

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

Submit 20 copies of this application, protocol, consent document

Study Title: **Is poor sperm motility associated with defects in RhoGTPase in infertile men?**

Sponsor Protocol Number (if applicable):

1. Study Staff:

Principal Investigator (PI): Rajesh Kumar Jha, Ph.D.

Department: Andrology/Urology Mail Code: A91.1 Phone: 216-444-4402 Email: jhar@ccf.org

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

Name: Ashok Agarwal, Ph. D. Dept: Urology Phone: 49485 Email: agarwaa@ccf.org

Study Coordinator: .Ashok Agarwal, Ph.D. Mail Code: A-19.1 Phone: 4-9485 Email: agarwaa@ccf.org

2. Study Sponsor:

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.

a. Identify the type and name of sponsor:

- Corporate/Commercial: [redacted]
 Investigator Initiated: **Internal study**
 Federal/Non-profit granting agency: [redacted] **Note that 2 copies of the grant protocol are required**

b. If commercially sponsored, does the sponsor agree to cover subject costs for research related injuries?

- Yes No If yes, provide a copy of the contract language for subject injury coverage approved by General Counsel.

c. If commercially sponsored, does the sponsor allow the Investigators to freely publish study results?

- Yes No If no, describe any restrictions:

d. If commercially sponsored, does the sponsor intend to register this trial on a national website?

- Yes No If no, state sponsor's rationale:

Note: The IRB supports public access to all clinically directive trials. www.clinicaltrials.gov is the site recommended by the IRB and ICMJE. Reference: JAMA 2005; 293:2927-2929
<http://jama.ama-assn.org/cgi/content/full/293/23/2927>

3. Study Aims: List the primary study aims:

1. Evaluate RhoGTPase (RhoA-B, Cdc42 and Rac1) expression in spermatozoa from infertile asthenozoospermic men (Group 1) and normal healthy volunteers (controls; Group 2).
2. Study the distribution of RhoGTPase in asthenozoospermic men (Group 1) and control (Group 2) after capacitation/ acrosome reaction
3. Examine the binding affinity of RhoGTPase (Rac1) from asthenozoospermic men with gp91phox / p67phox from controls for assessing the defects in sperm NADPH oxidase (Nox) signaling system.

4. Study Abstract: