IRB Waiver of Informed Consent vs Waiver of Documentation of Informed Consent

Informed consent is central to the Belmont Report principle of respect for persons, and it is fundamental to the protection of human subjects. There are circumstances, however, when requirement for informed consent or documentation of consent (obtaining a signature), may be waived or altered by the IRB. A **waiver of consent** occurs when an IRB waives the requirement to obtain informed consent for research, and **alteration of consent** means an IRB may approve a consent procedure that omits or alters some or all of the elements of informed consent. An IRB may **waive the requirement for documentation of consent** in which case the investigator is not required to obtain a signed informed consent if specific regulatory requirements are met. For the IRB to grant a **waiver or alteration of consent**, the research must meet the regulatory requirements for a waiver at 45 CFR 46.116(f)(3)(i-v).[1]

Criterion per 45 CFR 46.116(f)(3)(i-v)	**Explanation**
The research involves no more than minimal risk to the subjects.	The protocol must state how the probability of harm anticipated in the study poses no more risk than the subject would experience or encounter in daily life or during routine physical examination or blood draw.
The research could not practicably be carried out without the waiver or alteration.	Justification must be provided to the IRB about why it would be impossible to carry out the research without a waiver of consent. This refers to the scientific necessity for the waiver. Reasons such as inconvenience, cost, or that too many people might refuse to participate are not acceptable.
If the research involves using identifiable private information/biospecimens, the research could not practicably be carried out without using such information or biospecimens in an identifiable format.[2]	Waiver of consent removes the ability of a subject to make a voluntary choice regarding research participation, and normally the research should use the information and/or biospecimens posing the smallest risk to subject privacy and confidentiality. The protocol must explain why the specimens and/or data must be retained in an identifiable manner.
The waiver will not adversely affect the rights and welfare of the subjects.	The protocol must describe why the waiver will not negatively affect subjects' rights and welfare.
Whenever appropriate, the subjects or legally authorized representatives will be provided with additional pertinent information after participation.	If the research may reveal information that is important for an individual subject to know, the PI may provide a plan to inform them. In addition, some research (such as that involving deception) may require a waiver of certain elements of consent to disguise the true study purpose in order to maintain scientific validity. In such cases, the PI should present a plan to debrief the subjects after their study participation is completed.

Waiver or Alteration of Consent for Research that is Regulated by the Food and Drug Administration (FDA):

- For FDA regulated research, the IRB may also waive or alter elements of informed consent for non-emergency research in accordance with the July 2017 FDA guidance, *IRB Waiver or Alteration of Informed Consent for Clinical Investigations Involving No More Than Minimal Risk to Human Subjects,* when the following applies:[3]
  - Research involves no more that minimal risk;
  - Waiver or alteration will not adversely affect rights and welfare of subjects;
  - Research could not practicably be carried out without the waiver or alteration; AND
  - Whenever appropriate, the subjects will be provided with additional pertinent information after participation.
- For FDA regulated research, the IRB may allow an exception from the requirements for informed consent for emergency research as specified in 21 CFR parts 50.23 or 50.24.

[1] All references to 45 CFR 46 are from the 2018 Common Rule (CR)
[2] This criterion was added with 2018 Revision of the CR.
[3] The criteria listed here are from the 2017 FDA Guidance. However, FDA is the process of harmonizing these criteria to match those of the 2018 CR listed in the table above.

Waiver of Documentation of Consent:[4]

As per 45 CFR 46.117(c)(1)(i-iii), the requirement to obtain a subject's signature can be waived if:

- 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;
- 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; or
- If 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.

In cases in which the consent documentation requirement is waived, the IRB may require the investigator to provide subjects or legally authorized representatives with a written statement regarding the research (45 CFR 46.117(c)(2)).

Parental or Guardian Permission for Research Involving Children may be Waived by the IRB if the IRB determines:

In addition to the conditions required for waiver of consent noted in 45 CFR 46.116(f)(3)(i-v) (See table on 1st page):

- The research protocol is designed to study conditions in children or a subject population for which parental or guardian permission is not a reasonable requirement to protect the subjects (for example, neglected or abused children), provided that an appropriate mechanism is in place to protect the children, and provided that the waiver is not inconsistent with federal, state, or local law.
- The choice of an appropriate substitute mechanism (for example, appointing a child advocate or an assent monitor) for protecting children participating in research would depend on the nature and purpose of the activities described in the protocol, the risk and anticipated benefit to the research subjects, and the child's age, maturity, status, and condition.

Waiver of Child Assent

Just as parental permission is a protection for children as vulnerable research subjects, an additional research protection for minor subjects is obtaining assent. The IRB must determine that adequate provisions are made for soliciting the assent of the potential minor subjects ***unless*** the IRB waives the requirement for assent per 45 CFR 46.408(a) for any of the following reasons:

- The capability of some or all of the children is so limited that they cannot reasonably be consulted.
- The intervention or procedure involved in the research holds out prospect of direct benefit important to the health or well-being of the children and is available only in the context of the research.
- Criteria for waiver noted in 45 CFR 46.116(f)(3)(i-v) are met. (See the table on 1st page.)

IRB Member Considerations:

- If the PI is requesting a waiver or alteration of consent or assent or is requesting a waiver of documentation of consent from the IRB, verify that the protocol includes an explanation of how the required waiver criteria have been met.
- Consider applicable federal regulations, state and local laws and institutional policies when determining whether a waiver of documentation of consent is an option.
- Ensure there is adequate documentation of fulfillment of the criteria permitting waiver or alteration of consent (e.g., in IRB minutes and/or reviewer checklists).

[4] FDA has proposed harmonizing their regulations regarding waiver of documentation of consent to parallel the 2018 CR listed here, but these updates have not yet been adopted.