

INSTITUTIONAL REVIEW BOARD APPLICATION PACKET

(Incomplete applications will not be accepted)

Includes:

- Human Subjects Review Application
- Adverse Event Report Form
- Annual Renewal/Completion Report Form
- Listing of deadline dates for the submission of research applications

Cleveland Clinic Foundation
Institutional Review Board, A16
Extension: 42924 Fax: 58161

Assigned:
IRB#: _____ **GAP#:** _____ **RPC#:** **6509**

Review Month: _____

1. Principal Investigator (PI) Pavithra Ranganathan, M.D.

Department Urology Mail Code A19.1 Phone 4-4402 Fax 5-6049

2. Title: "The role of defective spermiogenesis in male infertility: Relationship between sperm immaturity and oxidative stress"

3. Project Period: From June 1, 2000 To May 30, 2001

4. **Funding:** Internal: X No Funding: _____
External: _____ External Source: _____

(If this study involves funding an RPC application must be completed, contact the RPC Office ext. 42295, FF5-06):

4a. if you are obtaining funding from a from a commercial sponsor, has the \$500.00 IRB review and monitoring fee been asked for? _____ Yes Provide cost center, if available _____

No Please explain why

5. Collaborating Investigators		
Name/Signature:	Mail Code/Dept.	Phone
<u>Rakesh K. Sharma, Ph.D.</u>	<u>A19.1</u>	<u>4-4350</u>
<u>Ashok Agarwal, Ph.D.</u>	<u>A19.1</u>	<u>4-9485</u>
<u>Anthony J. Thomas, Jr. M.D.</u>	<u>A100</u>	<u>4-6340</u>

6. Signatures/Assurances:

This research project is consistent with FDA regulations and IRB requirements. The Principal Investigator accepts scientific responsibility and agrees to notify the IRB of any adverse events involving human subjects, and provide annual and final reports of progress.

Principal Investigator/Date

Department Chairman