Waiving Documentation of Informed Consent

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Outline

- What is a Waiver of Documented Consent?
- Requirements for a Waiver of Documented 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 Waiver of Documented Consent?

- Anytime:
  - There is a consent process, and
  - The subject or LAR will not be required to sign the consent document.

- Three different situations in which documented consent can be waived:
  - Confidentiality is the main risk and ICF is the only linker
  - Procedures don't require written consent outside of research
  - Subjects are part of a distinct cultural group that doesn't sign forms

Requirements for All Documented Consent Waivers

- The research is not a medical experiment under California law
- The subject or LAR will be presented with all the elements of consent
  - Unless an alteration is approved
- The elements of consent will be provided to the subject or LAR:
  - In writing (must be an approved information sheet)
  - Orally (must be an approved consent script)

Additional Requirements for Documented Consent Waivers

- §117(c)(1)(i)
  - A breach of confidentiality is the principal risk to subjects
  - The ICF would be the only record linking the subject and the research
  - The research is not FDA-regulated
  - Each subject or LAR will be asked if they want documentation linking the subject and the research
    - The subject's or LAR's wishes shall govern
- §117(c)(1)(ii)/21 CFR 56.109(c)(1)
  - The research involves no procedures for which written consent is normally required outside of the research setting
  - The research is minimal risk
- §117(c)(1)(iii)
  - The subjects or LARs are members of a distinct cultural group or community in which signing forms is not the norm
  - There is an appropriate alternative mechanism for documenting informed consent
  - The research is minimal risk
  - The research is not FDA-regulated

References

- 21 CFR 56.109(c)(1)
- 45 CFR 46.117(c)
- California Health and Safety Code Section 24174
  - Definition of a “medical experiment”
- OIA-411