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| **INFORMED CONSENT REQUIREMENTS CHECKLIST** [**46.116**](https://www.hhs.gov/ohrp/regulations-and-policy/regulations/45-cfr-46/index.html#46.116) | | |
| **New: Concise Presentation of Key Information 46.116 (a)** | | |
|  | Consent begins with concise, focused, and organized presentation of key information  1a)  Key information is organized and presented in a way that facilitates comprehension  1b)  Key information will assist in understanding the reasons why one might or might not choose to participate in the research.  Note: This new section is NOT eligible for waiver or alteration of consent. | |
| **Basic Required Elements of Consent 46.116 (b)** | | |
|  | 1. **A statement that the study involves research**   1a) An explanation of the purposes of the research  1b) The expected duration of the subject's participation  1c) A description of the procedures to be followed  1d) Identification of any procedures which are experimental  OR  N/A | |
|  | 1. **A description of any reasonably foreseeable risks or discomforts to the subject** | |
|  | 1. **A description of any benefits to the subject or to others which may reasonably be expected from the research** | |
|  | 1. **A disclosure of appropriate alternative procedures or course of treatment, if any, that may be advantageous to the subject** OR  N/A | |
|  | 1. **A statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained** | |
|  | 1. **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** OR  N/A | |
|  | 1. **Identification of whom to contact for answers to pertinent questions about the research**   7a) Identification of researcher and contact information  7b) Identification of whom to contact for answers to questions about the research subjects' rights  7c) Identification of whom to contact in the event of a research-related injury to the subject  OR  N/A | |
|  | 1. **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** | |
|  | 1. **New: Research collecting identifiable information and/or identifiable private information and/or identifiable biospecimens must state plan for future use.**   9a) State that collected samples/data may be de-identified and used for future research or be given to another investigator for future research without additional informed consent  OR  9b) State that collected samples/data will not be used for future research, even if de-identified | |
| **Additional Elements That May Be Required by the IRB (when found appropriate)** [**46.116**](https://www.hhs.gov/ohrp/regulations-and-policy/regulations/45-cfr-46/index.html#46.116) **(c)** | | |
|  | N/A | 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 |
|  | N/A | Anticipated circumstances under which the subject's participation may be terminated by the investigator without regard to the subject's consent |
|  | N/A | Any additional costs to the subject that may result from participation in the research |
|  | N/A | The consequences of a subject's decision to withdraw from the research and procedures for orderly termination of participation by the subject |
|  | N/A | 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 |
|  | N/A | The approximate number of subjects involved in the study |
|  | N/A | New: A statement regarding whether clinically relevant research results will be given to the subject and under what conditions. Note: There may be College of American Pathologists (CAP) and Clinical Laboratory Improvement Amendments (CLIA) to consider relating to the return of research results to subjects. |
|  | N/A | New: A statement that biospecimens, even if de-identified, may be used for commercial profit and whether/if that profit will be shared |
|  | N/A | New: For research involving biospecimens, whether the research will or might include (specifically) whole genome or exome sequencing |
| **Other Consent Considerations** | | |
|  | Project clearly describes a plan/procedure for obtaining prospective, legally effective informed consent from each research subject or the subject's legally authorized representative. | |
|  | Consent will be sought under circumstances that provide the prospective subject or the representative sufficient opportunity to consider whether or not to participate and that minimize the possibility of coercion or undue influence | |
|  | The information that is given/presented to the subject is in a language understandable to the subject or the representative. | |
|  | Consent process and documents do not contain any exculpatory language through which the subject or the 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. Unless the consent process is waived, an appropriate written consent document is provided. | |
|  | All applicable federal, state, local laws or policies will be followed in order for informed consent to be legally effective. | |