MONTGOMERY COLLEGE

ELEMENTS OF INFORMED CONSENT

The 2018 Requirements of the revised Common Rule (45 CFR 46, Subpart A – "Federal Policy for the Protection of Human Subjects") had a general compliance date of January 21, 2019

BASIC ELEMENTS OF INFORMED CONSENT

(1) A statement that the study involves research;
(2) An explanation of the purposes of the research;
(3) The expected duration of the subject's participation;
(4) A description of the procedures to be followed;
(5) Identification of any procedures that are experimental;
(6) A description of any reasonably foreseeable risks or discomforts to the subject;
(7) A description of any benefits to the subject or to others which may reasonably be expected from the research;
(8) A disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject;
(9) A statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained;
(10) 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;
(11) **Research, Rights, or Injury:** 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;
(12) 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
(13) 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 for future research studies 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 studies.

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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 (LAR):

(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) that are currently unforeseeable;
(2) 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;
(3) Any additional costs to the subject that may result from participation in the research;
(4) The consequences of a subject's decision to withdraw from the research and procedures for orderly termination of participation by the subject;
(5) 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;
(6) The approximate number of subjects involved in the study;
(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;
(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
(9) For research involving biospecimens, whether the research will (if know) 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).