This guidance document is used to determine whether the consent process can be waived or altered for non-exempt Human Research Participation.

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<th>All criteria in 1 or 2 must be met</th>
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**1. Waiver of consent or permission for research involving no more than *Minimal Risk* to subjects** [45 CFR §46.116(d)]

1.1 The research involves no more than *Minimal Risk* to the subjects

1.2 The waiver or alteration will not adversely affect the rights and welfare of the subjects

1.3 The research could not practically be carried out without the waiver or alteration

1.4 Whenever appropriate, the subjects will be provided with additional pertinent information after participation

1.5 The research is not FDA-regulated

1.7 The research does not involve *Non-Viable Neonates* as subjects

**2. Waiver of consent or permission for state or local government research** [45 CFR §46.116(c)]

2.1 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 one or more of the following:

- Public benefit or service programs
- Procedures for obtaining benefits or services under those programs
- Possible changes in or alternatives to those programs or procedures
- Possible changes in methods or levels of payment for benefits or services under those programs

2.2 The research could not practically be carried out without the waiver or alteration

2.3 The research is not FDA-regulated

2.5 The research does not involve *Non-Viable Neonates* as subjects

**3. Waiver of Consent Process - Permission is not a reasonable requirement** [45 CFR §46.408(c)]

3.1 The research is designed for conditions or for a subject population for which parental or guardian permission is not a reasonable requirement to protect the subjects.

3.2 An appropriate mechanism for protecting the children who will participate as subjects in the research is substituted.

3.3 The research is not FDA-regulated.

**4. Notes**