

August 18, 2009

Amr Farouk Abdel Kader, MD
A19.1

RE: 09-127: Development and Validation of a Novel Sperm Vitrification System Using the Ohio-Cryo Vitrification Device

Dear Dr. Kader:

Your response received on 8/14/2009 in response to a prior review of this study has adequately addressed these conditions.

The requested revision includes Amendment/Change form notifying of change in study title and two revised Informed Consent Documents (Consent 1 of 2 "Donor" and Consent 2 of 2 "Patient") to reflect the change in the study title.

Attached are the approved revised consents with the IRB stamp authorizing use for the period 8/17/2009 to 2/10/2010. Research participants must be given a signed and dated copy of the consent.

You are granted permission to conduct your study as revised effective immediately. The date for continuing review remains unchanged at 2/10/2010, 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 Documents (2X)

Expiration Date: 2/10/2010

Attachments sent with original via interoffice mail