Request for Waiver of Documentation of Informed Consent

Hatton / IRB # (if assigned):

PI:

Protocol #:

Protocol Version / Version Date:

Sponsor:

Protocol Title:

Research Regulated by FDA: 21CFR56.109 (c) - An IRB shall require documentation of informed consent except as follows. Indicate if the following apply:

☐ (1) The IRB may, for some or all subjects, waive the requirement that the subject, or the subject's legally authorized representative, sign a written consent form if it finds that the research presents **no more than minimal risk of harm to subjects and involves no procedures for which written consent is normally required outside the research context**; **or**

☐ (2) The IRB may, for some or all subjects, find that the requirements in 50.24 of this chapter for an exception from informed consent for **emergency research** are met.

Federally Funded Research: 45 CFR 46.117 (c) - An IRB may waive the requirement for the investigator to obtain a signed consent form for some or all subjects if it finds the following. Indicate ifthe following apply:

☐ (1) That the **only record linking the subject and the research would be the consent document and the principal risk would be potential harm resulting from a breach of confidentiality**. Each subject will be asked whether the subject wants documentation linking the subject with the research, and the subject's wishes will govern; **or**

☐ (2) That 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**; **or**

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

This study is regulated by FDA: **Yes** ☐ **No** ☐

This study is Federally Funded: **Yes** ☐ **No** ☐

Using the regulatory criteria described above - 21CFR56.109 (c) or 45 CFR 46.117 (c) - provide rationale for waiver of documentation of informed consent for your study:

Remember: You must submit the oral script and /or written statement that will be given to the subjects.

Signature of Principal Investigator	Date