

March 3, 2008

Nisarg Desai, MD  
A 19.1

RE: 08-095: Defining sperm DNA damage in infertile men with varicocele and its correlation with oxidative stress (Internal)

Dear Dr. Desai:

Your response dated 2/28/2008 satisfies the conditional approval that was given at the convened meeting of the full Board on 2/22/2008.

Your study as described in your application and protocol the Application received February 8, 2008, the Clinical Study Protocol #2007-1101 (dated December 3, 2007), the two revised Informed Consent Documents (Consent 1 of 2 - "Infertile" and Consent 2 of 2 - "Fertile") both not dated and Signature Pages is now fully approved for the period 3/3/2008 to 2/21/2009.

Attached are the approved revised consents with the IRB stamp authorizing use for the period 3/3/2008 to 2/21/2009. Subjects must be given a signed and dated copy of the consent prior to their participation. Dr. Sabanegh's signature page is incomplete, the financial disclosure questions are not answered. He is ineligible to participate in this study until the signature page is corrected.

The approval period for this study will expire on 2/21/2009.

You are reminded to submit a continuing renewal report 30 days prior to the expiration date and ensure that no research activities will continue beyond the expiration date. If you are not renewing, a completion report is needed to close your study.

Please note that any changes to your study must be promptly reported and cannot be implemented without prior review and approval by the IRB.

Sincerely,

Daniel Beyer, M.S., MHA, CIP  
Executive Director, Institutional Review Board

DB:jk  
Attachment: Informed Consent Documents (2X)

**Expiration Date: 2/21/2009**