

**REVIEW CHECKLIST STAND ALONE**

**Elements of Consent Review Checklist**

|  |  |
| --- | --- |
| **PI Name:** | **Protocol Number:** |
| **Protocol Title:** | |
| **Consent Form:** | |
| **Reviewer:** | |

**Reviewer: This reviewer checklist is to use if a research study submission contains more than one informed consent document. For each additional consent document, please complete this reviewer checklist to ensure the presence of all applicable elements of consent.**

1. **Obtaining Informed Consent**

|  |  |  |  |
| --- | --- | --- | --- |
| 1. **Basic Elements of Informed Consent** | **Yes** | **No** | **Comments** |
| Indicate whether the informed consent is adequate by considering whether it provides the required basic elements of information to subjects. |  |  |  |
| 1. Each of the following:    * + - A statement that the study involves research  * An explanation of the purposes of the research * The expected duration of subject’s participation * A description of the procedures to be followed * Identification of any procedures which are experimental |  |  |  |
| 1. A description of reasonably foreseeable risks or discomforts. |  |  |  |
| 1. A description of any benefits to subjects or to others which may be reasonably be expected from the research. |  |  |  |
| 1. A disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to subjects. |  |  |  |
| 1. For FDA-regulated research, a statement that notes the possibility that the FDA might inspect the records. |  |  |  |
| 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: * an explanation as to what it consists of or where further information can be obtained. |  |  |  |

|  |  |  |  |
| --- | --- | --- | --- |
|  | | | |
|  | **Yes** | **No** | **Comments** |
| 1. An explanation of whom to contact:  * for answers to questions about the research. * for answers about research subjects’ rights * In the event of a research-related injury |  |  |  |
| 1. A statement that:  * participation is voluntary, * that refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled, and * that the subject may discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled. |  |  |  |

|  |  |  |  |
| --- | --- | --- | --- |
| 1. **Additional Elements of Consent (if applicable)** | **Yes** | **No** | **Comments** |
| If appropriate to the research, indicate whether the informed consent process provides the following additional elements of information |  |  |  |
| 1. 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. |  |  |  |
| 1. Anticipated circumstances under which a subject’s participation may be terminated by the investigator without regard to subject’s consent. |  |  |  |
| 1. Any additional costs to the subject that may result from participation in the research. |  |  |  |
| 1. The consequences of a subject’s decision to withdraw from the research and procedures for orderly termination of participation by the subject. |  |  |  |
| 1. 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 |  |  |  |
| 1. The approximate number of subjects involved in the study |  |  |  |

|  |  |  |  |
| --- | --- | --- | --- |
| 1. **FDA Regulated Studies** | **Yes** | **No** | **Comments** |
| 1. The consent form includes a statement disclosing that the FDA has access to review and copy all relevant records. |  |  |  |
| 1. The consent discloses that when subjects withdraw that the data collected on them up until the point of their withdrawal remains part of the study database and may not be removed. |  |  |  |

|  |  |  |  |
| --- | --- | --- | --- |
|  | **Yes** | **No** | **Comments** |
| 1. If the trial must be registered on clinicaltrials.gov under [FDAAA801](https://clinicaltrials.gov/ct2/manage-recs/fdaaa), the following statement verbatim:   “A description of this clinical trial will be available on <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.” |  |  |  |
| 1. The consent form captures both signature and date by the subject or legally authorized representative. |  |  |  |

|  |  |  |  |
| --- | --- | --- | --- |
| 1. **Genetics** | **Yes** | **No** | **Comments** |
| 1. For research involving genetic tests or information, the consent includes a disclosure of the protections provided by [GINA](http://www.hhs.gov/ohrp/regulations-and-policy/guidance/guidance-on-genetic-information-nondiscrimination-act/index.html) and the limitations of these protections. |  |  |  |
| 1. For studies subject to the [NIH Genomic Data Sharing Policy](https://gds.nih.gov/03policy2.html), the consent includes an option for subjects to provide consent for their genomic and phenotypic data to be used for future research purposes and to be shared broadly. The consent should include an explanation about whether participants’ individual-level data will be shared through unrestricted- or controlled-access repositories. |  |  |  |

1. **Additional Considerations**

|  |  |  |  |
| --- | --- | --- | --- |
|  | **Yes** | **No** | **Comments** |
| 1. Is the level of language appropriate for the subject population? |  |  |  |
| 1. Are complex or technical terms explained? |  |  |  |
| 1. Is the consent provided in the anticipated language(s) of the subject population? |  |  |  |
| 1. Does the consent contain 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? |  |  |  |
| 1. When applicable, does the consent disclose that a [Certificate of Confidentiality](https://humansubjects.nih.gov/coc/background) is in place, describe the protections it affords, and any limitations or exceptions to those protections? |  |  |  |
| 1. When appropriate, and the research is not FDA-regulated, does the consent describe whether and how subjects may withdraw data and/or specimens? |  |  |  |
| 1. When applicable, does the consent include an option to provide consent for future or secondary research using the data and/or specimens obtained for this research? |  |  |  |
| 1. For organizations subject to Joint Commission requirements, does the consent capture the name of the person who provided the consent information and the date the form was signed? |  |  |  |

**Comments or Concerns:**