

Date:
CPHS#:

**OPHS WORKSHEET – 45 CFR 46.408(c)
WAIVER OF PARENT OR GUARDIAN PERMISSION**

The Committee for Protection of Human Subjects may waive the requirements for obtaining parent or guardian permission for research involving children if EITHER of the following sets of conditions is met (check the applicable boxes below):

- I.** The Committee may waive some or all of the required elements of parent/guardian (informed consent) provided that it finds that all of the criteria are met under either A OR B (*check the applicable box below*):

Note: No informed consent requirements can be waived for studies regulated by the FDA, except under the FDA emergency treatment or emergency use exception.

A. Waiver Criteria under 45 CFR 46.116(e):

- (1) The research or demonstration project is to be conducted by or subject to the approval of state or local officials and is designed to study, evaluate, or otherwise examine: (i) public benefit or service programs; (ii) procedures for obtaining benefits or service; (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;
AND
- (2) The research could not practicably be carried out without the waiver or alteration.

B. Waiver Criteria under 45 CFR 46.116(f):

- (1) The research involves no more than minimal risk of harm to the subjects;
- (2) The research could not practicably be carried out without the waiver or alteration;
- (3) If the research involves using identifiable private information or identifiable biospecimens, the research could not practicably be carried out without using such information or biospecimens in an identifiable format;*
- (4) The waiver or alteration will not adversely affect the rights and welfare of the subjects;
AND
- (5) Whenever appropriate, the subjects will be provided with pertinent information after participation.

*If an individual was asked to provide broad consent for the storage, maintenance, and secondary research use of identifiable private information or identifiable biospecimens, and refused to consent, an IRB cannot waive consent for the storage, maintenance, or secondary research use of the identifiable private information or identifiable biospecimens.

Protocol-specific comments:

- II.** The Committee may waive the requirement for parent/guardian permission if it finds that a research protocol is designed to study conditions in children or a subject population for which parent or guardian permission is not a reasonable requirement to protect the subjects (e.g., neglected or abused

children), and also finds that: (i) an appropriate mechanism for protecting the children who will participate as subjects in the research is substituted; and (ii) the waiver is not inconsistent with federal, state, or local law.

The choice of an appropriate substitute mechanism will depend on the nature and purpose of the activities described in the protocol, the risk and anticipated benefit to the research subjects, and their age, maturity, status, and condition.

Protocol-specific comments: