

THE CLEVELAND CLINIC
FOUNDATION 

April 6, 2004

Kiran Nallella, M.D./A19.1

Institutional Review Board

Office: 216/444-2924

Fax: 216/445-4094

E-Mail: IRB@CCF.ORG / Wb2

RE: Your letter dated March 15, 2004 regarding study number IRB 6967: Characterization Of Intracellular Reactive Oxygen Species in Human Spermatozoa (No Funding)

Dear Dr. Nallella:

Thank you for your response to requests from a prior review of your application for the new study listed above which was conditionally approved at the February 13, 2004 Institutional Review Board meeting.

This is to confirm that your application is now fully approved. The Application dated January 29, 2004 includes the Clinical Study Protocol dated February 5, 2004, two revised Informed Consent Documents (Consent 1 of 2 - "Infertile" and Consent 2 of 2 - "Fertile Donors") both dated March 15 2004, the Statistical Review from Biostatistics dated January 30, 2004, the Advertisement ("Semen Donors Needed..." not dated) are acceptable.

A written consent must be obtained from all study participants. Attached are IRB stamp approved advertisement and consent form effective for the period April 2, 2004 to February 12, 2005. This consent form must be signed and dated by each subject prior to their participation and a copy must be given to them.

You are granted permission to conduct your study as most recently described effective immediately. The study is subject to continuing review on or before February 12, 2005, unless closed before that date.

Please note that any changes to the study as approved above and any unanticipated problems involving risks to subjects must be promptly reported to the IRB.

Sincerely,



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

DB:jk

Attachment: Informed Consent Document / Advertisement

EXPIRATION DATE: FEBRUARY 12, 2005