Informed Consent (IC)
Part 1:
Overview and IC Document

Agenda
• Guiding principles of the informed consent process
• Required elements of the informed consent document
• Optional elements of the informed consent document
• Strategies to improve writing an informed consent document

What is Informed Consent (IC)
• Having capacity to agree for one's self to participate in a given situation once risks and benefits are understood
• Ongoing process of communication and mutual understanding between an individual and investigator
• Participant's initial agreement is evidenced by signing an IC document

IC is NOT just a piece of paper, or a moment in time, or a contract.
Guiding Principles of IC

• Nuremberg Code
• Voluntary consent
• Subject free to stop
• The Belmont Report: *Respect for Persons*
  • People are autonomous agents and should be treated with respect
  • Informed consent must be freely and voluntarily given
  • Those of diminished capacity require additional protections

Code of Federal Regulations Protecting Human Subjects

DHHS: 45 CFR Part 46

FDA: 21 CFR Part 50

45 CFR 46 Subparts

• Subpart A: Protection of Human Subjects
• Subpart B: Pregnant Women, Human Fetuses and Neonates in Research
• Subpart C: Biomedical and Behavioral Research Involving Prisoners as Subjects
• Subpart D: Children Involved as Subjects in Research
IC Document

- Written form that provides a summary of the research study
- Explains subjects rights of participation
- Written in language understandable to the subject
- Contains no exculpatory language

Exculpatory Language

Unacceptable
- I waive any possibility of compensation for injuries that I may receive as a result of participation in this research.

Acceptable
- This hospital makes no commitment to provide free medical care or payment for any unfavorable outcomes resulting from participation in this research. Medical services will be offered at the usual charge.

8 Basic Elements*

- Invitation to participate
- Purpose, duration, procedures
- Foreseeable risks/benefits
- Alternatives
- Confidentiality conditions
- Compensation for injury
- Contact persons for questions for both research care related questions and humans subjects protection questions
- Voluntary nature of participation

*21 CFR 50 and 45 CRF 46
6 Additional Elements*

• Unforeseeable risks (e.g.: risk to subject or fetus)
• Circumstances where subjects participation may be terminated
• Consequences of discontinuing research participation
• How notification of significant new findings will be explained
• Added Costs
• Number of subjects to be enrolled

*21 CFR 50 and 45 CFR 46

Other Considerations

• Compensation
• Data Sharing
• Genetic and genomic
• Human gene transfer
• FDA regulated research [21 CFR 50.25(c)]
  • FDAAA Applicable Clinical Trial:
    "A description of this clinical trial will be available on
    http://www.ClinicalTrials.gov, as required by U.S. Law. This
    Web site will not include information that can identify you. At
    most, the Web site will include a summary of the results. You
    can search this Web site at any time."

Waiver of Informed Consent

• Research involves no more than minimal risk to the subjects;
• Waiver or alteration will not adversely affect the rights and welfare of the subjects;
• Research could not reasonably be carried out without the waiver or alteration; AND
• Whenever appropriate, the subjects will be provided with additional pertinent information after participation.
IRB IC Template

• Each IRB will have an informed consent document template that is to be used.
• When working on industry sponsored trials or multi-site trials a sample IC document will be provided.

Challenges in Writing an IC Document

• Two major challenges
  • Readability
  • Comprehension
• Ask yourself, "Does the patient need this information in order to make an informed decision?"

Improving in Readability

• State a clear purpose of the study
• Define all technical terms
• Use 2nd person singular
• Give explicit information
• Use cause and effect statements when describing potential toxicities
• Give concrete examples
• Highlight terms
• Create mental images
### Improving Comprehension

- Shorten words by removing unnecessary prefixes and suffixes, using simple synonyms
- Shorten sentence length
- Read sentence out loud
- Use topical headings or short questions
- Use active voice
- Minimum font size of 12 point

### Summary

- Ongoing process
- Regulations governing IC
  - HHS: 45 CFR Part 46
  - FDA: 21 CFR Part 50
- Wavier of IC
- IC document must contain the 8 required elements
  - 6 additional elements
- Challenges in writing the IC document