RUTGERS
New Jersey Medical School

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CONSENT TO TAKE PART IN A RESEARCH STUDY

TITLE OF STUDY: GnRH for luteal support in IVF/ICSI/FET cycles

Principal Investigator: Dr. Peter McGovern MD

This consent form is part of an informed consent process for a research study and it will provide information that will help you to decide whether you wish to volunteer for this research study. It will help you to understand what the study is about and what will happen in the course of the study.

If you have questions at any time during the research study, you should feel free to ask them and should expect to be given answers that you completely understand.

After all of your questions have been answered, if you still wish to take part in the study, you will be asked to sign this informed consent form.

The study doctor Peter McGovern MD or another member of the study team will also be asked to sign this informed consent. You will be given a copy of the signed consent form to keep.

You are not giving up any of your legal rights by volunteering for this research study or by signing this consent form.

Why is this study being done?

The purpose of this study is to evaluate the addition of GnRH agonist (Lupron®, leuprolide acetate) in helping to prepare the uterus to carry a baby. Other studies have shown that a small amount of Lupron when an embryo is transferred into the uterus increases the chances of a successful pregnancy.

Why have you been asked to take part in this study?

You are undergoing IVF, there is evidence that you may benefit from a single injection of Lupron at the time of implantation.

Who may take part in this study? And who may not?

Woman undergoing IVF/ICSI or frozen embryo transfers (FET) between the ages of 18 and 40 inclusive (until their 41st birthday) may participate. Women undergoing day 3 embryo transfer will not be eligible for the study.

How long will the study take and how many subjects will participate?

About 500 patients will participate in the study. Study participation just entails a single injection at the time of embryo transfer. There are no other procedures needed other than the routine follow-up including pregnancy outcome report.

What will you be asked to do if you take part in this research study?

Five hundred participants will be randomly chosen to receive either a single subcutaneous injection of Lupron or saline solution (placebo) into the abdomen. The injection will be given at the time of embryo transfer.

What are the risks and/or discomforts you might experience if you take part in this study?

The injection of Lupron or saline into the subcutaneous tissue generally causes mild local discomfort.
The chance of infection at the injection site is exceedingly rare.

Reproductive Risks of Harm

The FDA warns against using Lupron during pregnancy, due to adverse events seen in animal studies. However, Lupron use in human pregnancies has never been found to cause harm. Studies in humans have shown that using Lupron increases pregnancy and live birth rates during IVF. The formulation and dose of Lupron used in this study is short acting and is metabolized and excreted from the body before implantation occurs.

Are there any benefits for you if you choose to take part in this research study?

The benefits of taking part in this study may be:

Increased pregnancy and live birth rates

However, it is possible that you might receive no direct personal benefit from taking part in this study.

What are your alternatives if you don't want to take part in this study?

There are no alternative treatments available. Your alternative is not to take part in this study.

How will you know if new information is learned that may affect whether you are willing to stay in this research study?

During the course of the study, you will be updated about any new information that may affect whether you are willing to continue taking part in the study. If new information is learned that may affect you after the study or your follow-up is completed, you will be contacted.

Will there be any cost to you to take part in this study?

There is no cost to participate in this study

Will you be paid to take part in this study?

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

How will information about you be kept private or confidential?

All efforts will be made to keep your personal information in your research record confidential, but total confidentiality cannot be guaranteed.

De-identified data regarding participants will be kept in electronically protected files. The key to re-identify the data will be kept in a locked metal cabinet that is inaccessible to the providers participating in the study.

A description of this clinical trial will be available on ClinicalTrials.gov, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this website at any time.

What will happen if you are injured during this study?

Subjects in this study will be exposed to certain risks of personal injury in addition to those associated with standard forms of treatment, which include: local reaction to SC injection (see page 2)

In addition, it is possible that during the course of this study, new adverse effects of Lupron that result in personal injury may be discovered. The University will make appropriate referrals for medical and/or dental treatment for subjects who sustain personal injuries or illnesses as a direct consequence of participation in the research. The subject's health insurance carrier or other third-party payer will be billed for the cost of this treatment; provided that the University shall not submit to federally funded programs, e.g., Medicare, Medicaid or CHAMPUS, for reimbursement first if submission to such programs is prohibited by law. No financial compensation will be provided by the University and no other type of assistance is available from the University.

