SESSION II: The Informed Consent Process: An Interactive Discussion

Jane Perlmutter, Patient Advocate

March 10, 2015
Session II 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, MD, MFPM

Pfizer Clinical Development, Groton, Connecticut

March 10, 2015
Background

Ensuring respect for persons

The Informed Consent Process is important

What do we need to do to improve the process?
Proposed Recommendations

Defining the Process

Key Elements of the Informed Consent Process

Informed Consent Checklist

*Does not cover specialized situations*
Defining the Process

- Ongoing, interactive conversation between participant and research staff
- Document is part of the process but not the primary mechanism for consenting participants
- Process continues after the document is signed
  - Throughout course of trial, staff should continuously follow-up with participants to assure ongoing consent
Who should be involved in the process?

Potential Research Participant

Family, friends, witness, LAR

Persons obtaining Consent
When is the informed consent process conducted?

- Before the research participant undergoes any research related procedures
- If possible, document can be provided to the participant ahead of time
- At a time when the potential participant can focus on the process
- Ongoing throughout the trial, particularly when there are significant new findings
Where is the Informed Consent Process Conducted?

- When possible, in a nonthreatening, safe setting that reduces any feeling of coercion
- In the best possible location to protect a participant’s privacy
- Specifically:
  - Try to avoid
    - waiting rooms
    - or locations where a participant is not fully dressed
How is participant understanding facilitated?

- Use consent document as an outline
- Interactive discussion with participant
- If possible, a multimedia approach, such as tablets or internet access with visual aids, study calendars
Facilitate Understanding

- Consenter awareness of participant’s education, culture, and learning style
- Avoid jargon when consenting
- Presenting information in layers
- Offering additional educational materials and/or referrals
- Understanding the distinction between research and treatment
- Consenter awareness of participant anxiety and/or cognitive overload
How is understanding evaluated?

- Participant should explain in their own words what they understand about the study
- Teach-back method
- Ask participant open-ended questions
How is informed consent documented?

- Participant must sign and date the ICD
- Assure that optional areas have been signed, as needed
- Consenter signs and dates the consent document
Informed Consent Checklist

- Tool that may be used to document the consent process for each participant
- Can be reviewed before the process begins to serve as a reminder of what the process entails
<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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<tr>
<td>Inclusion of family/friends in the informed consent discussion, as desired by the research participant</td>
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<tr>
<td>The research participant’s individual needs and geared my discussion to match them</td>
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<tr>
<td>• Language facility</td>
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<tr>
<td>• Education level</td>
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<td>• Health literacy</td>
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<td>• Interest in learning as much as possible</td>
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<tr>
<td>• Comfort with numbers/probabilities</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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</table>
The following items have been described to the research participant:

<table>
<thead>
<tr>
<th>Item</th>
<th>Details</th>
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<tbody>
<tr>
<td>Purpose of the research</td>
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<tr>
<td>Research procedures, including those that are experimental, relative to visits required for standard care</td>
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<td>Duration of participation</td>
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<td>Reasonably foreseeable risks/discomforts</td>
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<td>Benefits to participants and others</td>
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<td>Compensation for research-related injury</td>
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<td>Additional costs to the subject for participation, compared to standard of care</td>
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<td>Voluntary nature of participation</td>
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<td>Available alternative treatments</td>
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<td>Whom to contact with questions/concerns</td>
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<tr>
<td>Number of trial participants (if required)</td>
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<td>Reasons for terminating participation by research team (if required)</td>
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<td>Consequences of subject withdrawal (if required)</td>
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<tr>
<td>Statement that participants will be updated throughout the process (if required)</td>
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<tr>
<td>✔️</td>
<td>I have:</td>
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<td></td>
<td>Answered all of the research participant’s questions before the document is signed</td>
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<tr>
<td></td>
<td>Evaluated the research participant’s understanding of the information discussed</td>
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<tr>
<td></td>
<td>Provided the research participant with a signed copy of the informed consent document, and a copy of the detailed reference section</td>
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Informed Consent Process Work Group

- Jane Perlmutter (Patient Advocate)
- Jayvant Heera (Pfizer, Inc.)
- Hallie Kassan (North Shore-LIJ Health System)
- Steve Mikita (Patient Advocate)
- Linda Morgan (Patient Advocate)
Thank you.
Panel Discussion

Helen Donnelly
- Clinical Research Nurse, Pulmonary and Critical Care Medicine, Northwestern University

Linda Neuhauser
- Clinical Professor, Community Health and Human Development, University of California - Berkeley

Kevin Prohaska
- Office of Good Clinical Practice, Food & Drug Administration