***NOTE: This documentation form applies to research subject to FDA regulations & policies.***

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

**Use this form for minimal risk clinical investigations subject to U.S. Food and Drug Administration (FDA) regulations. See FDA guidance, IRB Waiver or Alteration of Informed Consent for Clinical Investigations Involving No More Than Minimal Risk to Human Subjects (July 2017).**

Waiver of informed consent for certain FDA-regulated minimal risk clinical investigations will facilitate investigators’ ability to conduct studies that may contribute substantially to the development of products to diagnose or treat diseases or conditions, or address unmet medical needs. In light of the Cures Act amendment to the FD&C Act, FDA intends to revise its informed consent regulations to add this waiver or alteration under appropriate human subject protection safeguards to the two existing exceptions from informed consent (i.e., in lifethreatening situations and for emergency research). However, until FDA promulgates these regulations, we do not intend to object to an IRB8 approving a consent procedure that does not include, or that alters, some or all of the elements of informed consent set forth in 21 CFR 50.25, or waiving the requirements to obtain informed consent when the IRB finds and documents that:

1. The clinical investigation involves no more than minimal risk (as defined in 21 CFR 50.3(k) or 56.102(i)) to the subjects;

 *Why does the research meet this criterion?*

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

*Why does the research meet this criterion?*

1. The clinical investigation could not practicably be carried out without the waiver or alteration; and

*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 and the expected duration of the subject's participation, a description of the procedures to be followed, and 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 and that notes the possibility that the Food and Drug Administration may inspect the records. |
| [ ]  | [ ]  | 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, that refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled, and that 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 and 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. |
| [ ]  | [ ]  | The approximate number of subjects involved in the study. |
| Comments:       |
| [ ]  | [ ]  | When seeking informed consent for applicable clinical trials, as defined in 42 U.S.C. 282(j)(1)(A), the following statement shall be provided to each clinical trial subject in informed consent documents and processes. This will notify the clinical trial subject that clinical trial information has been or will be submitted for inclusion in the clinical trial registry databank under paragraph (j) of section 402 of the Public Health Service Act. The statement is: "A description of this clinical trial will be available on *http://www.ClinicalTrials.gov,* as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time." |
| Comments:       |

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