

## Clinical Research Management (CRM) Taskforce October 17, 2008 Meeting Summary

**Attendees:** T. Johnson, Yale Univ. (Co-Chair); D. Rosenblum, NCCR (NIH Coordinator); G. Bernard, Vanderbilt Univ.; J. Ennever, Columbia Univ.; D. Ford, Johns Hopkins Univ.; R. Hutchinson, Univ. of Michigan; B. Martell, Univ. of Chicago; L. Portilla, NCCR; E. Rubinstein, Univ. of Rochester; J. Sachs, NCCR; L. Salberg, Vanderbilt Univ.; K. Uscinski, Yale Univ.

**Time:** 3:00 PM – 4:00 PM ET

The **Contracts and IRB taskforces** have made progress in surveying centers, identifying metrics and processes in use at the centers, and defining the conditions that could be used to analyze processes across the CTSA. They are beginning to consider the nature of a pilot study to be followed by a broader, CTSA-wide study. Dan Ford and others made specific suggestions about protocol classification, number and nature of metrics, starting points and finishing points, difficulty of obtaining data/compliance/completion, nature of sponsor, and data management. Each taskforce should report back at the next CTSA Clinical Research Management Taskforce meeting on progress it has made defining metrics and recommending criteria for baseline protocol classification, data sets to describe the processing system (e.g. personnel characteristics, workload, ancillary approval groups, master agreements, etc.).

Another taskforce (“**Protocol Taskforce**” within the CTSA Clinical Research Management Taskforce) will be established to review the taskforce recommendations and develop pilot studies. The Protocol Taskforce will include some or all of the following: Dan Ford, Rob Califf, Mike Joyner, Tesheia Johnson, Gordon Bernard, Ray Hutchinson, Kathleen Uscinski, Libby Salberg, Adam Rifkind, (Dan Rosenblum, NIH coordinator). The goal is to complete the final draft of the pilot protocols by December 1, 2008.

**Publication:** Dan Ford is about halfway through the draft of a paper to be submitted to a peer-reviewed journal. His goal is to complete the draft by November 1, 2008.

**Workshop:** Tesheia Johnson will head a team to develop a plan for a Workshop for June 22-23, even though the 23<sup>rd</sup> is her wedding anniversary. She will need a half dozen volunteers. They should contact Dan Rosenblum e-mail: [rosenblumd@mail.nih.gov](mailto:rosenblumd@mail.nih.gov) or Paymon Hashemi ([hashemi\\_paymon@bah.com](mailto:hashemi_paymon@bah.com)).

**Membership** on the CTSA Clinical Research Management Taskforce is currently open to all CTSA sites. However, the CCSC is working on a plan to restructure participation in all committees in the near future to match the Strategic Plan. Members should watch for announcements.