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20111715*

<b>RESEARCH SUBJECT INFORMATION AND CONSENT FORM</b>	
<b>TITLE:</b>	Prospective Review to Evaluate Oocyte Cryopreservation

**This consent form contains important information to help you decide whether to participate in a research study.**

The study staff will explain this study to you. Ask questions about anything that is not clear at any time. You may take home an unsigned copy of this consent form to think about and discuss with family or friends.

- **Being in a study is voluntary – your choice.**
- **If you join this study, you can still stop at any time.**
- **No one can promise that a study will help you.**
- **Do not join this study unless all of your questions are answered.**

**After reading and discussing the information in this consent form you should know:**

- Why this research study is being done;
- What will happen during the study;
- Any possible benefits to you;
- The possible risks to you;
- Other options you could choose instead of being in this study;
- How your personal health information will be treated during the study and after the study is over;
- Whether being in this study could involve any cost to you; and
- What to do if you have problems or questions about this study.

**Please read this consent form carefully.**

**RESEARCH SUBJECT INFORMATION AND CONSENT FORM**

**TITLE:** Prospective Review to Evaluate Oocyte Cryopreservation

**PROTOCOL NO.:** None  
WIRB® Protocol #20111715

**SPONSOR:** Jacques Stassart, M.D.  
Woodbury, Minnesota  
United States

**INVESTIGATOR:** Jacques P Stassart, M.D.  
2101 Woodwinds Drive  
Woodbury, Minnesota 55125  
United States

**SITE(S):** RMIA  
2101 Woodwinds Drive  
Woodbury, Minnesota 55125  
United States

**STUDY-RELATED  
PHONE NUMBER(S):** Jacques P Stassart, M.D.  
651-222-6050

Chris Gooder  
651-222-6050

Please carefully read this consent form. It tells you what you need to know about this research study. If you agree to take part, you will need to sign this consent form. Your signature means that you have been informed about the research study and its potential risks. Your signature on this consent form also means that you are willing to take part in this research study.

**Why am I being asked to be in this data collection study?**

You are being asked to be in this data collection study because you are undergoing an experimental method for improving cryopreservation (freezing and long term storage of cells). This method involves your oocytes (eggs).

**Why is data being collected about this experimental (investigational) application of technology?**

The purpose of this research is to collect data regarding an experimental (investigational) method for improving cryopreservation (freezing and long-term storage of cells) and thaw survival of human oocytes (eggs). The study is being done to develop a standard of care model for patients undergoing oocyte cryopreservation. It also is being done to collect information to inform future patients about current data on cryopreservation and to demonstrate proficiency with experimental technological techniques.

The American Society of Reproductive Medicine and the Society for Assisted Reproductive Technology will receive information about the experimental techniques used in cryopreservation of your frozen and then thawed oocytes.

**How many individuals will take part in this study?**

Up to 40 subjects 45 years of age or younger will be recruited for this research study.

**What will happen if I join this study?**

Data collected will also include the number of your oocytes retrieved, the quality of the oocytes, the number of oocytes thawed for fertilization, the grading of embryos, the number of embryos transferred and the resulting outcomes.

For heterosexual couples (female and male) undergoing IVF, information will also be collected about the male partner's semen specimen and blood tests.

**What is the length of time that I will be in this data collection study?**

It is difficult to determine the length of time you will be in the study. The study is ongoing and will continue until final disposition of your oocytes. You will be notified when the study has ended.

**What are the reasons that I might discontinue my participation?**

Your participation in this study is voluntary. You may decide not to participate or you may leave the study at any time. Your decision will not result in any penalty or loss of benefits to which you are entitled.

You should contact the clinic and speak with your study physician directly if you decide to stop.

In addition, Reproductive Medicine and Infertility Associates and/or your study physicians may stop you from taking part in this research study at any time without your consent for any reason.

**What are the risks involved in participating in this research study?**

There is a risk of loss of confidentiality. However, we will do our best to keep your health information private. Information collected about you will be labeled with a code, not your name. The code is used to protect your privacy, but we cannot guarantee that your information will remain private.

**Who do I contact in the event of an emergency?**

If you experience a study-related problem during the course of your participation, you should immediately contact:

Dr. Jacques P. Stassart at 651-222-6050 or Chris Gooder at 651-222-6050.

**New Findings:**

You will be told about any new information that might change your decision to be in this study.

**Benefits:**

There is no benefit to your participation in this data collection study. Other patients in the future may benefit from this study.

**Costs:**

There is no cost to you for your participation in this data collection study.

You will be billed for all costs involved in your treatment and oocyte procedures.

**Study Compensation:**

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

**Alternatives:**

Your alternative is to not be in this study.

