**Consent without Signature (or “verbal consent”)**

Under specified circumstances, federal regulations allow the HSC to waive the requirement for a signature on the consent document. Investigators typically use the term “verbal consent,” but federal regulations consider this to be waiver of consent documentation. Note that even when the signature requirement is waived, the consent process still occurs, and the subject still makes an informed choice about participating in the research. The only difference is that subject’s signature is not obtained. The signature requirement can be waived if the HSC determines:

1. That 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. Each subject will be asked whether the subject wants documentation linking the subject with the research and the subject’s wishes will govern;  
   
   or

2. That 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.

When investigators are conducting research on sensitive topics such as risky behaviors, immigration status or substance abuse, it may be appropriate for the HSC to waive the requirement for a signed consent document. These examples fit category 1 above. A written consent document is used. The document contains all the elements required by federal regulation; only the signature lines on the last page will be omitted. Subjects should be given a copy of the (unsigned) consent document so they can continue to refer to the information or contact the investigator if they have questions.

A telephone phone survey would be an example of category 2 above. For information about phone surveys, please refer to the guidance document called “Phone Consent.”