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

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 Blieck
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.

Group 1a: Patient Centered Research

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