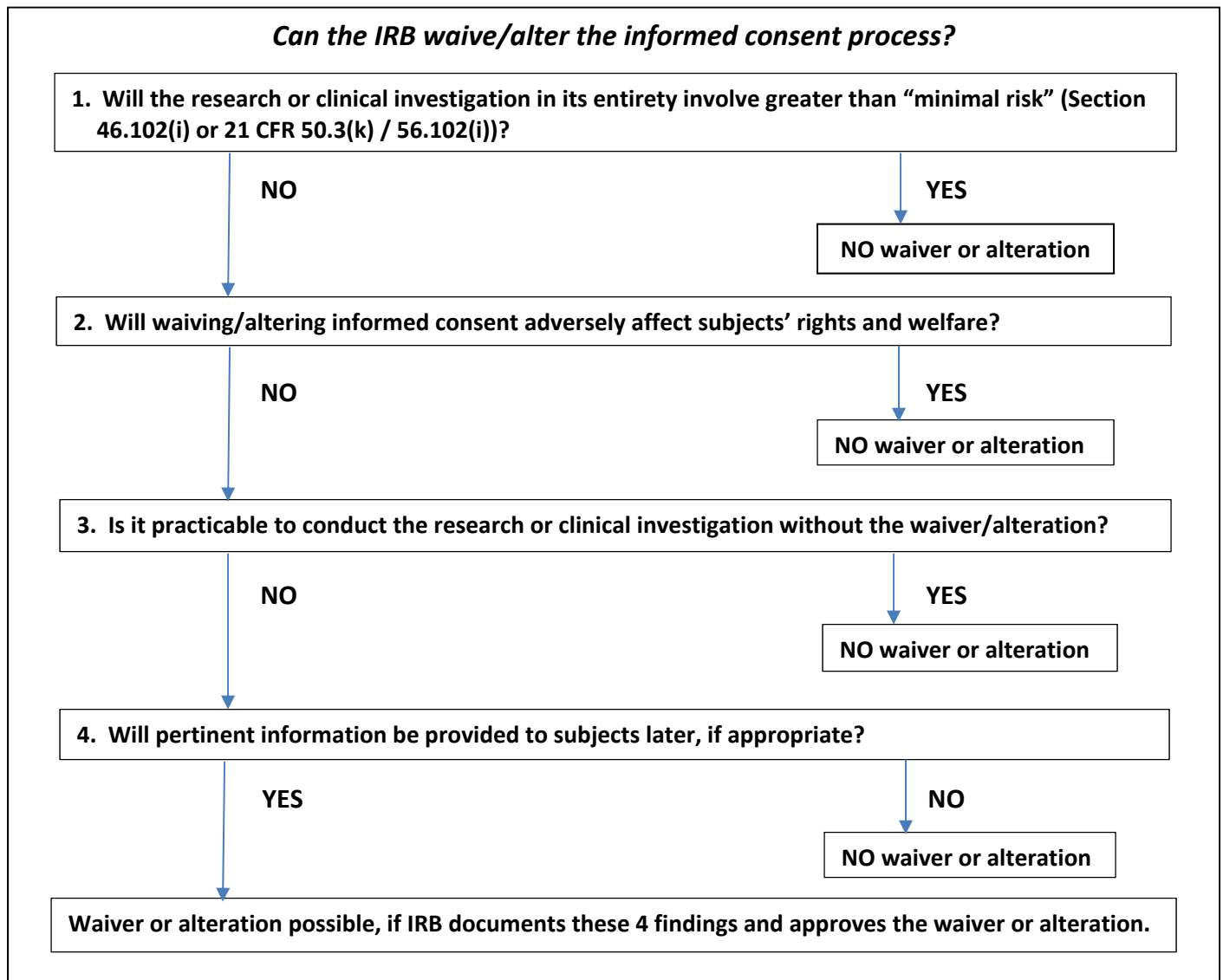


I. The IRB may grant a waiver or alteration of the informed consent process under OHRP 45 CFR 46.116(d) and FDA Guidance. The following criteria must be met:

- (1) The research or clinical investigation 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 or clinical investigation 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.



**Findings for Waiver or Alteration of Consent
Requirements and
Waiver of Documentation (waiver of signature) of
Consent**

II. The IRB may grant a waiver or alteration of the informed consent process under OHRP 45 CFR 46.116(c). The following criteria must be met:

- (1) The research or demonstration project is to be conducted by or subject to the approval of state or local government officials and is designed to study, evaluate, or otherwise examine: (i) public benefit or service programs; (ii) procedures for obtaining benefits or services under those programs; (iii) possible changes in or alternatives to those programs or procedures; or (iv) possible changes in methods or levels of payment for benefits or services under those programs; and
- (2) The research could not practicably be carried out without the waiver or alteration.

III. The IRB may waive the requirement to document informed consent (waiver of signature) if it finds that one of these criteria is met:

For research subject to OHRP 45 CFR 46.117(c)(1), 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.

For research subject either to OHRP 45 CFR 46.117(c)(2) or FDA 21 CFR 56.109(c)(1) 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.

**TOPICS FOR 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