Date:
CPHS#:

OPHS WORKSHEET - 45 CFR 46.408(a) and 21 CFR 50.55(c) or (d)
WAIVER OF CHILD ASSENT

The Committee for Protection of Human Subjects is responsible for deciding whether child assent is required in proposed research activities. The Committee should require child assent *unless* it determines that the research satisfies one of the conditions described below (check the applicable boxes below)**:**

☐ **I.** The capability of some or all of the children is so limited that they cannot reasonably be consulted.

Protocol-specific comments:

☐ **II.** The intervention or procedure involved in the research holds out the prospect of direct benefit to the health or well-being of the children and is available only in the context of the research.

Protocol-specific comments:

☐ **III.** Even where the Committee determines that the children are capable of assenting, the Committee may still waive the assent requirement under circumstances in which consent may be waived for adults as follows (see also IC 702 Waivers of Informed Consent).

The Committee may waive some or all of the required elements of informed consent, provided that it finds that all of the criteria are met under either A OR B (note that B is the only applicable category for FDA-regulated research):

☐ **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) and 21 CFR 50.55(d):**

(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 requested 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 or legally authorized representatives will be provided with pertinent information after participation.

*Criterion (3) is not described in 21 CFR 50.55(d). Under 45 CFR 46.116(f), 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: