INVESTIGATOR AGREEMENT

Morgan v. Nevyas et al.
No. 2621 April Term 2000
Plaintiff's Exhibit 7

1. Name and address of investigator and the research facility, medical school, or hospital where the clinical investigation will be done:

2. Name and address of any clinical laboratory facilities to be used in this study:
None

3. Name and address of the Institutional Review Board that is responsible for review and approval of this study:

4. Name of any subinvestigators who are assisting the investigator in the conduct of this study:

As an investigator for this study, I agree to conduct the study in accordance with the relevant current protocol and will only make changes in the protocol after notifying the sponsor-investigator, except when necessary to protect the safety, rights, or welfare of subjects. I agree to personally conduct or supervise the described investigation. I agree to inform any patients, or any persons used as controls, that the device is being used for investigational purposes and I will ensure that the requirements relating to 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 report to the sponsor-investigator adverse experiences that occur in the course of the investigation in accordance with 21 CFR Part 812. I have read and understood the information in the device manual and protocol, including the potential risks and adverse effects of using the device. 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 and to make those records available for inspection in accordance with 21 CFR Part 812.

I will ensure that an IRB 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 812.

Signature of Investigator: _____ Date: 3/18/97