OHSU Policy

I. Policy

A. Legally effective informed consent requires that the basic elements of informed consent 45 CFR 116, and additional elements when appropriate, are included in the consent form, unless a waiver or alteration is approved by the IRB. (Amendment A)

B. No informed consent, whether oral or written, may include any exculpatory language through which the subject or the representative 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.

C. The information that is given to the subject or the representative shall be in language understandable to the subject or the representative.

D. The consent form should only have language that minimizes the possibility of coercion or undue influence.

E. The document should have appropriate spaces to document legally effective informed consent of the subject or the subject's legally authorized representative as required by the IRB and the law.

Effective: 4/21/2008