2011 Web Seminar Series

Informed Consent in CTN Protocols

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Training Objectives

- Review of the principles behind informed consent
- The document vs. the process
- Informed consent language
- The informed consent development, review, and approval process
- Opportunities for improving the consent documentation/process

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Review of the principles

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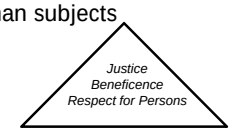
Informed Consent

- Nuremburg Code 1947
  - The voluntary consent of the human subject is absolutely essential
- Belmont Report 1979
  - Principles and guidelines for the protection of human subjects
- Federal regulation
  - HHS – 45 CFR 46
  - FDA – 21 CFR 50



Polling: Myth or Fact?

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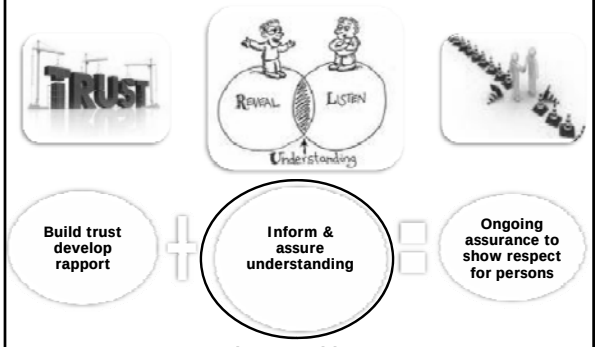

Time to achieve understanding varies greatly

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The Document and the Process

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Informed Consent Document

- Ensures
  - Initial and ongoing respect for human research participants
  - Informed and voluntary study participation

Proof is in the pudding. Our document is the pudding!

- Provides mechanism to
  - Provide study information
  - Document study participation agreement
    - Participant's signature indicates
      - o They agree to be in the study
      - o Understand they can withdraw their consent to participate at any time

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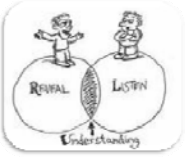
Informed Consent Process

- Ongoing effort by research staff to
  - Provide relevant information to participants
  - Promote fully understanding
  - Assure participation as voluntary



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Informed Consent Outcome

- Adequate knowledge and understanding of the research
- All questions were answered
- Assess and assure understanding
- The project representative signature
  - Documenting the completed consent process

Polling: Myth or Fact?

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Informed Consent Language

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Informed Consent Language

- Structural Elements
  - 8 Basic
  - 6 Additional
  - Written in 6th to 8th grade reading level
  - Avoid technical jargon
  - Clear document font and layout
- IRB reviewed and approved
- Process conducted by knowledgeable study staff member

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Basic 8 Elements

1. Statement that the study involves research
2. Description of foreseeable risks and discomforts
3. Description of potential benefits
4. Disclosure of alternative procedures or treatments that may be advantageous
5. Statement describing extent to which confidentiality will be maintained
6. Explanation of compensation, and any medical treatment available if injury occurs
7. Explanation of who to contact for questions
8. Statement that participation is voluntary, refusal to participate will involve no penalty or loss of benefits, may discontinue at any time

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Additional 6 Elements

1. Statement that research may involve currently unforeseeable risk
2. Circumstances under which the participant may be terminated by the investigator without regard to the participant's consent
3. Any additional costs to the subject that may result from participation
4. Consequences of withdrawal and procedures for orderly termination
5. Statement that significant new findings which may affect the participant's willingness to continue will be provided to the participant
6. The approximate number of participants involved in the research

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informed Consent Development, Review, and approval process

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Development, Review, and Approval Process

- Development – Protocol lead team
- Reviewers
  - CCC at EMMES
    - Regulatory Specialist
    - Protocol Specialists/Monitor
- Final Review and Approval
  - Institutional Review Board (IRB)
    - Approval date
    - Expiration period
    - Continuing review (with protocol review)

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IC Quality Review

- Sequence of review
  - Correct version
  - All pages are present and sequential
  - Signatures and dates present
  - Participant name corresponds with master enrollment log?
  - Who administered consent
    - Are they authorized via signature delegation log?

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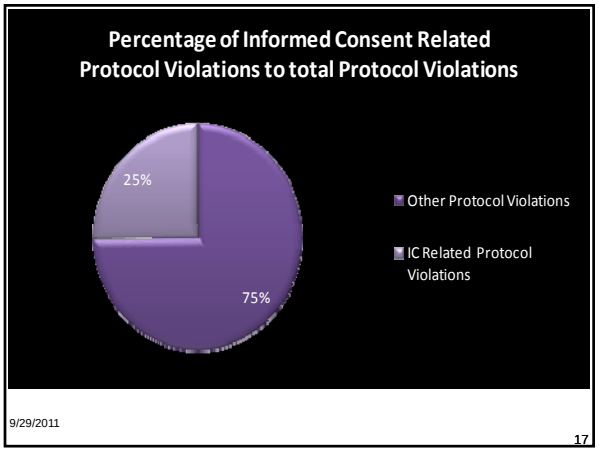

