GUIDANCE DOCUMENT:
WAIVER OF INFORMED CONSENT - WHEN IS IT APPLICABLE?

In certain cases, federal regulations allow the IRB to approve a consent procedure which does not include, or which alters, some or all of the elements of informed consent, or to waive the requirement to obtain any informed consent. Most complete waivers of consent involve studies in which there are minimal risks to subjects, but complete waivers are also possible in emergency care and a few other circumstances.
NOTE: Studies regulated under the FDA regulations differ from HHS regulations and are generally more restrictive in the area of waiver of informed consent. The differences are noted below.

I. Waiver of Informed Consent

Federal regulations [45 CFR 46.116(d)] establish four criteria for waiving consent or altering the elements of consent in minimal risk studies. There are no corresponding provisions in FDA regulations, and these criteria may not be used to waive or alter the elements of consent in FDA-regulated studies:

1. The research involves no more than minimal risk (Minimal risk is defined in 45 CFR 46.102 as "the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests").
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; and
4. Whenever appropriate, the subjects will be provided with additional pertinent information after participation.

II. Waiver of Documentation of Consent

Federal regulations [45 CFR 46.117(c)] allow the IRB to waive the requirement for obtaining signed consent if it finds that either:

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 a breach of confidentiality (These criteria cannot be used for FDA-regulated studies),

or

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. This paragraph only also applies to FDA-regulated studies per 21 CFR 56.109(c)(1).

The IRB can also waive signed consent in studies that meet the requirements for waiving all consent. Often verbal consent used with use of an information sheet***** or implied consent will still be required for most studies where a waiver of documentation of consent is granted by the IRB. Investigators may wish to replace signed consent with implied consent (e.g., a prospective subject is informed about a study where participation consists only of filling out an anonymous questionnaire; the person completes the questionnaire and, by doing so, agrees to participate in the research). The IRB will consider approving such requests based on appropriate justification and information regarding the consent process.

III. *Use of Information Sheets

As the regulations state, "in cases where the documentation requirement is waived, the IRB may require the investigator to provide subjects with a written statement regarding the research." In such cases, the IRB will usually call for use of an information sheet that includes most or all of the elements of a consent form but not the subject's signature.

***Some examples of approvable waiver of documentation of consent*:**

- When the identities of subjects will be completely anonymous and there is minimal risk involved in the study. The signed informed consent would be the only record linking the subject to the study therefore it would be the only identifier in the study.
- When obtaining signed consent is not appropriate or feasible according to the cultural standards of the population being studied, and there is minimal risk involved in the study.
- 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.
- When the study involves only a telephone interview.
- Investigators may wish to replace signed consent with verbal consent. The IRB will consider approving such requests in limited circumstances, and will usually require use of an information sheet. If this is not feasible (for example, the only contact is by phone), the IRB may ask to see a script of what would be said to prospective subjects to evaluate the consent process.