CTTI Informed Consent Project Recommendations

Jane Perlmutter, Patient Advocate
Jennifer Lentz, Eli Lilly and Company

January 8, 2016
Agenda

- Introduction to the Clinical Trials Transformation Initiative
  - Jane Perlmutter, Patient Advocate

- Project Overview
  - Jane Perlmutter

- Project Recommendations and Tools
  - Jennifer Lentz, Eli Lilly and Company

- Discussion
Introduction to The Clinical Trials Transformation Initiative

Jane Perlmutter, Patient Advocate
To identify and promote practices that will increase the quality and efficiency of clinical trials

Public-Private Partnership
Co-founded by FDA and Duke University
involving all stakeholders
60+ members
Collaboration Towards Solutions

Better Streamlined
Fit for purpose
Clinical Trials

- Government and regulatory agencies
- Industry: pharma bio device CRO
- IRBs
- Clinical investigators
- Academia
- Industry trade / Professional organizations
- Patients / Patient advocacy groups
CTTI Methodology

1. State Problem
   - Identify Research Impediments
     - Issue Statement, Project Plan

2. Gather Evidence
   - Identify Gaps/Barsriers
     - Literature Reviews, Multi-stakeholder Meetings, Surveys, Interviews

3. Find Solution
   - Analyze & Interpret Findings
     - Team Meetings, Multi-stakeholder Meetings

4. Refine Ideas
   - Develop Recommendations/Tools
     - Team Meetings, Multi-stakeholder Meetings

5. Action
   - Disseminate & Implement
     - Workshops, Pilot Studies, Measure Impact
Project Team Leaders and Members

- Michele Kennett, (Univ of Missouri)
- Jennifer Lentz (Eli Lilly)
- Jane Perlmutter (Patient Advocate)
- Annick Anderson (CISCRP)
- Fred Bloom (CDC)
- Karim Calis (FDA/CDER)
- Steve Cummings (UCSF)
- Molly Flannery (FDA/CDER)
- Cheryl Grandinetti (FDA/CDER)
- Julia Gorey (OHRP)
- Zachary Hallinan (CISCRP)
- Jayvant Heera (Pfizer)

- Kevin Hudziak (Eli Lilly)
- Hallie Kassan (North Shore-LIJ)
- Kathy Kopnisky (NIH/OD, former)
- Beverly Lorell (King & Spaulding)
- Ross McKinney (Duke)
- Marsha Melvin (FDA/CDER)
- Steve Mikita (Patient Advocate)
- Linda Morgan (Patient Advocate)
- Seth Schulman (Pfizer)
- Kaveeta Vasisht (FDA/CDER)
- Sheila Young (GSK)
- Rose Tiernan (FDA/CDER)

Project Manager: Annemarie Forrest
Informed Consent Project Overview

Jane Perlmutter
Issue

Informed consent documents are lengthy & may be difficult for patients to comprehend

Current informed consent process is often not meeting the needs of research participants
Project Objectives

- Understand *previous and current efforts* to improve informed consent documents and the informed consent process, including alternatives to the traditional paper informed consent document.

- Understand *barriers and identify potential remedies* to 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 and participants.

- Identify potential *strategies and opportunities for pilot testing informed consent process improvement recommendations*. 
Evidence Gathering

- Review of informed consent literature reviews
  - To be published

- Primary literature review
  - To be published

- Expert interviews (25)
  - Findings published in *Clinical Trials*, July 2015

- Expert Meeting
  * Mar 2015
We have lost sight of the primary goal of informed consent: To help research participants make an informed choice.

The informed consent discussion is more important than the informed consent document (but both matter).

Improving informed consent requires agreement on standards and how to measure ‘success’, potentially including:

- Objective understanding, satisfaction with understanding, and satisfaction with decision-making
- Accrual, retention, and/or adherence
Themes From the Expert Interviews

- Conversation with research staff
- Simplified Informed Consent document
- Train research staff on Informed Consent
- Allocate sufficient time
- Learn from previous research participants
- Appropriate setting
- Interactive learning component

Enhanced Research Participant Understanding of Clinical Trial
March 2015 Expert Meeting

- 60+ experts representing academia, nonprofit organizations, government agencies, IRBs, industry, independent consulting companies, health systems, patient representatives, law firms, site representatives, and professional societies

Objectives:
- Review findings and conclusions from the literature review and expert interview series
- Solicit feedback and develop consensus on recommendations to enhance the informed consent process

Recurring themes:
- Informed consent documents too lengthy and complex
- Informed consent process is not meeting the needs of potential research participants to make truly informed decisions
Informed Consent Project Recommendations

Jennifer Lentz, Eli Lilly and Company
Recommendations: Conducting the Informed Consent Process

- The informed consent process should involve an ongoing, interactive conversation between the research participant and the research staff, beginning with initial consideration of study participation and continuing through study completion.

- The informed consent process should be customized to meet the particular needs of individual study participants.

- The person or persons obtaining consent should be skilled in communicating trial-specific information and be responsive to the needs and concerns of individual research participants.

- Study participants should be provided with available resources to enhance their understanding of clinical trials, including sample questions to ask the investigator so he/she can better engage in a dialogue about the benefits and risks of participation.
Recommendations: Conducting the Informed Consent Process

A *discussion tool*, not intended as a required regulatory compliance document, could be used as part of the consent process to ensure the following:

- The specific needs of each study participant are considered,
- Key elements of the trial are reviewed and addressed, and
- Interactive techniques are used to facilitate participant understanding of the information imparted.
- This tool could be used for documenting the informed consent process.

The informed consent *document* should be viewed as *supportive to the consenting process*, rather than the primary focus.
Informed Consent Discussion Tool

This tool is not intended as a required regulatory compliance document, but may be useful for preparing for conducting the IC discussion, and/or documenting the IC process. The tool can be modified to include checkboxes or room for notes if the user chooses to use it as a documentation tool.

