

# Welcome to the CTTI Informed Consent Project Expert Meeting, Day 2

*March 11, 2015*



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# Preview

➤ **The Informed Consent Document**

➤ **Actionable Opportunities for Transformative**

➤ **Discussion!**

# Housekeeping

- Please remember to turn your phones on vibrate or silent
- Lunch
- Be sure check out of your room prior
  - You may store your luggage in the back of the meeting room.
- Meeting Evaluation
- Slides will be posted to the CTTI website
- Executive meeting summary will be posted to CTTI website in the near future

# Day 1 Summary

Jennifer Lentz, Eli Lilly & Co.

*March 11, 2015*



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# Summary

➤ Literature Review & Expert Interviews Results

➤ The Informed Consent Process

➤ Training on Conducting the Informed Consent Process

➤ Use of E-Consent Technology in the Informed Consent Process

# Literature Review & Expert Interviews Results

# The Informed Consent Process

# Training on Conducting the Informed Consent Process



# Use of E-Consent Technology in the Informed Consent Process

# Today's Agenda

➤ The Informed Consent Document

➤ Actionable Opportunities for Transformative Change

➤ Discussion!

# Keep In Mind

- Will this enhance the informed consent process?
- Are any changes needed to the recommendations?
- What are the barriers to success?
- How can adoption of the recommendations be facilitated?

# Session V: The Informed Consent Document

Seth Schulman, Pfizer

*March 11, 2015*



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# Session V Objectives

- Solicit feedback and develop consensus on a new proposed Informed Consent Document model

# Background

## ➤ Problem Statement:

- ICDs are too lengthy and confusing to some research participants

## ➤ Risk

- Signed ICDs without adequate review, comprehension

## ➤ Barriers to Change

- Inertia
- Fear (Sponsor, IRB)
  - Legal
  - Regulatory
- No Successful Precedent

# Assumptions

- A more effective IC *Process* facilitates understanding
- A simpler IC *Document* providing critically relevant information to aid in decision making supports a more effective IC Process
- Too much detailed information hinders participants' ability to focus on critical issues and impairs their ability to make an informed decision

# The Tiered Consent Model

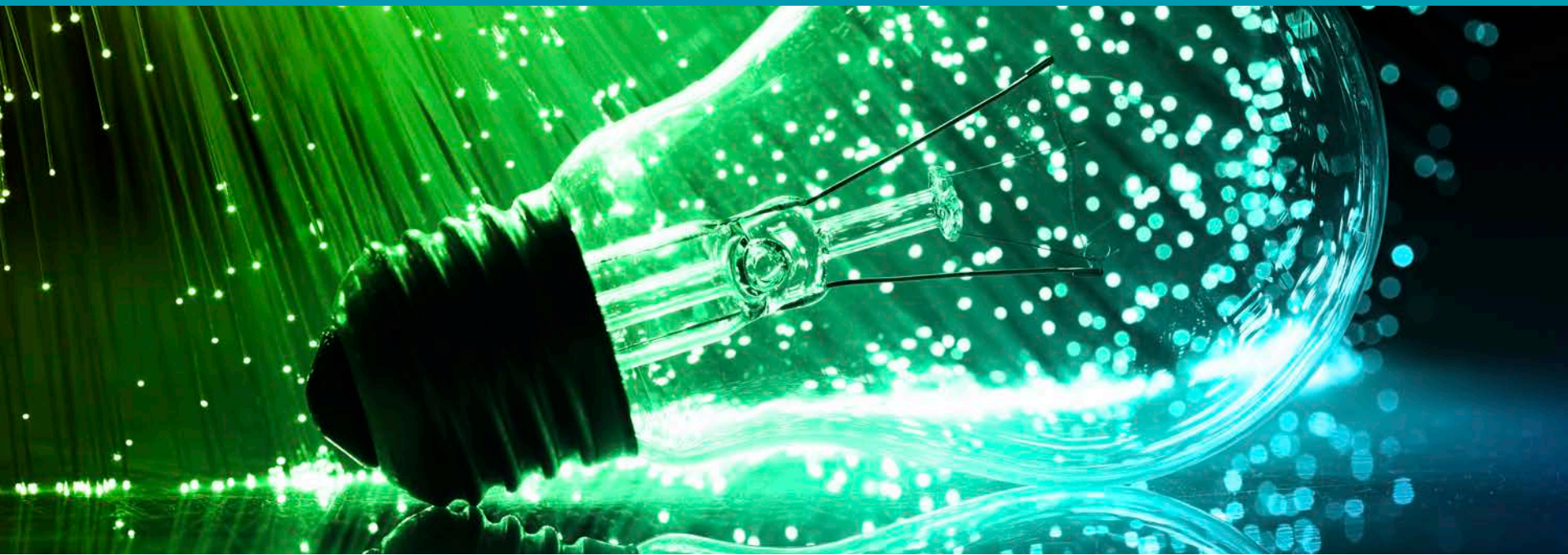
Ross McKinney, MD – Duke University

*March 11, 2015*



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## Disclaimer

The views and opinions expressed in this presentation are those of the individual presenter and do not necessarily reflect the views of the Clinical Trials Transformation Initiative.

