

August 16, 2001

Ramadan Saleh, M.D

Office of the Institutional
Review Board / Wb2

Office: 216/444-2924

Fax: 216/445-4094

E-mail: IRB_APP@ccf.org

RE: IRB 3841: Relevance of Leukocytes on Semen Parameters, Oxidative Stress and DNA Damage in Semen of Infertile Patients

Dear Saleh

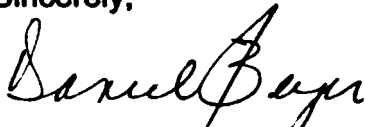
Your letter dated August 10, 2001 for expedited approval of the new study listed above has been reviewed and approved through the expedited review process on August 16, 2001. This type of study qualifies for expedited review under FDA and NIH (OHRP) regulations. The Institutional Review Board will be notified of this activity.

This is to confirm that your application is now fully approved. The protocol is approved through revised informed consent document (undated). The two informed 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 document.

You are granted permission to conduct your study as described in your application effective immediately. The study is subject to continuing review on or before September 7, 2001, unless closed before that date.

Please note that any changes to the study as approved, unanticipated problems, or serious adverse events or unanticipated adverse events must be promptly reported and approved by the IRB. Some changes may be approved by expedited review; others require full board review.

Sincerely,



Daniel Beyer, MS, MHA
IRB Executive Director

DB:jk

Attachment: (2) Informed Consent Document (correction letter)