SESSION II: The Informed Consent Process: An Interactive Discussion

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March 10, 2015

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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

Proposed Recommendations for the Informed Consent Process: Who, How, When, Where

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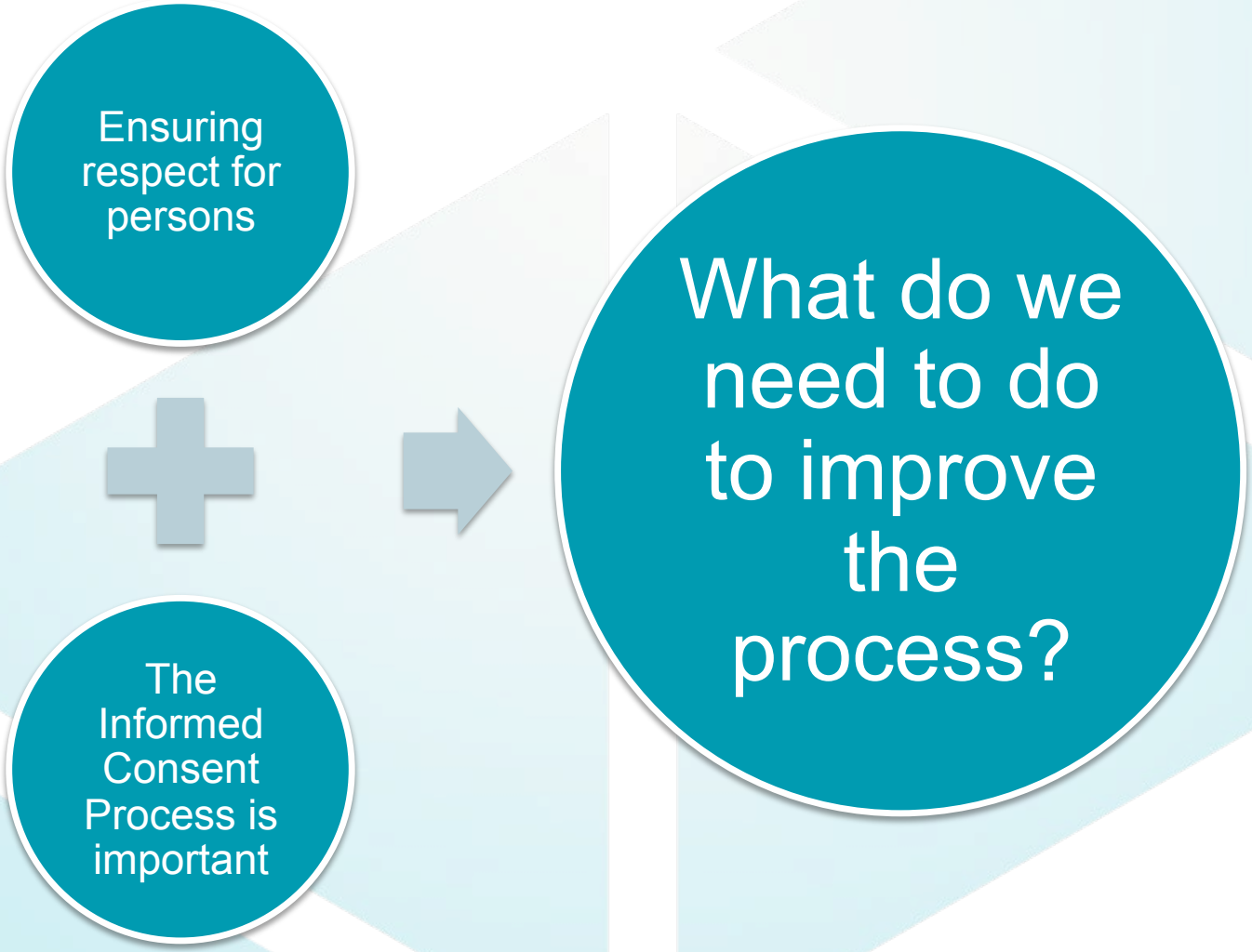
Background


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*

CTTI

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?

When is the informed consent process conducted?

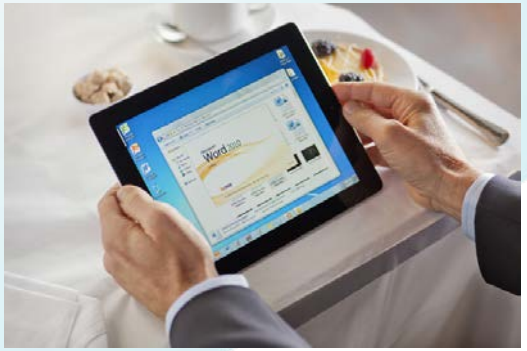
- Before the research participant undergoes any research related procedures
- If possible, document can be provided to the participant ahead of time
- At a time when the potential participant can focus on the process
- Ongoing throughout the trial, particularly when there are significant new findings

