

**Clinical Research Management (CRM) Key Function Committee (KFC)
December 12, 2008
Meeting Summary**

CTSA CRM KFC

Time: 3:00 PM – 3:30 PM ET

Attendees: M. Joyner, Mayo (Co-Chair); R. Moen, Duke (Interim Co-Chair); D. Rosenblum, NCRN (NIH Coordinator); C. Cairns, UNC; R. Califf, Duke; A. Chapman, Emory; J.P. Cobb, Wash U.; D. Ford, Johns Hopkins; D. McCloskey, NCRN; L. Portilla, NCRN; A. Rifkind, UPenn; E. Rubinstein, Rochester; L. Salberg, Vanderbilt; L. Suk, Cornell; K. Toussant, Ohio State; S. Winkler, Harvard

I. Pilot Studies

A. Contracts Group

The Contracts Group completed a draft proposal for a prospective pilot study. The BERD KFC will collaborate in further development of the study. The study aims to start soon after the Pilot and Metrics taskforce agrees on the protocol, which could be as early as mid-January 2009. The protocol will involve a limited number of easily reportable captured time points, perhaps about 4 of them, that mark the initiation, important mid-points, and completion of contracts' negotiation.

B. IRB Group

The IRB Group has nearly completed a draft of a protocol for a pilot study. They are seeking a waiver from the CTSA site IRB's to implement the study. They will also obtain collaboration with BERD KFC to improve the design of the study. The protocol will involve a limited number of easily reportable captured time points, perhaps about 4 of them, that mark the initiation, important mid-points, and completion of IRB approval.

II. Publication of 2008 Workshop on CTSA Clinical Research Management

Dr. Ford reported that he is in the process of drafting a publication entitled, "Initiation of Clinical Research Studies: The CTSA Response". The publication includes data from CTSA sites and includes material presented at the 2008 Workshop including the commitment to the use metrics to drive process improvement and the nature of the metrics for protocol processing that might do that. He will aim to have the manuscript published in either *JAMA*, the *Journal of Academic Medicine*, or the *Journal of the Society of Clinical Trials* (in that order). Ms. Portilla will send a draft document on behalf of the Public-Private Partnerships Key Function Committee on "Doing Business with the CTSA's" to avoid any contradictory statements.

III. Clinical Research Management Workshop – June 23-24, 2009

The next CRM Workshop will take place at the Natcher Auditorium on the NIH campus on June 22-23, 2009. The Workshop would be improved if it included data derived from the pilot studies, which may be available by April 2009. . Participants may be asked to highlight areas of strength and weakness in their site's protocol processing.

The first meeting of the Planning Group for the CRM Workshop will be on December 16, 2008 at 11 AM ET. The members of the group are listed below.

Paul Appelbaum (Columbia); Robert Califf (Duke); Arlene Chapman (Emory); Elaine Collier (NCRR); J. Perren Cobb (Washington U); Julie Eichenberger Gilmore (Iowa); Daniel Ford (Johns Hopkins); Nick Gaich (Stanford); Anthony Hayward (NCRR); Raymond Hutchinson (Ann Arbor); Darlene Kitterman (OHSU); Donna Jo McCloskey (NCRR); Lili Portilla (NCRR); Adam Rifkind (UPenn); Daniel Rosenblum (NCRR); Eric Rubinstein (Rochester); Libby Salberg (Vanderbilt); Lily Suk (Cornell); Kathleen Uscinski (Yale)

IV. Next Meeting

The CRM KFC will meet regularly on the 2nd Friday of every month from 3:00 – 4:00 PM ET. The next meeting will take place on Friday, January 9, 2009.

The meeting adjourned at 3:30 PM ET.

V. Action Items

| # | Action Items | Owner | Due Date |
|---|---|--------------------------|-----------------------|
| 1 | Send draft of "Initiation of Clinical Research Studies: The CTSA Response" to CRM Members and NCRR staff. | Dr. Ford | 12/19/2008 |
| 2 | Send "Doing Business with the CTSA's" document to Dr. Ford | Ms. Portilla | 12/17/2008 |
| 3 | Present protocol of Pilot on Contracts to Pilot and Metrics Committee | A Rifkind, L Salberg | 12/17/2008, 10: AM ET |
| 4 | Present protocol of Pilot on IRB to Pilot and Metrics Committee | R Hutchinson, K Uscinski | 12/17/2008, 10: AM ET |
| 5 | Obtain collaboration agreement with BERD KFC for both pilots | D Rosenblum | 12/16/2008 |
| 6 | Complete list of Workshop Planning Volunteers | D Rosenblum | 12/17/2008 |