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Informed Consent Requirements for Department of Health and Human Services (DHHS) Agency funded studies

For all DHHS funded studies approved, waived or exempted for ethical review on or after January 21, 2019

The complete revised US common rule regulation can be found at:
https://www.hhs.gov/ohrp/sites/default/files/2018-Common-Rule-reg-text-July2018.pdf

SECTION 116 A

- 116(a)(1) Legally effective consent of the subject or his/her legally authorized representative must be obtained before involving a human subject in research
- 116(a)(2) Sufficient opportunity to discuss and consider whether or not to participate must be provided and the circumstances must minimize the possibility of coercion or undue influence
- 116(a)(3) The participant must be provided with information that is in a language that is understandable to the participant or the legally authorized representative
- 116(a)(4) The prospective participant 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".*
- 116(a)(5)
  - i) Informed consent must begin with "*a concise and focused presentation of the key information that is most likely to assist a prospective participant or his 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 understand of the reasons why one might or might not want to participate.
- 116(a)(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

SECTION 116 B

Contains the same 8 **mandatory** basic elements as were in the pre-2019 Rule and two new mandatory basic elements.

(1) Statement that the study involves research
(2) Description of reasonably foreseeable risks and discomforts
(3) Description of any benefits
(4) Disclosure of alternative procedures or courses of treatment
(5) Statement describing the extent, if any, to which confidentiality of records identifying subjects will be maintained
(6) If the research is more than minimal risk, an explanation as to whether any compensation is available and an explanation as to whether any medical treatments are available if injury occurs and if so what they are or where they can get further information
(7) An explanation of whom to contact in the event of an injury
(8) A statement that participation is voluntary, that refusal to participate will involve no penalty or loss of benefits, and that they may discontinue at any time without consequence

Plus a new element

(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 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

Note: The statement referenced in (i) above could (and where possible should) also be in an optional data-banking / tissue-banking consent

SECTION 116 C

Contains the same **additional** elements as in the previous rule, **where appropriate** and adds two new additional elements where appropriate

(1) A statement that the treatment 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 consent
(3) Any additional costs to the subject
(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 will be provided

(6) The approximate number of subjects involved in the study
(7) A statement that the subject's biospecimens (even if identifiers will be removed) may be used for commercial profit and whether the subject will or will not share in the profit

Two new additional elements

(8) A statement 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 known) or might include whole genome sequencing (i.e. sequencing of a human germline or somatic specimens with intent to generate the genome or exome sequence of that specimen).