PRINCIPAL INVESTIGATOR RESPONSIBILITIES AND ASSURANCE OF COMPLIANCE:

The Principal Investigator has numerous responsibilities in the conduct of human research.
You will:

- Acknowledge and accept responsibility for protecting the rights and welfare of human research subjects and for complying with all federal, state, and institutional regulations and the RCHSD FWA;
- Acknowledge and accept responsibility for all activities related to the conduct of your research;
- Make certain that all research personnel have appropriate qualifications and training to perform the research activities they will carry out;
- Make certain that neither the investigator nor the study staff will attempt to coerce or unduly influence a subject to participate or to continue to participate in a study;
- Document that subjects are informed in a timely manner if new information becomes available that may be relevant to the subject's willingness to continue participation in the trial. The communication of this information should be documented;
- Provide the IRB with all required data necessary for continuing review;
- Promptly report to the IRB any deviations from approved protocol or from other regulations and policies;
- Report to the IRB any adverse events (serious and/or unexpected) within 10 working days and promptly report any off-site adverse events.
- Keep copies of signed Permission Forms, Consent Forms and Assent Forms, HIPAA Authorization Forms and other study materials readily accessible for review;
- Report any study suspension or termination by the sponsor.
- Report any audit or investigation by FDA, OHRP, or government agencies including notification prior to audit/investigation and the submission of any findings and PI's response if applicable.

Please acknowledge that:

- IRB approval is granted for a period of 12 months or less as determined by the IRB based upon the study design and risk level.
- Timely application for continuing review is your responsibility. It is recommended that continuing review materials be submitted 60 days prior to expiration.
- Permission, consent, assent, and HIPAA authorization must be obtained from the subject and parent or legal guardian prior to beginning the study utilizing the stamped IRB versions, unless waivers have been granted by the IRB.
- Permission, consent, assent, and HIPAA authorization forms must be provided in a language that is understandable to the subject. When non-English speaking subjects participate in the study, the written documents must be translated and accompanied with a verbal translation during the consenting process.
- Changes to the study protocol, permission, consent, assent, HIPAA authorization, and recruitment materials must be approved by the IRB prior to implementation, unless necessary for the safety of the subjects.
- Any change in the status of an IND or IDE governing the study must be reported to the IRB.
- All investigators and research staff require evidence of annual human subjects training from http://irb.chsd.org/webtraining/login.html.
- You are required to report to the IRB all monitoring findings by the sponsor or the sponsor's agent, including any reports prepared by a data safety monitoring board or other safety committee.
- You and/or the responsible member of the study team are certified and trained in the use of all study procedures.
- You will maintain the confidentiality of the study subjects and all study data, unless required by law.

CONFLICT OF INTEREST OR FINANCIAL INTEREST

Do you (including spouse and dependent children) have a potential conflict of interest in this project? ☐NO ☐YES - explain

Does any other member of the study team (including spouse and dependent children) have a potential conflict of interest in this project?
☐NO ☐YES - explain

- Equity & ownership >$10,000 or 5%;
- Direct/indirect ownership, (includes publicly traded stock) >$10,000;
- Position as a director, officer, partner, trustee, or employee of any management position held within the sponsor; or
- Payment (consultant fees, honoraria, grant payments) >$10,000;
- Intellectual Property Rights (patent, royalties, etc).

COMPLIANCE WITH LAWS

Have you been excluded from participation in, or otherwise sanctioned by, Medicare, Medicaid or any other federal, state or local health care program, or been otherwise barred from being a government contractor or subcontractor by any unit of the federal, state or local government?
☐NO ☐YES - explain

Have you been found by the United States Food and Drug Administration ("FDA") or any other state or federal government agency or enforcement body to have violated any federal, state or local laws, rules or regulations relating to clinical investigations?
☐NO ☐YES – explain

Have you ever been or are you currently under investigation by any government enforcement agency relating to clinical care, billing for clinical care, or clinical investigations?
☐NO ☐YES – explain

Signature			
Principal Investigator		Date:	