

Consent Process: Requesting a waiver of signed consent

IRBIS Office of Human Research Ethics
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>> 2. Waiver of written documentation of informed consent

Current Application: Quick View (HTML) PDF View FAQ

The default is for subjects to sign a written document that contains all the elements of informed consent. Under limited circumstances, the requirement for a signed consent form may be waived by the IRB. For example, this might occur for phone or internet surveys, when a signed consent form is either impractical or unnecessary, or in circumstances where a signed consent form creates a risk for the subject.

1. Are you requesting a waiver of any aspect of written (signed) documentation?
 Yes No

Choose which of the following consent approaches apply and attach the relevant document:

- Full consent form minus the signature lines
- Information or fact sheet (streamlined unsigned consent form)
Required document(s): Information or Fact Sheet
- Online consent form with electronic agreement
- Consent statement incorporated into a survey itself
- Verbal consent obtained in person or via the phone
- Short form (for subjects with limited ability to read full consent form) [view instruction](#)
- Other

If other, please describe

Choose which one of the following justifies the waiver of written documentation:

- The only record linking the subject and the research would be the consent document and the principal risk would be potential harm resulting from a breach of confidentiality (e.g., study topic is sensitive so that public knowledge of participation could be damaging). Participants should be asked whether they want documentation linking them with the research and the participants' wishes will govern whether they sign the form. Note: This justification cannot be used in FDA-regulated research.
 Explain
- The research presents no more than minimal risk of harm to subjects and involves no procedures for which written consent is normally required outside of the research context. (e.g., many phone or mail surveys, "man in the street" interviews, etc.).
 Explain

Part D.2 enables you to request a waiver of written consent. If requested, you must:

- indicate the alternative method by which you will obtain consent (note that you are required to submit a copy of your alternative method, as an attachment), and
- justify your request for a waiver.