

**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

Principal Investigator (PI): Tamer M. Said

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: Ashok Agarwal

Dept: Urology

2 Study Title: Correlation of apoptotic markers with sperm fertilization potential

3 Study Coordinator: Ashok Agarwal Mail Code: A19.1 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 commitment.

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. Does magnetic-activated cell separation of human spermatozoa correlate with the presence of apoptotic markers?

2. Can magnetic-activated cell separation provide a sperm population with higher fertilization potential?

3.

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

Spermatozoa contained in semen samples will be separated by magnetic activated cell separation.

Subsequently, the resulting sperm populations will be evaluated for fertilization potential and the presence of apoptotic markers.