*NOTE: This documentation form does not apply to research subject to FDA regulations & policies.*

|  |  |  |  |
| --- | --- | --- | --- |
| Study ID |  | PI |  |

**Use this form for studies subject to the pre-2018 Common Rule.**

**Select appropriate criteria to waive or alter informed consent and complete the required criteria:**

**Criteria for 45 CFR 46.116(c).**An IRB may approve a consent procedure which does not include, or which alters, some or all of the elements of informed consent, or waive the requirement to obtain informed consent provided the IRB finds and documents that:

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.

*Why does the research meet this criterion?*

1. The research could not practicably be carried out without the waiver or alteration.

*Why does the research meet this criterion?*

**Criteria for 45 CFR 46.116(d).** An IRB may approve a consent procedure which does not include, or which alters, some or all of the elements of informed consent, or waive the requirements to obtain informed consent provided the IRB finds and documents that:

1. The research involves no more than minimal risk to the subjects.

*Why does the research meet this criterion?*

1. The research could not practicably be conducted without the waiver or alteration.

*Why does the research meet this criterion?*

1. The waiver or alteration will not adversely affect the rights and welfare of the subject.

*Why does the research meet this criterion?*

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

*Why does the research meet this criterion?*

**Complete this section ONLY if the IRB is granting an alteration of consent.**

If the IRB is approving a consentprocedure which does not include or which alters some of the elements of informed consent, identify which elements of informed consent:

| **Does Not Include** | **Alters** | **Basic Elements of Consent:** |
| --- | --- | --- |
|  |  | A statement that the study involves research, an explanation of the purposes of the research & the expected duration of the subject's participation, a description of the procedures to be followed, & identification of any procedures which are experimental. |
|  |  | A description of any reasonably foreseeable risks or discomforts to the subject. |
|  |  | A description of any benefits to the subject or to others which may reasonably be expected from the research. |
|  |  | A disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject. |
|  |  | A statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained. |
|  |  | For research involving more than minimal risk, an explanation as to whether any compensation & an explanation as to whether any medical treatments are available if injury occurs &, if so, what they consist of, or where further information may be obtained. |
|  |  | An explanation of whom to contact for answers to pertinent questions about the research & research subjects' rights, & whom to contact in the event of a research-related injury to the subject. |
|  |  | A statement that participation is voluntary, refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled, & the subject may discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled. |
| Comments: | | |
| **Does Not Include** | **Alters** | **Additional Elements as applicable:** |
|  |  | A statement that the particular treatment or procedure may involve risks to the subject (or to the embryo or fetus, if the subject is or may become pregnant) which are currently unforeseeable. |
|  |  | Anticipated circumstances under which the subject's participation may be terminated by the investigator without regard to the subject's consent. |
|  |  | Any additional costs to the subject that may result from participation in the research. |
|  |  | The consequences of a subject's decision to withdraw from the research & procedures for orderly termination of participation by the subject. |
|  |  | A statement that significant new findings developed during the course of the research which may relate to the subject's willingness to continue participation will be provided to the subject. |
|  |  | Approximate number of subjects involved in the study. |
| Comments: | | |

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| IRB determination made by: | | | | | | | | | |
| Expedited reviewer | | Name: |  | | Date: |  | |  | |
|  | | | | | | | | | |
| Full board | Name of individual completing this form: | | |  | | | Meeting date | |  |
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