Ad Hoc Working Group on Clinical Trials Enrollment & Retention

Introduction for NCRA

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NIH NATIONAL CANCER INSTITUTE

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Who Am I?

- Epidemiologist by training
- 25 years of research experience
  - Primarily cancer screening and survivorship
  - Healthcare and academic settings
  - Emphasis on care delivery
- Several scientific leadership roles at NCI over past 7 years
  - Currently Lead Scientist for Cancer Care Delivery Research in the NCI Community Oncology Research Program (NCORP)

Why Form This Working Group?

- Financial hardship in general a concern for NCI senior leadership and program staff – always looking for opportunities to increase knowledge and develop interventions
- Congress directed NCI to examine this issue in more detail in the context of clinical trials
- Recognition of the importance of engaging advocates in process
- Do we understand the problem and have the information we need to act effectively?

What is a Clinical Trial?

- NIH definition: "a research study in which one or more human subjects are prospectively assigned to one or more interventions (which may include placebo or other control) to evaluate the effects of those interventions on health-related biomedical or behavioral outcome"
- Ann's expansion:
  - Human subjects include any person (patients, caregivers, clinicians, administrators, etc.)
  - Interventions take many forms (drugs, self-management, communication, electronic, etc.)
  - Control is often a simpler intervention
  - Goal is to see if one intervention is preferable to another
  - NIH trials focus on health

Why is Low Participation in Clinical Trials* a Concern?

- Eligible humans may miss an opportunity to
  - Directly benefit
  - Gain the satisfaction of contributing to science
- Practices and clinicians may be unable to provide the highest possible quality of care
- Scientific progress may be slowed

*Adult cancer

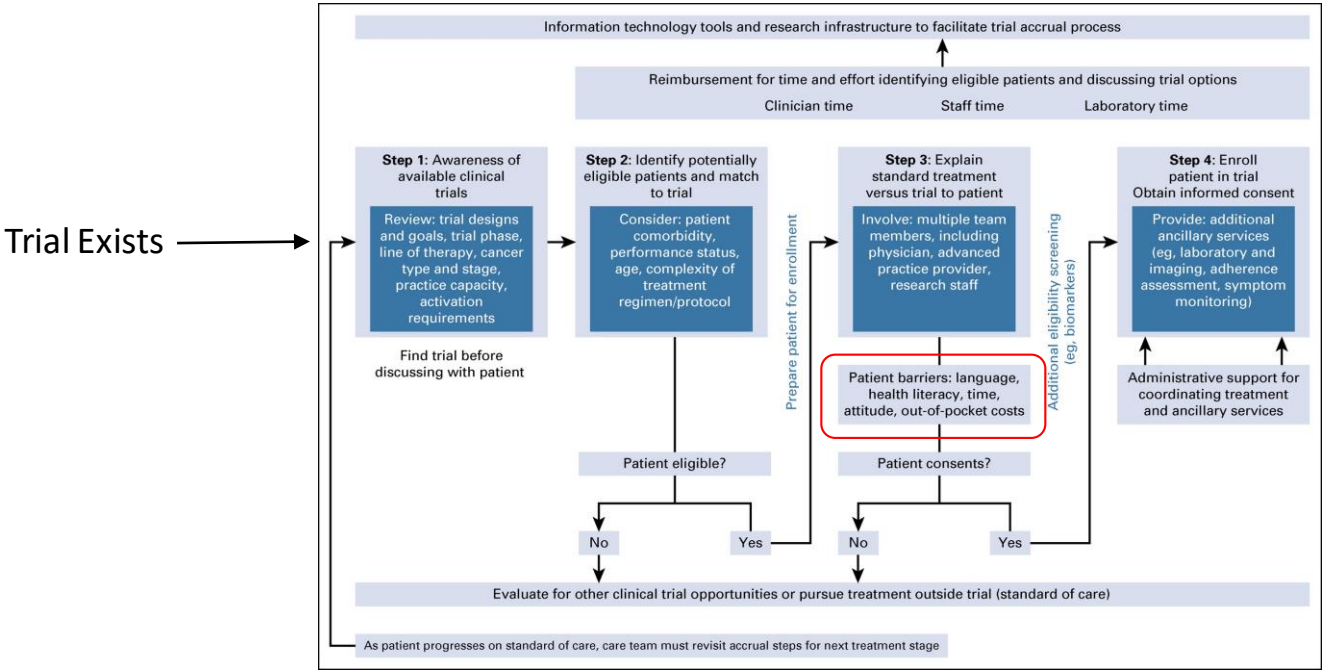

FIG 1. Process model that describes the steps of cancer clinical trial accrual.

