Date:
CPHS#:

OPHS WORKSHEET - 45 CFR 46.117(c) and 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 either 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: Criterion A is not described in 21 CFR 50 and therefore does 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: