

UMB Human Research Protections Program

**Waiver or Alteration of Requirement to Obtain Informed Consent
Checklist #15**

PROTOCOL NUMBER: _____

PRINCIPAL INVESTIGATOR: _____

TITLE OF STUDY: _____

KEY:

Solid box: All items in the box must be true

Dotted box: One item in the box must be true

One of the following is true:

(1) The consent process is waived based on:

(2) The research or demonstration project is to be conducted by or subject to the approval of state or local government officials.

(3) The research is designed to study, evaluate, or otherwise examine:

(4) Public benefit or service programs

(5) Procedures for obtaining benefits or services under those programs

(6) Possible changes in or alternatives to those programs or procedures

(7) Possible changes in methods or levels of payment for benefits or services under those programs

(8) The research could not practicably be carried out without the waiver or alteration.

(State reasons here)

(9) The research is **NOT** subject to FDA regulation (See Determining Whether a Proposed Activity is Human Research According to DHHS, FDA, or VA Regulatory Definitions)

The consent process is waived based on:

(10) The research involves no more than minimal risk to the participants.

(State reasons here)

(11) The waiver or alteration will not adversely affect the rights and welfare of the subjects.

(State reasons here)

(12) The research could not practicably be carried out without the waiver or alteration.

(State reasons here)

Continued on the next page.

