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| **Instructions** | |
| * This checklist is for IRB members | |
| Checklist | |
| Study ID | PI |

* = May be omitted if are none  = Included

**Basic elements of informed consent.** Except as provided in paragraph (c) or (d) of this section, in seeking informed consent the following information shall be provided to each subject

a statement that the study involves research

an explanation of the purposes of the research

the expected duration of the subject's participation

a description of the procedures to be followed

* identification of any procedures which are experimental
* a description of any reasonably foreseeable risks or discomforts to the subject
* a description of any benefits to the subject or to others which may reasonably be expected from the research
* a disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject
* a statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained [For FDA-regulated research, a statement that notes the possibility that the FDA might inspect the records]
* 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

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

a statement that participation is voluntary

a statement that refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled

a statement that the subject may discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled

Comments:

**Additional elements of informed consent.** When appropriate, one or more of the following elements of information shall also be provided to each subject:

* 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.

Comments:

**Should be included / followed when applicable**

Date Line

Written in second person

Title of research project

Description of the use of audio/video recording, including signed permission

Language before signature line should simply state “I voluntarily agree to participate in this study” or “Your signature below indicates your voluntary agreement to participate in this study”

If consent is in coverletter, face sheet, or via phone: “You indicate your voluntary agreement to participate by completing and returning this questionnaire” or “You indicate your voluntary agreement to participate by beginning this phone interview”

Description of any compensation (including amount and timing) or incentives

Description of alternative treatments, including standard therapy **before** the description of the research protocol

Risk of injury statements

Description of any potential for real or perceived conflict of interest

Placebo-control studies

Genetic testing language

Comments:

**Consent form should not contain**

Use of “understand”

MSU IRB endorsement of research

Comments:

**Consent process includes (when appropriate)**

Person who will conduct consent interview

Person who will provide consent or permission

Any waiting period between informing prospective participant and obtain consent

Steps taken to minimize possibility of coercion or undue influence

Language used by those obtaining consent

Language understood by prospective participant or legally authorized representative

Information to be communicated to prospective participant or legally authorized representative

Comments: