

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

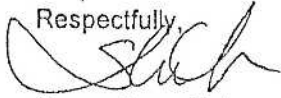
This letter is to inform you that the Board has approved the items listed above. You must use only the enclosed "SAIRB Approved" informed consents. We have included a copy of the most current Board membership list to maintain with your study binder.

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.

SAIRB APPROVED
IRB #08-3123-0
DATE: May 29, 2008

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.

The main purpose of this Registry study is to collect information on pregnancy rates from IVF cycles using previously frozen oocytes. Additional purposes of the study are to collect information on the health and development of babies born in the United States from frozen oocytes at birth and at twelve (12) months of age and to identify factors that may influence the pregnancy rate of IVF cycles using frozen oocytes.

NUMBER OF SUBJECTS / LENGTH OF PARTICIPATION

Approximately four hundred (400) women will be asked to participate in this Registry study at approximately thirty (30) different ART centers in the United States.

If you qualify and agree to participate in this Registry study, your participation will start at the time when you decide to thaw your frozen oocytes and will end after the twelve (12) month follow-up of any child(ren) you may have as a result of your ART procedures.

PROCEDURES

During your participation in this Registry study, your ART center will collect and enter information about you into a database. The data they will enter will include information about you such as date of birth, height and weight. Information about ART procedures and assessments you had using frozen and thawed oocytes, such as egg freezing and thawing techniques used, ovarian stimulation, embryo transfer and pregnancy detection will also be collected.

If you become pregnant and have a live birth(s), you and your partner (if applicable) will be asked to allow information about your child(ren)'s health, at birth and 12 months of age, to be collected and entered into the Registry database. You will be asked to read and sign a separate consent document to allow the collection of information about your child(ren).

There are no special tests or procedures for subjects who participate in this Registry study. You will undergo the ART procedures that your doctor decides are right for you. Your doctor will not be asked to do anything differently as a result of your participation in this Registry study.

SIDE EFFECTS, DISCOMFORTS AND/OR POTENTIAL RISKS

The risks associated with ART procedures or medications will be discussed with you by your doctor. Your decision whether or not to participate in this Registry study will not affect the ART procedures or their risks.

The only risk of Registry participation is the potential risk of loss of confidentiality or privacy. You should know that once information is disclosed under the attached authorization to a third party who is not required to comply with federal privacy laws, the third party does not have the same legal obligations to protect your information as the study investigator and staff. The third party may disclose your information to others. The study sponsor will, however, request that all third parties to whom your information is disclosed under the attached authorization provide appropriate protections of your information.

UNFORESEEN RISKS

There may be risks from participating in this Registry study that are unknown.

NEW FINDINGS

Any new important information that is discovered during the Registry study and that may influence your willingness to continue participation in the Registry study will be made available to you.

POTENTIAL BENEFITS ASSOCIATED WITH PARTICIPATION

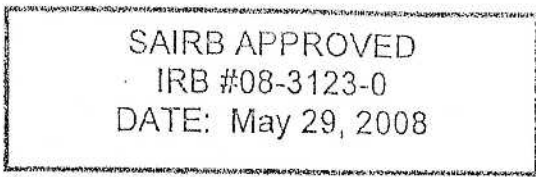
This Registry study is for research purposes only. You will not benefit from being in this Registry study. The information collected will help researchers learn more about oocyte cryopreservation, which could benefit research and other women and couples in the future.

ALTERNATIVES TO PARTICIPATION

This Registry study is for research purposes only. The alternative is to not participate. You do not have to participate in this Registry study to undergo ART procedures using frozen/thawed oocytes.

CONFIDENTIALITY OF YOUR RECORDS

Records of your participation in this Registry study will be held confidential except as disclosure is required by law or as described in this informed consent document (under "Confidentiality of Your Records" or "Authorization to Use and Disclose Protected Health Information"). The study investigator, the sponsor or persons working on behalf of the sponsor, and under certain circumstances, the United States Food and Drug Administration (FDA) and the Institutional Review Board (IRB) will be able to inspect and copy confidential study-related records which identify you by name. Therefore, absolute confidentiality cannot be guaranteed. If the results of this study are published or presented at meetings, you will not be identified.



COSTS

There will be no costs to you for participating in this Registry study. ART related tests and procedures will be billed to you or to your health insurance.

COMPENSATION FOR PARTICIPATION

You will not be paid for your participation in this Registry study.

EMERGENCY CONTACT / IRB CONTACT

If you have questions about the Registry study or in case of an emergency, please contact the study investigator at the telephone number listed on page one of this consent document.

If you have any questions about your rights as a research subject or complaints regarding this Registry study, you should write Schulman Associates Institutional Review Board, Inc. (SAIRB), 4290 Glendale-Milford Road, Cincinnati, Ohio 45242, or call toll-free 1-888-55SAIRB (1-888-557-2472) during business hours Monday - Friday 8:00 a.m. to 4:30 p.m. EST. SAIRB is an independent committee established to help protect the rights of research subjects.

