



NINDS INSPIRE Workshop

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

June 20 – 21, 2013

NIH Neuroscience Center in Bethesda, MD

The NINDS INSPIRE Workshop:

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

The Mission of NINDS is to reduce the burden of neurological disease through biomedical research. The ability of NINDS to facilitate faster cures and reduce the burden of neurological disease in the public is significantly threatened by the failure of studies to complete on time and within budget. Although this is not a situation unique to NINDS or to NIH-funded clinical studies, there are barriers unique to neurological research that should be explored in order to develop best practices for enhancing recruitment and retention to clinical studies funded by NINDS.

To that end, we have organized a workshop that brings together a number of stakeholders in the neurological research enterprise, including:

- Clinical research investigators
- Project coordinators and managers
- Study coordinators
- Disease advocates
- Patients
- Caregivers

The goals of the workshop are to bring these stakeholders to the table to discuss a number of themes relevant to neurology research design in order to teach and learn from one another. We hope to develop tools, resources, ideas and/or a list of "best practices" that inform the most appropriate process for designing neurological research that optimizes opportunities for efficient site selection, activation, management, recruitment and retention. **The ultimate goal of the workshop is a whitepaper or other report/toolkit of best practices, tools, and ideas to improve neurological study design in ways that enhance the potential for efficient recruitment and retention.**

The workshop includes:

- 4 plenary/panel sessions over two days (each morning and afternoon), intended to stimulate creative thinking about breakout topic sessions between
 - **Patient Centered Study Design in Neurology**
 - **The State of the Clinical Research Enterprise**
 - **Patient and Public Engagement**
 - **More than Metrics: Where the Qualitative Meets the Quantitative**
- 5 breakout roundtable working sessions that will meet 4 times (twice each day), including:
 - 1(a): Patient-Centered Research In Neurology**
 - 1(b): How Much Is Enough? Protocol Design, Burden Minimization and Data Collection**
 - 2: Communication: Consent, Outreach, Messaging, Motivating and Social Marketing**
 - 3: Recruitment & Retention Planning: Motivation, Disruptive Innovation and Leveraging New Technologies**
 - 4: It's About More Than Metrics: Study Management, Implementation & Activation**

NINDS INSPIRE is a **working** meeting. Attendees should come prepared to both contribute and learn and leave **inspired** with tools, ideas and new ways of thinking about clinical research in neurology that can be immediately implemented in their daily work.

AGENDA

Thursday June 20, 2013

7:00 – 7:45 AM	Onsite registration, sign-up for roundtable sessions		NSC E
7:45 AM	Welcome, Orientation & Scheduling	Jamie Roberts, NINDS	NSC Conf Room C
8:00 AM	Opening Remarks	Story Landis, PhD Director, NINDS	
8:10 AM	Opening Remarks	Robert Griggs, MD, Steering Committee Chair	
8:20 AM	Introduction of First Panel & Speakers	Petra Kaufmann, MD Director, Office of Clinical Research	
PANEL I	Patient-Centered Study Design In Neurology		NSC Conf Room C
	Session Chair: Robert Griggs, MD		
8:25 AM	Designing Patient-Centered Research for Rare Diseases Robert Griggs, MD University of Rochester Medical Center (URMC)		
8:43 AM	Defining Patient-Centered Research and Engaging the Public To Drive the Agenda David Hickam, MD Patient Centered Outcomes Research Institute (PCORI)		
9:00 AM	Perspectives on Integrating the Needs of Minority and Underserved Populations When Designing Research Questions and Protocols Dorothy Edwards, PhD University of Wisconsin, Madison		
9:15 AM	Panel Q & A Robert Griggs, MD David Hickam, MD Dorothy Edwards, PhD	Lauren Verizzo Veronica Todaro	
9:30 AM	Break, locate breakout session rooms		
10:00 – 12:00 PM	Roundtable working group sessions 1 - 4		Various tbd
	1(a): Patient Centered Research in Neurology Session Co-Chairs: Robert Griggs, MD, David Hickam, MD		
	1(b): How Much Is Enough? Protocol Design, Burden Minimization and Data Collection Session Chair: Walter Kernan, MD		
	2: Communication: Consent, Outreach, Messaging, Motivating and Social Marketing Session Co-Chairs: Peggy Clark, RN, MSN, PNP, Chris Speed, & Barbara Tilley, PhD		
	3: Recruitment Planning: Motivation, Disruptive Innovation and Leveraging New Technologies Session Chair: Steve Mayo, DrPH		
	4: More Than Metrics: When the Quantitative Meets the Qualitative in Study Management Session Chair: Scott Powers, PhD		

12:00 – 1:00 PM **Lunch (on own or at special topic table in NSC cafeteria)**
 Grab your lunch in the NSC cafeteria and join the numbered table for the topic that interests you for an informal discussion

Special Topics Lunch Tables:

1. Innovative Approaches to Feasibility Assessments & Site Selection –
Moderator: J. Roberts
2. Harnessing Online Conversations to Support CR –
Moderator: tbd
3. Using Performance Data for Site Selection –
Moderator: S. Mayo
4. Social Media as a Recruitment & Retention Tool –
Moderator: E. Buchanan
5. Engaging and Motivating CR Sites –
Moderator: H. West, J. Spilker
6. Engaging Providers in CR –
Moderator: B. Tilley, PhD
7. Designing & Implementing Enrollment Plans -
Moderator: R. Hallarn
8. Recruiting for Rare Disease Studies –
Moderator: R. Griggs, L. de Blicke
9. Metrics and Measurements: Separating the Wheat From the Chaff -
Moderator: C. Pierre
- 10: Working with Advocacy –
Moderator: B. Patrick-Lake
- 11: Community Engagement and Outreach –
Moderator: B. Boden-Albala

