

**THE CLEVELAND CLINIC
FOUNDATION**

July 25, 2000

**Office of the Institutional
Review Board / Wb2**

Office: 216/444-2924

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E-mail: IRB_APP@ccf.org

TO: Sharma, Rakesh K., A19.1

FROM: Office of the Institutional Review Board, Wb2

RE: IRB 3273 "Role of Reactive Oxygen Species in the Pathophysiology of Varicoceles and Effects of Antioxidant Therapy Alone or in Combination with Varicocele Repair on Pregnancy Outcome"

Thank you for responding to the Institutional Review Board's request from the August 20, 199 convened meeting in order to receive approval to initiate research in the above referenced research project. Your response dated July 10, the two revised informed consent documents and the advertisement for Semen Donors were reviewed and approved by a designee of the Board on July 14, 2000.

The Institutional Review Board approves the initiation of research for one year for the period of July 14, 2000 to July 13, 2001. The Board approves the clinical study protocol 'Research Proposal' submitted with your initial Board application and the two revised informed consent documents and the advertisement for Semen Donors submitted with your response. Attached please find the two approved informed consent documents (Consent 1 of 2 Consent for Use of Semen Specimen from Patients Undergoing Varicocele Treatment and Consent 2 of 2 Consent for Use of Semen from Fertile Donors for Research Study) and the advertisement 'Semen Donors Needed' all stamped with the IRB approval period (07/14/00 to 07/13/01) Only copies of these two current approved informed consent documents with the IRB stamped approval are to be used to obtain consent.

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A request for continuation or completion of the research project is due at least 30 days before the research project expiration date of July 13, 2001, unless otherwise requested by the Board. Please remember to report promptly to the Board any proposed changes in research activity and/or adverse events associated with this project.

Sincerely,



Paul Papagni, JD

Exec Dir., Institutional Review Board

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