Informed consent of the subject is one of the fundamental principles of ethical research for human subjects. Informed consent is also mandated by Federal regulations (45 CFR 46) and University policy for research with human subjects. An investigator should seek a waiver of written or verbal informed consent only under compelling circumstances. The IRB determines which type of consent applies to your research but please check the type that you recommend. The Guidelines for Determining Type of Consent will assist you in this process.

___ Waive Written Informed Consent (see Section A)
___ Waive Verbal and Written Informed Consent (see Section B)

SECTION A: Waive Written Informed Consent

I believe that this protocol is eligible for exemption of the written informed consent requirement because the protocol meets one of the following criteria:

(NOTE: Even when written informed consent is waived, the investigator is required to give subjects full informed consent verbally.)

___ (1) The only record linking the subject and the research would be the consent document and the principal risk would be potential harm resulting from breach of confidentiality. Each subject will be asked whether the subject wants documentation linking the subject with the research and the subject’s wishes will govern.

   Example: When there is a possible legal, social or economic risk to the subject entailed in signing the consent form, e.g., for immigrants who might be identified as being illegal aliens, or for HIV antibody-positive individuals who might be identified as such by signing the consent form;

___ (2) The research presents no more than minimal risk of harm to subjects and involves no procedures for which written consent is normally required outside of the research context.

   Examples: 1) When, such as a mail survey, subjects are clearly informed about the research and receipt of their responses can be taken as an indication that they agree to participate; 2) When the identities of subjects will be completely anonymous if the consent form is not signed and 3) When obtaining signed consent is not appropriate or feasible according to the cultural standards of the population being studied.

SECTION B: Waive Verbal and Written Informed Consent

I believe that this protocol is eligible for exemption of written and verbal informed consent because the protocol meets ALL of the following criteria:

___ (1) The research presents no more than minimal risk of harm to subjects
___ (2) The waiver or alteration will not adversely affect the rights and welfare of the subjects
___ (3) The research could not practicably be carried out without the waiver or alteration.
___ (4) Whenever appropriate, the subjects will be provided with additional pertinent information after participation.

As the federal regulations note, “in cases where the documentation requirement is waived, the IRB may require the investigator to provide subjects with a written statement regarding the research.” The Social and Behavioral Sciences Institutional Review Board often requires the use of such a written statement, in the form of an information sheet, which includes most or all of the same elements as a consent form, but does not require the signature of the subject. These elements would be as follows:

A) A statement that the study involves research, an explanation of the purposes of the research, the expected duration of the subject's participation, a description of the procedures, and identification of any procedures that are experimental.

B) A statement that participation in the research involves no known risks.

C) An explanation of whom to contact for answers to pertinent questions about the research (the PI and the PI’s office telephone number; faculty sponsor, if applicable) and questions about human research subjects’ rights (Social and Behavioral Sciences Institutional Review Board at 716.645.3321) and

D) A statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained.