

**CCF INSTITUTIONAL REVIEW BOARD APPLICATION PACKET**

(Application must be complete)

Please Check where applicable

- Application \_\_\_\_\_
- Advertisement \_\_\_\_\_
- Protocol \_\_\_\_\_
- Consent \_\_\_\_\_
- Biostats Memo \_\_\_\_\_
- FDA Letter \_\_\_\_\_
- Attestation Letter \_\_\_\_\_
- Grant \_\_\_\_\_
- Compliance Checklist \_\_\_\_\_

**Includes:**

- Research Compliance Checklist
- Human Subjects Review Application
- Adverse Event Report Form
- Project Renewal Report Form
- Project Completion/Termination Report
- Change in Investigator Panel Report

**Cleveland Clinic Foundation**

**Institutional Review Board, Wb2**

Extension: 42924 Fax: 54094

E mail address: IRB\_APP@ccf.org

Group Wise: IRB Account

Assigned

IRB#: \_\_\_\_\_ Review Date: \_\_\_\_\_

**SUBMIT 20 COPIES OF APPLICATION, PROTOCOL, AND INFORMED CONSENT**

1. Principal Investigator (PI): Ashok Agarwal, Ph.D.

Department: Urological Institute Mail Code: A-19.1 Phone: (216)-444-9485 Fax: (216) 445-6049

2. Title of Project: Levocarnitine fumarate and acetyl-L-carnitine (ProXeed) combined supplementation in subfertile males with high reactive oxygen species'

3. Project Period From: October 1, 2001 To: September 30, 2002

4a. **Funding:** Internal: (Internal Source): No Funding: (No IRB Fee)  
 External: (External Source): X **Commercial sponsor (Fee Required) X**  
 (External Source): **Grant (Submit 2 copies of Grant)\***

\*If this is a grant, there is no fee unless a fee is allowed for in the Grant.

4b. If the \$1,000.00 IRB review and monitoring fee has not been included, please explain why:  
\$1000.00 fee has been included

5. Signatures/Assurances: As principal investigator, I acknowledge that this research project is consistent with FDA, HHS regulations and IRB requirements. I acknowledge that I am responsible for providing continuing and final reports of progress, reporting promptly any proposed changes in research activity, or any serious, related, possibly related, probably related and unanticipated problems which involve risks to the human research subjects or others. No changes to protocol will be put into effect without prior Institutional Review Board (IRB) approval except where necessary to eliminate apparent immediate hazards to the subject. It is my responsibility to ensure that I and my research staff are fully trained and aware of this scientific protocol, human subjects and ethical matters relating to the conduct of this research. If any investigator is uncertain of any of these areas, then questions should be directed to the IRB prior to undertaking the research.

*A Agarwal/08/14/01*

Principal Investigator/Date

Department Chairman/Date