

UNIVERSITY OF HAWAI‘I
COMMITTEE ON HUMAN STUDIES (CHS)

GUIDLINES FOR THE PREPARATION OF A CONSENT FORM

In response to many queries, attached are CHS suggestions for preparation of a consent form, keyed to DHEW regulations. The guidelines on Side A of the attached sheet contemplate a “written consent document embodying all of the basic elements of informed consent.” An “oral/written” form (Side B) must contain all the basic elements of consent, see sample, and when submitted to the CHS must be accompanied by the written summary of the information to be presented orally to the subject or authorized representative.

Both the “written” form and the “oral/written” form must contain the information in Sections I, III, IV of the sample forms. The “oral/written” form must contain all the basic elements of consent plus the oral briefing to the subject must include the information given in Section II of the sample “written” form. The written summary of the oral briefing must also be signed by the witness that signs the consent form.

Suggested consent form wording for informing subjects on compensation and medical treatment if there are physical risks: “I understand that in the event of physical injury resulting from the research procedures, (state what is available, e.g., ‘medical treatment for injuries or illness is available ‘/’ only acute/immediate/essential medical treatment [including hospitalization] is available ‘/’ monetary compensation is available for wages lost because of injury’; or what is not available, e.g., ‘financial compensation is not available, but medical treatment is provided free of charge,’ etc.).”

All P.I.’s should endeavor to make sure that consent forms are written in plain, easy to understand language.

Signatures of minor subjects seven (7) years of age and older must be obtained in addition to the signature of the authorized legal representative.