

**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
- Renewal/Completion Report Form
- Listing of deadline dates for the submission of research applications

**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

Principal Investigator (PI): Ramadan S. Abdou, M.D.

Department: Urology

Mail Code: A 19.1 Phone: 4-4402

Fax: 5-6049

2. Title of Project: "Relevance of leukocytes on semen parameters, oxidative stress and DNA damage in semen of infertile patients"

3. Project Period From: September 15, 2000 To: September 14, 2001

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

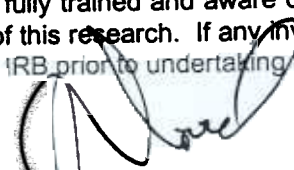
\*If you are obtaining funding from a commercial sponsor, the \$1,000.00 IRB review and monitoring fee must be included with this application.

\*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:

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 annual 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

  
 Principal Investigator/Date

  
 Department Chairman/Date