

December 4, 2001

Mohamed Hafez Moustafa, MD
A 19.1

Office of the Institutional
Review Board / Wb2
Office: 216/444-2924
Fax: 216/445-4094
E-mail: IRB_APP@ccf.org

RE: IRB 4716: Mechanisms of Nuclear DNA Damage in Mature Sperm from Infertile Men (Internal)

Dear Hafez Moustafa:

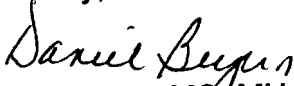
Thank you for your response dated November 27, 2001 to requests from a prior review of your application for the new study listed above has been reviewed and approved through the expedited review process on November 28, 2001. This type of response qualifies for expedited review under FDA and OHRP regulations. The Institutional Review Board will be notified of this activity.

This is to confirm that your application and protocol including Protocol (undated), Informed Consent Fertile Donors, Informed Consent Infertility Treatment Patients and Donor Advertisement was approved. The consent forms as most recently revised are approved. You must obtain signed written consent from all subjects. Attached is a copy of the IRB approved and stamped informed consent documents and donor advertisement.

The study is subject to continuing review on or before November 8, 2002. Recruitment and new enrollment beyond the expiration date is prohibited by federal regulations.

Any changes to the study, unanticipated problems, or serious adverse events or unanticipated adverse events must be promptly reported and approved by the IRB. You must submit a continuation/progress report prior to the expiration date for review and approval by the IRB.

Sincerely,


Daniel Beyer, MS, MHA
IRB Executive Director

DB:jk

Attachment: Informed Consent Documents (2X)