Informed Consent Project

Summary of the Expert Meeting held March 10 & 11, 2015

Double Tree by Hilton, Silver Spring, Maryland

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

Meeting presentations are available on the Clinical Trials Transformation Initiative (CTTI) website at: https://ctti-clinicaltrials.org/ctti-informed-consent-project-expert-meeting/

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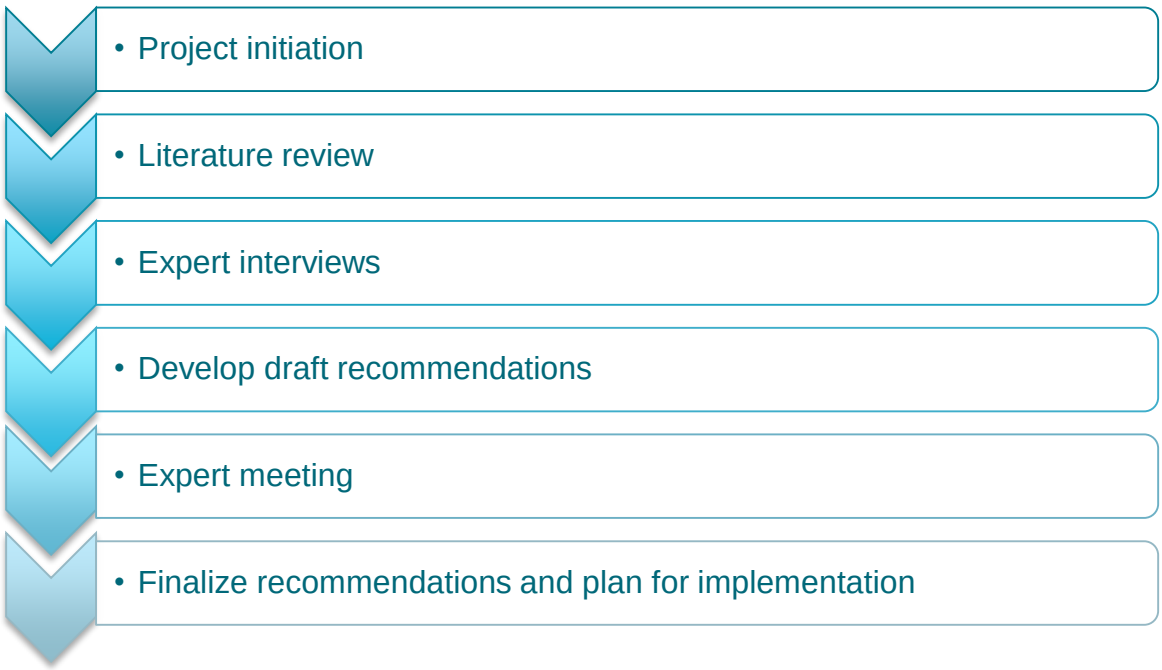
MEETING BACKGROUND

This meeting was born out of the informed consent project objectives, as follows:

- Understand previous and current efforts, whether successful or not, to improve informed consent documents and the informed consent process, including alternatives to the traditional paper informed consent document
- Understand barriers to and identify potential remedies for concisely communicating the required elements of informed consent
- Propose a more effective process, including informed consent documentation, for ensuring research participants' understanding of critical informed consent elements, taking into account variability among research settings
- Identify potential strategies and opportunities for pilot testing the informed consent process improvement recommendations

The progression of the project to realize these objectives is illustrated below.



To develop the draft recommendations, 6 work groups were formed—literature review, expert interviews, informed consent process, training, e-consent technology, and informed consent document.

MEETING OBJECTIVES

The objectives of the meeting were the following:

- Present findings and conclusions from the project literature review and expert interview series
- Solicit feedback and develop consensus on proposed draft recommendations to enhance the informed consent process

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MEETING EXECUTIVE SUMMARY

The Informed Consent Project convened a meeting involving stakeholders with expertise in this topic, on March 10 and 11, 2015. The participants included representatives from academia, nonprofit organizations, government agencies, institutional review boards (IRBs), industry (including pharmaceutical companies and contract research organizations), independent consulting companies, health systems, patient representatives, law firms, site representatives, and professional societies.

The findings and conclusions of the 6 work groups were presented at the expert meeting to solicit feedback and develop consensus. Recurring themes during the meeting were that informed consent documents generally in use now are too lengthy and complex and that the informed consent process is not meeting the needs of potential research participants to make truly informed decisions. There was much emphasis on having the participant more involved in the entire process, from designing the informed consent document to evaluation of the effectiveness of the document and the discussion.

For the next step, the CTTI informed consent team will consider feedback and discussion from the meeting to refine the recommendations, which will be finalized and disseminated via formal CTTI procedures.

MEETING/WORKSHOP SUMMARY

In opening remarks, the issues at hand were presented—the informed consent document is too lengthy and difficult for research participants to understand, and the informed consent process is not meeting the needs of the participants.

The first session was the presentation and discussion of the literature review and expert interviews findings and conclusions. While the literature review affirms the issues identified above, it is not clear what improvements would be best or how to measure their effectiveness. The barriers to a truly informed consent process are

many and wide ranging, such as process variability, expectations, trust in the relationship between patient and doctor, and demographics of participants. Recurrent observations across the literature are that we have lost sight of the primary purpose of informed consent, i.e., to help participants make an informed decision; the informed consent discussion is more important than the informed consent document; and that improving informed consent requires agreement on standards and how to measure "success," e.g., via subjective measures such as understanding and satisfaction and objective measures such as accrual, retention, and adherence.

The expert interviews were conducted to gather opinions and perspectives on the current state of informed consent and to get recommendations on how to transform the informed consent process into one that enhances participant understanding. The primary concerns identified with the current process are a single, standard approach to informed consent; variability in informed consent procedures across institutions; clinical research staff time constraints; no evidence or tool to measure participant understanding; that it is not constructed around participant decision-making; and the lack of general public knowledge about clinical research. The primary concerns identified with the informed consent document are that it is too lengthy and detailed, it is not written at the appropriate level, it contains too much legalese, and the extensive list of risks frightens participants away. Barriers to improving the informed consent process are lack of impetus on the parts of research stakeholders and regulatory authorities, inadequate training of research staff, lack of understanding by participants and an infrastructure that is not conducive to participant understanding, too many parties involved in the development and review of the informed consent document, and IRBs that are concerned with regulatory requirements and are inefficient and resistant to change. Much of the discussion that followed was centered on involvement of participants in both the process and the development of the informed consent document. Suggestions made included not only soliciting participant opinion, but also involving them in the development of the informed consent document and engaging them in the entire informed consent process; training participants, who can then train other participants; and having participants appear before the IRB. There was also discussion around the emphasis being placed on the informed consent document and acknowledgement of the limitations in what can be done to improve it. We need to focus instead on the informed consent discussion and training the people administering consent. And we need the tools to assess both the needs of potential participants and the effectiveness of the process and the document itself. We should look at other disciplines for tools to evaluate consent. Finally, in order to make any meaningful change, all of the approaches discussed must come together to form the necessary critical mass behind the effort.

The second session dealt with the informed consent process. The session objectives were to solicit feedback on recommendations for a more effective informed consent process that would achieve enhanced research participant understanding, to solicit feedback on the utility of the proposed informed consent

