

The Cleveland Clinic Foundation
Institutional Review Board

IRB CONTINUING RENEWAL APPLICATION

Submit the appropriate number of copies to the Institutional Review Board, Wb2 (Ext. 42924)
To move between fields use the tab key

IRB Number : 6519

Expiration Date:08/30/04

Title of Project: Demographics of Male Patients Seeking Intervention for Infertility (Chart Review)

PI: Tamer Said, MD

Dept/Mail Code:A19.1

Phone:44402

Submit this application if you are planning to continue this study.

1. **Project Status:** (Check all that apply)

- Open to continuing enrollment of new subjects and have enrolled at least one subject (requires submission of consent document and any advertising materials) **(20 copies)**
- Open to continuing enrollment of new subjects, **however** no subjects have been enrolled and no additional risks have identified **(1 copy)**
- Active only for follow-up of enrolled subjects **(1 copy)**
- The remaining research activity is limited to data analysis **(1 copy)**
- Permanently closed to enrollment **(1 copy)**

2. **Summary of the Proposed Research:** provide/attach ~250 word summary from original application

- a) Are there any changes in the research procedures or protocol? Yes No If yes, explain _____

3. **Study Enrollment:**

- _____ Total number of subjects enrolled "on-site"
1125 Total number of subjects enrolled during this past reporting period
_____ Total number of subjects anticipated to be recruited "on-site"
_____ Total number of subject withdrawals/complaints Provide additional explanation: _____

4. **Adverse Events:**

Attach a summary of all unexpected adverse events that are related or possibly related and all deaths and serious adverse events related or not to the study drug, device or intervention covering the entire study period (attach copy of sponsor summary if applicable). N/A

- a) Are there any new findings or other relevant information about new risks associated with this study? Yes No If yes, explain _____
- b) Has your opinion of the study's risks and benefits changed by your analysis of these adverse events? Yes No If yes, explain _____

5. **Informed Consent:** (Applicable only for continuing enrollment) N/A

- a) Are there any changes to the previously approved consent form? Yes No
If yes, explain _____
- b) Attach both a "highlighted copy" and a "clean copy" of the consent with a new version date.

6. **Protocol Deviations:**

Provide/attach a summary of all protocol deviations occurring during the entire study period. N/A

7. **Study Personnel:** If you answer yes to any of these questions, attach appropriate documentation.

- a) Are there any changes in the research personnel? Yes No
- b) Are there any changes in the conflict of interest for any study personnel? Yes No
- c) Are there any study personnel who have not completed the CITI training? Yes No

8. **Sign and return this form along with the applicable attachments.**

Signature of Principal Investigator: _____  _____ Date: 08/30/200