

September 17, 2002

TO: Akshay Gupta, M.D. / A19.1

Office of the Institutional  
Review Board / Wb2

Office: 216/444-2924

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RE: IRB 5474: Oxidative stress mediated sperm DNA damage in infertile patients - possible role of Apoptosis (No funding)

Dear Dr. Gupta:

Thank you for your memo dated September 4, 2002 in response to requests from a prior review of your application for the new study listed above. Your response has been reviewed and approved through the expedited review process on September 12, 2002. This type of response qualifies for expedited review under FDA and DHHS (OHRP) regulations. The Institutional Review Board will be notified of this activity.

This is to confirm that your application is now fully approved for the period of 09/12/02 to 08/08/03. The protocol is approved through the revised Application dated June 26, 2002 including the revised Clinical Study Protocol (not dated), the RPC application (not dated), the advertisement 'Semen Donors Needed' (not dated) and the letter from Biostatistics regarding Sample Size Calculations and Data Analysis dated July 1, 2002. The consent forms, Consent 1 of 2 'Infertile' and Consent 2 of 2 'Fertile' both (not dated) have been approved. You must obtain signed written consent from all subjects. Attached is a copy of the IRB approved and stamped informed consent documents and advertisement.

You are granted permission to conduct your study as most recently described effective immediately. The study is subject to continuing review on or before August 8, 2003, unless closed before that date.

Please note that any changes to the study as approved must be promptly reported and approved. Some changes may be approved by expedited review; others require full board review. Contact the IRB office, if you have any questions or require further information.

Sincerely,



Daniel Beyer, MS, MHA  
IRB Executive Director

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