

THE CLEVELAND CLINIC  
FOUNDATION



October 22, 2004

TO: Ravindrakumar Guruswamy, M.D. / A 19.1

**Institutional Review Board**

/ Wb 2

Office: 216/444-2924

Fax: 216/445-4094

E-mail: IRB@CCF.ORG

**RE: IRB 7644: CHART REVIEW: VARYING PATTERNS OF SEMEN ANALYSIS IN MEN  
EVALUATED FOR INFERTILITY: A RETROSPECTIVE REVIEW**

Dear Dr. Guruswamy.

Your new study application dated October 19, 2004 was reviewed and approved under the expedited review process on October 22, 2004. This action will be reported to the full committee of the IRB.

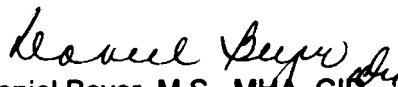
Your Signature Page and CITI Certificate for Kiran Nallella to be added as a Co-Investigator, CITI Documentation for Ravidrakumar Guruswamy and the Data Collection Sheet have been fully approved for the period October 22, 2004 to October 21, 2005.

The IRB has determined this research involves no more than minimal risk and the criteria for waiver of consent, as contained in the federal regulations, have been satisfied. This waiver of consent will not adversely affect the rights and welfare of the research subjects. This research could not practicably be conducted without the waiver of consent. The researchers are authorized to use identifiable subject information for review and analysis in accordance with procedures for maintaining subject privacy and confidentiality. This information shall not be removed from CCF premises nor disclosed to others outside CCF. Additional review and approval by the IRB is required if subject information is intended to be shared outside CCF.

This study is subject to continuing review before October 21, 2005. You are required to submit a renewal or completion report before the expiration date.

Please note that any changes to the study as approved must be promptly reported and approved. Any unanticipated problems or adverse events that are serious, unexpected, and associated with the research must be promptly reported to the IRB.

Sincerely,

  
Daniel Beyer, M.S., MBA, CIP  
Executive Director  
Institutional Review Board

DB:ju

**EXPIRATION DATE: OCTOBER 21, 2005**