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

CLINICAL TRIALS TRANSFORMATION INITIATIVE

Tuesday March 10th, 2015

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

11:20am **Proposed Recommendations for the Informed Consent Process: Who, How, When, Where**
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)**

Tuesday March 10th, 2015 *(Continued)*

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**

CLINICAL TRIALS TRANSFORMATION INITIATIVE

Wednesday March 11, 2015

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.