Roundtable Working Groups Topics	Chair* / Facilitators & Core Members / Sponsored Attendees
1a: Patient-Centered Research in Neurology *Framework (tentative) – to be fleshed out by members prior to workshop* How should you design neurology studies to maximize recruitment and retention? How should you implement recruitment and retention planning in parallel with study design? What does patient-centric study design mean in neurology studies? What do patients offer in terms of driving the research agenda? How should the inclusion of minorities be integrated into designing patient-centric studies in neurology?	Berch Griggs, MD* Daniel Corcos, PhD Lauren Verlizzo Ronnie Todaro Pat Furlong David Hickam, MD (PCORI) Dixie Ecklund (statistician) <u>Invited Attendees</u>: Dorita DeLemos Down, CircleofRights.org (3 time stroke survivor, Hispanic Stroke Advocate) – Bethesda Local Margaret Fulcher (stroke survivor, study subject) Janet Hieshetter, Dystonia Medical Research Foundation Lisa de Blieck
1b: Protocol Design, Burden Minimization and Data Collection: How Much is Enough? *Framework (tentative) – to be fleshed out by members prior to workshop* How can we minimize the burden of participation (for patients, providers, investigators and coordinators)? How much data do we actually need? How many tests/procedures are necessary to answer the question? Is / Should there be a mechanism for measuring the burden of participation in a study? The right trial for the right patient at the right time – ensuring patients understand expectations, responsibilities and rights. How should the inclusion of the needs of minorities/disadvantaged populations be included in determining study design and minimizing burdens?	Walter Kernan, MD* Yuko Palesch, PhD Christina Clark (advocate) Bill Barsan, MD Dorothy Edwards, PhD (Inclusion) Private practitioner (non-academic) Elaine Parreco (stroke survivor, advocate) <u>Invited Attendees</u>: Susan Baker Karen Lane Brien Smith, MD

2: Communication, Consent, Outreach, Messaging, Motivating and the Role of Social Marketing
Framework (draft 1) – to be further fleshed out by members prior to workshop
1. How do you develop a strategic communication plan?
  a. What are the elements of a good communication plan in neuro trials?
  b. Is the community aware and can we leverage that awareness?
2. What tools are already available to facilitate more effective communication planning?
3. Patient and community engagement:
  a. Needs assessment: Who is the community you are trying to reach?
  b. How can engaging advocacy benefit the neurological clinical research enterprise?
  c. What do the advocacy groups need from research teams? What do research teams need from the advocacy groups?
  d. What is the breadth of minority representation in advocacy groups?
4. Messaging
  a. What's the product? Who are the audience(s)?
  b. What messages do we need to convey?
  c. How do you develop culturally sensitive, relevant and meaningful messages about the benefits of clinical research participation for various communities?
  i. What are the best ways to reach your target
	Peggy Clark, RN*
	Chris Speed*
	Barbara Tilley, PhD* (Inclusion, community engagement)
	Jen Farmer, FARA
	Marian Emr, NINDS
	Bernadette Boden-Albala, PhD
	Helen West, MMG
	Teri Albrecht, PhD
	Ken Getz
	Bray Patrick-Lake (advocate)
	
	<u>Invited Attendees</u>:
	Dorita DeLemos Down, CircleofRights.org (3 time stroke survivor, Hispanic Stroke Advocate)
	Jackie Parker
	Dan Woo, MD

DRAFT

audience(s)? ii. What models have worked? (case studies, exercises, messaging issues) d. How can we better engage and inform the public about the social good that is clinical research? i. What is our role in improving awareness? ii. How do we change the culture to something similar to Pediatric Oncology Research (every patient in a trial)? 5. Communication and consent: are we asking the right questions? **Potential Deliverable: Model Template for Developing a Communications Strategy, Points to Consider, List of Existing Communication Tools and Social Marketing Techniques applicable to the Neuro CRE.**	
3: Recruitment Planning: Motivation, Disruptive Innovation and Leveraging New Technologies *Framework (draft 1) – to be further fleshed out by members prior to workshop* • What components are necessary for a well-designed recruitment strategy that addresses the needs of ALL relevant stakeholders and communities? o Defining successful recruitment for an individual study (e.g. what metrics to collect) • How can/should investigators be encouraged to consider recruitment as a business process/plan that requires identifying all of the relevant stakeholders, including: o Patients o Sites o Hospitals (e.g. structural/institutional stakeholders) o Financial stakeholders (hospitals, payers, etc.) o Data consumers (clinicians, advocacy organizations, patients) o FDA (for NDAs) • What tools or messages are necessary to encourage this change in perspective? • How can/should investigators use the new web-based or mobile technologies at our fingertips, including: o How can these tools be used to scale up research in various communities (e.g. disease specific (rare), minorities, etc.)? o What do patients expect in terms of technology? o How can/should we use technology to facilitate their engagement and commitment? o How do minority communities use new technology and how can we engage them with it? **Potential Deliverable: Model Recruitment Plan Template and Checklist of Issues to Consider in the Design of a Recruitment Strategy**	Steve Mayo, DrPH (eClinical technologies expert)* Elizabeth Buchanan, PhD (internet research ethics) Patient / Parent Rose Hallarn, ResearchMatch, CTSA Representative Lily Cappelletti (MJFF) Inclusion specialist Angelica Carter, MMG <u>Invited Attendees</u>: Jenna Linde Kelley Scholz Mary Longbottom Amy Bartlett, NEXT, SMA biomarker study Rob Moss (Seizure Tracker)
4: Study Management: Moving Beyond the Metrics to Where the Quantitative Meets the Qualitative *Framework (tentative) – to be fleshed out by members prior to workshop* What are the characteristics and skills of an effective project manager? What are the skill sets/competencies needed to effectively manage a large, multicenter (multinational) study? Does NINDS need to provide training/education in this area?	Scott Powers, PhD* Chris Speed Judy Spilker, RN Patient / Parent Christine Pierre, PhD Nazem Natassi, MD Marianne Kearney (NEXT) Valerie Stevenson (NETT

DRAFT

What is needed RIGHT NOW to improve efficiency in the start-up period (from NGA to first site activated)? What standard metrics should be collected so benchmarks can be defined? 1) Date final protocol sent to sites 2) Date of IRB decision 3) Date contract sent to site 4) Date contract executed 5) Date of Site Activation 6) Date of First Enrollment 7) Others? How do you plan realistic recruitment trajectories based on site activation delays and other unpredictable variables? Effective site selection and management: What are the Metrics and Optimal Characteristics of effective and efficient sites? What benchmarks should be used to measure site efficiency? Pre-trial registries: is this the way to go? Pros? Cons? What minority inclusion issues need to be addresses in site selection, management, activation and monitoring? What is the relationship between recruitment and site management? What can we do to leverage both to enhance efficiency and quality?	Invited Attendees: Kim Hart Mariann Ward Karen Johnston, MD Susan McMahan, RN

DRAFT