

The Cleveland Clinic Foundation  
Institutional Review Board – Wb2 (x42924)  
IRB New Study Application

Revised 11/4/04

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**Study Title:** Utility of Poly (ADP-Ribose) Polymerase Alterations Following Apoptotic and Oxidative DNA Damage in Human Spermatozoa

**Sponsor Protocol Number (if applicable):**

**Study Staff:**

**Principal Investigator (PI):** Tamer Said, MD

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

Name: Ashok Agarwal, PhD  
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**Study Coordinator:** Ashok Agarwal, PhD  
Agarwaa@ccf.org

Mail Code: [REDACTED]

Phone: [REDACTED]

Email:

**2. Study Sponsor:**

a Identify the type of sponsor:

- Corporate/Commercial company (full /partial funding or supply of drug/device): [REDACTED]  
 Federal/Non-profit granting agency : [REDACTED]  
(Submit 2 complete copies of the grant)  
 Internal/RPC

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, upload the documentation from the sponsor verifying this commitment on the document tab or mail/fax one copy to the IRB.
- c. Does the sponsor allow the Investigators to freely publish study results?  Yes  No  
If no, describe any restrictions:

**3. Study Aims: List the primary study aims:**

1. To validate the role of Poly(ADP-ribose) polymerase (PARP) in DNA damage repair in ejaculated human sperm and if to assess its potential modulation in order to prevent such damage.
2. To isolate DNA damaged sperm based on PARP activity using magnetic cell separation technique.
- 3.

**4. Study Protocol:**

- a. Provide a **Summary of the proposed research** (≤250 words). Describe clearly and concisely, in language readily understandable to both scientific and non-scientific reviewers, the broad objectives, specific aims, general procedures, and the potential significance of the research. ~~Please refer to the attached summary.~~