checklist, and to discuss roadblocks to implementation and ways to overcome them. The informed consent process should be an ongoing, interactive conversation between the participant and the clinical research staff that continues after the informed consent document is signed. The informed consent document is an important, necessary part of the process. However, the most important part of the process is the discussion between the investigator and potential research participant. Important considerations during the informed consent process are who, when, and where, and how participant understanding is facilitated and evaluated. The purpose of the proposed checklist is to serve as a reminder for research staff and to document the process for each participant. In this session, a panel with representatives from clinical research staff, academia, the federal government, and a research advocate discussed their viewpoints on the informed consent process. It was suggested that we use design sciences to rethink informed consent. Again, much of the discussion centered on the participants' needs. Suggestions included providing the informed consent document to participants before the discussion so they have adequate time to read and understand it; having participants who have been in clinical trials talk to potential participants and sharing contact information among participants; involving participants in the design of the informed consent document at an early stage; and listening to participants, making sure that they talk during at least half of the informed consent discussion, as research shows that participants learn better when they talk more. Attention needs to be paid to the people selected to administer informed consent, too. They need to be able to converse with participants, show empathy, and put aside their own biases and truly listen to the participant. The panel felt it is important to be completely honest with participants, including about what we do not know, and to tell the participants that they are free to leave the study at any time. One way of evaluating participant understanding that was discussed was the teach-back method. Some panelists were concerned with it being another task required of an already overworked research staff, and one said that it should be explicit about how to incorporate it into the informed consent process (e.g., should perhaps be scripted). Some of the panel thought the checklist would serve as a good reminder but that it should be optional. Suggestions were made for items that are missing from the checklist presented, such as confidentiality of records and a statement that the study involves research (although someone pointed out that we should avoid using the word "research" [negative connotation] in favor of "clinical trial"). Again, emphasis was placed on the participants, that the process should be applicable to them and not governed by rules. During the discussion that followed the panel presentation, suggestions made included asking participants their preferred learning style; the necessity for all participants to be able to ask questions and get answers; being clear with participants about potential costs to them to be in the study and about conflict of interest; relabeling "discussion" as "conversation"; giving participants the informed consent document ahead of time; utilizing webinars and multimedia; and having a frequently-asked-questions (FAQs) section in the informed consent document.

The third session was on training in administering informed consent to potential research participants. The objectives were to present examples of innovative informed consent training programs and to solicit feedback and develop consensus on proposed recommendations. Two representatives from the Human Subjects Protection Unit (HSPU) of the National Institute of Mental Health (NIMH) discussed the training program created there as a result of the thousands of informed consent discussions they have monitored and during which they observed a wide range of communication styles. This training is provided monthly to investigators, and the NIMH's IRBs require it. The program consists of a video and didactic presentation, and modifications may be made as needed; there are also pretests and posttests. The next presenter, from the Karmanos Cancer Institute, described how they use reenactments of actual clinical visits to improve oncologists' communication with potential participants. The purpose of their training is to provide background and examples of informational (key elements) and relational (patient-centered) communications. They found that while future research is needed to assess effectiveness, reenactments are appropriate for training and should be integrated into informed consent process training programs. In the last part of this session, recommendations for informed consent training programs were proposed, including that study personnel administering informed consent should be strongly encouraged to take part in a formal training program, that the training may be required by individual research sites but should not be federally mandated, and that the training programs should be evaluated periodically and adjusted to ensure they are meeting the needs of trainees. They further recommend that training programs contain didactic and interactive elements and that there be continuing education opportunities. Further research is needed on clinical research staff and participant satisfaction with the informed consent process, a comparison of participant comprehension of the informed consent when conducted by research staff with formal training and when conducted by untrained research staff, the effect of research staff training on enrollment and retention, and a comparison of different training models on the effectiveness of research staff training. Comments during the discussion that followed were that training does not necessarily make a person good at conducting the informed consent process, but consenters can be trained to communicate better; that physicians already complain about all of the training they must complete; and that the differences between generic informed consent process training and training for a particular trial needs to be taken into account. Attendees suggested research participants be involved in staff training. Attendees also noted that experienced consenters may have either honed health-communication skills or developed poor habits in their consenting style that are difficult to overcome.

