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In most cases, federal regulations require that every adult study subject sign an IRB-approved informed consent document before any research procedures involving that subject may begin. Under certain circumstances outlined in the regulations, an IRB may grant a waiver of documentation of informed consent, allowing a researcher to consent and enroll subjects without obtaining their signatures. Under a waiver of documentation, a subject must still provide consent, but does not need to sign an informed consent document.

Department of Health and Human Services' regulations—located at 45 CFR 46—permit a waiver of documentation of consent if

- the study at hand presents no more than minimal risk to subjects and involves no procedures for which consent is required outside the research context;

*or*

- the consent document is the only record linking a subject to study participation, and the principal risk the study presents to subjects is breach of confidentiality.

Under the Food and Drug Administration's regulations—at 21 CFR 56—an IRB may grant a waiver of documentation *only* if the study presents no more than minimal risk and involves no procedures for which consent is required outside research.

Since the criteria differ, an IRB must consider which federal agency—HHS or FDA—will oversee the research, in order to determine whether a waiver of documentation is allowed.

Even when granting a waiver of documentation of informed consent, the IRB may require the researcher to provide subjects with written material about the study.

Contact the IRB for more information about informed consent documentation requirements and waivers.

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