

February 17, 2009

Vaishali Kale / A-19

RE: 09-128: Comparison of temperature regulated vs. non-regulated bench-top centrifuge for sperm quality improvement

Dear Kale:

Your response dated 2/13/2009 satisfies the conditional approval that was given on 2/11/2009. Your new study is now fully approved for the period 2/16/2009 to 2/10/2010. This action was reviewed under the expedited review process and will be reported to the full Board. Category #5: research involving data, documents or records collected in clinical practice.

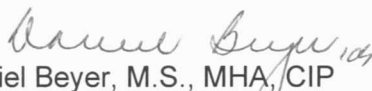
You are approved to conduct this research in accordance with the new study Application received 2/6/2009, the Study Protocol and the revised Informed Consent Document.

The approved revised consent with the IRB stamp authorizing use for the period 2/16/2009 to 1/29/2010 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.

The approval period for this study will expire on 2/10/2010. Research activities may not continue beyond the study expiration date without additional review and approval by the IRB. A continuing renewal report 30 days prior to the expiration date is required. If you are not renewing, submit a completion report to close your study.

Any changes to the study must be promptly 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: 2/10/2010

Informed Consent Document can be obtained electronically via webkit