

APPROVED: 05/29/08
EXPIRATION DATE: 05/28/09

May 29, 2008

FROM: Schulman Associates Institutional Review Board, Inc. (SAIRB)
TO: Zsolt Peter Nagy, M.D., Ph.D.
SUBJECT: Clinical Trial Protocol, Administrative Clarification Letter, Informed Consent and Informed Consent – Parental Consent for Child Participation
SPONSOR: EMD Serono, Inc.
PROTOCOL NO: 28599
PROTOCOL TITLE: A Phase IV, Prospective, Multicenter, Observational Oocyte Cryopreservation Registry

PLEASE NOTE:

THE FOLLOWING ITEMS WERE REVIEWED AND APPROVED BY FULL BOARD OR EXPEDITED REVIEW ON THE DATES LISTED BELOW:

- CLINICAL TRIAL PROTOCOL DATED 03/31/08, INFORMED CONSENT AND INFORMED CONSENT – PARENTAL CONSENT FOR CHILD PARTICIPATION: FULL BOARD: 05/16/08
- ADMINISTRATIVE CLARIFICATION LETTER DATED 05/21/08: EXPEDITED REVIEW: 05/22/08
- INFORMED CONSENT AND INFORMED CONSENT – PARENTAL CONSENT FOR CHILD PARTICIPATION DOCUMENTS VERSION DATED 05/28/08 (DATE ON WHICH FINAL REVISIONS TO THE TEMPLATE ICDS WERE APPROVED BY "SAIRB"): EXPEDITED REVIEW: 05/28/08

THE FOLLOWING ITEMS WERE REVIEWED AND APPROVED BY EXPEDITED REVIEW ON MAY 29, 2008:

- YOUR SITE(S) WAS APPROVED TO CONDUCT THIS STUDY: 05/29/08
- SITE SPECIFIC INFORMED CONSENT AND INFORMED CONSENT – PARENTAL CONSENT FOR CHILD PARTICIPATION DOCUMENTS: 05/29/08
- STUDY EXPIRATION DATE: 05/28/09

This letter is to inform you that the Board has approved the items listed above. You must use only the enclosed "SAIRB Approved" informed consents. We have included a copy of the most current Board membership list to maintain with your study binder.

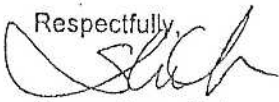
Under FDA regulations, this approval will last only one year. If the study is expected to last beyond a year, you must request re-approval for the next year at least 8 weeks prior to the expiration date noted above. Your first report to the Board on the status of this study is due six months from the approval date or at the time the study closes, whichever is earlier. You can find the SAIRB Study Status Report Form at www.sairb.com. When submitting the completed form, please indicate whether it is an interim, continuing review or final report.

Please note: If the consent is obtained through a legal guardian, the guardian must verify his/her legal authority to give permission for the minor to participate in this study. The legal guardian must provide copies of the guardianship papers to the study doctor or designee documenting that he/she has the described authority.

The FDA requires you to notify the IRB of any new advertisements or recruiting material, change of investigator or site location, serious adverse events, amendments or changes in the protocol, significant protocol deviations, patient death or termination of the study. Please note that you must submit all protocol amendments and/or advertisements to the Board for review, and await a response from the Board, prior to implementing the amendments and/or advertisements.

Schulman Associates Institutional Review Board, Inc. is in compliance with the regulations of the Food and Drug Administration as described in 21 CFR parts 50 and 56, as well as the International Conference on Harmonization (ICH) Good Clinical Practice (GCP) guidelines for IRBs.

Respectfully,



Sharon Lynn Nelson, M.S.N., R.N., C.N.S., Chairperson
Schulman Associates Institutional Review Board, Inc.

SLN/lal

Enclosures

cc: Sherie Pierce –REGISTRAT, Inc. – Via Web Portal

PLEASE USE OUR IRB # 08-3123-0 ON ALL CORRESPONDENCE FOR THIS STUDY.

INFORMED CONSENT

TITLE: A Phase IV, Prospective, Multicenter, Observational Oocyte Cryopreservation Registry

SPONSOR: EMD Serono, Inc.

PROTOCOL NO: 28599

INVESTIGATOR: Zsolt Peter Nagy, M.D., Ph.D.

TELEPHONE: (404) 257-1840 -- office number
(404) 609-0644 -- 24-hour number

INTRODUCTION

Before agreeing to participate in this research Registry study, it is important that you read and understand the following explanation of the proposed Registry study. This consent document describes the purpose, procedures, benefits, risks, discomforts and precautions of the Registry study. It also describes the alternative procedures that are available to you and your right to withdraw from the Registry study at any time. No guarantees or assurances can be made as to the results of the Registry study.

The Registry study is being conducted for EMD Serono, Inc. The study investigator is being paid by EMD Serono, Inc. to conduct this study.

BACKGROUND AND PURPOSE OF THE STUDY

You are being asked to take part in an observational research study called a Registry. In a registry study, researchers collect and study information about patients and their regular medical care.

You are being asked to participate in this Registry study because you will try to get pregnant using previously frozen oocytes (eggs) and *in vitro* fertilization (IVF). The researchers are collecting information from Assisted Reproductive Technology (ART) clinics on the success of IVF cycles using previously frozen (cryopreserved) oocytes. Oocyte cryopreservation is an experimental technique for preserving female fertility. Researchers estimate that more than 450 babies worldwide have been born from IVF cycles that used cryopreserved eggs.

The researchers and EMD Serono, Inc. hope to use the information collected in the Registry to learn more about oocyte cryopreservation.

