



NINDS INSPIRE Workshop

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

June 20 – 21, 2013

NIH Neuroscience Center in Bethesda, MD

Breakout Group/Workshop: 1a Patient Centered Research

Introduction:

That “clinical research should be patient centered” is a self-evident truth. However, the “patient-centeredness” of clinical research is a multi-dimensional concept that includes the topics of the other three workshops and encompasses many domains including:

- The development and collection of outcomes that are important to patients
- The burden of participation in the research
- The engagement of patients/families/caregivers in the research
- The design of the study
- How information is shared among participants, families, clinician investigators, and the sponsor
- The involvement of patients in all stages of a research project: Reviewing objectives and design, method of obtaining consent and much more
- Involving a diverse population of subjects
- Research on the processes and experiences

“Patient-centered” either is or will soon become a term used by researchers to bless their own particular viewpoint as to what should be studied and how it should be studied.

Workshop goals:

- To consider how patient-centered outcomes can facilitate research and patient recruitment and retention
- To consider strategies to foster (and barriers that impede) patient engagement, involvement, participation, recruitment
- To consider elements of study design amenable to patient input
- To identify relevant topics for research and/or solution seeking
- To develop templates or check lists useful for all stages of study design and review.
- To consider ways to facilitate communications among patients, clinicians and investigators before, during and after the study



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Group 1a: Patient Centered Research

Agenda

Session I: Focusing the Issues (1)

Thursday, June 20

10:00 AM – 12:00 Noon

10:00 – 10:05 AM	Introductions	Berch Griggs
10:05 - 10:25 AM	Patient-centered outcomes: Implications for study design and patient recruitment	David Hickman
10:25 - 10:45 AM	Empowering patients	Ronnie Todaro
10:45 – 11:00 AM	Break	
11:00 – 11:20 AM	Optimal use of registries, telemedicine and advocacy organization to entice research participants	Lisa de Blicke
11:20 – 11:40 AM	Designing studies to provide answers that patients are asking	Dan Corcos
11:40 – 11:50 AM	Navigating between compassion and study rigor	Holly Peay
11:50 – 12:00 Noon	Summarize	Berch Griggs David Hickam

Each talk should leave 5 minutes or more for discussion.

Session 2: Focusing the Issues (2)

3:00 – 4:30 PM

3:00 – 3:05 PM	Introduction	David Hickam
3:05 – 3:20 PM	Enticing patients to enter and remain in the study	Dixie Ecklund
3:20 – 3:30 PM	Comments from a patient/an investigator	Lauren Verlizzo
3:30 – 4:00 PM	Other attendees?	

Each talk should leave 5 minutes or more for discussion.



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Session 3: Patient Centered Research

Friday, June 21

10:00 AM – 12:00 Noon

- Summary of previous sessions: David Hickam
- Other topics essential to include relative to patient-centered research
 - “The one page consent form” [or other approach to promote patient understanding]
 - Special populations: children, cognitively impaired, others unable to consent
 - Fostering the involvement of a diverse, multi-ethnic population
 - Fostering a collaborative study atmosphere
 - Disclosing and managing conflicts of interest, biases of investigators; presenting these to research subjects
 - Investigator, patient and advocate equipoise
 - Managing expectations for study processes and timelines (i.e., extension, reinforcing possibility of trial stopping early, eligibility for future phases)

Session 4: Final Session: 3:30 – 4:30 PM

- Weighting of issues considered:
- Importance?
- In need of research?
- Needing further discussion



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Group 1b 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

Agenda		
Session 1: Developing a taxonomy of Burden. Thursday June 20, 10:00-12:00pm		
Time	Topic/event	Convener
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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Group 1b Workshop: Protocol Design to Minimize Burden

Agenda		
Session 2: Mitigation Strategies for Burden. Thursday June 20, 3:00-4:30pm		
Time	Topic/event	Convener
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.		
Session 3: Guidance for Reviewers. Friday June 21, 10:00-12:00pm		
Time	Topic/Event	Convener
10"	Introductions and agenda*	Yuko Palesch
20"	An Scientific Review Officer's perspective	Shanta Rajaram
15"	Dos and Don'ts in Grant Reviews	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		
Session 4: Shaping Final Recommendations. Friday June 21, 2:30-3:30pm		
Time	Topic/Event	Convener
5"	Introductions and agenda	Dorothy Edwards
10"	Review taxonomies	Walter Kernan
45"	Devise recommendations for: Investigators & Sponsors	Dorothy Edwards



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Group 2

Communication: Consent, Outreach, Messaging, Motivating and Social Marketing Session
Co-Chairs: Peggy Clark, RN, MSN, PNP, Chris Speed, & Barbara Tilley, PhD

Outline:

