

Touro University Nevada **I**nstitutional **R**eview **B**oard (**IRB**)

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**Addendum 4: Alteration or Omission of Elements from Consent, Permission or Assent Process**

|  |  |
| --- | --- |
| **Principal Investigator:** |  |
| **Study Title:** |  |

**This form is not for complete waiver of informed consent, permission and/or assent. If you are requesting to dispense with attaining consent/permission/assent, instead submit Addendum 6 (Waiver of Informed Consent Process).**

**If you are requesting IRB approval for alteration or omission of some of the elements of informed consent process (i.e. medical record review, deception research, or collection of biological specimens), choose below from section 1 to section 6 to indicate which elements of consent will be altered, and/or omitted, and justify the alteration or omission in section 7.**

Note: *The IRB does not approve alteration of the consent process for research that is subject to FDA regulations, except for planned emergency/acute care research as provided under FDA regulations. Contact the IRB for regulations that apply to single emergency use waiver or acute care research waiver.*

**SECTION 1. Does My Study Qualify for Alteration or Omission?**

**There are two separate ways that your study can qualify for alteration or omission to the informed consent. Use the following questions to determine if you are eligible.**

1. Is your research part of a public benefit and/or service program conducted by or subject to the approval of state or local officials?

[ ]  Yes [ ]  No

If yes, check the following boxes if applicable. The work is designed to study, evaluate or otherwise examine:

 [ ]  Public benefit or service programs

 [ ]  Procedures for obtaining benefits or services under those programs

 [ ]  Possible changes in or alternatives to those programs or procedures

[ ]  Possible changes in methods or levels of payment for benefits or services under those programs

**If you did not check any boxes**, you are not eligible under 45 CFR 46.116(e). Go to question 2.

 **If you checked one or more boxes**, determine if the following statement is true:

[ ]  The research could not be practicably carried out without a waiver or alteration

 **If you checked the box above**, you are eligible under 45 CFR 46.116(e). **Go to Section 2.**

**If you did not check the box, you are not eligible under 45 CFR 46.116(e). Go to Question 2.**

1. **Check boxes to affirm that each criterion is applicable, and explain your answer for each statment that applies to your study**:

[ ]  The research involves no more than minimal risk to the subject.

*Explain how this condition is met***:**

[ ]  The rights and welfare of subjects will not be adversely affected.

*Explain how this condition is met***:**

[ ]  The research could not practicably be carried out without the waiver or alteration.

*Explain how this condition is met***:**

[ ]  If the research involves using identifiable private information or identifiable biospecimens, the research could not practicably be carried out without using such information or biospecimens in an identifiable format.

*Explain how this condition is met***:**

[ ]  Whenever relevant, the subject will be provided with additional pertinent information after they have participated in the study

*Explain how this condition is met***:**

**If any relevant boxes are not checked, your study does not meet the criteria for an alteration of the informed consent process.**

**If all boxes which are relevant to the study are checked, the study is eligible under 45 CFR 46.116(f). Proceed to Section 2.**

**SECTION 2. Requested Alterations or Omissions**

***If you have multiple consent, permission or assent forms that need alteration or omission of elements, submit addendum 4 for each request separately and include it with your IRB application.***

1. This addendum request is for

[ ]  Consent form

[ ]  Permission form

[ ]  Assent Form

4. Does your research involve deception (Refer to Section 10 on the non-exempt application) and needs alteration or omission of elements in the consent, permission and/or assent form?

[ ]  Yes [ ]  No

If ‘**Yes**’, talk about the deception in the justification below.

If the answer is ‘**No**’ and you still would like to alter or omit the elements, **check and explain what all will be altered or omitted in the following pertinent sections.**

