



October 20, 2004

Tamer Said, M.D.
A19.1

Institutional Review Board/Wb2
Office: 216/444-2924
Fax: 216/445-3094
E-mail: IRB@CCLCF.ORG / Wb2

RE: IRB 7546: Correlation of apoptotic markers with sperm fertilization potential

Dear Dr. Said:

Thank you for your response dated October 4, 2004 to requests from a prior review of your new study application which was approved on October 19, 2004 under expedited review.

This is to confirm that your study is now fully approved for the period October 19, 2004 to September 23, 2005 and includes the following documents: The Application dated September 10, 2004, Study Protocol (not dated), the revised Informed Consent Document dated October 4, 2004, revised Advertisement "Semen Donors Needed" and CITI Certificates for Drs. Tamer Said and Ashok Agarwal, Ph.D.

Attached are the approved revised consent and advertisement with the IRB stamp for the period October 19, 2004 to September 23, 2005. The revised consent form must be signed and dated by new study subjects 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 September 23, 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: SEPTEMBER 23, 2005