Informed Consent Process: Opportunities for Flexibility

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A Laundry list of flexibility opportunities with consent (permitted under the Common Rule)

Waiver of Consent/Documentation Permitted

Waiver of documentation of consent is underused and allowed by the regs\(^1\)

- Waive documentation of consent in expedited research
  Consent documentation may be waived for almost all research approved using the expedited procedure; i.e. when written consent is normally not required for procedures (in expedited categories (1)-(7)) performed outside of the research context.
  
  Note: The standard requirements for informed consent (or its waiver, alteration, or exception) apply regardless of the type of review--expedited or convened--utilized by the IRB.

- Waive signature/documentation of informed consent/parental permission
- Waive informed consent/parental permission/assent entirely
- Allow waiver/alteration of certain elements of informed consent
- Emergency Research Consent Waiver must meet strictly limited but differing conditions when subject to FDA regulations than when not subject to FDA regulations

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\(^1\) Documentation is completed via an IRB approved consent form or description of the consent procedure within the IRB approved study plan. If there is no signature line on the IRB approved consent form, the IRB has waived the requirement to obtain a signature. If there is no consent form approved, the default is that there is no consent form required. Minutes may reflect these decisions but this further documentation is not required.

See more flex info at oprs.usc.edu/flex
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- Waive the requirement for the investigator to obtain a signed consent form for some or all participants if the IRB finds: that the research presents no more than minimal risk of harm to participants; and involves no procedures for which written consent is normally required outside of the research context. [45 CFR 46.117(c)(2), 21 CFR 56.109]

Signature Options in Consent

- Electronic/digital signatures are permitted on informed consent documents
- Witness signature is not required on informed consent unless a short form is used
- Faxed/mailed signed informed consents are permitted
- Person obtaining consent is not required to sign consent unless short form is used
- PI and subject need not sign on same day
- Consent form does not have to be signed on the day consent process is initiated
- When person obtaining consent is assisted by a translator, the translator may serve as witness.
- Signatures/initials of subject or witness are not required on every page
- Exact time that the consent is signed is not required on consent form
- Use of legally authorized representative may be flexible in certain jurisdictions and allow LAR to consent

Simplification and Customization of Consent

- Use of short forms is an option for any kind of research (very few know about this or that it is an option) regs do not limit use of short form to translations only
- Info/fact sheet can be recommended and need not be reviewed by IRB (Exempt research does not require informed consent)
- Significant new information or findings (SNIFs) as required in the regs for transmittal to currently enrolled subjects should be provided in a separate, focused document as soon as possible and provided to enrolled subjects. Only new study subjects should get a full revised informed consent (approved by the IRB).
- Extraneous information and detailed study procedures may be placed in educational materials or study handouts, do not have to be upfront in the consent
- Situations allowing info/fact sheet (rather than consent) are under utilized

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- Elements of Consent may be omitted when not applicable, for example:

  4) A disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject;

  5) A statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained;

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

Child Assent Made Simple

- Documenting of child of assent not required by regulations.

- Waiver of assent for minors allowed if the conditions for waiver of consent with adults is met (46.116.(c),(d))

- Minors who initially were enrolled under parental consent and reach the legal age of consent while enrolled in a study need to be consented as an adult (unless the IRB waives the consent requirements)

IRB Processing of Consent Documents

- Informed consent stamping is not required

- Recruitment documents need not be stamped

- Studies may begin after Certificate of Confidentiality has been applied for (not obtained) because data are protected retroactively

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