The fourth session was on the use of electronic consent (e-consent) technology. The objectives were to discuss the advantages and challenges of the use of e-consent in the informed consent process and to solicit feedback on proposed recommendations for this technology. Following the presentation of the advantages and opportunities, the potential/perceived barriers, and recommendations, a panel of representatives from clinical research, an IRB,

patient advocacy, and the federal government addressed the issue. Further benefits pointed out were that e-consent offers the ability to monitor the informed consent process remotely, research participants are able to opt out of supplementary information, permissions can be tracked over time, it might help participants learn more quickly and comfortably, it is more mobile, it offers greater flexibility, and it might alleviate some of the burden on research sites. But it might offer challenges when multiple IRBs are used. During the discussion that followed, one attendee thought that there would be much resistance to e-consent on the part of local IRBs and that they would insist on their own wording, which would be very expensive. Security questions were raised, i.e., protected health information and computer security. Additional discussion included the number of studies utilizing e-consent and the availability of research comparing e-consent with paper consent. Limited research is available, but one study found that there was greater comprehension with e-consent and that the participant retains the information longer. No studies were found that directly correlate compliance and enrollment with e-consent vs. written. Concern was expressed that the participants should be at the center of everything we do, so the informed consent should be focused on them.

In the fifth session, the informed consent document was discussed, with the objective of soliciting feedback and developing consensus on a new informed consent document model. It is generally agreed that informed consent documents currently being used are too lengthy and detailed, causing confusion for research participants and concern that they are not really making an informed decision. Better understanding of the study will benefit both the participants (affording them greater respect and autonomy) and the study (greater compliance and retention). The challenges faced with a simpler, shorter informed consent document are that complicated studies may not lend themselves to this, limited medical literacy of the participants, therapeutic misconceptions on the part of participants, and the fact that the document has to meet certain legal requirements. The foremost objective of the informed consent process should be to provide potential participants with information that enables them to make a sound decision. To this end, the new informed consent document model recommended is a 2-tiered one, with the main body of the consent comprising the elements required by regulatory agencies, the most common and serious risks involved in the study, and references to the second part of the document for further information. The first part of the informed consent document would be no longer than 6 pages. The second part would be a detailed reference section, comprising information not legally required and elaboration on material in the main body that might be of particular interest or help to some participants; it would not be limited in length. The proposed 2-tiered model would use plain language, be flexible, focus on risk-benefit considerations, contain clear statements of expectations related to participation in the study, and be a pathway to e-consent. The disadvantages of this new model are that IRBs (and some sponsors) are conservative, it does not fit existing templates, it has the potential for information creep and expansion, and sponsors may desire the blessing of regulatory agencies. In the discussion that followed the presentation,

the primary concern was with the detailed reference section, that it may become a dumping ground, that it would be used to hide essential information, and that if participants sign the consent after the main body of the informed consent document, they may not read anything beyond that page. During the discussion, the detailed reference section of the new model was often referred to as an "appendix," but the presenter cautioned that it should not be viewed that way—it is intended to contain information for participants who want more detail. When an attendee suggested that the FDA needs to formally endorse the new model to get it accepted by research sites, the response was that the FDA can regulate the content of the document, but not the format. The Office for Human Research Protections has viewed the template and thinks it is a good idea; it has not been vetted by IRBs. Another suggestion for the informed consent document was to have a 1- to 2-page precis at the beginning, written in a participant-friendly manner and summarizing what the participant would be getting into by participating in the study. There was concern with this suggestion that the participant would read only the precis and sign off on the entire document. Participant input is needed in the design of the informed consent document. We should also be measuring the effectiveness of different informed consent documents, but there is no tool available to do this. Therefore, in the view of the presenter, we should try it; we need to be able to make comparisons to be able to make a decision.

During the latter part of the meeting, attendees broke out into 4 discussion groups—informed consent process, training, informed consent document template, and e-consent—with representatives of the various types of stakeholders in each group. The goals of the breakout groups were to review and provide feedback on the proposed recommendations, discuss existing barriers to transforming the informed consent process and strategies to overcome these barriers, and consider ways to facilitate adoption of proposed project recommendations. In the final session, feedback from each of the breakout groups was presented and actionable opportunities for change were discussed.

