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 Neuhauser (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 Brintnall-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.