Chart 11: Can Documentation of Informed Consent Be Waived Under 45 CFR 46.117(c)

From Chart 10

Would the consent document be the only record linking the subject and the research, and would the principal risk be potential harm resulting from a breach of confidentiality? [45 CFR 46.117(c)(1)]

- YES
- NO

If IRB allows Waiver of Documentation under 45 CFR 46.117.(c)(1)

Investigator will ask each subject if he/she wants documentation linking the subject with the research. [45 CFR 46.117.(c)(1)]

- YES
- NO

IRB may waive the requirement for a signed consent form for some or all subjects.

Does the research present no more than minimal risk and involve no procedures for which written consent is normally required outside the research context? [45 CFR 46.117(c)(2)]

- YES
- NO

Subject’s wishes will govern whether informed is documented. [45 CFR 46.117(c)(1)]

IRB may require investigator to provide subjects with a written consent regarding the research. [45 CFR 46.117 (c)]

IRB may NOT waive the requirement for a signed consent form for any subjects

Adapted from http://www.hhs.gov/ohrp/policy/checklists/decisioncharts.html#c11