Waivers: Documentation and Consent

Waiver of Documentation

45 CFR 46.117.c(2)

- An IRB may waive the requirement for the investigator to obtain a signed consent form for some or all of the subjects if it finds either:
  - 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;
  - The research presents no more than minimal risk of harm to the subjects and involves no procedures for which written consent is normally required outside the research context.

Waiver of Consent

45CFR46.116(d)

- An IRB may approved the waiver of consent or altering of the elements of consent provided the IRB finds and documents all of the following:
  - The research involves no more than minimal risk;
  - The waiver or alteration will not adversely affect the rights and welfare of the subjects;
  - The research could not practically carried out without the waiver or alteration;
  - And…whenever appropriate the subjects will be provided with additional pertinent information after participation.

Waiver of Documentation Examples

- The consent form would be the only place the participant's name is linked to the study (the study is otherwise anonymous) and association with the study via a signature (or possession of consent form) poses risk. There is still an informed consent conversation, with a script.
- An minimal risk study involves a phone survey. Subjects give oral consent over the phone but are not available to sign a form. Telephone call may be followed with mailing of information.
- An expedited review internet survey that retains the identity of the respondent provides all required elements of informed consent, however documentation is waived.

Waiver of Consent Example

- Non-sensitive data will be obtained from 5,000 existing medical records. ALL data being reviewed is already in existence at time of IRB submission. Investigators need to document and maintain identifiers in order to compare medical records from different sources.
  - There will be no participant contact and it is not feasible to contact all participants for consent