

## Tool Summary Sheet: Informed Consent Document Review Checklist for NIDCR-Supported Research

**Purpose:** To provide a checklist for quality control review of informed consent documents to ensure that the consent document complies with all relevant regulations and local IRB requirements, as appropriate.

### Audience/User

Individuals responsible for reviewing informed consent documents to ensure quality and compliance to relevant requirements

### Details

This checklist is based on guidance from the Office for Human Research Protections (OHRP) and includes references to [45 CFR 46.116](#) sources.

### Best Practice Recommendations

- Customize this checklist for the needs/requirements of your protocol and IRB. Add clarification about IRB specific requirements not otherwise specified in the form (see the final line in the sample checklist).
- Store the customized, blank version electronically with study files for use with possible future amendments to the consent document.
- As noted in the purpose above, this document serves as a representation of the quality review process for protocol specific consent documents and therefore should be used for *each* formally reviewed draft version. By definition a formally reviewed draft is considered to be a draft presented as final for internal review OR a draft sent externally for review and comment.

### Tool Revision History:

Version		
Number	Date	Summary of Revisions Made:
1.0	30Aug2018	First approved version.

# Informed Consent Document Review Checklist for NIDCR-Supported Research<sup>1</sup>

<b>Protocol Number and Name:</b>		<b>Study PI Name:</b>	
<b>Protocol Version Number and Date:</b>		<b>Site Name / Number:</b>	
<b>Informed Consent Document Version Number and Date:</b>		<b>Grant Number:</b>	

Source Reference <a href="#">45 CFR 46.116</a>	Element <sup>2</sup>	Acceptable or Not Applicable	Not Acceptable	Comments
<b>Introductory Paragraph</b>	<b>General Requirements</b>			
	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	<input type="checkbox"/>	<input type="checkbox"/>	
	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.	<input type="checkbox"/>	<input type="checkbox"/>	
	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.	<input type="checkbox"/>	<input type="checkbox"/>	
<b>(a)</b>	<b>Basic Elements</b>			
(1)	A statement that the study involves research	<input type="checkbox"/>	<input type="checkbox"/>	
(1)	An explanation of the purposes of the research	<input type="checkbox"/>	<input type="checkbox"/>	
(1)	The expected duration of the subject's participation	<input type="checkbox"/>	<input type="checkbox"/>	
(1)	A description of the procedures to be followed	<input type="checkbox"/>	<input type="checkbox"/>	
(1)	Identification of any procedures that are experimental	<input type="checkbox"/>	<input type="checkbox"/>	

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Source Reference <a href="#">45 CFR 46.116</a>	Element <sup>2</sup>	Acceptable or Not Applicable	Not Acceptable	Comments
(2)	A description of any reasonably foreseeable risks or discomforts to the subject	<input type="checkbox"/>	<input type="checkbox"/>	
(3)	A description of any benefits to the subject or to others that may reasonably be expected from the research	<input type="checkbox"/>	<input type="checkbox"/>	
(4)	A disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject	<input type="checkbox"/>	<input type="checkbox"/>	
(5)	A statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained	<input type="checkbox"/>	<input type="checkbox"/>	
(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	<input type="checkbox"/>	<input type="checkbox"/>	
(7)	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	<input type="checkbox"/>	<input type="checkbox"/>	
(8)	A statement that participation is voluntary, refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled, and the subject may discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled	<input type="checkbox"/>	<input type="checkbox"/>	
<b>(b)</b>	<b>Additional Elements (as appropriate)</b>			
(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), that are currently unforeseeable	<input type="checkbox"/>	<input type="checkbox"/>	
(2)	Anticipated circumstances under which the subject's participation may be terminated by the investigator without regard to the subject's or the legally authorized representative's consent	<input type="checkbox"/>	<input type="checkbox"/>	
(3)	Any additional costs to the subject that may result from participation in the research	<input type="checkbox"/>	<input type="checkbox"/>	
(4)	The consequences of the subject's decision to withdraw from the research and procedures for orderly termination of participation by the subject	<input type="checkbox"/>	<input type="checkbox"/>	

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(5)	A statement that significant new findings developed during the course of the research, that may relate to the subject's willingness to continue participation, will be provided to the subject	<input type="checkbox"/>	<input type="checkbox"/>	
(6)	The approximate number of subjects involved in the study	<input type="checkbox"/>	<input type="checkbox"/>	
IRB	Other governing IRB required elements not otherwise specified above. Specifically:	<input type="checkbox"/>	<input type="checkbox"/>	

<sup>1</sup> <https://www.hhs.gov/ohrp/regulations-and-policy/guidance/checklists/index.html>

<sup>2</sup> The IRB may waive some or all elements of informed consent if (a) the research involves no more than minimal risk to the subjects; (b) the waiver or alteration will not adversely affect the rights and welfare of the subjects; (c) the research could not practicably be carried out without the waiver or alteration; and (d) whenever appropriate, the subjects will be provided with additional pertinent information after participation.