

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

Revised 11/4/04

Study Title: Comparison Protocol for Human Semen Samples: SQA-V versus Microscopic Assessment

Sponsor Protocol Number (if applicable):

1. **Study Staff:**

Principal Investigator (PI): Ashok Agarwal, Ph.D

Department: **Urology** Mail Code: **A19.1** Phone: **X 4-9485** Email: **Agarwaa@ccf.org**

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

Name: [] Dept: [] Phone: [] Email: []

Study Coordinator: Ashok Agarwal, PhD Mail Code: **A19.1** Phone: **X 4-9495** Email: **Agarwaa@ccf.org**

2. **Study Sponsor:**

a. Identify the type of sponsor:

- Corporate/Commercial company (full /partial funding or supply of drug/device): []
- Federal/Non-profit granting agency : []
(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. **Evaluate the efficiency of an automated semen analyzer (SQA-V).**
- 2. **Compare the results of SQA-V semen analyzer with those of manual microscopic analysis.**
- 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 see attached summary.**
- b. **Upload the Complete Protocol on the document tab or mail 20 copies.**