

May 25, 2007

TO: Amr Farouk Abdel Kader, MD / A19.1

RE: 06-425: Antioxidants Combinations to Minimize Human Sperm Apoptosis and DNA Damage during Cryopreservation (Investigator Initiated)

Dear Dr. Kader:

Your response dated May 23, 2007 to requests from a prior review of your continuing review application for the study listed above was reviewed and approved under expedited review on May 25, 2007 and will be reported to the full Board.

This is to confirm that your application for continuation is now fully approved. You are granted permission to conduct this study with the two informed consent documents, Consent 1 of 2 - 'Infertile Subject' and Consent 2 of 2 - 'Donor' both (not dated).

Attached are the two consents with the IRB stamp authorizing use for the period of May 26, 2007 to May 25, 2008. Research participants must be given a signed and dated copy of the consent prior to their participation.

The approval period for this study **will expire on May 25, 2008**. You are reminded to submit a continuing renewal report up to 30 days prior to the expiration date. You must ensure that no research activities will continue beyond the expiration date. If you are not renewing, a completion report is required.

Please note that any changes to the study as approved must be promptly reported and approved by the IRB prior to implementation. Any study deviations and unanticipated problems, including adverse events that are unexpected and related or possibly related to the research intervention must be promptly reported to the IRB. Please refer to IRB Policies #60 and #70 regarding specific reporting timeframes.

Sincerely,



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

DB:sr
Attachments (Consent 1 of 2 & Consent 2 of 2)

EXPIRATION DATE: May 25, 2008