IRB Waiver or Alteration of Informed Consent and Waiver of Documentation of Consent

The Common Rule permits an IRB to waive or alter informed consent and to waive documentation of consent when the applicable regulatory criteria are met.[1] FDA regulations also permit waiver or alteration of informed consent for certain minimal-risk clinical investigations and provide other exceptions from informed consent requirements.[2]

Waiver of consent: IRB approves waiver of the requirement to obtain informed consent.

Alteration of consent: IRB approves a consent procedure that omits or alters some or all of the elements of informed consent permitted by the applicable regulations.

Waiver of requirement to document consent: IRB approves a plan in which investigators are not required to obtain a signed informed consent form.

Criteria for waiver or alteration of consent	What should the IRB expect the protocol to include?
The research involves no more than minimal risk to the subjects.	Explanation of why the probability and magnitude of anticipated harm poses a risk that is no more than minimal risk to the subjects.
The research could not practicably be carried out without the requested waiver or alteration.	A study-specific justification for why obtaining consent, or obtaining all required elements of consent, would make the research impracticable. Avoid relying on inconvenience, cost, or speed alone.
If the research involves using identifiable private information or identifiable biospecimens, the research could not practicably be carried out without using such information or biospecimens in an identifiable format.	Explanation of why identifiers are necessary to accomplish the research aims and why de-identified information or biospecimens would not be sufficient.
The waiver or alteration will not adversely affect the rights and welfare of the subjects.	Description of how subjects' rights and welfare remain protected. Investigators may include privacy and confidentiality protections and any relevant expectations or prior permissions.
Whenever appropriate, subjects or legally authorized representatives will be provided with additional pertinent information after participation.	Description of post-participation information as appropriate for participants. Investigators should specify what will be provided, to whom, when, and how; if not, explain why not.

[1] HHS: 45 CFR 46.116(f)(3)(i)-(v) (waiver/alteration criteria) and 45 CFR 46.117(c) (waiver of documentation).

[2] FDA: 21 CFR 50.22 (minimal-risk waiver/alteration); 21 CFR 56.109(c) (waiver of documentation); and 21 CFR 50.23 and 50.24 (other exceptions from informed consent requirements).

Waiving Documentation of Consent (HHS regulations): The protocol should support at least one of the following findings:

- The only record linking the subject and the research would be the informed consent document, and the principal risk would be potential harm resulting from a breach of confidentiality. Each subject (or legally authorized representative) will be asked whether the subject wants documentation linking the subject with the research, and the subject's wishes will govern;
- The research presents no more than minimal risk of harm to subjects and involves no procedures for which written consent is normally required outside the research context; OR
- If the subjects or legally authorized representatives are members of a distinct cultural group or community in which signing forms is not the norm; the research presents no more than minimal risk of harm to subjects and provided there is an appropriate alternative mechanism for documenting that informed consent was obtained.

FDA-regulated research: For minimal-risk FDA-regulated clinical investigations, 21 CFR 50.22 permits an IRB to waive or alter informed consent when the IRB finds and documents the five criteria in the HHS regulations above. For waiver of the signature/documentation requirement, FDA regulations at 21 CFR 56.109(c) permit waiver when the research presents no more than minimal risk and involves no procedures for which written consent is normally required outside the research context. Other FDA exceptions from informed consent, including emergency circumstances, remain governed by 21 CFR 50.23 and 50.24.