Chart 10: Can Informed Consent Be Waived or Consent Elements Be Altered?

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? Yes

Will the research involve greater than minimal risk? Yes

Is it practicable to conduct the research without the waiver or alteration? Yes

Will waiving or altering the informed consent adversely affect the subjects' rights and welfare? Yes

Will pertinent information be provided to subjects later, if appropriate? Yes

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

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? Yes

Is it practicable to conduct the research without the waiver or alteration? Yes

No waiver of informed consent or alteration of consent elements is allowed.

Go to Chart 11

If informed consent is not waived entirely?

No