The informed consent process group identified existing barriers to an improved process as time and space (equals money), institutional buy-in and support of research, and the communication abilities of providers and participants. Their strategies for overcoming these barriers were (1) changes to the checklist and recommendations to eliminate potential compliance concerns and misuse of the tool—and to call it an informed consent document tool rather than a checklist—and (2) creation of a list of FAQs for potential trial participants. To facilitate adoption of the proposed recommendations, the group suggested obtaining institutional and IRB buy-in and marketing and disseminating the recommendations to professional organizations, noting that sustained marketing would be necessary to facilitate adoption over time. Much of the ensuing discussion centered around the checklist, such as how to make it truly interactive and if research sites would find it more helpful if there was a template that they could add site-specific information to. It was suggested that it be adopted by institutions as a standard operating procedure, but that it not be required. Concern was expressed that it would be just one more task to do. There was also much discussion about how to evaluate

participants' understanding during the informed consent process. It was suggested that to elicit participant understanding, the person obtaining consent should present it as they themselves needing to know what was understood about what they just said; do not make the participant feel as if he or she is being tested.

The training group identified existing barriers to training as who defines it, who pays for it, how to operationalize it, the time requirement, and at what intervals retraining should be conducted. Strategies for overcoming these barriers include engaging CTTI to create didactic, video, and evaluation modules; and exploring the use of professional organizations to assist in leveraging training. The group agreed with the proposed learning strategies recommendations and also suggested possible implementation strategies. During the discussion, the question of certification of presenters was raised and whether it should be required before a person could consent a participant. Comments were made that training now is too repetitive and that it should be centralized and standardized, even though different situations may call for different training.

The informed consent document template group reported that existing barriers to the new template model are acceptance, including IRB control of language and format vs. standardization; its accommodation to high-risk vs. low-risk trials (complexity); the content of the main document and concern that the detailed reference section might become a dumping ground; the significance of the participant's signature, i.e., whether it is an attestation of the entire informed consent document or just a part of it; and naming conventions for the detailed reference section, e.g., "chapter," "section," or "appendix." Strategies for overcoming the barriers included formative testing with participants and obtaining their feedback; getting 3 sponsors and 3 IRBs to adopt the model, to make it more palatable, and getting key opinion leaders from local IRBs to write perspective pieces; using "chapter"/"section" language; clarifying signature significance and that the participant is signing off on the entire document; having a library of risk categories, i.e., standard ways of explaining the risks of drugs, procedures, etc.; having continuing conversations with the FDA; moving the process forward with consortium ownership; and using metrics to gauge how it is working (e.g., impact on institutional/sponsor use, IRB approval times). To facilitate the adoption of the proposed recommendations, the group recommended making it analogous to the package insert (a summary with more expansive information following); getting the 3-sponsor/3-IRB adoption and perspective pieces from key opinion leaders; and continuing to have conversations with the FDA, including on the template itself and on their current draft guidance via comments.

The e-consent group reported that they had no objections to the recommendations proposed and thought the barriers to e-consent being widely adopted are research site resources, time, and technology; the cost of technology; no proof of return on investment, or that return is intangible; the belief that the paper system is working; fear of noncompliance; and the challenges faced with technology, e.g., internet access. The recommendations the group thought were the most important are to take a more limited adoption approach, i.e., United States only, to keep costs down; collaboration among sponsors; FDA support of sites, with their questions

and concerns addressed; participants should be engaged as constructive collaborators and part of the solution; FDA guidance, helpful to allay fears; and a utility for re-consent and samples management. They identified the top 3 barriers to transforming the process as cost, fear and reluctance with new tools and compliance on the part of both research sites and IRBs, and lack of support and prioritization by study teams and sponsor leadership to implement the tool. During the discussion, an attendee said that in his experience, e-consent takes longer, but the participants think it takes less time; e-consent is less painful, easier; and it can be shorter because participants can click on items where they want more information. The tiered informed consent document was designed with e-consent in mind.

