

Agarwal, Ph.D., Ashok

From: Allamaneni, Shyam
Sent: Sunday, September 05, 2004 11:51 AM
To: Agarwal, Ph.D., Ashok
Subject: FW: IRB 6519: Demographics of Male Patients Seeking Intervention for Infertility

Respected Sir,

I am forwarding the e-mail from IRB office on extension of the above study till August 28, 2005.

Thanking you

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

From: irb@ccf.org [mailto:irb@ccf.org]
Sent: Saturday, September 04, 2004 4:09 AM
To: Allamaneni, Shyam
Cc: IRB Account, IRB
Subject: IRB 6519: Demographics of Male Patients Seeking Intervention for Infertility

September 3, 2004

TO: Shyam Allamaneni M.D. / A.19.1

IRB 6519: Demographics of Male Patients Seeking Intervention for Infertility (Chart Review)

Dear Dr. Allamaneni:

Your renewal report dated August 30, 2004 is eligible for expedited review and was approved on September 1, 2004. This action will be reported on the Activity report to the full committee of the IRB.

The requested continuation involves no changes to the protocol or consent form. You are granted permission to continue your study as described effective for the period of September 1, 2004 to August 28, 2005.

The IRB has determined this research involves no more than minimal risk and the criteria for waiver of consent, as contained in the federal regulations, have been satisfied. This waiver of consent will not adversely affect the rights and welfare of the research subjects. This research could not practicably be conducted without the waiver of consent. The researchers are authorized to use identifiable subject information for review and analysis in accordance with procedures for maintaining subject privacy and confidentiality. This information shall not be removed from CCF premises nor disclosed to others outside CCF. Additional review and approval by the IRB is required if subject information is intended to be shared outside CCF.

The study is next subject to continuing review on or before August 28, 2005. You are required to submit a renewal or completion report before the expiration date.

As with the initial approval, changes to the study must be promptly reported and approved by the IRB. Any unanticipated problems or adverse events that are serious, unexpected, and associated with the research must be promptly reported to the IRB.

Sincerely,

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

DB:sr

EXPIRATION DATE: August 28, 2005