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

Interactive Exercise

Disclaimer :

The information within this presentation is based on the presenter's expertise and experience, and represents the views of the presenter for the purposes of a training workshop.