Guidance -
Findings for Waiver or Alteration of Consent Requirements

The IRB may waive the requirement to obtain ***written documentation of informed consent***, as allowed by OHRP (45 CFR 46.117 (c)) and FDA regulations (21 CFR 56.109(c)). This provision can be used only for the waiver of documentation of consent, not for waiver or alteration of the consent process itself. A waiver of documentation of consent does not mean that requirements of the consent process are removed.

Even if a waiver of documentation is granted by the IRB, permitting the investigator to forego obtaining the participant's signature on a written consent document, the investigator still must provide the participant with all of the information required to constitute a complete and appropriate consent process, through an information sheet, or through an oral script in a language understandable to the participants.

To approve a waiver of documentation, the IRB must find that the protocol-specific justification for waiving documentation satisfies regulatory criteria. Specifically, the IRB must determine the regulatory basis for the waiver.

PLEASE NOTE: FDA-regulated research (using test articles – drugs(IND) and devices (IDE) is NOT eligible for a waiver or alteration of consent, except for emergency use of a test article FDA 21 CFR 50.23, or planned emergency research FDA 21 CFR 50.24.

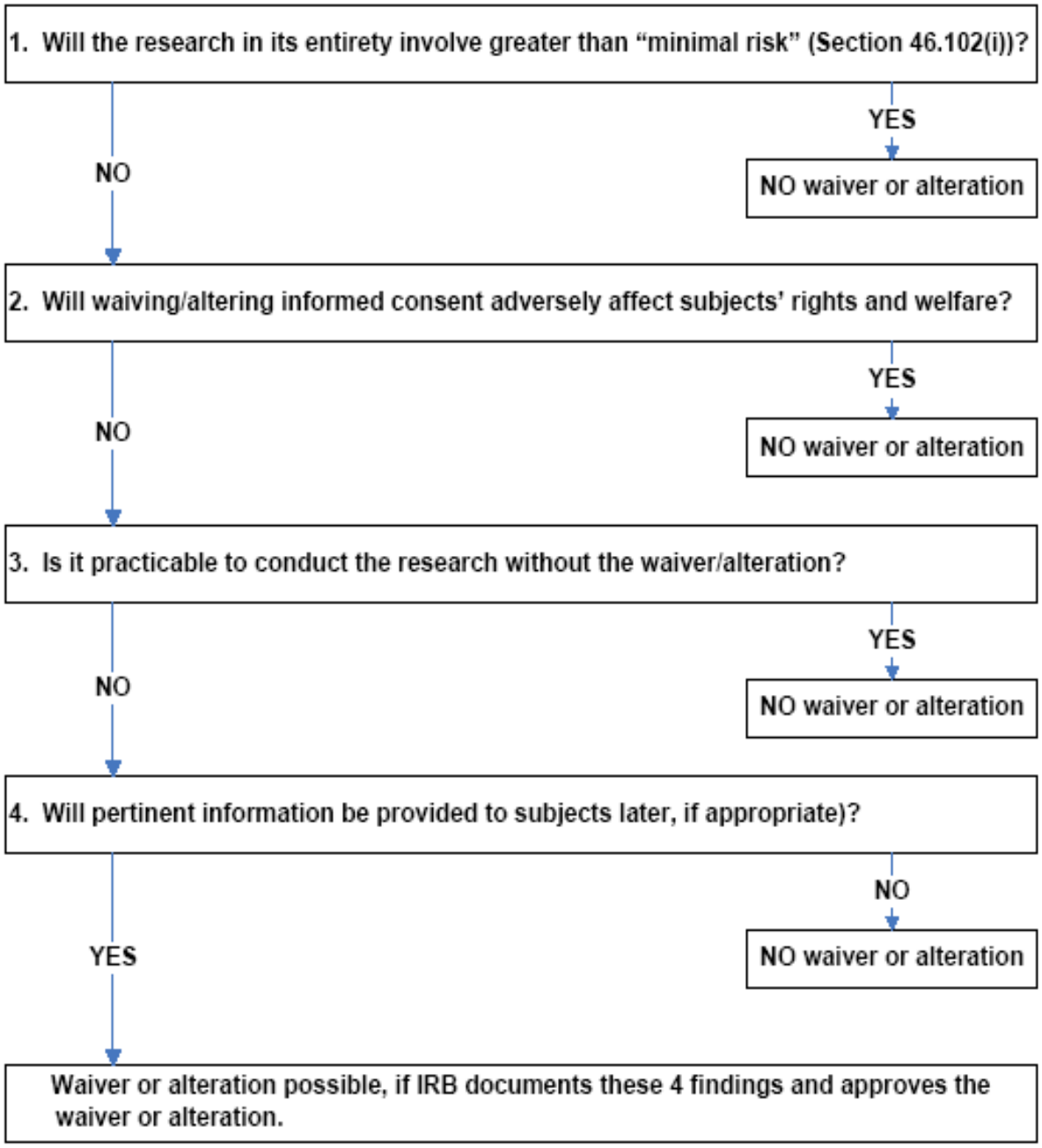
OHRP 45 CFR 46.116(d)

Requests for waiver or alteration of the informed consent process:

1. The research involves no more than minimal risk to the subjects;
2. the waiver or alteration will not adversely affect the rights and welfare of the subjects;
3. the research could not practicably be carried out without the waiver or alteration; and
4. whenever appropriate, the subjects will be provided with additional pertinent information after participation.

IRB CONSIDERATION IN DETERMINING WHEN PARENTAL PERMISSION MAY NOT BE WAIVED OR ALTERED

1. Illegal, antisocial, or self-incriminating behavior
2. Relationship legally recognized as privileged (lawyers, doctors, clergy)
3. Sexual behavior or attitudes
4. Mental or psychological problems
5. Religious affiliations or beliefs
6. Parental political affiliations or beliefs
7. Appraisals of other individuals with whom the child has a familial relationship
8. FDA-regulated research (unless the emergency use of a test article exception applies)


1. Will the research in its entirety involve greater than "minimal risk" (Section 46.102(i))?
YES
NO waiver or alteration
NO
2. Will waiving/altering informed consent adversely affect subjects' rights and welfare?
YES
NO waiver or alteration
NO
3. Is it practicable to conduct the research without the waiver/alteration?
YES
NO waiver or alteration
NO
4. Will pertinent information be provided to subjects later, if appropriate)?
NO
NO waiver or alteration
YES
Waiver or alteration possible, if IRB documents these 4 findings and approves the waiver or alteration.

OHRP 45 CFR 46.116(c)

Qualified research/demonstration projects:
See regulations for full text.

An IRB may waive the requirement to document informed consent if it finds that one of these criteria is met:

OHRP 45 CFR 46.117(c)(1)

For research not subject to FDA regulation, the IRB finds:
That the only record linking the subjects and the research would be the consent document and the principal risk would be potential harm resulting from a breach of confidentiality. Each subject will be asked whether the subject wants documentation linking the subject with the research, and the subject's wishes will govern.

OHRP 45 CFR 46.117(c)(2)
FDA 21 CFR 56.109(c)(1)

For research subject either to OHRP or FDA regulation, the IRB finds:
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. In cases in which the documentation requirement is waived, the IRB may require the investigator to provide subjects with a written statement regarding the research.