

The Cleveland Clinic Foundation
Institutional Review Board
IRB CONTINUING RENEWAL APPLICATION

IRB Number : 06-425

Expiration Date:05/25/07

Title:Antioxidants Combinations to Minimize Human Sperm Apoptosis and DNA Damage during Cryopreservation

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Phone:444-4402

Dept/Mail Code:A19.1

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

1. **Enrollment Status:** (Check applicable categories)

Open to continuing enrollment of new subjects (**requires 20 copies of the renewal application, consent document, questionnaires, advertisements, AE flow sheet, protocol deviation flow sheet, list of research personnel**)

At least one subject has been enrolled

No subjects have been enrolled and no additional risks have been identified

Permanently closed to enrollment of new subjects (**requires 1 copy of the renewal application, questionnaires, AE flow sheet, protocol deviation flow sheet, list of research personnel**)

Subjects have completed all research interventions and research remains active only for long term follow-up of enrolled subjects

Subjects are still receiving research-related interventions

The remaining research activity is limited to data analysis

2. **Current Protocol in Use:**

a) What version/date of the protocol are you using? 06-425

b) Are you requesting any modifications or amendments to the research? Yes No
If yes, attach a summary description of those modifications or amendments.

3. **Summary of the Proposed Research:**

Provide/attach ~250 word summary of the research that reflects the current protocol being followed.

4. **New Findings Since the last IRB Review**

a) Have there been any publications in the literature relevant to this research? Yes No
If yes, attach a copy of all publications.

b) Have there been any interim findings? Yes No
If yes, attach a summary of the interim findings.

c) Have there been any reports involving safety or efficacy from other studies using the same research intervention (drug/device)? Yes No
If yes, attach a copy of all reports.

d) Have there been any data and safety monitoring board reports? Yes No
If yes, attach a copy of all data and safety monitoring board reports.

5. **Study Accrual:**

a) Number of Subjects Enrolled:

0 Total number of subjects enrolled "on-site"