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**Checklists of requirements for informed consent**

**Information is organized into tables by theme to assist you in locating the most appropriate tables for your research.**

**BASIC ELEMENTS OF INFORMED CONSENT**

|  |  |
| --- | --- |
|  | Elements (45 CFR 46.116(b)) |
|  | 1a) A statement that the study involves research; |
|  | 1b) An explanation of the purpose(s) of the research; |
|  | 1c) Expected duration of the subject’s participation (time required/involved); |
|  | 1d) A description of procedures to be followed. |
|  | 1e) Identification of any procedures which are experimental. |
|  | 2) A description of any reasonably foreseeable risks or discomforts to the participant. |
|  | 3) A description of any benefits to the participant or to others which may reasonably be expected from the research. *Note: remuneration, or payment for participation, may not be considered a benefit*) |
|  | 4) A disclosure of appropriate alternative procedures of courses of treatment, if any, that might be advantageous to the participant—**Usually biomedical research.** |
|  | 5) A statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained. |
|  | 6) **Greater than minimal risk research only**: An explanation regarding compensation, whether any medical treatments are available if injury occurs and, if so, what they consist of, or where further information may be obtained. *Note that compensation refers to reparations for damages incurred during participation, not payment for participation, which is referred to as remuneration.* |
| Research | 7) An explanation of whom to contact for answers to pertinent questions about the research, subjects’ rights, concerns, or complaints, and whom to contact in the event of a research-related injury to the subject. |
| Subject Rights |
| Injury |
|  | 8) A statement that:  **a**. participation is voluntary,  **b**. refusal to participate will involve no penalty or loss of benefits to which the participant is otherwise entitled, and  **c.** the participant may discontinue participation at any time without penalty or loss of benefits to which the participant is otherwise entitled. |
|  | 9) One of the following statements about any research that involves the collection of identifiable private information or identifiable biospecimens:  **a**. A statement that 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  **b**. 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. The participant may discontinue participation at any time without penalty or loss of benefits to which the participant is otherwise entitled. |

**ADDITIONAL ELEMENTS OF INFORMED CONSENT, AS APPROPRIATE TO THE STUDY**

|  |  |
| --- | --- |
|  | Elements (45 CFR46.116(c)) |
|  | 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. |
|  | 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. |
|  | 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. |
|  | The approximate number of subjects involved in the study. |
|  | 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. |
|  | A statement regarding whether clinically relevant research results, including individual research results, will be disclosed to subjects, and if so, under what conditions. |
|  | 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). |

**ELEMENTS OF INFORMED CONSENT REQUIRED BY TUN**

|  |  |
| --- | --- |
|  | Elements |
|  | Study title and name(s) of researcher(s) are at the beginning of the consent form. |
|  | A statement that the study has been approved for human subject participation by the Touro University Nevada Institutional Review Board. |
|  | Consent document is written at a reading and comprehension level appropriate for the age and/or background of the participant (6th-8th grade for most). |
|  | The language and its documentation (especially explanation of purpose, duration, experimental procedures, alternatives, risks, and benefits) are written in "lay language," (i.e. understandable to the people being asked to participate). |
|  | Signature block includes participant, researcher(s), witness if appropriate, and date of signature. |
|  | When appropriate, check box or signature provided to indicate agreement to audio or videotape is included. |
|  | Statement that the participant will receive a copy of the consent form. |
|  | Consent form is free of exculpatory language through which the subject is made to waive, or appear to waive, any of the subject's legal rights. \* |

*\*Note: No informed consent, whether oral or written, may include any exculpatory language through which the subject 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. ---* [*45 CFR 46.116*](http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.htm)

**ELEMENTS OF INFORMED CONSENT REQUIRED FOR PARENT/GUARDIAN PERMISSION**

|  |  |
| --- | --- |
|  | Elements |
|  | Statement that the researcher is asking for parent permission:   1. for their child to take part in research,   **and**   1. to ask the child if they are willing to take part in the study (assent). |
|  | Statement that the child/dependent may choose not to take part even if parent gives permission. |
|  | Statement that the child/dependent may choose not to take part **even if parent gives permission**. |
|  | Description of what, if any, study data about their child/dependent will be shared with the parent. |
|  | Purpose, risks, risk minimization, benefits, procedures, and confidentiality protections described **in relation to the child/dependent as participant**. |
|  | Disclosure of the researcher(s) obligation as a mandatory reporter (*example: discovery of child abuse*). |

**ELEMENTS OF INFORMED CONSENT REQUIRED FOR CHILD/DEPENDENT ASSENT**

|  |  |
| --- | --- |
|  | Elements |
|  | Explanation that parent/guardian(s) knows the participant is being asked to take part in the study. |
|  | Purpose, procedure, risks, benefits, and data confidentiality explained in lay language, appropriate to the participant’s developmental or cognitive capacity. |
|  | Description of what, if any, information the be shared with shared with their parent/guardian(s). |
|  | Statement about audio taping, photographing, or videotaping if required for participation. If not required, check box or signature indicate agreement. |
|  | Disclosure of the researcher(s) obligation as a mandatory reporter (*example: discovery of child abuse*). |