***(Note: If subjects include children to whom 45 CFR part 46, subpart D applies, an alternative provision for waiver of parental permission might apply. [See 45 CFR 46.408(c)])

From Chart 8 or 9

Will the research or demonstration project be conducted by or subject to the approval of state or local government officials? [45 CFR 46.116(c)(1)]

NO

Will the research involve greater than minimal risk, as defined in Section 46.102(i)? [45 CFR 46.116(d)(1)]

NO

Is it practicable to conduct the research without the waiver or alteration? [45 CFR 46.116(d)(3)]

NO

Will waiving or altering the informed consent adversely affect the subjects' rights and welfare? [45 CFR 46.116(d)(2)]

NO

Will pertinent information be provided to subjects later, if appropriate? [45 CFR 46.116(d)(4)]

NO

Waiver of informed consent or alteration of consent elements is allowed if IRB documents these findings and approves waiver or alteration.

YES

Is the project designed to study, evaluate, or otherwise examine: (i) Public benefit of service programs; (ii) procedures for obtaining benefits or services under those programs; (iii) possible changes in or alternatives to those programs or procedures; or (iv) possible changes in methods or levels of payment for benefits or services under those programs? [45 CFR 46.116(c)(1)]

YES

Is it practicable to conduct the research without the waiver or alteration? [45 CFR 46.116(c)(2)]

NO

Go to Chart 11

NO

If informed consent is not waived entirely

NO

* Note: See OHRP guidance on informed consent requirements in emergency research at http://www.hhs.gov/ohrp/regulations-and-policy/guidance/emergency-research-informed-consent-requirements/index.html for further information on emergency research informed consent waiver.

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Chart 11: May Documentation of Informed Consent Be Waived Under 45 CFR 46.117(c)?  View text version of Chart 11

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)]

NO

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

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

AND

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

AND

If IRB Allows Waiver of Documentation Under 45 CFR 46.117(c)(1)

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

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

END

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