Institutional Review Board
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What is the Difference between a Full Waiver of Consent, Alteration of Consent, and a Waiver of Consent Documentation?

	Full Waiver of Consent	**Alteration of Consent**	**Waiver of Consent Documentation**
Regulatory Citation	45 CFR 46.116(f)(3)		45 CFR 46.117(c)
What is it?	Waiving the consent process entirely. Individuals will not be approached for consent or it is not possible to approach them for consent (e.g. secondary data analysis)	Altering some or all of the elements of informed consent (e.g. through deception)	Waiving the requirement for a signed consent document (physical or typed), in favor of verbal consent or clicking a button to indicate consent. This is also used for opt-out parental consent, where parents must sign a form for a child *not* to participate. In cases in which the documentation requirement is waived, the IRB may require the investigator to provide subjects or legally authorized representatives with a written statement regarding the research.
How do I request it?	*In Part 2 Section 7, describe how the project meets **each** of the following criteria:* -The research involves no more than minimal risk to the subjects; -The research could not practicably be carried out without the requested waiver or alteration; -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; -The waiver or alteration will not adversely affect the rights and welfare of the subjects; and -Whenever appropriate, the subjects or legally authorized representatives will be provided with additional pertinent information after participation. Notice that the regulatory criteria for requesting an alteration of consent and a waiver of consent are the same but that they reflect different processes.		*In Part 2 Section 7, describe how the project meets **at least one** of the following criteria:* -That 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; -That the only record linking the subject and the research would be the informed consent form 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; 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, that 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.

Please note: In the past, the IRB required investigators to address each of the criteria listed at 45 CFR 46.116(f)(3) (no more than minimal risk, impracticality, maintains the rights and welfare, and additional information), when requesting a waiver of consent documentation. Moving forward, the IRB will approve a waiver of consent documentation if investigators address each of the criteria listed at 45 CFR 46.116(f)(3), or at least one of the criteria listed at 45 CFR 46.117(c).

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