Required Elements of Informed Consent

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Outline

- General Requirements of Informed Consent
- Basic Elements of Informed Consent
- References

General Requirements of Informed Consent

- No human subject shall participate in research before they or their Legally Authorized Representative (LAR) give legally effective informed consent
  - Except when a consent waiver is approved or Exception From Informed Consent (EFIC) criteria are met
- Consent shall be sought only under circumstances that:
  - provide the subject or LAR with sufficient opportunity to discuss and consider whether or not to participate
  - minimize the possibility of coercion and undue influence
- Information provided to a subject or their LAR shall be in language understandable to them
- The subject or LAR must be provided with the information a reasonable person would want to make an informed decision

General Requirements of Informed Consent

- Informed consent must begin with the concise and focused key information most likely to assist in understanding why one might or might not want to participate
  - This must be organized and presented in such a way as to facilitate comprehension
- The informed consent must present information that:
  - is in sufficient detail
  - is organized and presented to facilitate the subject's or LAR's understanding of why one might or might not want to participate
- No exculpatory language may be included

Basic Elements of Informed Consent

- A statement that
  - The study involves research
  - Explains the purpose(s) of the research
  - Describes the expected duration of the subject's participation
  - Participation is voluntary
  - Refusal to participate will involve no penalty or loss of benefits to which the subject or LAR is entitled
  - The subject may discontinue participation at any time without penalty or loss of benefits to which they are entitled
- A description of the procedures to be followed
  - Includes identification of any procedures which are experimental
- A description of any reasonably foreseeable risks or discomforts
- A description of any reasonably expected benefits
- A disclosure of alternatives to participation that may be advantageous to the subject
- A statement describing the extent to which confidentiality of the records identifying the subject will be maintained

Basic Elements of Informed Consent

- For studies involving more than minimal risk, an explanation as to if any compensation or treatment is available if injury occurs
  - If so, what it consists of or where further information may be obtained is required
- An explanation of whom to contact for:
  - Answers to questions about the research
  - Information about research subject's rights
  - Research-related injury to the subject
- A statement that:
  - Researchers might wish to share de-identified information or biospecimens for future research
  - Identifiers will be removed from the identifiable private information or identifiable biospecimens
  - Additional informed consent from the subject or LAR will not be sought for such future use

References

- 21 CFR 50.20
- 21 CFR 50.25(a)
- 45 CFR 46.116(a) & (b)
- OIA-314B