|  |  |
| --- | --- |
| Basic Elements of Consent (Elements Added with the 2018 Common Rule) | |
| Yes  No | A concise summary explaining the research precedes the body of the consent form |
| Yes  No | A statement that the study involves research |
| Yes  No | An explanation of the purposes of the research |
| Yes  No | The expected duration of the subject’s participation |
| Yes  No | A description of any procedures to be followed |
| Yes  No | Identification of any procedures that are experimental |
| Yes  No | A description of any reasonably foreseeable risks or discomforts to the subject |
| Yes  No | A description of any benefits to the subject or to others that may reasonably be expected from the research |
| Yes  No | A disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject |
| Yes  No | A statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained |
| Yes  No  N/A | 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 |
| Yes  No | 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 |
| Yes  No | 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 |

|  |  |
| --- | --- |
| Yes  No | One of the following statements about any research that involves the collection of identifiable private information or identifiable biospecimens:   * A statement that the 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-**   * 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. |
|  |  |
| FDA-Regulated Clinical Trials | |
| Yes  No | The following statement must be included: "A description of this clinical trial will be available on [http://www.ClinicalTrials.gov(link is external)](http://www.clinicaltrials.gov/), as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time." |
|  |  |
| Additional Elements of Consent (include as appropriate) (Elements Added with the 2018 Common Rule) | |
| Yes  No  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 |
| Yes  No  N/A | Anticipated circumstances under which the subject's participation may be terminated by the investigator without regard to the subject's or the LAR’s consent |
| Yes  No  N/A | Any additional costs to the subject that may result from participation in the research |
| Yes  No  N/A | The consequences of a subject's decision to withdraw from the research and procedures for orderly termination of participation by the subject |
| Yes  No  N/A | 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 |
| Yes  No  N/A | The approximate number of subjects involved in the study |
| Yes  No  N/A | 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 |
| Yes  No  N/A | A statement regarding whether clinically relevant research results, including individual research results, will be disclosed to subjects, and if so, under what conditions |
| Yes  No  N/A | 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 specimen with the intent to generate the genome or exome sequence of that specimen) |
|  |  |
| HIPAA Authorization Core Elements & Required Statements | |
| Yes  No | Description of PHI to be used or disclosed that identifies the information in a specific and meaningful manner |
| Yes  No | The name(s) or other specific identification of person(s) or class of persons authorized to make the requested use or disclosure |
| Yes  No | The name(s) or other specific identification of the person(s) or class of persons who may use the PHI or to whom the covered entity may make the requested disclosure |
| Yes  No | Description of each purpose of the requested use or disclosure (this element must be research study specific, not for future unspecified research) |
| Yes  No | Authorization expiration date or event that relates to the individual or to the purpose of the use or disclosure (“end of the research study” or “none” may be used, including for the creation and maintenance of a research database or repository) |
| Yes  No | Signature of the individual and date (if the Authorization is signed by an individual's personal representative, a description of the individual's authority to act for the individual) |
| Yes  No | The individual's right to revoke his/her Authorization in writing and either:   * The exceptions to the right to revoke and a description of how the individual may revoke his/her Authorization   **- OR-**   * Reference to the corresponding section(s) of the covered entity's Notice of Privacy Practices |
| Yes  No | Notice of the covered entity's ability or inability to condition treatment, payment, enrollment or eligibility for benefits on the Authorization, including research-related treatment, and if applicable, consequences of refusing to sign the Authorization |
| Yes  No | The potential for the PHI to be re-disclosed by the recipient and no longer protected by the Privacy Rule. This statement does not require an analysis of risk for re-disclosure but may be a general statement that the Privacy Rule may no longer protect health information |