

Informed Consent Checklist

(Refer to DHS HHS OHRP 45 CFR 46 §46.116 for details)

Proposal Title:

Basic Elements of Informed Consent Check "Yes," "No," or "N/A" to indicate if the element is present. Provide comments, as needed, at the bottom of the checklist.	Indicate		
	Yes	No	N/A
1. A statement that the study involves research.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
2. An explanation of the purposes of the research.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
3. The expected duration of the individual's participation.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
4. The approximate number of study participants.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
5. A description of the procedures to be followed.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
6. Identification of any procedures which are experimental.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
7. A description of any reasonably foreseeable risks or discomforts to the participant.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
8. A description of any benefits to the participant or to others which may reasonably be expected from the research.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
9. A disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the participant.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
10. A statement describing the extent, if any, to which confidentiality of records identifying the participant will be maintained.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
11. 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"/>	<input type="checkbox"/>
12. A statement that participation is voluntary, refusal to participate will involve no penalty or loss of benefits to which the individual is otherwise entitled, and the individual may discontinue participation at any time without penalty or loss of benefits, to which he/she is otherwise entitled.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
13. An explanation of whom to contact for answers to pertinent questions about the research and participant's rights (i.e., the Principal investigator), whom to contact in the event of a research-related injury to the participant, and to contact the IRB for questions related to their rights as a participant.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Additional Elements, as appropriate	Indicate		
	Yes	No	N/A
14. A statement that the intervention may involve risks to the individual (or to the embryo or fetus, if the individual is or may become pregnant), which are currently unforeseeable.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
15. Anticipated circumstances under which the individual's participation may be terminated by the investigator without regard to the subject's consent.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
16. Any additional costs to the individual that may result from participation in the research.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
17. The consequences of an individual's decision to withdraw from the research and procedures for orderly termination of participation by the individual.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
18. A statement that significant new findings developed during the course of the research, which may relate to the individual's willingness to continue participation, will be provided to the individual.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Comments: (Provide the item # for each comment.)