**BASIC ELEMENTS OF INFORMED CONSENT**

**Indicate below the element or elements of informed consent/permission/assent you wish to remove or alter.**

|  |  |
| --- | --- |
| I wish to remove or alter this element | Elements (45 CFR 46.116(b)) |
| [ ]  | 1a) A statement that the study involves research; **Explain if checked**:  |
| [ ]  | 1b) An explanation of the purpose(s) of the research; **Explain if checked**:  |
| [ ]  | 1c) Expected duration of the subject’s participation (time required/involved); **Explain if checked**:  |
| [ ]  | 1d) A description of procedures to be followed; **Explain if checked**:  |
| [ ]  | 1e) Identification of any procedures which are experimental; **Explain if checked**:  |
| [ ]  | 2) A description of any reasonably foreseeable risks or discomforts to the participant; **Explain if checked**:  |
| [ ]   | 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*) **Explain if checked**:  |
| [ ]   | 4) A disclosure of appropriate alternative procedures of courses of treatment, if any, that might be advantageous to the participant—**Usually biomedical research;** **Explain if checked**:  |
| [ ]   | 5) A statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained; **Explain if checked**:  |
| [ ]   | 6) 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; (*Note that compensation refers to reparations for damages incurred during participation, not payment for participation, which is referred to as remuneration*)**Explain if checked**:  |
| 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. **Explain if checked**:  |
| 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, andc. The participant may discontinue participation at any time without penalty or loss of benefits to which the participant is otherwise entitled.**Explain if checked**:  |
| [ ] [ ]  | 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; ORb. 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. **Explain if checked**:  |

**ELEMENTS OF INFORMED CONSENT REQUIRED BY TUN**

**Indicate below the element or elements of informed consent/permission/assent you wish to remove or alter.**

|  |  |
| --- | --- |
| I wish to remove or alter this element | Elements  |
| [ ]  | Study title and name(s) of researcher(s) are at the beginning of the consent form.**Explain if checked**:  |
| [ ]  | A statement that the study has been approved for human subject participation by the Touro University Nevada Institutional Review Board.**Explain if checked**:  |
| [ ]  | 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). **Explain if checked**:  |
| [ ]  | 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).**Explain if checked**:  |
| [ ]  | Signature block includes participant, researcher(s), witness if appropriate, and date of signature. **Explain if checked**:  |
| [ ]  | When appropriate, check box or signature provided to indicate agreement to audio or videotape is included.**Explain if checked**:  |
| [ ]  | Statement that the participant will receive a copy of the consent form.**Explain if checked**:  |
| [ ]   | 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. \***Explain if checked**:  |

*\*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**

**Indicate below the element or elements of informed consent/permission/assent you wish to remove or alter.**

|  |  |
| --- | --- |
| I wish to remove or alter this element | Elements |
| [ ]  [ ]  | Statement that the researcher is asking for parent permission:* for their child to take part in research,

**Explain if checked**: and* to ask the child if they are willing to take part in the study (assent).

**Explain if checked**:  |
| [ ]  | Statement that the child/dependent may choose not to take part even if parent gives permission; **Explain if checked**:  |
| [ ]  | Statement that the child/dependent may choose not to take part **even if parent gives permission**;**Explain if checked**:  |
| [ ]  | Description of what, if any, study data about their child/dependent will be shared with the parent; **Explain if checked**:  |
| [ ]  | Purpose, risks, risk minimization, benefits, procedures, and confidentiality protections described **in relation to the child/dependent as participant**; **Explain if checked**:  |
| [ ]  | Disclosure of the researcher(s) obligation as a mandatory reporter (*example: discovery of child abuse*); **Explain if checked**:  |

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

**Indicate below the element or elements of informed consent/permission/assent you wish to remove or alter.**

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

**ADDITIONAL ELEMENTS OF INFORMED CONSENT**

**Indicate below the element or elements of informed consent/permission/assent you wish to remove or alter.**

|  |  |
| --- | --- |
| I wish to remove or alter this element | 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; **Explain if checked**:  |
| [ ]  | Anticipated circumstances under which the subject's participation may be terminated by the investigator without regard to the subject's consent; **Explain if checked**:  |
| [ ]  | Any additional costs to the subject that may result from participation in the research; **Explain if checked**:  |
| [ ]  | The consequences of a subject's decision to withdraw from the research and procedures for orderly termination of participation by the subject;**Explain if checked**:  |
| [ ]   | 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; **Explain if checked**:  |
| [ ]  | The approximate number of subjects involved in the study. **Explain if checked**:  |
| [ ]  | 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.**Explain if checked**:   |
| [ ]  | A statement regarding whether clinically relevant research results, including individual research results, will be disclosed to subjects, and if so, under what conditions.**Explain if checked**:   |
| [ ]  | 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).**Explain if checked**:  |