The presenter is an Employee of Duke University. Salary support comes from pooled membership fees of the Clinical Trials Transformation Initiative and from FDA Cooperative agreement.

# Issue

- ▶ The informed consent process has multiple objectives
  - Foremost should be to provide information to the potential research participant to enable sound decision making
    - The information can be provided in multiple ways
      - Written
      - Verbal
      - Electronic
    - Each method has strengths and weaknesses
  - A second goal is be certain the implications of participation are clear

# Process Objectives

- A sound decision by the participant
  - Intrinsically, valuing autonomy shows respect for persons
  - Better understanding of the study means better adherence to the study design
    - Medication adherence
    - Attendance at research visits
    - Participation until the designed end of the trial
    - Potential for word-of-mouth marketing of the study to other potential participants
- A legal affirmation – in short, a signature

# Challenges

- Complicated studies
- Limited medial literacy
  - Vocabulary
  - Conceptual naiveté – e.g. Randomization, placebos
- Therapeutic misconceptions
- Use of the document to meet certain legal obligations
  - Signature presumed to protect the researchers and host institution

# Concerns and Consequences

- A verbal process is, for many people, most clear and understandable
- Investigators are suspected of being biased in favor of the research
  - Assumed they will provide a less than dispassionate and balanced presentation (i.e. they will “sell” the study)
- To protect subjects, by regulation we rely on written documentation to provide that desirable optimal level of unbiased information
- We also rely on the document as proof of the agreement to participate

# Informed Consent Methods

## ➤ Oral discussion

- Lack of consistency
- Could be scripted and recorded

## ➤ Written document

- Must contain 8 basic and 6 additional elements, as applicable
- Tends to be rigid
- Can we make it flexible?

## ➤ Electronic formats

- At best, optimized and reproducible
- At worst, the software licensing agreement model



# Regulations: 45 CFR 46.116

- Eight basic and 6 additional elements in an ICD
- Waiving any element requires:
  - 1) No more than minimal risk
  - 2) No effect on rights or welfare of participants
  - 3) Study cannot be practicably done without the waiver
- Standards for #1 and #3 are not consistent across IRBs

# Proposed Tiered Consent Model

- Two part document
  - Informed Consent Document
  - Detailed Reference Section
- Use of plain-language principles
- Compliant with regulations
- Flexible in meeting the needs of those with
  - Limited health literacy
  - A desire for more detail than average
- Focus on risk-benefit considerations
- On a pathway to electronic consent processes



# The Informed Consent Document

- 5-6 pages at most
- All 8 basic and 6 additional elements are present, as applicable
- Clear statements of expectations related to participation, but not in detail
- Can reference the second (e.g. "See chapter 2 of the detailed reference section")
- Acknowledges that additional materials are being provided in the Detailed Reference Section
- Signature as per current norms

# Detailed Reference Section

- Contains, in chapter format, additional detailed information on a range of issues not specifically required by regulations
  - Full protocol schedule
  - Complete list of potential side effects, including those less common
  - The details of indemnification
  - HIPAA language
  - Whatever else seems appropriate
- Intended to be kept as a reference
- Materials that can provide clear information for those of low health literacy or those interested in greater detail
- Not limited in length

# Advantages

- Meets current regulations
- Flexible
- Focuses on decision making process for the potential participant
- Maintains a record for the institution
- Adaptable to an electronic format (by cross-linking)

# Disadvantages

- IRBs are conservative (sponsors may be as well)
- Doesn't fit pre-existing templates
- Potential for information-creep and expansion in the Informed Consent Document
- Needs to be formally reviewed by regulatory agencies to be sure their expectations are met (i.e. OHRP and the FDA)
- Requires learning a new model

# Summary

- Recommend a tiered consent model
  - The Informed Consent Document with 8 basic and 6 additional elements, as applicable, and key information for decision making
  - Detailed Reference Section with background and supplemental information to meet the needs of the broad range of potential participants
  - The Informed Consent Document is signed, and research participants go home with copies of both

# Informed Consent Document Template Work Group

- ▶ Molly Flannery (FDA)
- ▶ Jayvant Heera (Pfizer, Inc.)
- ▶ Kevin Hudziak (Eli Lilly & Co.)
- ▶ Beverly Lorell (King & Spalding)
- ▶ Ross McKinney (Duke University)
- ▶ Steve Mikita (Patient Advocate)
- ▶ Jane Perlmutter (Patient Advocate)
- ▶ Seth Schulman (Pfizer, Inc.)

# Thank you.



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Ross McKinney, Jr, MD

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# Discussion

- Is there a problem? (1 min)
- Is the Tiered Consent Model a viable alternative to the status quo? (34 min)
  - Does e-Consent replicate this model?
  - Deal breakers?
  - Checklist helpful?
  - Better options?
- What needs to be done to implement this model? (30 min)
  - Does this fit within existing regulations?
  - Pilot



**Break 10:15 – 10:30am**