



Waiver of Documentation of Signed Consent Checklist

This checklist is to be used when researchers are requesting a waiver of documentation of signed consent (consent is still obtained and documented, but subjects are not signing their name (either written or electronically))

All important elements of consent are still provided to research subjects (see informed consent checklist).

Consent is documented in another format aside from signed consent

Subject provides consent orally (either in person or virtually) and this is documented by the researcher(s).

Subject engages in an action to document consent (e.g., click an option that reads "I agree").

Consent is assumed by subject participation (e.g., they begin completing a questionnaire)

It is clearly stated in the informed consent that this is how consent is assumed

One of the following is indicated to be true:

The research presents no more than minimal risk of harm to the subject, and the research involves no procedures for which written consent is normally required outside of the research context

The only record linking the subject and the research would be the consent document, and the principal risk of a signed consent document would increase potential harm resulting from a breach of confidentiality.