Supplement D. Waiver of Informed Consent

In some cases, informed consent processes can be waived. If a waiver was granted, the researcher would not need to obtain informed consent from participants before conducting the study. Waiver or alteration of the requirements for obtaining informed consent from adult subjects can occur under the following provisions, according to HHS. Please establish which provision suits your situation.

1. Project Title:

2. Principal Investigator:

3. Is your proposal related to a public service program? ◯ Yes ◯ No. If No, go to #4.

4. If yes, check all of the following that are true.

____ The research could not practicably be carried out without the waiver or alteration.

____ The research is subject to the approval of state or local government officials.

____ The research is designed to study, evaluate, or otherwise examine (a) public benefit or service programs; (b) procedures for obtaining benefits or services under those programs, (c) possible changes in or alternatives to those programs or procedures; or possible changes in methods or levels of payment for benefits or services under those programs.

5. Does your research meet all of the following four stipulations?

____ The research involves no more than minimal risk to the subjects.

____ The waiver or alteration will not adversely affect the rights and welfare of the subjects.

____ The research could not practicably be carried out if informed consent was obtained.

____ Participants will be provided with additional pertinent information after participation.

6. If you checked all of the boxes on #3 or all of the boxes on #4, your research may qualify for a waiver of informed consent. Please explain how your research qualifies and meets the stipulations for waiver of informed consent under the guideline above.

Signature of Principal Investigator: