I. The IRB may grant a **waiver or alteration of the informed consent** process under OHRP 45 CFR 46.116(f)(3)(i-v), and/or **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 research or clinical investigation could not practicably be carried out without the waiver or alteration;
3. 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;*
4. The waiver or alteration will not adversely affect the rights and welfare of the subjects; and
5. Whenever appropriate, the subjects or legally authorized representatives will be provided with additional pertinent information after participation.

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**Can the IRB waive/alter the informed consent process?**

1. Will the research or clinical investigation in its entirety involve greater than “minimal risk” (OHRP 46.102(j) or FDA 21 CFR 50.3(k) / 56.102(j))?
   - **NO**
     - NO waiver or alteration
   - **YES**
     - NO waiver or alteration

2. Could the research or clinical investigation be practicably carried out without the waiver or alteration?
   - **NO**
     - NO waiver or alteration
   - **YES**
     - NO waiver or alteration

3. If the research involves using identifiable private information or identifiable biospecimens, could the research be practicably carried out without using such information or biospecimens in an identifiable format?*
   - **NO**
     - NO waiver or alteration
   - **YES**
     - NO waiver or alteration

4. Will the waiver or alteration adversely affect the rights or welfare of the subjects?
   - **NO**
     - NO waiver or alteration
   - **YES**
     - NO waiver or alteration

5. Will pertinent information be provided to subjects or LARs later, if appropriate?
   - **YES**
     - NO waiver or alteration
   - **NO**
     - NO waiver or alteration

The IRB may grant a waiver or alteration of consent if the above criteria have been met.
II. The IRB may grant a **waiver or alteration of the informed consent** process under OHRP 45 CFR 46.116(e)(3). 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 grant a **waiver of the requirement to document informed consent** (waiver of signature) under OHRP 45 CFR 46.117(c)(1), if the IRB finds any of the following criteria have been met:

1. The only record linking the subjects and the research would be the 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;
2. The research presents no more than minimal risk of harm to the subjects and involves no procedures for which written consent is normally required outside of the research context; or
3. 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 mechanism for documenting that informed consent was obtained.

In cases in which documentation of consent is waived, the IRB waives the signature requirement, not the consent process. The IRB may still require the investigator to provide subjects or legally authorized representatives with a written statement regarding the research.

IV. The IRB may grant a **waiver of the requirement to document informed consent** (waiver of signature) under FDA 21 CFR 56.109(c)(1) if the IRB finds the following criteria have been met:

1. The research presents no more than minimal risk of harm to the participants and involves no procedures for which written consent is normally required outside of the research context.

In cases in which documentation of consent is waived, the IRB waives the signature requirement, not the consent process. The IRB may still require the investigator to provide subjects or legally authorized representatives with a written statement regarding the research.
TOPICS TO CONSIDER WHEN DETERMINING WHETHER PARENTAL PERMISSION MAY 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