Alteration or Waiver of Consent and Waiver of Documentation in Nonmedical Research and International Research

When conducting research in certain communities or social contexts, whether in the U.S. or abroad, it may be inappropriate to document consent by using the standard written and signed consent document. Other consent procedures may be more culturally or socially sensitive and may afford better protection to participants. The two most useful regulatory options are:

1) waiver of consent or alteration of some of the mandatory elements of consent [45 CFR 46.116(d)], or
2) waiver of documentation of consent [45 CFR 46.117(c); 21 CFR 56.109(c)].

Research subject to FDA regulations is only eligible for the "minimal risk" type of a waiver of documentation of consent, and is not eligible for a waiver of informed consent except in emergency research (21 CFR 56.109(c)).

Sample Scenarios
The following are three sample scenarios when the IRBs may consider these two options. The first scenario involves a request for a waiver or alteration of "consent" in minimal-risk research that is not subject to FDA regulations. The second involves a waiver of "documentation" of consent, also is available only for minimal-risk research, but does not require that the research be impractical to carry out without the waiver of documentation. The third scenario involves a request for a waiver of "documentation" where the research potentially involves more than minimal risk and is not subject to FDA regulations.

Scenario 1: Research is proposed to be carried out in a location where no written or signed contracts are used. The discussion of all the mandatory elements of consent under the Common Rule would not fit with cultural norms and could introduce an element of fear and distrust towards the researcher. The researcher provides protocol-specific justification showing that:

1. The research presents no more than minimal risk;
2. The requested alteration of consent (or requested waiver) will not adversely affect the rights and welfare of the subjects;
3. The research could not practically be carried out without the alteration or waiver;
4. Whenever appropriate, the participants will be provided with additional pertinent information after participation; AND
5. The research is not subject to FDA regulations.

If the research satisfies all conditions 1-5 (i.e., 45 CFR 46.116(d)), the IRBs will consider granting a waiver or alteration of some of the mandatory elements of informed consent.)
Scenario 2: Research is proposed to be carried out in a location where there is little experience with written or signed contracts. The presentation of a written consent form requiring an identifying signature could introduce an element of fear and distrust towards the research and researcher, but the research would not necessarily be impractical to conduct if it was required. The researcher provides protocol-specific justification showing that the research:
1. Presents no more than minimal risk, and
2. Involves no procedures for which written documentation of consent is required outside of the research context.

If the research satisfies all conditions 1-2 (i.e., 45 CFR 46.117(c)(1) or FDA regulation 21 CFR 56.109(c)), the IRBs will consider granting a waiver of “documentation” of informed consent.

Scenario 3: Research is proposed to be carried out in a location where protecting the confidentiality of their information is a primary concern of the participants, and there is little experience with written and signed contracts. The research presents the potential for greater than minimal risk to participants, due to the sensitive nature of the study, e.g., illegal activities or incriminating behaviors. Additionally, the presentation of a written consent form that requires their identifying signature could introduce an element of fear and distrust towards the research and researcher. The researcher provides protocol-specific justification showing that the research:
1. Has the potential harm of a breach of confidentiality as its principal risk
2. Has the consent document as the only record linking the participant and the research
3. Could be carried out by asking each participant whether the participant wants documentation (i.e., his or her signature) linking the participant with the research and abide by the answer, and
4. Is not subject to FDA regulations.

If the research satisfies all conditions 1-4 (i.e., 45 CFR 46.117(c)(2)), the IRBs will consider granting a waiver of “documentation” of informed consent.

Additional IRB Requirements
In all three of the above scenarios, the IRBs will generally require that the researcher provide to all participants who are not signing a consent form:
- Either a copy of the consent form without a signature line or an information sheet concerning the research with contact information in a language understandable to all participants,
- Or an oral script to be delivered in a language understandable to the participants with an information card that includes contact information that can take the form of a name card, which is commonly used in many cultural contexts.