**Institutional Review Board**

**Waiver or Alteration of Consent Process Worksheet**

The purpose of this worksheet is to help IRB members review protocols requesting a waiver or alteration of the consent process.

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| Waiver | An IRB may waive the requirements to obtain informed consent for research using the general, basic, and/or additional elements of informed consent, provided that the IRB satisfies the requirements set out in Sections 1 or 2 of this form |
| Alteration | An IRB may approve a consent procedure that omits some, or alters some or all, of the basic and additional elements of informed consent, provided the IRB satisfies the requirements set out in Sections 1 or 2 of this form. |

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| Protocol ID |  |
| Title of Protocol |  |
| PI/Researcher(s) |  |
| Type of Waiver or Alteration Request |[ ]  Waiver of Informed Consent (Section 1) |[ ]  Alteration of Informed Consent (Section 1) |
|  |[ ]  Waiver of Informed Consent for Public Demonstration Projects (Section 2) |[ ]  Alteration of Informed Consent for Public Demonstration Projects (Section 2) |
|  |[ ]  Waiver of Consent Documentation (Section 3) |[ ]  Waivers used in Deception or Complete Non-Disclosure (Section 4) |

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| **Section 1: Requirements for Waiving or Altering the Consent Process (all must be checked)** |
|[ ]  The research does not involve nonviable neonates (45 CFR 46.205(c)(5)) |
|[ ]  The research involves no more than minimal risk to subjects |
|[ ]  The research could not practicably be carried out without the requested waiver or alteration |
|[ ]  If the research involves using identifiable private information or identifiable biospecimens, the research could not practicably be carried out without using information or biospecimens in an identifiable format |
|[ ]  The waiver or alteration will not adversely affect the rights and welfare of the subjects |
|  |[ ]  If the waiver is required because the research involves deception, subjects are not “tricked” into participating in a study that they would find objectionable |
|[ ]  Whenever appropriate, the subjects or legally authorized representatives will be provided with additional pertinent information after participation |

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| **Section 2: Waiving or Altering the Consent Process for Public Demonstration Projects (all must be checked)** |
|[ ]  The research does not involve nonviable neonates (45 CFR 46.205(c)(5)) |
|[ ]  The research or demonstration project is to be conducted by or subject to the approval of state or local government officials |
|[ ]  The research or demonstration project is designed to study, evaluate, or otherwise examine:  |
|  |[ ]  Public benefit or service programs |
|  |[ ]  Procedures for obtaining benefits or services under those programs |
|  |[ ]  Possible changes in or alternatives to those programs or procedures, or |
|  |[ ]  Possible changes in methods or levels of payment for benefits or services under those programs |
|[ ]  The research could not practicably be carried out without the requested waiver or alteration |

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| **Section 3: Requirements for the Waiver of Documentation of Consent (check all that apply)** |
|[ ]  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 LAR will be asked whether the subject wants documentation linking the subject with the research, and the subject’s will govern |
|[ ]  The research presents no more than minimal risk of harm to subjects and the research involves no procedures requiring consent outside the context of participation in a research study, e.g., a telephone survey |
|[ ]  The research involves no procedures for which written consent is normally required outside of the research context |
|[ ]  If the subjects or LARs are members of a distinct cultural group or community in which signing forms is not the norm [ ]  N/A |
|  |[ ]  The research presents no more than minimal risk  |
|  |[ ]  There is an appropriate mechanism for documenting that informed consent was obtained |
|[ ]  The documentation requirement is waived, but the IRB requires the investigator to provide subjects or legally authorized representatives with a written statement regarding research |

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| **Section 4: Requirements for Partial or Complete Waivers used in Deception and Complete Non-Disclosure** |
|[ ]  Conditions for Sections 1, 2, and/or 3 are met, when applicable |
|[ ]  Deception or complete non-disclosure of information to subjects is necessary to avoid subject response bias in the research |
|[ ]  The IRB has reviewed the research plan for deception or complete non-disclosure of information to ensure there is adequate justification for the technique as well as an adequate debriefing plan for after the research |
|[ ]  Subjects are not “tricked” into participating in a study they would find objectionable |