

THE CLEVELAND CLINIC
FOUNDATION 

November 18, 2005

Institutional Review Board/Wb2

Office: 216/444-2924

Fax: 216/445-4094

E-mail: IRB@ccf.org

Tamer Said, M.D.
A19.1

RE: IRB 8530: Utility of Poly (ADP-Ribose) Polymerase Alterations Following Apoptotic and Oxidative DNA Damage in Human Spermatozoa (Internal)

Dear Dr. Said:

Thank you for your response dated October 31, 2005 to requests from a prior review of your new study application which conditionally approved at the October 14, 2005 meeting of the full Board.


This is to confirm that your study is now fully approved for the period November 11, 2005 to October 13, 2006 and includes the following documents: the Application dated September 29, 2005, the Clinical Study Protocol dated October 5, 2005, the revised Informed Consent Document dated October 30, 2005 and the statistical analysis dated September 28, 2005.

Attached is the approved revised consent with the IRB stamp for the period November 11, 2005 to October 13, 2006. 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 October 13, 2006, 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

EXPIRATION DATE: OCTOBER 13, 2006