The Cleveland Clinic Foundation
Institutional Review Board
IRB Review Application

To move between fields use the TAB key, to spell check this form at any time use CTRL 9
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 06/26/02

1 Principal Investigator (PI): Akshay Kumar Gupta

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

If the PI is a Resident/Fellow, identify the Staff member serving as their Preceptor:
Name: Dr Ashok Agarwal Dept: Urological Institute

2. Study Title: Oxidative stree mediated sperm DNA damage in infertile patients - possible role of apoptosis

3. Study Coordinator: Dr Ashok Agarwal Mail Code: A19.1 Phone: 4-9485

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** 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 a letter of attestation. If no, explain why not.
NA

C. Will this study involve any patient costs/expenses? ☐ Yes ☒ No
If yes, complete the Clinical Research Billing Compliance Checklist and forward directly to Kathy O'Connor, Manager, Center for Clinical Research, W28, ext. 4/1805

5. Study Information: List the primary research questions

1. Assess and localize any active apoptotic process in the form of caspase activity in mature and immature spermatozoa of infertile patients and evaluate the possible correlation between caspase activity and DNA damage in them.

2. Evaluate the ability of mature and immature spermatozoa from infertile patients to generate ROS in response to exogenous NADPH.

3. Evaluate the ability of induced OS to initiate any apoptotic activity in ejaculated spermatozoa of infertile patients and measure the extent of DNA damage caused by induced OS with and without caspase activity in the same group

6 Briefly identify the research procedures, tests, drugs, devices, or patient information/materials (medical records, data, questionnaires, specimens) that are **solely for research purposes.**
Discarded human semen samples will be used for routine semen examination and for measuring apoptotic activity in the spermatozoa.