

12 Elements of Broad Consent:

- A description of any reasonably foreseeable risks or discomforts to the subjects (§__.116(d)(1), incorporating basic elements of informed consent in §__.116(b)(2));
- A description of any benefits to the subject or to others that may reasonably be expected from the research ((§__.116(d)(1), incorporating basic elements of informed consent in §__.116(b)(3));
- A statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained ((§__.116(d)(1), incorporating basic elements of informed consent in §__.116(b)(5));
- 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 ((§__.116(d)(1), incorporating basic elements of informed consent in §__.116(b)(8));

320

- If applicable, 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 ((§__.116(d)(1), incorporating additional elements of consent in §__.116(c)(7));
- When appropriate, for research involving biospecimens, whether the research will (if known) or might include WGS (i.e., sequencing of a human germline or somatic specimen with the intent to generate the genome or exome sequence of that specimen.) ((§__.116(d)(1), incorporating the additional element of consent in §__.116(c)(9));
- A general description of the types of research that may be conducted with identifiable private information or identifiable biospecimens. This description must include sufficient information to permit a reasonable person to expect that the broad consent would permit the types of research conducted (§__.116(d)(2));
- A description of the identifiable private information or identifiable biospecimens that might be used in research, whether sharing of such information or biospecimens might occur, and the types of institutions or investigators that might conduct research with such information or biospecimens (§__.116(d)(3));
- A description of the period of time allowed that the identifiable private information or identifiable biospecimens may be stored and maintained (which period of time could be indefinite), and a description of the period of time that such information or biospecimens may be used for research purposes (which period of time could be indefinite (§__.116(d)(4));
- Unless the subject or legally authorized representative will be provided details about specific research studies, a statement that they will not be informed of the details of any
321
specific research studies that might be conducted using the subject's identifiable private information or identifiable biospecimens, including the purposes of the research and that they might have chosen not to consent to some of those specific research studies (§__.116(d)(5));
- Unless it is known that clinically relevant research results, including individual research results, will be disclosed to the subject in all circumstances, a statement that such results

may not be disclosed to the subject; (§__.116(d)(6)); and

- An explanation of whom to contact for answers to questions about the subject's rights about storage and use of the subject's identifiable private information or identifiable biospecimens, and whom to contact in the event of a research-related harm (§__.116(d)(7)).