BASIC AND ADDITIONAL ELEMENTS OF INFORMED CONSENT

PER 45 CFR 46.116 and 21 CFR 50.25

BASIC ELEMENTS

- 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 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 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, 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.
- ***Research collecting identifiable private information and/or identifiable biospecimens MUST:***
    - ***State that collected samples/data may be de-identified and used for future research or be given to another investigator for future research without addition informed consent, OR***
    - ***State that collected samples/data will not be used or distributed for future research even if de-identified.***

ADDITIONAL ELEMENTS. When appropriate, one or more of the following elements of information should also be provided to each subject.

- 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.
- ***Statement that biospecimens, even if de-identified, may be used for commercial profit…and whether/if that profit will be shared.***
- ***Statement regarding whether clinically relevant research results will be given to the subject and under what conditions.***
- ***For research involving biospecimens, whether the research will or might include (specficially) whole genome or exome sequencing.***

For applicable clinical trials only, to notify subjects that clinical trial information has been or will be submitted for included in the clinical trial registry databank add this statement:

'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.'

*most current additions in ***bold*** and ***italic*** above

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