Washington State University Institutional Review Board

Informed Consent Checklist for Investigators

Basic Elements (OHRP Required):

Present & Adequate			Elements
Yes	No	N/A	
☐	☐	☐	1a) A statement that the study involves research. Comments:
☐	☐	☐	1b) An explanation of the purpose(s) of the research. Comments:
☐	☐	☐	1c) Expected duration of the subject's participation (time required/involved). Comments:
☐	☐	☐	1d) A description of procedures to be followed. Comments:
☐	☐	☐	1e) Identification of any procedures which are experimental. Comments:
☐	☐	☐	2) A description of any reasonably foreseeable risks or discomforts to the participant. Comments:
☐	☐	☐	3) A description of any benefits to the participant or to others which may reasonably be expected from the research. Comments:
☐	☐	☐	4) A disclosure of appropriate alternative procedures of courses of treatment, if any, that might be advantageous to the participant—**Usually biomedical research** Comments:
☐	☐	☐	5) A statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained. Comments:
☐	☐	☐	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:
Research ☐	☐	☐	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:
Subject Rights ☐	☐	☐	
Injury ☐	☐	☐	
☐ ☐ ☐	☐ ☐ ☐	☐ ☐ ☐	8) A statement that: • participation is voluntary, • refusal to participate will involve no penalty or loss of benefits to which the participant is otherwise entitled, and • the participant may discontinue participation at any time without penalty or loss of benefits to which the participant is otherwise entitled Comments:

Additional WSU Requirements:

Present & Adequate			Elements
Yes	No	N/A	
☐	☐	☐	Study title and name(s) of researcher(s) are at the beginning of the consent form. Comments:
☐	☐	☐	A statement that the study has been approved for human subject participation by the Washington State University Institutional Review Board. Comments:
☐	☐	☐	Consent document is written at a reading and comprehension level appropriate for the age and/or background of the participant (6^{th}-8^{th} grade for most). Comments:
☐	☐	☐	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:
☐	☐	☐	Signature block includes participant, researcher(s), witness if appropriate, and date of signature. Comments:
☐	☐	☐	When appropriate, check box or signature provided to indicate agreement to audio or videotape is included. Comments:
☐	☐	☐	Statement that the participant will receive a copy of the consent form. Comments:
☐	☐	☐	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**