<table>
<thead>
<tr>
<th>I have considered:</th>
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<tbody>
<tr>
<td>A private, nonthreatening place to hold the informed consent discussion</td>
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<td>Inclusion of family/friends in the informed consent discussion, as desired by the research participant</td>
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<td>The research participant’s individual needs and geared my discussion to match their</td>
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<tr>
<td>• Learning style</td>
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<td>• Language facility</td>
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<td>• Education level</td>
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<td>• Health literacy</td>
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<tr>
<td>• Interest in learning as much as possible</td>
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<td>• Comfort with numbers/probabilities</td>
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<td>• Disabilities that may hinder the ICP</td>
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<td>Providing the research participant with ample time to review the informed consent document and ask questions as needed</td>
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<td>The following items have been described to the research participant using plain language:</td>
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<tr>
<td>• Purpose of the research</td>
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<td>• Research procedures, including those that are experimental, relative to visits required for standard care</td>
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<td>• Duration of participation, compared to standard of care</td>
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<td>• Reasonably foreseeable risks/discomforts, compared to standard of care</td>
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<td>• Adverse expected of participants during the trial, compared to standard of care</td>
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Recommendations: Training of Research Staff

- Research staff obtaining consent should be trained to do so.

- Training programs should be determined by individual research sites and tailored to local and organizational needs. A uniform training program is not required and programs need not be nationally driven or sponsor-specific.

- For research staff designated to obtain consent, an informed consent training program should aim to improve their knowledge and communication skills, including best practices to impart trial-specific information while remaining sensitive to participants’ needs.

- An ideal training program should include the following:
  - Didactic information, which may be part of other general clinical research training
  - Interactive opportunities to practice or get feedback on communication techniques, and
  - Continuing education as needed.
Professional organizations and/or NIH should develop comprehensive training programs research sites can choose to use as, or as a part of, their organizational informed consent training program.

Patients should be included in the development and/or implementation of the training program. Resources for meaningful patient engagement should be utilized.

We provide potential criteria by which to evaluate training programs.

The benefits and effectiveness of training should be assessed.
# Evaluation Criteria for Training Programs

<table>
<thead>
<tr>
<th>Organization</th>
<th>Didactic</th>
<th>Interactive</th>
<th>Testing</th>
<th>Review of Required Elements</th>
<th>CME Credit</th>
<th>Documentation of the IC Process</th>
<th>Patient Communication</th>
<th>In person</th>
<th>On-line or Webcast</th>
<th>Ideal for Continued Education Purposes</th>
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<tbody>
<tr>
<td>Program A</td>
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<td>Program B</td>
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<td>Program C</td>
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Recommendations: Informed Consent Document Template

A tiered approach should be used in the informed consent document.

- The first tier of the informed consent document should contain only the elements of informed consent required by federal regulation (See example, Appendix III).
- The second tier should contain additional information, in chapter format, on a range of study-related issues for each study participant to review as deemed necessary. This detailed reference section would provide an elaboration of the information in the informed consent document and be made available to study participants who wish to review it.
- A third tier consisting of a 1-2 page introduction or a summary of the study may be valuable for more complex studies.
Recommendations: Informed Consent Document Template

Draft informed consent documents should be *evaluated* with the following methods:

- Standardized health literacy/plain language assessments
- Reading level assessments
- Usability testing with patients similar to those who would be eligible for the study

A *standard language library* should be developed for text that is not specific to the study, and is universally accessible to study sponsors.
Sample Tiered Informed Consent Model

- Intended as an example of the Tiered Informed Consent Model basic structure.
- Not intended to be an informed consent document template.
- We encourage flexibility in individual informed consent document language, dependent upon the nature of the study.
Recommendations: E-Consent

E-consent *facilitates* the use of the recommended *tiered informed consent document*.

Research sponsors and investigative sites should continue to *explore the use of e-consent* and share best practices and lessons learned. Interventionsal trials of e-consent documents should be conducted to *evaluate* the effects on study feasibility and participant comprehension, decision-making, and satisfaction.
# Summary of Recommendations & Tools

<table>
<thead>
<tr>
<th>Topic</th>
<th>Key Points</th>
<th>Tool</th>
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</table>
| Informed Consent Process | • Ongoing & interactive  
  • Customized to individual participants needs  
  • Provide participants with supporting material                                                                                                             | Discussion Tool             |
| Training Research Staff | • Tailored to local organizational needs  
  • Knowledge & communication skills  
  • Include:  
    1. Didactic information  
    2. Interactive opportunities  
    3. Continuing education                                                                                                                                     | Training Evaluation Rubric  |
# Summary of Recommendations & Tools

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<th>Tool</th>
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</thead>
<tbody>
<tr>
<td>Informed Consent Document</td>
<td>• Tiered approach &lt;br&gt;1. Basic required elements &lt;br&gt;2. Additional information in chapter format &lt;br&gt;3. Optional 1-2 page intro or summary &lt;br&gt;• Evaluation &lt;br&gt;1. Health literacy/plain language &lt;br&gt;2. Reading level &lt;br&gt;3. Usability testing</td>
<td>Sample</td>
</tr>
<tr>
<td>E-Consent</td>
<td>• Facilitate use of tiered consenting &lt;br&gt;• Lot’s of potential advantages &amp; barriers &lt;br&gt;• Ripe for experimentation</td>
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</table>
Next Steps

- Dissemination and publication of recommendations
- Potential future implementation project work at CTTI
Related Tools and Resources


Contact [annemarie.forrest@duke.edu](mailto:annemarie.forrest@duke.edu) with feedback or to be added to our contact list.
Thank you.