Chart 10: Can Informed Consent Be Waived or Consent Elements Be Altered Under 45 CFR 46.116(c) or (d)?**

**(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)]

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)]

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)]

YES → No waiver of informed consent or alteration of consent elements is allowed.*

NO → Will waiving or altering the informed consent adversely affect the subjects' rights and welfare? [45 CFR 46.116(d)(2)]

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

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

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