



# NINDS INSPIRE Workshop

Improving Neurology Subject (and Provider) Participation In the Research Enterprise

June 20 – 21, 2013

NIH Neuroscience Center in Bethesda, MD

## Workshop

### Protocol Design to Minimize Burden

#### INTRODUCTION:

A successful clinical trial answers an important question rapidly and with minimum cost. Careful preparation, adequate resources, and meticulous execution are the basic requirements. When a trial stumbles, it is sometimes the result of an error in the estimated burden imposed by the trial on participants or investigators. More precisely, it is usually an error in anticipating how participants or investigators will estimate, for themselves, the balance of benefits and burdens. The purpose of this workshop is to develop a deeper understanding of this balance as a basis for improving trial design, peer-review, and progress monitoring.

#### Specific Workshop Objectives

1. Develop taxonomies for:
  - a. The manifestations or consequences of excessive burden relative to benefit
    - i. How does the problem reveal itself?
  - b. The types of burden encountered by
    - i. Investigators
    - ii. coordinators
    - iii. Participants
    - iv. Sponsors
  - c. Mitigation strategies
2. Develop an understanding of the causes of excessive burden, relative to benefit, as a cause of problems in the conduct of a trial.
3. Develop a list of potential solutions to mitigate burden and assure balance in burden and benefit
4. Develop recommendations for improving the review process to account for burden
  - a. How can reviewers recognize a trial that may be vulnerable to burden?
  - b. What mitigation/planning strategies should reviewers look for?
5. Develop recommendations for investigators and sponsors

<b>Agenda</b>		
<b>Session 1: Developing a Taxonomy of Burden. Thursday June 20, 10:00-12:00pm</b>		
<b>Time</b>	<b>Topic/event</b>	<b>Convener</b>
5"	Introductions and agenda	Walter Kernan
30"	Framing the Topic: 3 Trials with various challenges*	Walter Kernan/Yuko Palesch
20"	Discussion: Taxonomies of burden for: Participants, coordinators, investigators, sponsors	Walter Kernan
10"	Break	
55"	Refine Taxonomies	Walter Kernan
*IRIS, COSS, PROTECT		



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<b>Agenda</b>		
<b>Session 2: Mitigation Strategies for Burden. Thursday June 20, 3:00-4:30pm</b>		
<b>Time</b>	<b>Topic/event</b>	<b>Convener</b>
5"	Introductions and agenda	Bill Barsan
15"	Case Review – CLEAR IVH	Dan Hanley/Karen Lane
15"	Case Review - RAMPART	Robert Silbergleit/Bill Barson
55"	Discussion*	Bill Barsan
*As part of discussion, consider parsimony in data collection and the common data elements project.		
<b>Session 3: Guidance for Reviewers. Friday June 21, 10:00-12:00pm</b>		
<b>Time</b>	<b>Topic/Event</b>	<b>Convener</b>
10"	Introductions and agenda*	Yuko Palesch
20"	An Scientific Review Officer's perspective	Shanta Rajaram
15"	Review of failed published pilot trial	Dorothy Edwards
40"	Discussion: To develop or not to develop guidance for reviewers? Who should be on the review panel?	Yuko Palesch
10"	Break	
35"	Suggested Guidance for guidance, if appropriate	Yuko Palesch
*Description of usual advice to reviewers on NSD-K. Hand out instructions.		
<b>Session 4: Shaping Final Recommendations. Friday June 21, 2:30-3:30pm</b>		
<b>Time</b>	<b>Topic/Event</b>	<b>Convener</b>
5"	Introductions and agenda	Dorothy Edwards
10"	Review taxonomies	Walter Kernan
45"	Devise recommendations for: Investigators & Sponsors	Dorothy Edwards