BON SECOURS
RICHMOND HEALTH SYSTEM
Bon Secours Health System

February 28, 2007

ATTN: Sara Pearson
Terry Whipple, MD
3407 Old Parham Road
Richmond, VA 23294

Ankle Instability: An Evaluation of the Safety and effictiveness of Non-invasive Radiofrequency for the Treatment of Ankle Instability: Pilot Study
Protocol
Informed Consent, v. 1.0, dated 2/9/07

Dear Dr. Whipple:

This letter is to advise you that on 2/28/2007, the Bon Secours Richmond Health System IRB reviewed the protocol and informed consent listed above with you serving as Principal Investigator.

Your application is fully approved. The term of approval is for one (1) year. The study is next subject to continuing review on or before 2/27/2008, unless closed before that date. At the time of continuing review, a copy of the informed consent and the Bill of Rights signed by each subject placed on the investigational study must be returned with a yearly study summary and the completed continuing review form. A copy of the IRB-approved informed consent form stamped with an approval date is included with this letter for your use and for your study files.

You are expected to report promptly (within 48 hours of the date you are notified of the event for an on-site event and within 10 working days from the date you are notified of the event for an off-site event) to the Bon Secours Richmond Health System IRB all unanticipated problems or serious adverse events involving risk to human subjects. Protocol deviations should be reported to the Bon Secours Richmond Health System IRB within 30 days of their occurrence. Changes to the study also must be promptly reported and approved by the Bon Secours Richmond Health System IRB. Please contact Lyn Clarke at 627-5157 if you have any questions.

Sincerely,

Dr. Maurice Finnegan, Jr.
Chair, Institutional Review Board