1. Developing a strategic communications plan for neurological studies
2. Using a communications model for success
3. Communicating effectively before, during and after the recruitment process
4. Utilizing resources and partnerships

Session I: Developing a strategic communications plan for neurological studies

(following Panel I)

- 1) How do you develop a strategic communication plan in advance of recruitment?
- 2) What makes communicating with neuro populations different and more difficult (e.g. rarity of disease, acute vs. chronic studies, different audiences that may need to be identified)?
- 3) What considerations/principles do you need to consider to develop a document/checklist/framework or similar tool to that can serve as a starting point?
- 4) Are there tools available that can facilitate more effective communications planning? Would logic models be useful?
- 5) Can we develop a flow chart or decision tree that would allow study teams to answer questions about the specific needs of a given study (e.g. study type, patient population, target audiences, etc.) that a good communication plan should include?



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Group 2

Communication: Consent, Outreach, Messaging, Motivating and Social Marketing (cont')

Session II: Using a communications model for success

(following Plenary I)

WHO: Primary and secondary audience identification

- 1) Who is the primary audience that you are talking to? (*Potential participants? Those who are in a position to influence potential participants? Champions in the community?*)
- 2) What is the level of engagement of the target population and advocacy groups in your community when it comes to clinical research?

WHAT: Determining messages

- 1) What message do you need to convey? What do they hear when you say it?
- 2) What is going to make them pay attention to your message? (*Emotion? Personal relevance? Facts?*)
- 3) How do you develop culturally sensitive, relevant and meaningful messages about the benefits of clinical research participation for various communities? (*What role do demographics play? Other factors?*)
- 4) What is the outcome you're looking for?

WHERE/HOW: Outreach Planning

- 1) What are the best means to reach your audience? (*TV/radio/print? Online/social media?*)
- 2) Who do they trust? (*Community gatekeepers? Medical practitioners?*)
- 3) What media outlets make the most sense for your budget?

WHY:

- 1) Why should they be interested (*Altruism vs. Realism? What's in it for them?*)



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Group 2

Communication: Consent, Outreach, Messaging, Motivating and Social Marketing (cont')

Session III: Communicating effectively before, during and after the recruitment process *(following Panel II)*

- 1) What are the best ways to reach your target audience(s) before, during and after the recruitment process?
- 2) What models have worked or not worked? *(case studies, exercises, messaging issues)*
- 3) Are you creating awareness or do you want recipients to take action? At what stage?
- 4) Communication and consent: are we asking the right questions?
- 5) What are the characteristics/clues that a subject may not be a good fit *(e.g. that they may not be committed to staying in the study, that they may not be adherent to the treatment regimen)*?
- 6) What is the role of performance tracking? *(How will you know when tactics are working? What do you do if an expensive tactic is not working?)*

Session IV: Utilizing resources and partnerships

(following Panel III)

- 1) Is the target audience *(patient, provider, lay community)* aware of the study and/or understand the need for the study and can you leverage that awareness?
- 2) How can engaging advocacy groups benefit the neurological clinical research enterprise?
- 3) What do the advocacy groups need from research teams? What do research teams need from the advocacy groups?
- 4) What is the breadth of minority representation in advocacy groups?
- 5) How do you access and engage the communications experts at your local institution and at NINDS?
- 6) How do we change the culture to something similar to Pediatric Oncology Research *(every patient in a trial)*?
- 7) How can you better engage and inform the public about the social good that is clinical research? What is your role in improving awareness?



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Working Group #3 Agenda

Recruitment Planning: Motivation, Disruptive Innovation and Leveraging New Technologies

We will approach recruitment planning from 3 different perspectives. First, from the perspective of the sponsor and site team, then from the perspective of the study participant and finally we will look at ethical aspects of recruitment, especially in terms of using social recruitment tools.

The panelists will make brief presentations to introduce topics from each perspective and then lead the audience in a group discussion. Panelists and attendees will be asked to share differing opinions, new ideas and practical approaches from their own experiences.

Session 1: The Sponsor's & Site Team's Perspective Part 1 (Thursday, 10:00 – 12:00)

- Intros & Agenda Review
- Recruitment & Retention Plans
- Centralized Trial Support

Session 2: The Sponsor's & Site Team's Perspective Part 2 (Thursday, 3:00 – 4:30)

- Recruitment Strategy
- Practical Applications

Session 3: The Study Participant & Community Perspective (Friday, 10:00 – 12:00)

- Intros & Agenda Review
- Potential Study Participant Education and Community Support
- Patient-driven Initiatives & Social Aspects

Session 4: Recruitment from an Ethical Viewpoint (Friday, 2:30-3:30)