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Improvement Opportunities

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Process Improvement Methodology

- List Critical to Quality (CTQ) requirements
- Identification of CTQs to improve
- Link identified deficiencies with process source / performance features
- Recommend a strategy to address deficiencies
- Implement and test process strategy
- Develop standard operating procedures

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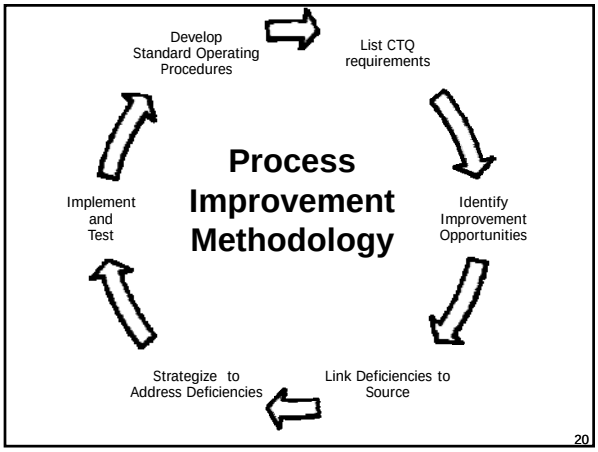

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Informed Consent

Critical to Quality (CTQ) Requirements

- Provide participant with initial and ongoing information needed to make an informed decision to participate
- Assess participant comprehension
  - Discussion and Quiz
    - Quiz scoring
      - Participant corrects error, initials & dates correction
- Document the participant's voluntary agreement for study participation

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Verifying IC Quality (CTQs) Requirements

- Critical to Quality (CTQ) requirements
  - **Documentation is Evidence**
    - Participant and research staff communication
    - Understanding
    - Voluntary agreement to participate
  - Documentation includes
    - Signatures, Dates, Initials, Quiz

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Critical to Quality

1. Elements that facilitate IC Quality
   - IC area set up
2. Process that assure IC Quality Documentation
   - Step by step process map
3. Verification of Quality achieved
   - Quality rubric and
   - Documented quality verification

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Documentation Errors / Critical to Quality (CTQ) Characteristics / Requirements	**Actions to facilitate Quality** THE SET UP	**Process and Review for Quality** THE PERFORMING
Expired, obsolete or "retired" consent version used and signed by participant	X	
Incomplete consent forms, missing pages	X	
Faded copies, sections of the consent are unreadable	X	
Signature of staff obtaining consent is missing, undated, or dated incorrectly		X
Consent is signed and dated by required study staff days after the participant signs		X
Participant did not initial all required sections within the consent form		X
Participant signs wrong date	X	
Signature and date errors are crossed out and are not initialed and dated		X
The participant answers the quiz incorrectly with no documentation of correction	X	
Participant corrects a quiz question and does not initial and date the correction where the error occurred.		X
Participant did not receive a copy of the signed consent form		X
No progress note written documenting that the consent process was conducted and the consent form was signed prior to conducting any study-related procedures.		X

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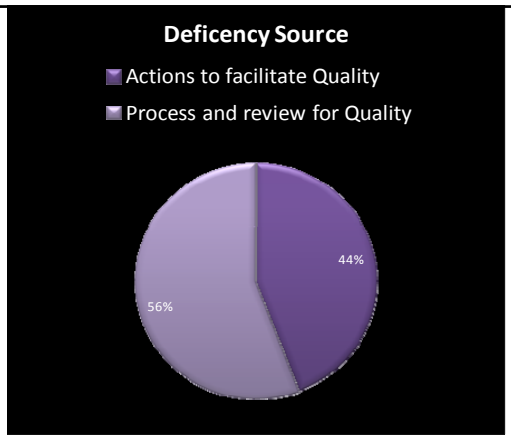

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Documentation Errors / Critical to Quality (CTQ) Characteristics / Requirements	**Strategies to address deficiency**
Expired, obsolete or "retired" consent version used and signed by participant	
Incomplete consent forms, missing pages	
Faded copies, sections of the consent are unreadable	
Signature of staff obtaining consent is missing, undated, or dated incorrectly	
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Strategies to Improve Quality

- Complete quality review process
  - BEFORE Participant leaves the site
- Don't take process shortcuts
  - Stick to the process that brings quality

Time constraints may impact quality

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Perceptions of Value

- Accounting
- Accurate accounting processes
  - Review and verification of financial transactions

- Research
- Accurate documentation of IC
  - Review and verification of ethical transactions
- Site Specific Checks and balance is essential
  - Time must be allotted for quality and for variances
  - Does time constraint impact on quality

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Quality Verification

- Quality IC documentation is
  - 2 staff member job
    - IC process staff member
    - IC Quality Assurance staff member
- IC quality review prior to research activities
  - Reviewed by qualified staff member
- IC review template
  - Use an overlay to highlight areas requiring documentation of process

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Questions or Comments?

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Mark Your Calendar

- **December 7**
  - A New Look at Manual of Procedure (MOP) Development

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