(1) Before involving a human subject in research covered by this policy, an investigator shall obtain the legally effective informed consent of the subject or the subject's legally authorized representative.

(2) An investigator shall seek informed consent only under circumstances that provide the prospective subject or the legally authorized representative sufficient opportunity to discuss and consider whether or not to participate and that minimize the possibility of coercion or undue influence.

(3) The information that is given to the subject or the legally authorized representative shall be in language understandable to the subject or the legally authorized representative.

(4) The prospective subject or the legally authorized representative must be provided with the information that a reasonable person would want to have in order to make an informed decision about whether to participate, and an opportunity to discuss that information.

(5) Except for broad consent obtained in accordance with paragraph (d) of this section: (i) Informed consent must begin with a concise and focused presentation of the key information that is most likely to assist a prospective subject or legally authorized representative in understanding the reasons why one might or might not want to participate in the research. This part of the informed consent must be organized and presented in a way that facilitates comprehension. (ii) Informed consent as a whole must present information in sufficient detail relating to the research, and must be organized and presented in a way that does not merely provide lists of isolated facts, but rather facilitates the prospective subject's or legally authorized representative's understanding of the reasons why one might or might not want to participate.

(6) No informed consent may include any exculpatory language through which the subject or the legally authorized representative is made to waive or appear to waive any of the subject's legal rights, or releases or appears to release the investigator, the sponsor, the institution, or its agents from liability for negligence.

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### Study involves research; study description

(1) 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;

### Reasonably foreseeable risks

(2) A description of any reasonably foreseeable risks or discomforts to the subject;

### Benefits

(3) A description of any benefits to the subject or to others which may reasonably be expected from the research;

### Alternative procedures or treatment

(4) A disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject;

### Confidentiality of records

(5) A statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained; [FDA regulated research only: “and that notes the possibility that the Food and Drug Administration may inspect the records”]

### Compensation and treatment for injury

(6) 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;

### Contact information

(7) 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;

### Voluntary participation

(8) 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; and

### Use of identifiable private information or biospecimens*

(9) One of the following statements about any research that involves the collection of identifiable private information or identifiable biospecimens:

(i) 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 without additional informed consent from the subject or the legally authorized representative, if this might be a possibility; or (ii) 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.

**Additional elements** of informed consent. One or more of the following elements of information, when appropriate, shall also be provided to each subject or the legally authorized representative:

| **Risks which are currently unforeseeable** | (1) 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; |
| **Investigator may terminate participation** | (2) Anticipated circumstances under which the subject's participation may be terminated by the investigator without regard to the subject's consent; |
| **Additional costs** | (3) Any additional costs to the subject that may result from participation in the research; |
| **Consequences of subject's withdrawal** | (4) The consequences of a subject's decision to withdraw from the research and procedures for orderly termination of participation by the subject; |
| **Significant new findings** | (5) 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; |
| **Number of subjects** | (6) The approximate number of subjects involved in the study; |
| **Commercial Value** | (7) 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; |
| **Return of results** | (8) A statement regarding whether clinically relevant research results, including individual research results, will be disclosed to subjects, and if so, under what conditions; and |
| **Whole genome sequencing** | (9) 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). |

**Posting of clinical trial consent form**

For each clinical trial conducted or supported by a Federal department or agency, one IRB-approved informed consent form used to enroll subjects must be posted by the awardee or the Federal department or agency component conducting the trial on a publicly available Federal website that will be established as a repository for such informed consent forms. If the Federal department or agency supporting or conducting the clinical trial determines that certain information should not be made publicly available on a Federal website (e.g., confidential commercial information), such Federal department or agency may permit or require redactions to the information posted. The informed consent form must be posted on the Federal website after the clinical trial is closed to recruitment, and no later than 60 days after the last study visit by any subject, as required by the protocol.

**Clinical trial registration ++**

A statement that a description of the trial will be available on http://www.ClinicalTrials.gov

* Common Rule general requirements, basic elements, and additional elements of consent do not apply to FDA regulated research because the FDA has not yet harmonized with the revised OHRP regulations at 45 CFR 46. ++ FDAAA Section 801 as implemented by 42 CFR Part 11 and the NIH Policy on Dissemination of NIH-Funded Clinical Trial Information.