1:00 PM Regroup NSC Conf Room C

PLENARY I The State of the Clinical Research Enterprise NSC Conf Room C

1:05 – 1:10 PM Introduction of Plenary I Speakers Jamie Roberts, NINDS

1:10 - 1:55 PM How Well Are We Meeting Public Health Needs with Clinical Research?
 Changing the National Mindset
Ken Getz
Center for Information and Study on Clinical Research Participation

1:58 – 2:20 PM Structural and Systemic Barriers to the Inclusion of Minorities in Neurological Research
Bernadette Boden-Albala, PhD
Mt. Sinai School of Medicine, New York, NY

2:20 – 2:45 PM **Plenary Q & A**

2:45 – 3:00 PM Break, locate breakout session rooms

3:00 – 4:30 PM	Roundtable working group sessions 1 - 4	Various tbd
	<p>1(a): Patient Centered Research in Neurology Session Co-Chairs: Robert Griggs, MD, David Hickam, MD</p> <p>1(b): How Much Is Enough? Protocol Design, Burden Minimization and Data Collection Session Chair: Walter Kernan, MD</p> <p>2: Communication: Consent, Outreach, Messaging, Motivating and Social Marketing Session Co-Chairs: Peggy Clark, RN, MSN, PNP, Chris Speed, & Barbara Tilley, PhD</p> <p>3: Recruitment Planning: Motivation, Disruptive Innovation and Leveraging New Technologies Session Chair: Steve Mayo, DrPH</p> <p>4: More Than Metrics: When the Quantitative Meets the Qualitative in Study Management Session Chair: Scott Powers, PhD</p>	
4:45 – 5:00 PM	Regroup, round-up, scheduling, adjourn	NSC Conf Room C
5:00 – 6:00 PM	CLOSED SESSION: Steering committee, roundtable facilitators, OCR staff	NSC 2172

Friday June 21, 2013

7:30 AM	Welcome, review previous day's work, etc.	Jamie Roberts, NINDS	NSC Conf Room C
PANEL II	Patient and Public Engagement Session Chair: Walter Kernan, MD		
7:45 AM	Introduction of Panel II	Jamie Roberts, NINDS	
7:50 AM	Educating the Public about CTs and the Commitment to Participate Walter Kernan Yale University, New Haven, CT		
8:15 AM	Asking the Right Question: Communication and the Consent Process Terry Albrecht, PhD Wayne State University, Detroit, MI		
8:40 AM	Inclusion, community engagement, and The RECRUIT Study Barbara Tilley, PhD University of Texas, Houston		
9:00 AM	Panel Q & A Walter Kernan, MD Teri Albrecht, PhD Barbara Tilley, PhD Bernadette Boden-Albala, PhD Marian Emr (NINDS)	Rose Hallarn, ResearchMatch.org Helen West, MMG Jen Farmer, FARA Dorita DeLemos Down (stroke survivor, Circle of Rights)	
9:30 AM	Break, locate breakout session rooms		

10:00 –12:00PM

Roundtable working group sessions 1 - 4

Various tbd

1(a): Patient Centered Research in Neurology

Session Co-Chairs: David Hickam, MD

1(b): How Much Is Enough? Protocol Design, Burden Minimization and Data Collection

Session Chair: Walter Kernan, MD

2: Communication: Consent, Outreach, Messaging, Motivating and Social Marketing

Session Co-Chairs: Peggy Clark, RN, MSN, PNP, Chris Speed, & Barbara Tilley, PhD

3: Recruitment Planning: Motivation, Disruptive Innovation and Leveraging New Technologies

Session Chair: Steve Mayo, DrPH

4: More Than Metrics: When the Quantitative Meets the Qualitative in Study Management

Session Chair: Scott Powers, PhD

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Moderator: B. Boden-Albala

1:00 PM	Regroup, Introduction of Panel III	Jamie Roberts, NINDS	NSC Conf Room C
PANEL III	More than Just Metrics: Where The Quantitative Meets the Qualitative		
	Session Chair: Scott Powers, PhD		
1:05 PM	The Intersection of Central Study Management and Local Site Needs: Aligning for Efficiency and Productivity Scott Powers, PhD University of Cincinnati		
1:20 PM	Performance Metrics to Motivate or Demotivate Improvements in Productivity and Efficiency Steve Mayo, DrPH Emissary		
1:35 PM	Identifying the Right Metrics and Benchmarks to Measure Christine Pierre Society for Clinical Research Sites		
1:50 PM	The Internet as a Research Platform: Ethical Implications Elizabeth Buchanan, PhD University of Wisconsin, Stout		
2:05 PM	Panel Q & A Scott Powers, PhD Steve Mayo, DrPH Christine Pierre, PhD Elizabeth Buchanan, PhD		
	Barbara Tilley, PhD Dorothy Edwards, PhD Judy Spilker, RN Valerie Stevenson		
2:20 PM	Break, locate breakout session rooms		
2:30 – 3:30 pm	Roundtable working group sessions 1 - 4		Various tbd
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	4: More Than Metrics: When the Quantitative Meets the Qualitative in Study Management Session Chair: Scott Powers, PhD		
3:30 – 3:45 pm	Break		
3:45 – 5:15 pm	Presentations/Summaries from Roundtable Working Groups		NSC Conf Room C
5:15 – 5:30 pm	Closing remarks, wrap-up, adjourn workshop Jamie Roberts, NINDS		
5:30 – 6:00 pm	CLOSED SESSION: Steering committee, roundtable facilitators, OCR staff		NSC 2172

My Schedule Notes: