

Sent: Saturday, June 14, 2008 1:00 AM

To: Sabanegh, Edmund
Subject: 08-304: Smoking and Semen Parameters: Is the Effect of Smoking on Male Fertility a Reversible Process?

June 13, 2008

Edmund Sabanegh, M.D.

A100

RE: 08-304: Smoking and Semen Parameters: Is the Effect of Smoking on Male Fertility a Reversible Process?

Dear Dr. Sabanegh:

Your response dated 6/11/2008 satisfies the conditional approval that was given at the convened meeting of the IRB on 6/13/2008. Your new study is now fully approved for the period 6/13/2008 to 6/5/2009. This action was reviewed under the expedited review process and will be reported to the full Board. N/A

You are approved to conduct this research in accordance with the new study Application received 4/28/2008, the Research Protocol (not dated), the further revised Informed Consent Document (not dated) and Smoking Cessation Program Fertility Questionnaire

The approved revised consent and advertisement with the IRB stamp authorizing use for the period 6/13/2008 to 6/5/2008 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.

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Subjects must be given a signed and dated copy of the consent prior to their participation. The questionnaire were reviewed and approved but will not be stamped. Any revisions to this form must be submitted to the IRB for approval.

The approval period for this study will expire on 6/5/2009. 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