Committee also discussed the concept of randomization to select sites for evaluation of specific variables.

## **Wiki Communications**

[refer to [http://www.ctsaweb.org/uploadedfiles/Kameha%20Kidd\\_2.8.08.ppt](http://www.ctsaweb.org/uploadedfiles/Kameha%20Kidd_2.8.08.ppt)]

Dr. K. Kidd (NCRR) provided an overview and demonstration of the Wiki. She informed the Committee that the Wiki is one communication tool that is separate from other communication tools (i.e. the CTSA E-Newsletter, CTSAweb.org and email), but also overlapping so that committee members have multiple avenues to engage in interactions. The Wiki, a Hawaiian translation for 'Quick', offers the end user an opportunity to have a 'quick' interface with others in the CTSA community.

Dr. K. Kidd demonstrated Wiki features, in particular, how to log onto the Wiki, designate a favorite page, receive update alerts, add an email link and how to add an attachment. She also informed the Committee that receiving a 24 hour summary update is available.

## **Social Network Analysis Workgroup Report**

[refer to [http://www.ctsaweb.org/uploadedfiles/Rainwater\\_SNA\\_Workgroup.ppt](http://www.ctsaweb.org/uploadedfiles/Rainwater_SNA_Workgroup.ppt)]

Dr. J. Rainwater (UC Davis) explained that the value of this workgroup is important in program evaluation (of the CTSA) in 'making relationships visible' leading to the development and support of network relationships, as well as intentionally creating them (D. Introcaso, 2005). The uniqueness of this workgroup is its collaboration of evaluation and informatics to complete analysis.

[refer to <http://www.ctsaweb.org/uploadedfiles/SocialNetworkAnalysis.ppt>]

Drs. S. Lurie (Rochester) and S. Johnson (Columbia) presented experiences from their respective institutions on network analyses. Dr. S. Lurie presented social network analyses. as a management and diagnostic tool for program implementation and Dr. S. Johnson presented on tools to identify key research collaborations and its success.

Dr. S. Lurie discussed relationships among key functions (or cores), using a simple survey distributed among directors of key functions at Rochester. Looking at this evaluation process in a formative way, he derived two key questions from the survey:

- How familiar are you with the 11 key functions?
- How much do you plan on interacting with key functions?

He reported that there can be difficulties of relationships among key functions and that such relationships are not bidirectional. Moreover, further analysis revealed the existence of vulnerabilities and/or isolations with some key functions.

[refer to <http://www.ctsaweb.org/uploadedfiles/Johnson.ppt>]

Dr. S. Johnson presented to the Committee literature search focusing on obesity at Columbia and the idea of betweenness (co-authorship) among investigators, using Sitespace, a mathematical software. He showed activity in 2000 -2007 to understand time and productivity of publications. This tool allows for the review of publication data and begins to ask questions about how are investigators related to one another through their work; are investigators interdisciplinary; can investigators be viewed as gateways of conducting research that will be published, etc. In addition, from an evaluation perspective, use of these data viewed could be to identify investigators who collaborate on research and foster an environment where others also collaborate (i.e. graduate students, junior researchers, etc.).

### **Definitions Workgroup Report**

[refer to [http://www.ctsaweb.org/uploadedfiles/Trochim%2008\\_2008.ppt](http://www.ctsaweb.org/uploadedfiles/Trochim%2008_2008.ppt)]

Dr. W. Trochim introduced the members of his workgroup and solicited invitations from the Committee to join the workgroup. He made a charge to the Committee to identify, prioritize and analyze potential constructs in the 'queue' relevant to the CTSA. Possible next steps for the Workgroup are to develop evaluation 'briefs' or 'whitepapers' and overall, to receive and offer feedback from the Committee, via the Wiki. Dr. F. Wolf (University of Washington) requested the Committee to list additional constructs that are of interest.

Dr. F. Wolf conducted an exercise requesting the meeting participants to write out additional key concepts, best definitions, etc. that this workgroup should address. These concepts will be further discussed and will be posted on the Wiki for developmental dialog. Some terms that the Committee would like to be further defined are the terminology of informatics, investigator, community engagement, translational research and what is a unit of translation and types of interventions (i.e. what are 'pilot projects'?).

Dr. W. Trochim posed the following additional questions to the Committee for further discussion:

- What 'products' would help you?

- How should this workgroup involve CTSA outside of this workgroup?
- How should this workgroup involve CTSA people outside of the Evaluation Steering Committee?
- How should this workgroup outside the CTSA?

## **Shared Resources Workgroup Report**

[refer to <http://www.ctsaweb.org/uploadedfiles/Shared%20Resources.ppt>]

Dr. J. Segal (Johns Hopkins) presented the workgroup's goals of allowing an avenue of cross-sharing opportunities and requesting to draw from other workgroups. Dr. J. Segal also charged the Committee to brainstorm about domains into which the resources may be categorized and requested suggestions. The following domains identified are:

- Needs assessment
- User satisfaction
- Culture change
- Multidisciplinary
- Attribution
- Leveraging existing data
- Identifying users
- CTSA impact
- Feedback
- Service request forms

Dr. J. Segal informed the Committee that the workgroup will conduct monthly calls, utilize the Wiki space and listserv, conduct a Shared Resources Wiki-potluck and discuss the domain of the month.

## **Reports from Round Robin Sessions**

### **IRB and Evaluation**

[refer to <http://www.ctsaweb.org/uploadedfiles/IRB%20and%20Evaluation.ppt>]

Dr. P. Moberg (Wisconsin) recapped from the round robin session on IRB and Evaluation by first explaining the hierarchy of IRB Involvement in research. The interpretation of exemption criteria was explored and how discrepancies exist based on the language and scope of research conducted. For example, does evaluation of CTSA fit under an exemption as stated in the Common Rule? Does the definition of research versus evaluation have an impact on IRB review and rulings?

Dr. P. Moberg presented an argument of the advantages and disadvantages of IRB review for program evaluation projects discussed among the Committee and suggested next steps for the Committee which are: consideration of a central IRB for CTSA

evaluations; discussing how to harmonize across institutions; engage and leverage discussion with other CTSA Committees; and discuss ways that there could be greater transparency across IRBs.

### *Role of Evaluator*

[refer to <http://www.ctsaweb.org/uploadedfiles/Role%20of%20the%20Evaluator.ppt>]

Dr. D. Rubio (Pittsburgh) summarized from the round robin session, which discussed different models, identifying role structure of the evaluator, reviewing existing partnerships and their respective cores to understand what infrastructures are in place. Bringing together core leaders would prove useful in leveraging discussions to further enhance the role of an evaluator and what cores the evaluator is measuring. The evaluator may face challenges such as determining how to conduct scholarly work, performing rigorous qualitative methodologies and evaluating core performance versus program evaluation. A more in-depth look at these challenges and issues may prove useful.

### *Measuring Indirect Benefits of the CTSA*

[refer <http://www.ctsaweb.org/uploadedfiles/Measure%20Benefits%20Temp.ppt>]

Dr. A. Dozier (Rochester) discussed defining how 'direct' and 'indirect' benefits of the CTSA would be measured and then taking it further to acknowledge sensitivities of intentional and unintentional consequences of how the CTSA can impact stakeholders; benefits of CTSA as the 'community' by those who have access to the 'community'; the possible shift in culture change with CTSA's mission; and an impact on NIH data systems, long term tracking, and data collection. Dr. A. Dozier emphasized to the Committee that the benefits of the CTSA will have a 'ripple' effect touching many institutions over a long period of time.

### **Wrap-up and Next Steps**

Dr. H. Pincus thanked all participants who attended the meeting and stated that he found the meeting to be very valuable in succeeding with facilitating interactions. Dr. H. Pincus summarized the meeting with the following action items:

1. Continue the level of communication, via web conferences, seminars, Wiki and Workgroup calls.
2. Consideration of additional workgroups (i.e. IRB Workgroup)
3. Convene a web conference in April or May to have the 2007 cohort present a brief description of their activities. Submission of topics for the meeting are encouraged.
4. Develop a page for updates on National CTSA Evaluation on Wiki.

Dr. W. Trochim offered the invitation to the Committee to attend the American Evaluation Association conference in Denver, Colorado on November 3-8, 2008.