VOLUNTARY PARTICIPATION / WITHDRAWAL

Your participation in this Registry study is voluntary. You may refuse to participate or you may withdraw from this Registry study at any time without penalty or loss of benefits to which you are entitled. Your decision to not participate or to withdraw will not affect your future medical care.

The study investigator or sponsor may remove you from the Registry study without your consent for any of the following reasons: if you fail to follow directions for participating in the Registry study, if it is discovered that you do not meet the Registry study requirements, at the discretion of the study investigator, if the Registry study is canceled, or for administrative reasons.

SAIRB APPROVED
IRB #08-3123-0
DATE: May 29, 2008

CONSENT

I have read and understand the information in this document. I have had an opportunity to ask questions, and all of my questions have been answered to my satisfaction. This document is being signed voluntarily by me, indicating my agreement to participate in this Registry study, until I decide otherwise. I will not lose any legal rights by signing this consent document. I will receive a copy of this signed consent document.

Subject's Signature

Date

Subject's Printed Name

Subject Partner Signature*

Date

Subject Partner Printed Name*

*If applicable

Signature of Person Conducting
the Consent Discussion

Date

Printed Name of Person Conducting
the Consent Discussion

AUTHORIZATION TO USE AND DISCLOSE PROTECTED HEALTH INFORMATION

During your participation in this research study, the study investigator and study staff will collect or create personal health information about you (for example, medical histories and results of any tests, examinations or procedures you undergo while in the study) and record it on study documents. The study investigator will keep this personal health information in your study-related records (that we will refer to as "your study records"). In addition, the study investigator may obtain, and include in your records, information regarding your past, present and/or future physical or mental health and/or condition. Your study investigator may ask you to sign a separate authorization to obtain some or all of your medical records from your doctor. Your study records may include other personal information (such as social security number, medical record numbers, date of birth, etc.), which could be used to identify you. Health information that could identify you is called "Protected Health Information" (or "PHI").

Under federal law (the "Privacy Rule"), your PHI that is created or obtained during this research study cannot be "used" to conduct the research or "disclosed" (given to anyone) for research purposes without your permission. This permission is called an "Authorization." Therefore, you may not participate in this study unless you give your permission to use and disclose your PHI by signing this Authorization. By signing, you are agreeing to allow the study investigator and staff to use your PHI to conduct this study.

By signing this Authorization, you also are agreeing to allow the study investigator to disclose PHI as described below:

- The sponsor of this study and anyone working on behalf of the sponsor to conduct this study (referred to as "the sponsor"). The sponsor will analyze and evaluate the PHI and may use it to develop new tests, procedures and commercial products. The study staff will assign a code number and/or letters to your records, which means that you will not ordinarily be identified in the records sent to the

sponsor. The sponsor may, however, look at your complete study records that identify you. In addition, the sponsor may visit the study site to oversee the way the study is being conducted and may review your PHI during these visits to make sure the information is correct.

- The Institutional Review Board ("IRB") may have access to your PHI in relation to its responsibilities as an Institutional Review Board.

The study investigator or sponsor may disclose your PHI to the United States Food and Drug Administration ("FDA") or similar regulatory agencies in the United States and/or foreign countries.

These disclosures also help ensure that the information related to the research is available to all parties who may need it for research purposes.

Except for the disclosures described above, your PHI will not be shared with others unless required by law. If your PHI is given to the parties listed above and/or to others who are not required to comply with the federal law, your PHI will no longer be protected by this law and could possibly be used or disclosed in ways other than those listed here.

You have a right to see and make copies of your PHI. You are agreeing, however, by signing this document, not to see or copy some or all of your PHI until the sponsor has completed all work related to this study. At that time, you may ask to see your records.

This Authorization will never expire unless and until you revoke (cancel or withdraw) it. If you sign this Authorization in the states of California or Washington, however, it will expire 50 years from the date you sign it unless you revoke (cancel or withdraw) it sooner.

You have a right to revoke your Authorization at any time. If you revoke it, your PHI will no longer be used for this study, except to the extent the parties to the research have already taken action based upon your Authorization or need the information to complete analysis and reports for this research. To revoke your Authorization, you must write to the study investigator stating that you are revoking your Authorization to Use and

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Disclose Protected Health Information. If you revoke this Authorization, you will not be allowed to continue to be in this study.

You will receive a copy of this Authorization after you have signed it.

Signature of Subject

Date

Printed Name of Subject

Signature of the Person Obtaining the
Authorization

Date

Printed Name of the Person Obtaining the
Authorization

05/29/08/lal/08-3123-0/Version Date: 05/28/08

