

## Consent / Assent Checklist Quality Improvement Review

Investigator's Name:  
Review Date:

Protocol Number:  
Reviewer:

	Y	N	Comments
<b>Does the informed consent document contain:</b>			
Protocol Title	<input type="checkbox"/>	<input type="checkbox"/>	
Principal Investigator	<input type="checkbox"/>	<input type="checkbox"/>	
Co-investigators / Study Staff	<input type="checkbox"/>	<input type="checkbox"/>	
Department(s)	<input type="checkbox"/>	<input type="checkbox"/>	
Phone number(s)	<input type="checkbox"/>	<input type="checkbox"/>	
Statement that study involves research	<input type="checkbox"/>	<input type="checkbox"/>	
Explanation of the purposes of the research	<input type="checkbox"/>	<input type="checkbox"/>	
Expected duration of the subject's participation	<input type="checkbox"/>	<input type="checkbox"/>	
A description of the procedures to be followed	<input type="checkbox"/>	<input type="checkbox"/>	
Identification of any procedures which are experimental	<input type="checkbox"/>	<input type="checkbox"/>	
Description of any reasonably foreseeable risks or discomforts to the subject including social and psychological risks	<input type="checkbox"/>	<input type="checkbox"/>	
A statement indicating the likelihood of risks or discomforts occurring, if any, and the ramifications associated with the risks/discomforts	<input type="checkbox"/>	<input type="checkbox"/>	
Description of any benefits to the subject or to others which may reasonably be expected from the research	<input type="checkbox"/>	<input type="checkbox"/>	
Disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject	<input type="checkbox"/>	<input type="checkbox"/>	
A statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained and possibility of records being reviewed by sponsor, FDA, OHRP, university authorized personnel	<input type="checkbox"/>	<input type="checkbox"/>	
For research involving more than minimal risk, an explanation as to whether any compensation is available, 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"/>	
A statement that describes contact information details (e.g., phone numbers) and whom to contact for the following situations: questions about the research, questions about subjects' rights, comments/suggestions, and in the event of a research-related injury	<input type="checkbox"/>	<input type="checkbox"/>	
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"/>	

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	Y	N	Comments
Investigator statement of financial gain from research	<input type="checkbox"/>	<input type="checkbox"/>	
<b>Additional elements, as appropriate (required unless IRB concurs otherwise (e.g., item does not apply to the research)):</b>			
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	<input type="checkbox"/>	<input type="checkbox"/>	
Anticipated circumstances under which the subject's participation may be terminated by the investigator without regard to the subject's consent (e.g., subject non-compliance)	<input type="checkbox"/>	<input type="checkbox"/>	
Any additional costs to the subject that may result from participation in the research	<input type="checkbox"/>	<input type="checkbox"/>	
Description of a subject's right to withdraw from research and any procedures that may be necessary after an early withdrawal for subject's safety	<input type="checkbox"/>	<input type="checkbox"/>	
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	<input type="checkbox"/>	<input type="checkbox"/>	
The approximate number of subjects involved in the study	<input type="checkbox"/>	<input type="checkbox"/>	
Information concerning payment including but not limited to amount and schedule of payment			
Disposition of subject's blood samples: DNA testing, cell lines, development of future products	<input type="checkbox"/>	<input type="checkbox"/>	
Applicable FDA regulated clinical trials statement regarding registration on national clinical trial registry data bank (clinicaltrials.gov)	<input type="checkbox"/>	<input type="checkbox"/>	
<b>Additional Review Items for Assent Forms</b>			
Language is appropriate for subjects aged 12-17			
<b>Additional Review Items for VA Consents</b>			
VA template language is in the consent form	<input type="checkbox"/>	<input type="checkbox"/>	
VA consents are on VA Form 10-1086	<input type="checkbox"/>	<input type="checkbox"/>	

Additional Comments and/or Other Items Reviewed