What will happen if you do not wish to take part in the study or if you later decide not to stay in the study?

Participation in this study is voluntary. You may choose not to participate or you may change your mind at any time.

If you do not want to enter the study or decide to stop participating, your relationship with the study staff will not change, and you may do so without penalty and without loss of benefits to which you are otherwise entitled.

You may also withdraw your consent for the use of data already collected about you, but you must do this in writing to Dr. Peter McGovern MD- 214 Terrace Avenue, Hasbrouck Heights, NJ, 07604

If you decide to withdraw from the study for any reason, you may be asked to return for at least one additional visit for safety reasons.

Who can you call if you have any questions?

If you have any questions about taking part in this study or if you feel you may have suffered a research related injury, you can call the study doctor:

Dr. Peter McGovern MD
University Reproductive Associates
214 Terrace Avenue
Hasbrouck heights, NJ 07604
Contact Number: (201) 288-6330

If you have any questions about your rights as a research subject, you can call:

IRB Director
(973)-972-3608 Newark

Please note that Dr. Peter McGovern has financial interests as a partial owner of University Reproductive Associates, PC, 214 Terrace Avenue Realty, LLC, and Hasbrouck Heights Surgery Center, LLC.

What are your rights if you decide to take part in this research study?

You have the right to ask questions about any part of the study at any time. You should not sign this form unless you have had a chance to ask questions and have been given answers to all of your questions.

PERMISSION (Authorization) TO USE OR SHARE HEALTH INFORMATION THAT IDENTIFIES YOU FOR A RESEARCH STUDY

Information about you and your health is personal and private, so this information generally cannot be used in research without your written permission. The next few paragraphs tell you about how researchers want to use and share your health information in this research study. Your information will only be used as described here or as allowed or required by law. Ask questions if you do not understand any part of the research or the use of your health information. If you sign this consent form, you agree to let the researchers use your information in the research and share it with others as described below.

What is the purpose of the research and how will my information be used?

You are being invited to take part in this research study which is described at the beginning of this form. The purpose of collecting and using your health information for this study is to help researchers answer the questions that are being asked in the research.

What information about me will be used?

- *Medical history or treatment*
- *Medications*
- *Laboratory/diagnostic tests or imaging*
- *Operative reports*
- *Fertility treatment*
- *Pregnancy outcome*

Who may use, share or receive my information?

The research team may share your de-identified information collected or created for this study with the following people and institutions:

- Rutgers University researchers involved in the study;
- The Rutgers University Institutional Review Board and Compliance Boards
- The Office for Human Research Protections in the U.S. Dept. of Health and Human Services
- The Society for Assisted Reproductive Technology

Those persons or organizations that receive your information may not be required by Federal privacy laws to protect it and may share your information with others without your permission, if permitted by the laws governing them.

Will I be able to review my research record while the research is ongoing?

No. We are not able to share information in the research records with you until the study is over. To ask for this information, please contact the Principal Investigator, the person in charge of this research study.

Do I have to give my permission?

No. You do not have to permit use of your information. But, if you do not give permission, you cannot take part in this research study. (Saying no does not stop you from getting medical care or other benefits you are eligible for outside of this study.)

If I say yes now, can I change my mind and take away my permission later?

Yes. You may change your mind and not allow the continued use of your information (and to stop taking part in the study) at any time. If you take away permission, your information will no longer be used or shared in the study, but we will not be able to take back information that has already been used or shared with others. If you say yes now but change your mind later for use of your information in the research, you must write to the researcher and tell him or her of your decision: Dr. Peter McGovern MD

How long will my permission last?

Your permission for the use and sharing of your health information will last until the end of the research study.

AGREEMENT TO PARTICIPATE

I have read this entire form, or it has been read to me, and I believe that I understand what has been discussed. All of my questions about this form or this study have been answered.

Subject Name:_____

Subject Signature:_____ Date:_____

Signature of Investigator/Individual Obtaining Consent:

To the best of my ability, I have explained and discussed the full contents of the study including all of the information contained in this consent form. All questions of the research subject and those of his/her parent or legal guardian have been accurately answered.

Investigator/Person Obtaining Consent:_____

Signature:_____ Date: _____