Informed Consent - Basic and Additional Elements. New requirements (effective Jan 21, 2019) are in blue.

- Statement that the study involves research and an explanation of the purposes of the research
- The expected duration of the subject's participation
- Description of the procedures to be followed and identification of any procedures which are experimental
- Description of any reasonably foreseeable risks or discomforts to the subject
- Description of any benefits to the subject or to others which may reasonably be expected
- Disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject
- Statement describing the extent to which confidentiality of records identifying the subject will be maintained
- For research involving more than minimal risk, an explanation as to whether any compensation and any medical treatments are available if injury occurs, and if so, what they consist of, or where further information may be obtained
- Research, Rights or Injury: An explanation of whom to contact for answers to questions about the research and research subjects' rights, and whom to contact in the event of a research-related injury
- 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
- Informed consent must begin with a concise and focused presentation of the key information most important for helping a potential subject decide whether to participate.
  Note: This requirement is met if the entire consent is only a few pages. If the consent is more than 4 pages, include a concise and focused presentation at the beginning.
- One of the following:
  - Statement that identifiers might be removed from the data or biospecimens, and, after this de-identification, the data or biospecimens could be used for future research studies or distributed to another investigator without additional informed consent; OR
  - Statement that the subject's data or biospecimens will not be used or distributed for any future research, not even if de-identified.

Additional Elements as Appropriate

- 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
- 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 the subject's biospecimens may be used for commercial profit, and whether the subject will or will not share in this profit
- Statement regarding whether clinically relevant research results will be disclosed to subjects, and if so, under what circumstances
- For research involving biospecimens, whether the research will or might include whole genome sequencing

Broad Consent - new

The regulations allow for a new type of consent document, to be used in situations where data or biospecimens will be banked for future research use. If you are creating a bank, include the following required and additional elements:

Required

- Description of any reasonably foreseeable risks or discomforts to the subject
- Description of any benefits to the subject or to others which may reasonably be expected from the research
- Statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained
- 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
- General description of the types of research that may be conducted
- Description of the data or biospecimens that might be used, whether sharing of data or biospecimens might occur, and the types of institutions or researchers that might conduct research with the data or biospecimens
- Description of the period of time that the data or biospecimens may be stored and maintained (could be indefinite), and the period of time that the data or biospecimens may be used in research (could be indefinite)
- Statement that the subject will not be informed of the details of any specific research studies that might be conducted using the data or biospecimens, including the purposes of the research, and that they might have chosen not to consent to some of those specific research studies. This requirement does not apply if subjects will be told information about specific studies done with their data or biospecimens.
- Statement that clinically relevant research results may not be disclosed to the subject, unless it is known that such results will be disclosed in all circumstances
- Explanation of whom to contact for answers to questions about the subject's rights and about storage and use of the subject's data or biospecimens, and whom to contact in the event of a research-related harm

Additional Elements as Appropriate

- Statement that the subject's biospecimens may be used for commercial profit, and whether the subject will or will not share in this profit
- For research involving biospecimens, whether the research will or might include whole genome sequencing