Published in: Simon J. Craddock Lee; Caitlin C. Murphy; Ann M. Geiger; David E. Gerber; John V. Cox; Rasmi Nair; Celette Sugg Skinner; *Journal of Clinical Oncology* 2019 371993-1996.
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PATIENT-REPORTED REASONS FOR DECLINING TRIALS

	Rank of Response			
STUDY	**1ST**	**2ND**	**3RD**	**4TH**
Cancer Patients				
Meropol, (2007) [72]	**Fear of side effects** "I fear side effects that might come with treatment on a clinical trial"	**Control** "I am uncomfortable with being randomly assigned (for example, a coin toss) to a treatment"	**Control** "I fear receiving a placebo (for example a sugar pill) on a clinical trial."	**Logistics** "I would be unable to fulfill trial requirements due to logistical barriers such as transportation."
Unger, (2013) [30]	**Control** "Random treatment, and protocol would determine care"	"Did not want treatment"	**Fear of side effects** "Treatment side effects"	"No personal benefit"
Lara, (2001) [139]	**Control** "Desire for other treatment"	**Logistics** "Distance from clinic"	"Unknown"	**Costs** "Insurance denial"
Klabunde, (1999) [111]	"Concerns about experimentation"	"Unspecified"	**Costs** "Concern about cost" and "Insurance refusal"	**Fear of side effects** "Concerns about toxicity"
Zaleta, (2017) [206] (Minorities)	**Control** "Feeling uncomfortable with being randomly assigned to a treatment"	**Control** "Fearing receiving a placebo"	**Fear of side effects** "Fearing side effects that may come with treatment."	**Costs** "Believing that health insurance would not cover a clinical trial."
Javid, (2012) [34]	**Control** "Did not like that protocol dictated treatment"	**Fear of side effects** "Concerned that offered treatment had too many side effects"	Lack of personal benefit "Did not want treatment offered on clinical trial"	**Logistics** "Test and procedures and getting to/from required too much effort"
Public				
CISCRP, (2017) [5] (International)	**Fear of side effects** "Side effects scared me"	**Logistics** "Too many study visits"	"Medical procedures too invasive"	**Control** "Afraid of receiving placebo and too many medical procedures"
Memorial Sloan Kettering, (2016) [95]	**Fear of side effects** "Worried about side effects/ safety"	**Costs** "Uncertain about insurance coverage, out-of-pocket costs"	**Logistics** The CT location is inconvenient"	**Control** "Worried about getting a placebo"
Research America, (2017) [6]	**Fear of side effects** "Too risky" & "Adverse outcomes"	"Lack of trust"	**Costs** "Little or no monetary compensation"	"Lack of access"

American Cancer Society Cancer Action Network. Barriers to Patient Enrollment in Therapeutic Clinical Trials for Cancer – A Landscape Report. 2018.

Functional Statement

The NCRA Council of Research Advocates will convene a Working Group to identify opportunities to promote research aimed at identifying the most successful strategies for improving patient enrollment and retention in cancer clinical trials, particularly for patients from underrepresented and minority populations. The primary focus will be on the financial costs of participation in cancer clinical trials. Secondary consideration will be given to the role of researchers, clinicians, sponsors and other health care organizations in addressing these financial burdens as well as other related inclusion and retention issues.

What is "Promote Research"?

- NCI Mission:

  "NCI leads, conducts, and supports cancer research across the nation to advance scientific knowledge and help all people live longer, healthier lives"

- Activities
  - Research conducted by NCI staff, contractors, and grantees
  - Support infrastructure such as NCORP, NCI-Designated Cancer Centers, Biospecimen Repositories and data resources
  - Training
  - "Convening power"

Membership

- Co-Chairs: Rick Bangs, SWOG (NCRA Member)
  Deb Barton, University of Michigan (CTAC Member)
- Suanna Bruinooge, ASCO
- Dana Dornsife, Lazarex Cancer Foundation
- Annie Ellis, Ovarian Cancer Research Alliance (NCRA Member pend.)
- Mark Fleury, American Cancer Society Cancer Action Network
- Mona Fouad, University of Alabama at Birmingham
- Kathleen Moore, University of Oklahoma
- Adedayo Onitilo, Marshfield Clinic (NCORP)
- Phyllis Pettit Nassi, Huntsman Cancer Center
- Roberto Vargas, University of California San Francisco

Ex Officio NCI Membership

- Andrea Denicoff, Cancer Therapy Evaluation Program
- Lori Minasian, Division of Cancer Prevention
- Sheila Prindiville, Coordinating Center for Clinical Trials
- Sanya Springfield, Center to Reduce Cancer Health Disparities
- Amy Williams, Office of Advocacy Relations

Anticipated Timeline

- July 22: webinar to receive charge from Ned
- July 28: co-chair meeting
- August to ???: deliberation via webinar
- End 2020: final report
- Report presentation to NCRA & other groups TBD