

# Informed Consent Requirements Checklist

Informed consent is required from any subjects put at risk. A copy of the informed consent form to be used on the project must be submitted to the Human Subjects Review Committee with the Human Subjects Activity Review Form and the Human Subjects Research Exemption Request. The consent form should include the following:

1.  A statement that the study involves research and an explanation of the purposes of the research.
2.  A brief, clear explanation of the research procedures to be followed (in non-technical terms, or where necessary, with technical terms defined), including the expected duration of the subject's participation.
3.  A description of discomforts or risks to be expected.
4.  A description of the benefits of the research (to the individual, to the field, etc.).
5.  An offer to answer inquiries from participants concerning the procedures (provide contact information for the primary research or, for student research, faculty advisor). Instructions that questions about subject's rights as a research subject should be directed to: Geri Walker, WWU Human Protections Administrator (HPA), (360) 650-3220. Directions that in the event the subject suffers any research related injuries or adverse effects as a result of participation in the study the primary researcher and/or HPA should be contacted.
6.  A statement that participation is voluntary and that the subject is free to withdraw his/her consent and to discontinue participation without penalty or loss of benefits to which the subject is otherwise entitled.
7.  A statement describing the extent, if any, to which confidentiality of records and data identifying the subject will be maintained.
8.  A reference to any age restrictions or associated permissions for the subject population. If minors are to be excluded from your study, include a line on the consent form which reads "I am at least 18 years of age." If the subjects are or can be minors, include a line for the required parental signature.
9.  A statement saying that a copy of the consent form will be given to the person signing the form. (Give the subject two copies of the form-one marked "Researcher" and one marked "Participant"-have them sign both copies and retain the copy marked "Participant.")
10.  Oral Consent: Only in special and/or unusual circumstances can consent of the subjects be obtained orally. The Committee must approve a waiver of the requirement to document informed consent. A waiver of written consent might be granted in the case where: (a) the risk to the subject is minimal; (b) use of primary procedures for obtaining consent would invalidate important research objectives; or (c) where alternative means would be less advantageous to the subjects.

For further guidance on preparing your consent form, see the samples given on the RSP website at <http://www.wvu.edu/depts/rsp/stdconsent.pdf> for a standard consent form and <http://www.wvu.edu/depts/rsp/childconsent.pdf> for a parental consent/child assent form (used when your subjects are under 18 years of age). The numbers in parentheses at the end of statements on the templates refer to the numbered listing above.