The meeting was closed by thanking the experts for their thoughts and ideas, which will be used to finalize and disseminate recommendations and plan for a future CTTI implementation project.

FUNDING STATEMENT

Financial support for this project are provided by grant #U19 FD003800 from the U.S. Food and Drug Administration and CTTI membership fees. In kind contribution of effort was provided by North Shore-LIJ Health System, University of Pennsylvania, FDA, CITI Program at the University of Miami, Pfizer Inc, AstraZeneca Inc., St. Jude Medical, and ACI Clinical.

ABOUT CTTI

The Clinical Trials Transformation Initiative (CTTI) is a public-private partnership to identify and promote practices that will increase the quality and efficiency of clinical trials. The CTTI vision is a high-quality clinical trial system that is patient centered and efficient, enabling reliable and timely access to evidence-based prevention and treatment options.

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

Appendix A. Meeting Agenda

Tuesday March 10, 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)**

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**

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**

Informed Consent Expert Meeting Participants

March 10 & 11, 2015 · Silver Spring, MD

Attendees

Patricia Adams	Duke University
Annick Anderson	CISCRP
David Borasky	Copernicus Group IRB
Julie Brintnall-Karabelas	National Institutes of Health
Mary Ellen Cadman	National Institutes of Health
Karim Calis	Food and Drug Administration
Sabrina Comic-Savic	The Medicines Company
Alison Cooper	Texas Diabetes & Endocrinology
Anthony Costello	Mytrus, Inc.
Eric Delente	Enforme Interactive
Susan Donahue	PMG Research, Inc.
Helen Donnelly	Northwestern University
Susan Eggly	Karmanos Cancer Institute
Dawn Furey	Merck & Co.
George Gasparis	The PEER Consulting Group
Cami Gearhart	Quorum Review IRB
Cindy Geohegan	Patient Representative
Julia Gorey	OHRP
Cheryl Grandinetti	Food and Drug Administration
Zachary Hallinan	CISCRP
Peter Hassett	Secure Consent
Jayvant Heera	Pfizer, Inc.
Kevin Hudziak	Eli Lilly and Company
John Isidor	Human Subject Protection Consulting, LLC
Julie Jeanes	Celgene
Cheryl Jernigan	Patient Representative
Ellen Kelso	Chesapeake IRB
Michele Kennett	University of Missouri
Sarah Kiskaddon	AAHRPP
Kathy Kopnisky	National Institutes of Health
Andy Lee	Merck & Co.
Jennifer Lentz	Eli Lilly and Company
Jennifer Li	Duke University

Attendees

Alexander Liu	Lillestol Research
Beverly Lorell	King & Spalding
Frederick Luthardt	Johns Hopkins University
Joanne Mancini	Karmanos Cancer Institute
Holly Massett	National Cancer Institute
Ross McKinney	Duke University
Marsha Melvin	Food and Drug Administration
Stephen Mikita	Patient Representative
Linda Neuhauser	University of California Berkeley
Megan O'Boyle	Phelan-McDermid Syndrome Foundation
Helen Peck	Karmanos Cancer Institute
Jane Perlmutter	Patient Representative
Kevin Prohaska	Food and Drug Administration
Leonard Sacks	Food and Drug Administration
Fabienne Santel	Food and Drug Administration
Grace Schroer	National Cancer Institute
Seth Schulman	Pfizer, Inc.
Carol Simmons	Food and Drug Administration
Denise Sturdy	Duke University
Elyse Summers	AAHRPP
Yvonne Tan	Janssen Research & Development, LLC
Rose Tiernan	Food and Drug Administration
Karen Ulisney	Food and Drug Administration
Kaveeta Vasisht	Food and Drug Administration
Joan Wilson	Duke University

CTTI Attendees

Annemarie Forrest	Clinical Trials Transformation Initiative
Matthew Harker	Clinical Trials Transformation Initiative
Jamie Roberts	Clinical Trials Transformation Initiative
Kimberley Smith	Clinical Trials Transformation Initiative
Jenny Walker	Duke University