Altering Informed Consent

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Outline

- What is a Consent Alteration?
- Refresher on Consent Waiver Requirements
  - Considerations for All Consent Waivers
  - Additional Considerations for Waivers of Informed Consent
- Additional Requirements for an Alteration of Consent
- References

	Waiver of Consent	Alteration of Consent	Waiver of Documented Consent	Exception from Informed Consent (EFIC)
Consent Process?	No	Yes	Yes	Eventually[v]
Consent Document/ Information Sheet?	No	Yes	Yes	Yes
Elements of Consent Changed or Missing?	No	Yes	Maybe*	Maybe*
Consent Signed by Subject/LAR?	No	Maybe*	No	Eventually[v]

*The alteration of consent may be combined with the waiver of documented consent or EFIC when all criteria are met.

[v]EFIC requires that there be a consent process and signed consent when practicable. For subjects enrolled without consent, researchers must continue to attempt to obtain consent after enrollment.

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What is a Consent Alteration?

- Anytime the consent will not contain:
  - All the required basic elements of consent
    - E.g., purpose of the research, voluntary participation, etc.
  - Appropriate additional elements of consent
    - E.g., unforeseen risks, number of subjects, costs, etc.
- This may be commonly done when revealing the true nature of the research would affect the responses or outcomes of the research.
  - E.g., a study about morality may want to hide the true purpose since participants might respond differently.
- Must meet all the criteria for a consent waiver and a few additional requirements to be allowable.

Considerations for All Consent Waivers

- The research is no greater than minimal risk
- The research could not be practicably done without the waiver
- The research is not a medical experiment under California law
- The research does not involve non-viable neonates
- No individuals were asked to provide broad consent and declined

Additional Considerations for Waivers of Informed Consent

Requirements for General Consent Waivers

In addition to considerations for all waivers:

- The waiver won't adversely affect the rights and welfare of subjects
- If identifiable private information or identifiable biospecimens are needed, must have justification why identifiers are needed
- When appropriate, the subject or LAR will be provided with additional pertinent information after participation

Requirements for Waivers of Consent for Public Benefit or Service Program Research

In addition to considerations for all waivers:

- The research is not FDA regulated
- The research is to be conducted by or subject to the approval of state or local government officials
- The research is designed to study, evaluate, or examine:
  - Public benefit or service programs
  - Procedures for obtaining benefits or services under those programs
  - Possible changes in or alternatives to those programs or procedures
  - Possible changes in methods or levels of payment for benefits or services under those programs

Additional Requirements for an Alteration of Consent

- 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

Additional Requirements for an Alteration of 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

References

- 21 CFR 50.22
- 45 CFR 46.116(e) & (f)
- California Health and Safety Code Section 24174
  - Definition of a “medical experiment”
- OIA-410