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

* = May be omitted if are none  = Included

**General requirements of informed consent**

An investigator shall seek informed consent only under circumstances that provide the prospective subject or the legally authorized representative sufficient opportunity to discuss and consider whether or not to participate and that minimize the possibility of coercion or undue influence.

The information that is given to the subject or the legally authorized representative shall be in language understandable to the subject or the legally authorized representative.

Revised Common Rule Requirement: The prospective subject or the legally authorized representative must be provided with the information that a reasonable person would want to have in order to make an informed decision about whether to participate, and an opportunity to discuss that information. (Revised Common Rule Requirement)

Revised Common Rule Requirement: Informed consent must begin with a concise and focused presentation of the key information that is most likely to assist a prospective subject or legally authorized representative in understanding the reasons why one might or might not want to participate in the research. This part of the informed consent must be organized and presented in a way that facilitates comprehension. (Revised Common Rule Requirement)

Revised Common Rule Requirement: Informed consent as a whole must present information in sufficient detail relating to the research, and must be organized and presented in a way that does not merely provide lists of isolated facts, but rather facilitates the prospective subject's or legally authorized representative's understanding of the reasons why one might or might not want to participate. (Revised Common Rule Requirement)

No informed consent may include any exculpatory language through which the subject or the legally authorized 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.

**Basic elements of informed consent.** Unless the IRB approves an alteration, 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

* Revised Common Rule Requirement: one of the following statements about any research that involves the collection of identifiable private information or identifiable biospecimens:

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

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.

Comments:

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

* 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
* Revised Common Rule Requirement: 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
* Revised Common Rule Requirement: a statement regarding whether clinically relevant research results, including individual research results, will be disclosed to subjects, and if so, under what conditions
* Revised Common Rule Requirement: 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)
* clinicaltrials.gov statements for applicable clinical trials:"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."

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 cover letter, 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: