STUDY TITLE:

Investigator Assurances:

Subject to approval of this project by the Institutional Review Board (IRB), I agree not to involve human subjects in this project until I have received the IRB's formal written approval, nor to involve human subjects in this project until I have obtained the legally effective informed consent of the subjects' legally authorized representative. No changes in the protocol affecting human subjects or the text of the informed consent documentation will be made without the prior written approval of the IRB.

I understand that approval of this research study involving human participants is contingent upon my agreement to:

1. Notify the Institutional Review Board (IRB) immediately upon changes to this research study prior to implementation
2. Completion of continuing education as required by the IRB.
3. Adhere to the principles of the Belmont Report
4. Conduct this research study according to the Code of Federal Regulations (21 CFR Parts 50, 56, 312 and 812 and/or 45 CFR Parts 46 and 164), as applicable
5. Conduct this research study according to ICH (International Conference on Harmonisation) guidance relating to GCP (Good Clinical Practice), as applicable and the Policies and Procedures of the IRB
6. Follow all established institutional compliance policies

By signing this form, the Principal Investigator/Co-Investigator(s) assures that any and all regulations will be compiled with, including suspension and disbarment, conflict of interest and misconduct in research.

Principal Investigator: _____ _____ Date: _____
Printed Name Signature

Co-Investigator: _____ _____ Date: _____
Printed Name Signature

Co-Investigator: _____ _____ Date: _____
Printed Name Signature

Co-Investigator: _____ _____ Date: _____
Printed Name Signature

Co-Investigator: _____ _____ Date: _____
Printed Name Signature

STUDY TITLE: (continued from Page 1)

Co-Investigator: _____ _____ Date: _____
Printed Name Signature

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