

Washington State University Institutional Review Board  
**Informed Consent Checklist for Investigators**  
**Parental Permission and Child Assent**

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**Basic Elements (OHRP Required):**

Present & Adequate			Elements
Yes	No	N/A	
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	1a) A statement that the study involves research. Comments:
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	1b) An explanation of the purpose(s) of the research. Comments:
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	1c) Expected duration of the subject's participation (time required/involved). Comments:
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	1d) A description of procedures to be followed. Comments:
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	1e) Identification of any procedures which are experimental. Comments:
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	2) A description of any reasonably foreseeable risks or discomforts to the participant. Comments:
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	3) A description of any benefits to the participant or to others which may reasonably be expected from the research. Comments:
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	4) A disclosure of appropriate alternative procedures of courses of treatment, if any, that might be advantageous to the participant— <b>Usually biomedical research</b> Comments:
<input type="checkbox"/>	<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. Comments:
<input type="checkbox"/>	<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. Comments:
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	7) An explanation of whom to contact for answers to pertinent questions about the research, subjects' rights, concerns, or complaints, and whom to contact in the event of a research-related injury to the subject. Comments:
Research			
Subject Rights			
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	8) A statement that: <ul style="list-style-type: none"> <li>• participation is voluntary,</li> <li>• refusal to participate will involve no penalty or loss of benefits to which the participant is otherwise entitled, and</li> <li>• the participant may discontinue participation at any time without penalty or loss of benefits to which the participant is otherwise entitled</li> </ul> Comments:
Injury			
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	

## Additional WSU Requirements:

Present & Adequate			Elements
Yes	No	N/A	
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Study title and name(s) of researcher(s) are at the beginning of the consent form. Comments:
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	A statement that the study has been approved for human subject participation by the Washington State University Institutional Review Board. Comments:
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Consent document is written at a reading and comprehension level appropriate for the age and/or background of the participant (6 <sup>th</sup> -8 <sup>th</sup> grade for most). Comments:
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	The language and its documentation (especially explanation of purpose, duration, experimental procedures, alternatives, risks, and benefits) are written in "lay language," (i.e. understandable to the people being asked to participate) Comments:
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Signature block includes participant, researcher(s), witness if appropriate, and date of signature. Comments:
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	When appropriate, check box or signature provided to indicate agreement to audio or videotape is included. Comments:
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Statement that the participant will receive a copy of the consent form. Comments:
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Consent form is free of exculpatory language through which the subject is made to waive, or appear to waive, any of the subject's legal rights.* Comments:

**\*Note: No informed consent, whether oral or written, may include any exculpatory language through which the subject 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. --- 45 CFR 46.116**

## **Additional Requirements for Parental Permission Form:**

Present & Adequate			Elements
Yes	No	N/A	
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Statement that the researcher is asking for parent permission: <ul style="list-style-type: none"> <li>for their child to take part in research, and</li> <li>to ask the child if they are willing to take part in the study (assent)</li> </ul> Comments:
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Description of procedures explained in terms of what the child will be asked to do. Comments:
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Statement that child may choose not to take part even if parent gives permission. Comments:
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Description of what, if any, study data about their child will be shared with the parent , if applicable. Comments:
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Purpose, risks, risk minimization, benefits, procedures, and confidentiality protections described in relation to the child as participant. Comments:
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	When relevant, statement of mandatory reporting requirements included. Comments:

## **Requirements for Child Assent Form**

Present & Adequate			Elements
Yes	No	N/A	
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Explanation that parent(s) knows the child is being asked to take part
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Purpose, procedure, risks, benefits, and data confidentiality explained in developmentally-appropriate lay language. Comments:
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Description of what, if any, information the be shared with shared with their parent(s), if applicable. Comments:
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Statement about audio or video taping if required for participation; check box or signature to opt out of taping, if not required. Comments:
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	When relevant, statement of mandatory reporting requirements included. Comments:

**\*Note: No informed consent, whether oral or written, may include any exculpatory language through which the subject 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. --- 45 CFR 46.116**