

-----Original Message-----

From: irb@ccf.org [mailto:irb@ccf.org]
Sent: Thursday, April 28, 2005 1:00 AM
To: Agarwal, Ph.D., Ashok
Cc: IRB Account, IRB
Subject: IRB 8045: Comparison Protocol for Human Semen Samples SQA-V versus
Microscopic Assessment

27, 2005

Ashok Agarwal, Ph.D.
A19.1

RE: IRB 8045: Comparison Protocol for Human Semen Samples SQA-V versus
Microscopic Assessment (No Funding)

Dr Agarwal:

Thank you for your response dated April 16, 2005 to requests from a prior review of your new study application which conditionally approved on March 18, 2005 by the full Board.

This is to confirm that your study is now fully approved for the period April 25, 2005 to April 7, 2006 and includes the following documents: the Application dated March 21, 2005 and revised Application, the Clinical Study Protocol dated March 21, 2005, Research Summary (not dated), Comparison Protocol for Human Semen Samples dated April 15, 2005, two revised Informed Consent Documents (Consent 1 of 2 - "Infertile" and Consent 2 of 2 - "Fertile Donors") both dated April 15, 2005 and the revised Poster ("Semen Donors Needed..." not dated).

Attached are the approved revised consent and advertisement with the IRB stamp for the period April 25, 2005 to April 7, 2006. The revised consent form must be signed and dated by new study subjects prior to their participation and a copy must be given to them.

You are granted permission to conduct your study as most recently described effective immediately. The study is subject to continuing review on or before April 7, 2006, unless closed before that date.

Please note that any changes to the study as approved above and any unanticipated problems involving risks to subjects must be promptly reported to the IRB.

Sincerely,

Daniel Beyer, M.S., MHA, CIP
Executive Director
Institutional Review Board

DB:jk

Attachment: Informed Consent Document / Advertisement

Expiration Date: April 7 2006