



September 08, 2000

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

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Ranganathan, MD, Pavithra, A19.1

FROM: Office of the Institutional Review Board, Wb2

**IRB 3853 "The Role of Defective Spermiogenesis in Male Infertility:
Relationship Between Sperm Immaturity and Oxidative Stress"**

Thank you for responding to the Institutional Review Board's request from the July 28, 2000, convened meeting in order to receive approval to initiate research in the above referenced research project. Your response dated August 11, 2000, and the revised informed consent documents (Consent for Use of Semen from Fertile Donors for Research Study, 1 of 2, and Consent for Use of Semen from Patients Undergoing Infertility Treatment (2 of 2) were reviewed and approved by a designee of the Board on September 1, 2000.

The Institutional Review Board approves the initiation of research for one year for the period of September 1, 2000 to August 31, 2001. The Board approves the clinical study protocol and the revised informed consents submitted with your response. Attached please find the approved informed consent documents stamped with the IRB approval period. Only copies of these current approved informed consent documents with the IRB stamped approval are to be used to obtain consent.

A request for continuation or completion of the research project is due at least 30 days before the research project expiration date of August 31, 2001, unless otherwise requested by the Board.



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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

PP:klk

Attachment (Informed Consent Documents, 1 of 2 and 2 of 2)

PROJECT EXPIRATION DATE: August 31, 2001