Informed Consent

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APEC GCP Inspection Workshop

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Overview

- Background
- FDA regulations
- ICH GCP guidance
- Basic (Essential) elements
- Additional elements

Background -1-

- Nuremberg Code 1947
- Declaration of Helsinki 1964
- United States
 - Belmont Report 1979
 - 21 CFR Parts 50 and 56 1980 & 1981
 - The Common Rule 45 CFR Part 46 1991
- ICH GCP 1997

Background -2-

- Belmont Report: 3 Ethical Principles
 - Respect for persons
 - Individual autonomy
 - Protection of individuals with reduced autonomy
 - Beneficence
 - Maximize benefits and minimize harms
 - Justice
 - Fairness in selection of subjects and distribution of burdens and benefits

Background -3-

- Informed consent
 - Sufficient information
 - Comprehension
- Legally authorized representative
- Free of coercion and undue influence

Informed Consent

- Not a single event
- Not simply a form to be signed
- Educational process that starts by informing a potential study subject and continues throughout the study
- Requires disclosure of information, adequate comprehension, and a voluntary decision to participate

FDA's Regulation

- 21 CFR Part 50 requires
 - Use of IRB/IEC approved document
 - Voluntary participation, after sufficient time is allowed for consideration
 - Minimization of coercion and undue influence
 - Understandable information
 - No exculpatory language

Exculpatory language

- Language that waives or appears to waive
 - any of the subject's legal rights

or

 releases or appears to release the investigator, the sponsor, the institution, or its agents from liability for negligence

ICH GCP

ICH GCP definition (1.28)

"A process by which a subject voluntarily confirms his or her willingness to participate in a particular trial, after having been informed of all aspects of the trial that are relevant to the subject's decision to participate. Informed consent is documented by means of a written, signed, and dated informed consent form."

Basic Elements -1-

The following elements of information must be provided to all study subjects

A statement that the study involves research, an explanation of the purpose of the research, the expected duration of the subject's participation, and a description of the procedures to be followed

Basic Elements -2,3,4-

- A description of any foreseeable risks or discomforts to the subject
- A description of any benefits to the subject or to others which may be reasonably expected from the research
- A disclosure of appropriate alternative procedures for courses of treatment, if any, that might be advantageous to the subject

Basic Elements -5-

 A statement describing the extent to which confidentiality of records identifying the subject will be maintained [specifically noting regulatory authorities – FDA – may inspect the records]

Basic Elements -6-

 For research involving more than minimal risk, an explanation whether any medical treatments or compensation are available if any injury occurs and, if so, what they consist of or where further information may be obtained

Basic Elements -7-

 An explanation of whom to contact for answers to pertinent questions about the research or research subjects' rights or in the event of a research-related injury or adverse occurrence

Basic Elements -8-

A statement that participation is voluntary, that refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled, and that the subject may discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled

Additional Elements -1,2-

When appropriate, the following elements must also be provided to subjects

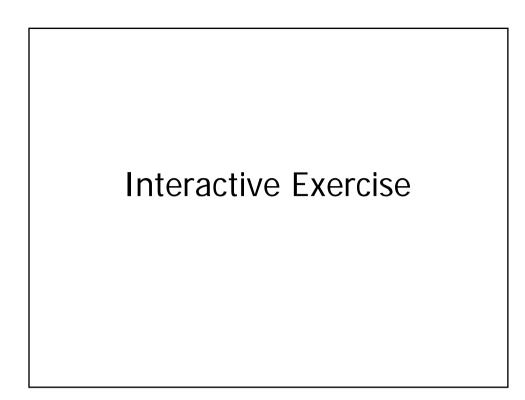
- A statement that the research may involve risks to the subject that are currently unforeseeable
- Anticipated circumstances under which the subject's participation may be terminated without regard to the subject's consent

Additional Elements -3,4-

- Any additional cost to the subject that may result from participation
- The consequences of a subject's decision to withdraw from the research and procedures for orderly termination of participation by the subject

Additional Elements -5,6-

- A statement that significant new findings developed during the course of the research which may relate to the subject's willingness to participate will be provided to the subject
- The approximate number of subjects involved in the study



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