CTTI Informed Consent Project

Agenda of the Expert Meeting held March 10-11, 2015

DoubleTree by Hilton Hotel Washington DC – Silver Spring
8727 Colesville Road, Silver Spring, MD

CTTI MISSION: To identify and promote practices that will increase the quality and efficiency of clinical trials

MEETING OBJECTIVES:

▸ Present findings and conclusions from the project literature review and expert interview series
▸ Solicit feedback and develop consensus on proposed recommendations to enhance the informed consent process
9:00am  CTTI Introduction  
Matthew Harker (CTTI)

9:10am  Welcoming Remarks  
Issue, Project Overview and Meeting Objectives  
Michele Kennett (University of Missouri)

9:25am  Session I: Presentation of the Literature Review & Expert Interviews Results  
Session Facilitator: Zachary Hallinan (The Center for Information & Study on Clinical Research Participation)
Session Objectives:  
► Present and discuss findings and conclusions from the project literature review and expert interviews series

9:30am  Literature Review Findings  
Zachary Hallinan (CISCRP)

10:00am  Expert Interview Findings  
Steve Mikita (Patient Advocate)  
Beverly Lorell (King & Spalding)

10:30am  Discussion

11:00am  Break

11:15am  Session II: The Informed Consent Process: An Interactive Discussion  
Session Facilitator: Jane Perlmutter (Patient Advocate)
Session Objectives:  
► Solicit feedback on proposed recommendations for ensuring a more effective informed consent process to achieve enhanced research participant understanding  
► Solicit feedback on the utility of the proposed informed consent checklist  
► Discuss roadblocks to implementation and steps that can be taken to overcome them

Jayvant Heera (Pfizer)

11:40am  Panel Discussion  
Helen Donnelly (Northwestern University)  
Laura Cleveland (Patient Advocate)  
Linda Neuhauer (University of California-Berkeley)  
Kevin Prohaska (Food & Drug Administration)

12:30pm  Lunch (Provided)
1:30pm  Session III: Training on Conducting the Informed Consent Process
Session Facilitator: Jennifer Lentz (Eli Lilly & Co)
Session Objectives:
► Present examples of innovative informed consent training programs
► Solicit feedback and develop consensus on proposed recommendations related to informed consent process training programs

1:35pm  A Training Program for Improving the Informed Consent Discussion Between Clinical Researchers and Their Subjects
Mary Ellen Cadman (National Institute of Mental Health, NIH)
Julie Brinnall-Karabelas (National Institute of Mental Health, NIH)

1:55pm  Based on a True Story…: Using Re-Enactments of Actual Clinical Visits to Improve Oncologist Communication about Clinical Trials
Susan Eggly (Karmanos Cancer Institute)

2:15pm  Proposed Recommendations for Informed Consent Training Programs
Michele Kennett (University of Missouri)

2:35pm  Discussion

3:00pm  Break

3:15pm  Session IV: Use of E-Consent Technology in the Informed Consent Process
Session Facilitator: Kevin Hudziak (Eli Lilly & Co)
Session Objectives:
► Discuss the advantages and challenges to use of e-consent technology in the informed consent process
► Solicit feedback on proposed recommendations related to e-consent technology in the informed consent process

3:40pm  Proposed E-consent Recommendations
Kevin Hudziak (Eli Lilly & Co)

4:00pm  Panel Discussion
Alison Cooper (Texas Diabetes & Endocrinology)
Ellen Kelso (Chesapeake IRB)
Steve Mikita (Patient Advocate)
Leonard Sacks (Food & Drug Administration)

4:45pm  Wrap-up
Jennifer Lentz (Eli Lilly & Co)

5:00pm  Adjourn

5:30pm  Reception
8:25am  Welcoming Remarks  
   Annemarie Forrest

8:30am  Summary of Day 1  
   Jennifer Lentz (Eli Lilly & Co)

8:45am  Session V: The Informed Consent Document  
   Session Facilitator: Seth Schulman (Pfizer)  
   Session Objectives:  
   ► Solicit feedback and develop consensus on a new proposed Informed Consent Document model

8:50am  The Tiered Consent Model  
   Ross McKinney (Duke University)

9:10am  Moderated Group Discussion  
   Seth Schulman (Pfizer)

10:15am  Break

10:30am  Session VI: Actionable Opportunities for Transformative Change  
   Session Facilitator: Jane Perlmutter (Patient Advocate)  
   Session Objectives:  
   ► Review and provide feedback to proposed recommendations  
   ► Discuss existing barriers to transforming the informed consent process and strategies for overcoming those barriers  
   ► Consider ways to facilitate adoption of proposed project recommendations

10:45am  Break-Out Group Discussion: Actionable Opportunities for Transformative Change

11:45am  Report Out

12:15pm  Large Group Discussion:  
   Actionable Opportunities for Transformative Change  
   Working Lunch (Provided)

2:00pm  Adjourn

For more information, contact the CTTI Informed Consent project manager, Annemarie Forrest, at annemarie.forrest@duke.edu or visit http://www.ctti-clinicaltrials.org.