

The Cleveland Clinic Foundation
Institutional Review Board
IRB Review Application

To move between fields use the TAB key

Submit the original and 20 copies of the **IRB Application**, the **Protocol**, and the **Consent Form**
2 copies of the Investigators Brochure and 1 copy of each Human Subject Training Completion Certificate

Extension: 42924 Fax: 54094 Mail code: Wb2

Revised 3/25/03

1. **Principal Investigator (PI):** Kiran P. Nallella

Department: Urology

Mail Code: A19.1

Phone: 4-44402

Fax: 5-6049

If the PI is a Resident/Fellow, identify the Staff member serving as their Preceptor:

Name: Ashok Agarwal

Dept: Urology

2. **Study Title:** Characterization Of Intracellular Reactive Oxygen Species In Human Spermatozoa

3. **Study Coordinator:** Ashok Agarwal Mail Code: 19.1

Phone: 4-9495 Fax: 5-6049

4. **Sponsor/funding:**

A. Identify the type of sponsor:

Internal/investigator initiated

Corporate/Commercial company: _____

Federal/Non-profit granting agency : _____

(Submit 2 complete copies of the grant)

Note: **IRB fees** of \$1,500 as of 8/1/02 are applicable to all corporate/commercial sponsors and will be directly charged to your account by the Research Accounting dept. IRB fees are waived for internal studies and federal/non-profit granting agencies.

B. Does the sponsor agree to cover subject costs for research related injuries? Yes No
If yes, attach documentation from the sponsor verifying this committment.

C. Does the sponsor allow the Investigators to freely publish study results? Yes No
If no, describe any restrictions: _____

D. Are there any patient service charges (professional or technical costs) generated as a result of this research? Yes No
If yes, complete the Office of Sponsored Research "Billing Compliance Checklist". This can be obtained from the OSR website and forward directly to OSR, NB-21, x4-5223.

5. **Study Protocol:** Summarize the primary research questions (**attach 20 copies of the complete protocol**)

1. Standardize measurement of intracellular levels of reactive oxygen species by flow cytometric analysis.

2. Define intracellular ROS levels in normal healthy donors and male factor infertility patients and identify the pathology resulting from each specific oxidant.

3. Study the protective effect of antioxidants vitamin E and vitamin C on reactive oxygen species.

6. **Briefly identify the research procedures, tests, drugs, devices, or patient information/materials** (medical records, data, questionnaires, specimens) that are **solely for research purposes**.

Semen samples will be subjected to routine semen examination and measurement of reactive oxygen species levels by 2 different assays (chemiluminscence and flow cytometry).