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

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

**Use this form for studies subject to the Revised Common Rule (2018 Requirements).**

If an individual was asked to provide broad consent for the storage, maintenance, and secondary research use of identifiable private information or identifiable biospecimens in accordance with 45 CFR 46.116(d), and refused to consent, an IRB cannot waive consent for the storage, maintenance, or secondary research use of the identifiable private information or identifiable biospecimens.

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

**[ ]  Criteria for 45 CFR 46.116(e).** In order for an IRB to waive or alter consent, the IRB must find and document 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: (A) Public benefit or service programs; (B) Procedures for obtaining benefits or services under those programs; (C) Possible changes in or alternatives to those programs or procedures; or (D) 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).** In order for an IRB to waive or alter consent as described in this subsection, the IRB must find and document 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?*

1. Does the research involve using identifiable private information or identifiable biospecimens?

[ ]  No

[ ]  Yes

If yes, the research could not practicably be carried out without using such information or biospecimens in an identifiable format.

*Why does the research meet this criterion?*

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

An IRB may approve a consent procedure that omits some, or alters some or all, of the elements of informed consent. An IRB may not omit or alter any of the requirements described in 45 CFR 46.116(a) (general requirements of informed consent). If the IRB is approving a consent procedure 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 and the expected duration of the subject's participation, a description of the procedures to be followed, and identification of any procedures that 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 that 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 and an explanation as to whether any medical treatments are available if injury occurs and, 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 and research subjects' rights, and 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, and the subject may discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled |
| [ ]  | [ ]  | One of the following statements about any research that involves the collection of identifiable private information or identifiable biospecimens:* A statement that identifiers might be removed from the identifiable private information or identifiable biospecimens and that, after such removal, the information or biospecimens could be used for future research studies or distributed to another investigator for future research studies without additional informed consent from the subject or the legally authorized representative, if this might be a possibility; or
* A statement that the subject's information or biospecimens collected as part of the research, even if identifiers are removed, will not be used or distributed for future research studies
 |
| 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) that are currently unforeseeable; |
| [ ]  | [ ]  | Anticipated circumstances under which the subject's participation may be terminated by the investigator without regard to the subject's or the legally authorized representative'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 and procedures for orderly termination of participation by the subject; |
| [ ]  | [ ]  | A statement that significant new findings developed during the course of the research that may relate to the subject's willingness to continue participation will be provided to the subject; |
| [ ]  | [ ]  | The approximate number of subjects involved in the study; |
| [ ]  | [ ]  | A statement that the subject's biospecimens (even if identifiers are removed) may be used for commercial profit and whether the subject will or will not share in this commercial profit; |
| [ ]  | [ ]  | A statement regarding whether clinically relevant research results, including individual research results, will be disclosed to subjects, and if so, under what conditions |
| [ ]  | [ ]  | For research involving biospecimens, whether the research will (if known) or might include whole genome sequencing (i.e., sequencing of a human germline or somatic specimen with the intent to generate the genome or exome sequence of that specimen). |
| 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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