

July 8, 2009

Rakesh K. Sharma, PhD
A19.1

RE: 09-503: Role of Curcumin in reducing oxidative stress-induced sperm damage

Dear Dr. Sharma:

Your response dated 7/7/2009 satisfies the conditional approval that was given at the convened meeting of the IRB on 6/26/2009. Your new study is now fully approved for the period 7/8/2009 to 6/25/2010. This action was reviewed under the expedited review process and will be reported to the full Board.

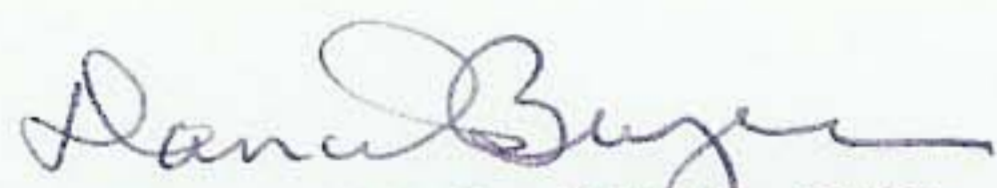
You are approved to conduct this research in accordance with the new study Application received 6/16/2009 and the revised Informed Consent Document. The IRB office made a slight modification to the consent document, the words "24 h on call fellow is available" were removed.

The approved revised consent with the IRB stamp authorizing use for the period 7/8/2009 to 6/25/2010 may be found in Webkit under the study, at the bottom of the column in blue, entitled "View Approved Consent Form". Please print and use this consent. Subjects must be given a signed and dated copy of the consent prior to their participation.

Research activities may not continue beyond the study expiration date of 6/25/2010 without additional review and approval by the IRB. To continue this research beyond the expiration date requires submission of a renewal application and approval by the IRB. If you are not renewing, you will need to submit a completion report to close this study.

Investigators must conduct the research in accordance with the approved protocol. Any changes or amendments must be reported and approved by the IRB prior to implementation. Any study deviations and unanticipated problems, including adverse events that are unexpected and related or possibly related to the research intervention must be promptly reported to the IRB in accordance with timeframes and procedures provided in IRB Policy #60: Adverse Event Reporting and IRB Policy #70: Reporting Unanticipated Problems.

Sincerely,



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

DB:jk

Expiration Date: 6/25/2010

Informed Consent Document can be obtained electronically via webkit