

Date:

CPHS#:

**OPHS WORKSHEET - 45 CFR 46.117(c) & 21 CFR 56.109(c)(1)
WAIVER OF REQUIREMENT FOR DOCUMENTED CONSENT**

The Committee for Protection of Human Subjects may waive the requirement for the investigator to obtain a signed consent form for some or all of the subjects if the Committee finds that one of the following criteria is met (check the applicable box below):

Note: If this waiver is granted, the investigator may be required to provide subjects with an Information Sheet containing the elements of a consent form but formatted appropriately (e.g., without signature lines) and/or a Script for Oral Consent reflecting the investigator's side of the dialogue.

Note: Criteria A and C are not described in 21 CFR 50 and therefore do not apply to FDA-regulated research.

- A.** The only record linking the subject and the research would be the consent document AND the principal risk of the research would be potential harm resulting from a breach of confidentiality.

Protocol-specific comments:

-OR-

- B.** The research presents no more than minimal risk of harm to subjects AND involves no procedures for which written consent is normally required outside of the research context.

Protocol-specific comments:

-OR-

- C.** The subjects or legally authorized representatives are members of a distinct cultural group or community in which signing forms is not the norm, the research presents no more than minimal risk of harm to subjects AND there is an appropriate alternative mechanism for documenting that informed consent was obtained.

Protocol-specific comments: