Data Coordinating Centers' Best Practices Working Group
May 24-25, 2011
National Heart, Lung, and Blood Institute
6701 Rockledge Drive
Rooms 9100-9104

Day 1
9:00-5:30
NIH Videocast (Day 1 only) available at http://videocast.nih.gov/

9:00-9:10 NHLBI Welcome — **Dr. Lauer**

9:10-9:30 Welcome and Introductions — **Drs. Lee and McKinlay**

- Review goals of the WG in the context of different DCC models (Networks, Multicenter Trials, Multi-site collaborations, CTCC/DCCC models incorporating DCC and CCC work scopes)
  - To understand current capabilities of DCCs
  - To identify minimum requirements of a DCC to support a large clinical program
  - To understand the costs associated with services or practices
  - To compile a compendium of "Best Practices" (define best practices)
  - To write review criteria for FOAs to reflect our expectations for an effective DCC
- Summarize meeting format

9:30-10:30 Developing Partnerships between Institute and DCC Staff

- *Robert Byington (Wake Forest University), Marissa Miller (NHLBI)* will discuss the importance and processes for developing a shared vision for a clinical program, problems and solutions when the visions are discordant.

10:30-11:30 Trial Operations

- *Sheryl Kelsey (University of Pittsburgh), Mary Horowitz (Medical College of Wisconsin), Don Stablein (Emmes)* will discuss the following key points about trial operations in multicenter clinical research:
  - Optimal organizational structure
  - Main types of services provided
  - Types of personnel needed
  - Best modes of communication
  - Development and implementation of protocols, policies and procedures
  - Challenges for the future

11:30-12:30 Lunch

12:30-1:30 Human Subjects Protections and Regulatory Affairs

- *Curtis Meinert (Johns Hopkins University), Daniel Molina (Technical Resources International) and Liz Wagner (NHLBI)* will discuss key points in multicenter clinical research:
  - Human subjects training methods/certifications and IRB-related regulatory issues
  - Working with the FDA , IRB, OHRP and other regulatory bodies (IND/IDE management, AE reporting)
  - Anonymized bio-repositories/data sets for future genetic and other assays, and related emerging issues

1:30-3:00 Data Management and Analysis

- *Liz Thom (George Washington University), Bruce Thompson (Clinical Trials and Survey Corporation), Mike Miller (Wake Forest University) and Foss Tighe (New England Research Institute)* will discuss key points in multicenter clinical research:
  - o Optimal types of data capture and transfer systems
  - o Eligibility, randomization, recruitment, and retention methods
  - o Technologies for randomization systems and IT security measures
  - o Analytic strategies (interim and final data analyses, reports preparation)

3:00-3:15 Break

3:15-4:15 Quality Control/Quality Assurance

- *Sarah Pressel (University of Texas – Houston), and Selma Kunitz (KAI Research Inc.)* will discuss key points in multicenter clinical research:
  - o Quality Control - site performance/monitoring, data acquisition, analyses, reports, etc
  - o Quality assurance audits – both internal by DCC institution and external by sponsor

4:15-5:15 Costs of DCC Services

- *Jack Cahill and Marsha Hasson (Westat), Diane Catellier (Research Triangle Institute) and Trina Billingsley (George Washington University)* will present on methods they use to determine accurate costs for specific services and payment structure for the 3 largest costs associated with large clinical trials; site payments, monitoring and DCC costs.

5:15-5:30 Wrap-up (15 minutes)

Day 2
8:00-2:00

8:00-8:10 NHLBI Welcome/ Comments — Dr. Shurin

8:10-8:40 Key Concepts from Day 1 — Drs. Lee and McKinlay

8:40-9:10 A Clinical PI's Vision of a Great DCC

- *Stephanie Davis (University of North Carolina)* will discuss PI needs and beneficial services/elements of an efficient DCC

9:10-9:25 Charge to Break-out Groups — Drs. Lee and McKinlay

9:25-11:25 Break-out Groups

- Each group will be assigned a facilitator and recorder.
- Each group will compile "best practices" for one of the 4 topic areas.

11:25-1:25 Working Lunch and Reports from Groups with Discussion

1:25-2:00 Next Steps — Drs. Lee and McKinlay

Break-out Group Assignments:

Trial Operations (Conference Room 9100-9104)

- Sheryl Kelsey (University of Pittsburgh)
- Mary Horowitz (Medical College of Wisconsin)
- Don Stablein (Emmes)
- Jack Cahill (Westat)
- Robert Byington (Wake Forest University)
- Marissa Miller (NHLBI)
- Jewell Martin (NHLBI) *Recorder

Human Subjects Protections and Regulatory Affairs (Conference Room 9091)

- Curtis Meinert (Johns Hopkins University)
- Daniel Molina (Technical Resources International)
- Liz Wagner (NHLBI)
- Trina Billingsley (George Washington University)
- Vicki Pemberton (NHLBI) *Recorder

Data Management and Analysis (Conference Room 8046)

- Liz Thom (George Washington University),
- Bruce Thompson (Clinical Trials and Survey Corporation)
- Mike Miller (Wake Forest University)
- Foss Tighe (New England Research Institute)
- Marsha Hasson (Westat)
- Myron Waclawiw (NHLBI) *Recorder

Quality Control/Quality Assurance (Conference Room 7111)

- Sarah Pressel (University of Texas– Houston)
- Selma Kunitz (KAI Research Inc.)
- Diane Catellier (Research Triangle Institute)
- Stephanie Davis (University of North Carolina)
- Julie Bambad (NHLBI) *Recorder

Not Assigned:
Sonja McKinlay (New England Research Institute)
Kerry Lee (Duke Clinical Research Institute)