

Date:
CPHS#:

OPHS WORKSHEET
45 CFR 46.116(e) OR 46.116(f) WAIVER OF ONE OR MORE
ELEMENTS OF INFORMED CONSENT OR
21 CFR 50.22 EXCEPTION FROM INFORMED CONSENT
REQUIREMENTS FOR MINIMAL RISK CLINICAL
INVESTIGATIONS

The Committee for Protection of Human Subjects may waive some or all of the required elements of informed consent, provided that the Committee finds all of the criteria are met under either 45 CFR 46.116(e) or 45 CFR 116(f), or under 21 CFR 50.22.

- **Informed consent requirements can also be waived for studies regulated by the FDA under the FDA emergency treatment or emergency use exception. <https://www.ecfr.gov/current/title-21/chapter-I/subchapter-A/part-50/subpart-B/section-50.24>**
- **The Committee may require the investigator to provide subjects with an Information Sheet about the study and/or a Script for Consent Process.**

(Check the applicable boxes below. If specific elements of consent will be waived as opposed to all elements, these should be indicated on the Informed Consent Checklist.)

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.

Protocol-specific comments:

B. Waiver Criteria under 45 CFR 46.116(f) or 21 CFR 50.22

- (1) The research or clinical investigation involves no more than minimal risk of harm to the subjects;
- (2) The research or clinical investigation could not practicably be carried out without the requested waiver or alteration;
- (3) If the research or clinical investigation 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.

* 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: