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

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 waiver of informed consent or alteration of consent elements is allowed. Is it practicable to conduct the research without the waiver or alteration? [45 CFR 46.116(c)(2)]

Start from Chart 8 or 9.

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

Is the project designed to study, evaluate, or otherwise examine: (i) public benefit or 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)]

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

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

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

Waiver of informed consent or alteration of consent elements is allowed if the Institutional Review Board documents these findings and approves waiver or alteration.

Go to Chart 11.

(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)].)

Adapted from: http://www.hhs.gov/ohrp/policy/checklists/decisioncharts.html#c10