



Ethical Review Committee, Inc.

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## **COMMITMENT TO THE CONDUCT OF A CLINICAL STUDY**

I hereby make the following commitment to the conduct of a clinical study under the following:

Protocol #

I agree to conduct the study in accordance with the relevant, current protocol and will only make changes in a protocol/deviate from the protocol after notifying the sponsor, except when necessary to protect the safety, rights, or welfare of subjects.

I agree to personally conduct or supervise the described investigation.

I will ensure that the correct consent form will be presented to all study subjects by me or a qualified member of my staff and that the subjects will have adequate time in a private environment to read, review, and consider the form. I further agree to ensure that I or a member of my staff will be available to answer any questions or concerns the subjects may have regarding their participation in this study and to give the subjects as much time as they feel they need to make a decision about participating.

I will ensure that the requirements relating to obtaining informed consent in 21 CFR Part 50 and institutional review board (IRB) review and approval in 21 CFR Part 56 are met.

I agree to ensure that all associates, colleagues, and employees assisting in the conduct of the study are informed about their obligations in meeting the above commitments.

I agree to maintain adequate and accurate records in accordance with 21 CFR 312.62 and to make those records available for inspection in accordance with 21 CFR 312.68.

I will ensure that an IRB that complies with the requirements of 21 CFR Part 56 will be responsible for the initial and continuing review and approval of the clinical investigation. I also agree to promptly report to the IRB all changes in the research activity and all unanticipated problems involving risks to human subjects or others. Additionally, I will not make any changes in the research without IRB approval, except where necessary to eliminate apparent immediate hazards to human subjects.

I agree to comply with all other requirements regarding the obligations of clinical investigators and all other pertinent requirements in 21 CFR Part 312.

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Signature of Principal Investigator

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Date

\_\_\_\_\_  
Type or Print Name

Commitment to Conduct  
Ethical Review Committee  
12/08/08