**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.

|  |  |
| --- | --- |
| 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. |

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| 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) |

|  |  |  |
| --- | --- | --- |
| **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 | |

|  |  |  |
| --- | --- | --- |
| **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 | |

|  |  |  |
| --- | --- | --- |
| **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 | |

|  |  |
| --- | --- |
| **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 |