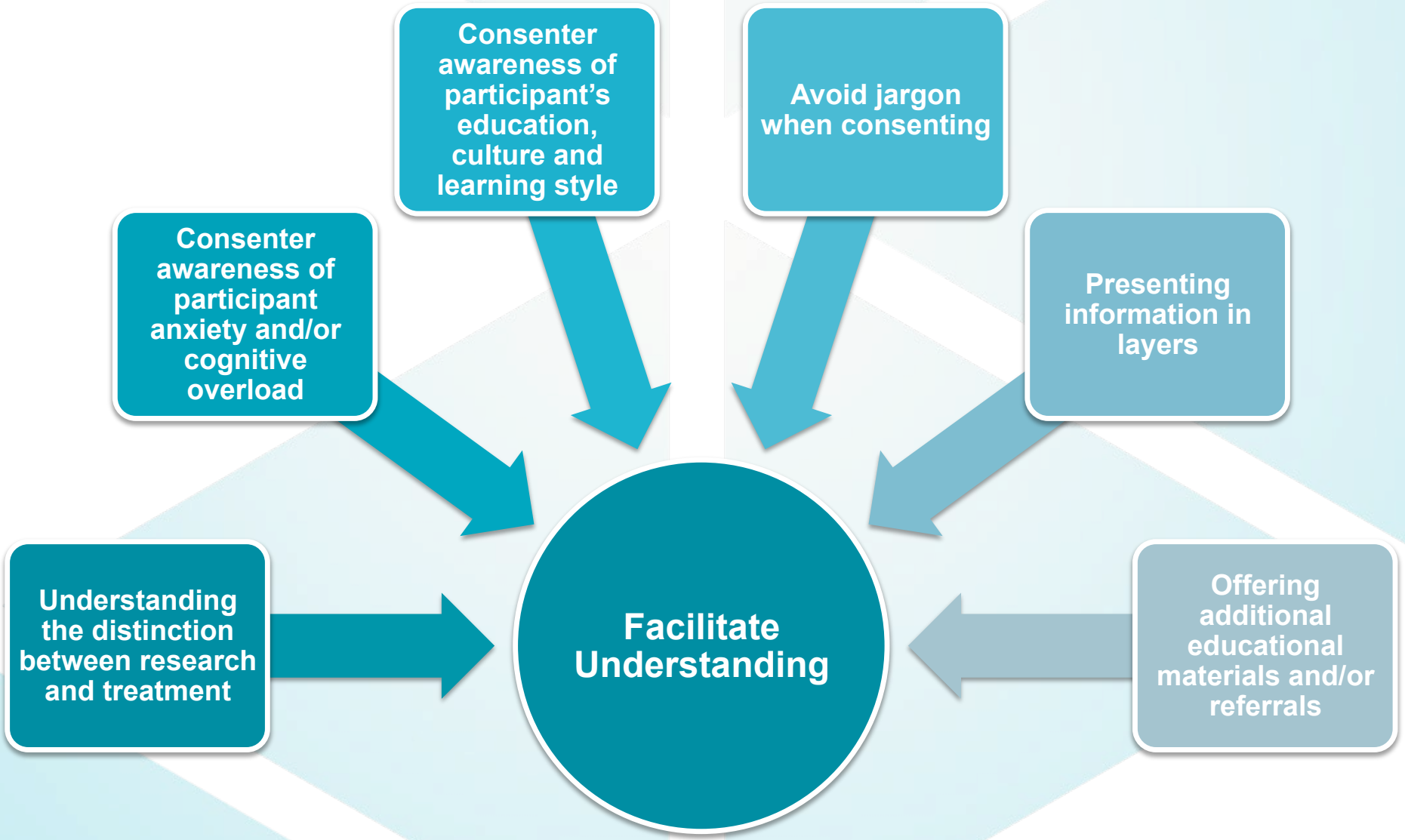
Where is the Informed Consent Process Conducted?

- 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




Consenter awareness of participant's education, culture and learning style
Avoid jargon when consenting
Consenter awareness of participant anxiety and/or cognitive overload
Presenting information in layers
Understanding the distinction between research and treatment
Facilitate Understanding
Offering additional educational materials and/or referrals

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

(✔) I have considered:	Notes:
A private, nonthreatening place to hold the informed consent discussion	
Inclusion of family/friends in the informed consent discussion, as desired by the research participant	
The research participant's individual needs and geared my discussion to match them • Language facility • Education level • Health literacy • Interest in learning as much as possible • Comfort with numbers/probabilities	
Providing the research participant with ample time to review the informed consent document and ask questions as needed	

(✔)	The following items have been described to the research participant:	Notes:
	• Purpose of the research • Research procedures, including those that are experimental, relative to visits required for standard care • Duration of participation • Reasonably foreseeable risks/discomforts • Benefits to participants and others • Compensation for research-related injury • Additional costs to the subject for participation, compared to standard of care • Voluntary nature of participation • Available alternative treatments • Whom to contact with questions/concerns • Number of trial participants (if required) • Reasons for terminating participation by research team (if required) • Consequences of subject withdrawal (if required) • Statement that participants will be updated throughout the process (if required)	

(✔) I have:	Notes:
Answered all of the research participant's questions before the document is signed	
Evaluated the research participant's understanding of the information discussed	
Provided the research participant with a signed copy of the informed consent document, and a copy of the detailed reference section	

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.

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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