Chart 11: Can Documentation of Informed Consent Be Waived?

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?

Yes

Does the research present no more than minimal risk and involve no procedures for which written consent is normally required outside the research context?

No

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

Yes

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

No

If IRB Allows Waiver of Documentation

Investigator will ask each subject if he or she wants documentation linking the subject with the research.

And

IRB may require investigator to provide subjects with a written statement regarding the research.

And

Subject’s wishes will govern whether informed consent is documented.