**Confidentiality:**

Records of your participation in this data collection study will be held confidential so far as permitted by law. However, your study doctor, and under certain circumstances, the Food and Drug Administration (FDA) and the Western Institutional Review Board® (WIRB®) will be able to inspect and have access to confidential data that identifies you by name. Any publication or presentation of the data will not identify you. By signing this consent form, you authorize the research study physician to release your medical records to the FDA and WIRB®.

Your information may be given to the sponsor of this research, Dr. Jacque Stassart. Sponsor includes any persons or companies that are working for or with the sponsor, or are owned by the sponsor.

Information about you and your health which might identify you may be given to:

- The U.S. Food and Drug Administration (FDA)
- Department of Health and Human Services (DHHS) agencies
- Governmental agencies in other countries
- Governmental agencies to whom certain diseases (reportable diseases) must be reported
- The Western Institutional Review Board® (WIRB®)
- The American Society of Reproductive Medicine
- The Society for Assisted Reproductive Technology
- The Centers for Disease Control and Prevention

Total confidentiality cannot be guaranteed because of the need to give information to these parties. The results of this research study may be presented at meetings or in publications. Your identity will not be given out during those presentations.

**Who can answer my questions?**

You may talk to Dr. Jacques P. Stassart or other RMIA staff at any time about any questions or concerns you may have about this study or if at any time you feel you have had a research-related problem. You may contact Dr. Stassart or RMIA staff by calling 651-222-6050 or Chris Gooder at 651-222-6050.

You may obtain information about policies, conduct of this data collection study, or your rights regarding the research study from Reproductive Medicine and Infertility Associates.

If you have questions about your rights as a research subject or if you have questions, concerns or complaints about the research, you may contact:

Western Institutional Review Board® (WIRB®)  
3535 Seventh Avenue, SW  
Olympia, Washington 98502  
Telephone: 1-800-562-4789 or 360-252-2500  
E-mail: Help@wirb.com

WIRB is a group of people who perform independent review of research.

WIRB will not be able to answer some study-specific questions, such as questions about appointment times. However, you may contact WIRB if the research staff cannot be reached or if you wish to talk to someone other than the research staff.

Once you sign the authorization to participate in this research study, it will remain in effect until such time as Reproductive Medicine and Infertility Associates (RMIA) informs you that the research study has been completed, or you authorize RMIA to stop your participation in the research study by writing to:

Reproductive Medicine and Infertility Associates  
2101 Woodwinds Drive  
Woodbury, MN 55125

If you stop your authorization, Reproductive Medicine and Infertility Associates may continue to use your information already collected as part of the research study, but will not collect any additional new information.

If you choose not to sign this authorization, you will not be in this research study.

A copy of this consent form will be placed in your medical record.

**CONSENT:**

I have read the information in this consent form (or it has been read to me). I have had an opportunity to have my questions answered. I have been given a copy of this consent form. I agree to take part in this research study.

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**Date/Time**

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**Printed Name of Participant**

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**Clinic Number**

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**Signature of Participant**

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**Date/Time**

---

**Printed Name of Person Conducting  
Informed Consent Discussion**

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**Signature of Person Conducting  
Informed Consent Discussion**

----- Use this witness section only if applicable -----

*If this consent form is read to the subject because the subject is unable to read the form, an impartial witness not affiliated with the research or investigator must be present for the consent and sign the following statement:*

I confirm that the information in the consent form and any other written information was accurately explained to, and apparently understood by, the subject. The subject freely consented to be in the research study.

\_\_\_\_\_  
**Date/Time**

\_\_\_\_\_  
**Printed Name of Impartial Witness**

\_\_\_\_\_  
**Signature of Impartial Witness**

Note: This signature block cannot be used for translations into another language. A translated consent form is necessary for enrolling subjects who do not speak English.

I confirm that the research study was thoroughly explained to the subject. I reviewed the consent form with the subject and answered the subject's questions. The subject appeared to have understood the information and was able to answer the following questions correctly:

1. What is the purpose of this study?
2. If you decide to be in the study, what will you be asked to do?
3. What is the possible benefit of participating in this study?
4. What are the possible risks of participating in this study?
5. If you decide not to participate in this study, what options do you have?
6. Will participating in this study cost you anything? If so, what will you have to pay for?
7. Do you have to be in this study?
8. If you decide to be in the study, can you leave the study when you want to?

\_\_\_\_\_  
Printed Name of Person Conducting the  
Informed Consent Discussion

\_\_\_\_\_  
Position

\_\_\_\_\_  
Signature of Person Conducting the  
Informed Consent Discussion

\_\_\_\_\_  
Date