- Ethical Implications of Recruitment Technology

Expected Deliverables

- Mock Recruitment Plan
- List of Recruitment Resources



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Group 4: More Than Metrics

Chair* / Facilitators & Core Members

Scott Powers, PhD* (CHAMP Study)
 Judy Spilker, RN (IMS III Trial)
 Patient / Parent
 Christine Pierre (metrics, cycle times)
 Nazem Atassi, MD (NEXT)
 Marianne Kearney (NEXT)
 Valerie Stevenson (NETT)

Invited Attendees:

Kim Hart
 Mariann Ward, ARNP
 Karen Johnston, MD
 Susan McMahan, RN

Thursday June 20, 10:00-12:00pm		
Agenda		
<p>Session 1: Discuss the attributes, skills, and needs of a project manager as a team member for large NIH-funded clinical trial in neurology. Goal would be to generate a sense of best practices and training needs.</p>		
Time	Topic/event	Convener
	Discussion: Evolution of PM role in NIH funded trials	
	Attributes of PM*	
	Skills of a PM*	
	Refine attributes and skills for best practice and training needs	
Thursday June 20, 3:00-4:30pm		
Agenda		
<p>Session 2: Project management and leadership applied to the central coordinating center context. Goal would be to identify the processes in terms of the lifespan of an NIH funded clinical trial in neurology from study planning to grant submission to trial launch to trial execution to trial closeout.</p>		
Time	Topic/event	Convener
20 min	How can the coordination center plan and test realistic recruitment strategies before trial launch?	Nazem Atassi, Mariann Ward
20 min	What performance metrics should the coordination center collect in order to improve trial recruitment and retention?	Nazem Atassi, Mariann Ward
10 min	Break	
20 min	How can the coordination center enhance recruitment?	Nazem Atassi, Mariann Ward
20 min	How can the coordination center help maintain good trial retention?	Nazem Atassi, Mariann Ward



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Friday June 21, 10:00-12:00pm

Group 4: More Than Metrics Agenda

Session 3: Project management and **leadership** applied to the **trial site context**. This session will explore the relationship between site management and recruitment. Goal would be to take the site perspective on needs, metrics, efficiencies, and how to best work with a project manager and central trial team (clinical coordinating center and data coordinating center).

Time	Topic/Event	Lead Discussant
20 minutes	Resources and facilities assessment –Site selection is more than just about machines and space, assessing and understanding site personnel and interpersonal dynamics needed for successful subject recruitment and retention. <ul style="list-style-type: none"> • Is there an appropriate trial team available? • What are the interpersonal dynamics for successful site recruitment and retention? • How do we assess the investigators commitment to randomization? • Are the skills available for obtaining ICS? • Are skills available for subject follow-up? • Does early site planning and evaluation prevent last minute “fixing”? 	Judy Spilker, RN
20 minutes	New dimensions in communication with sites - What is the best approach and frequency of contact for building and maintaining a study-wide team? <ul style="list-style-type: none"> • Face to face meetings/visits? • Voice communications - phone calls and conference calls and webinars • Electronic communication -email, list serves, websites, YouTube videos? • Printed resources including study tools and newsletters? • What are <i>other</i> incentives and rewards and recognitions? (personal vs. financial?) 	Judy Spilker, RN
10 minutes	Break	
20 minutes	How can sites use central coordinating and site generated metrics as tools – <ul style="list-style-type: none"> • What benchmarks are best to measure site efficiency? • How do (or not) recruitment tools inspire competition and if not at what point does it backfire? • Do (or can) PV/PD lists really improving quality-protocol compliance? • What are the efficiencies of site data entry and does it affect data quality? • What is the right balance of “Busy work” and recruitment? 	Judy Spilker, RN
20 minutes	Finding and fixing knowledge gaps in clinical and research knowledge at the site level	Judy Spilker, RN
20 minutes	“Sites” as customers – The “how can we help you” approach to site management	Judy Spilker, RN
Final 15-20 minutes	Additional Suggestions and Wrap-Up	All



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Friday June 21, 2:30-3:30pm		
Group 4: More Than Metrics Agenda		
<p>Session 4: Bring the discussions from sessions 1-3 together into a framework for a deliverable. We have discussed the idea of project management along the time line of an NIH grant; what are the take home learnings?</p>		
Time	Topic/Event	Convener
15 minutes	What have we learned about skilled project management?	Scott Powers
15 minutes	How is “skilled project management” applied in the central coordinating center and trial site contexts?	Scott Powers
30 minutes	If we think about the life cycle of an NIH-funded trial, from inception to trial close out, what are the practical learnings from our working group that will advance recruitment and retention of participants, families, and staff?	Scott Powers, Marianne Kearney, Nazem Atassi, Valerie Stevenson, Judy Spilker