CONSENT TO PARTICIPATE IN A RESEARCH STUDY

TITLE: YOGA and Infertility: How to Lower Stress When Trying to Conceive

PRINCIPAL INVESTIGATOR: Dr. Jennifer Hirshfeld-Cytron

SPONSOR: Presence St Joseph Hospital, Fertility Centers of Illinois, Pulling Down the Moon: Integrative Care for Fertility

RESEARCH
You are being invited to participate in a research study that will use a pre-test and post-test data analysis.

PURPOSE OF THE STUDY
You are being invited to participate in a research study to evaluate the effect of a six-week fertility specific yoga intervention on anxiety and infertility related stress.

Approximately 150 patients who are undergoing assisted reproduction will be enrolled in this study, with all expected to be enrolled from this institution. Your participation is expected to last for approximately six weeks.

This study has been reviewed, approved and will be monitored according to Federal law by the Institutional Review Board of Presence St Joseph Hospital 2500 North Lakeshore Drive, Chicago IL 60657.

PROCEDURES
Before starting this study, you will be evaluated to make sure you qualify for this study. This evaluation will include a review of your medical history and an assessment of your ability to perform basic, gentle yoga without injury if you are interested in the treatment group.

If it is decided that you are eligible to participate in this study, you will be assigned to one of two groups. This determination will be based on whether you would like to include yoga as part of your fertility treatments. Your physician and you will know to which group you have been assigned. You will fill out two questionnaires, The Fertility Problem Inventory and the State-Trait Anxiety Inventory, at the beginning of your participation and then again six weeks later. The questionnaires should take approximately ten to fifteen minutes to complete each time. If you are in the treatment group, you will participate in a six-week yoga for fertility program thru Pulling Down the Moon: An Integrative Center for Fertility. The classes will meet once a week for ninety minutes per session. You will be expected to complete at least five of the six sessions in order to complete the study.

RISKS
The major risk involves physical injury during the yoga intervention. Caution will be taken by the instructors to modify the yoga poses based on your physical abilities and comfort levels. The yoga instructors are certified to teach all levels of participants, and this awareness and ability to adjust to differing capabilities is standard. If you are ever uncomfortable with the physical demands, you will be encouraged to stop the activity to avoid any physical injury.

The psychological risks include a possible increased awareness of anxiety and infertility-related stress. You may find that filling out questionnaires that identify potential reactions or problems related to

infertility, as well as hearing the stories of other women facing infertility may be upsetting. You may also unexpectedly encounter friends or colleagues in the yoga studio or physician's office who are unaware you are facing infertility.

BENEFITS
No direct benefits can be guaranteed by your participation in this research study. However, you may benefit by a possible reduction in anxiety and infertility-related stress. Information gained from this study may help other people in the future.

ALTERNATIVE THERAPY
The alternative to participating in this study is to receive the standard infertility care. You may also seek alternative support from counselors trained in fertility related concerns at your doctor's office. Your doctor should discuss this alternative with you.

COSTS
The participants in the treatment group are responsible for the cost of the six-week yoga for fertility intervention. The exact cost will be provided to the participant prior to final decision. Any other research related costs would be provided at no cost to you.

COMPENSATION
There is no compensation for participating in this study. Parking expenses will not be reimbursed, but tickets may be validated for a decreased rate.

CONFIDENTIALITY
Your identity in this study will be kept confidential. Results of this study may be published, or presented at scientific meetings, but your identity will not be disclosed. Your name or any material identifying you as a participant will not be released without written permission except on the occasion that such release is required by law. You agree that the Food and Drug Administration (FDA) or other appropriate governmental oversight agencies as required by law, and representatives of the Presence St Joseph Hospital Institutional Review Board (IRB) may inspect your medical records related to this study.

RESEARCH RELATED INJURY
If you are injured as a direct result of taking part in this study, emergency medical treatment will be made available.

Further information can be obtained from Dr. Jennifer Hirshfeld-Cytron (708)633-1999 who is prepared to advise you about medical treatment in case you believe you have been injured as a result of this study.

In the event of injury or illness resulting from the research procedures, medical treatment for injuries or illness is available through Presence St Joseph Hospital in Chicago, Illinois. Payment for this treatment will be your responsibility. Saint Joseph Hospital in Chicago, Illinois is not responsible for provision of medical care or for compensation of any expenses associated with such injury or illness unless the injury or illness is a result of any of the following:

1. caused by Saint Joseph Hospital's failure to carry out the protocol;
2. failure to follow the Food and Drug Administration (FDA) or other governmental rules; or
3. caused by the neglect of Saint Joseph Hospital.

QUESTIONS
For information on your rights as a study subject, you may contact the Chairman of the Institutional Review Board of Presence St Joseph Hospital 2500 North Lakeshore Drive, Chicago IL 60657 at (773) 665-6730.

VOLUNTARY PARTICIPATION/WITHDRAWAL
You are under no obligation to participate in this study. If you choose not to participate in this study, your medical care will not be affected in any way.

You are free to withdraw from this study at any time by notifying Dr. Jennifer Hirshfeld-Cytron (708) 633-1999. Your withdrawal will not affect your current or future medical care in any way. Your physician may also withdraw you from this study at any time if he/she feels it is in your best interest. If you are withdrawn from the study, or if you withdraw voluntarily, you may be asked to cooperate by having whatever laboratory tests and/or examinations your doctor thinks are necessary.

You will be informed of any significant new developments that may arise or if any new information becomes available during the course of this study that may influence your continued participation.

RESEARCHER CONFLICT OF INTEREST DISCLOSURE STATEMENT
There is no conflict of interest of the principal investigator with this study. The decision whether to enroll in the study is yours alone. To assist with your decision, you may also want to consult with your personal physician or a physician not affiliated with this study. You should have all the information you need to be comfortable with your decision.

CONTACT PERSONS

In the event I have any further pertinent questions regarding the above named research study, I can contact the clinical investigator Dr. Jennifer Hirshfeld-Cytron (708) 633-1999.

Nkemakolam Iroegbu, MD, MPH, Chairman of the Institutional Review Board (IRB) for Saint Joseph Hospital at (773) 665-6730 can provide you with further information about your rights as a research subject. The IRB is a committee that has reviewed this research project to help ensure that your rights and welfare as a research patient are protected and that the project is carried out in an ethical manner. Any research-related injuries should be reported to the Institutional Review Board.

RESEARCH SUBJECT'S BILL OF RIGHTS

The rights explained below are the rights of every person who is asked to be in a research study. As a research participant I have the right:

1. to have the purpose of the study clearly explained; to learn what the study is attempting to find out;

2. to be told what choices for care I have and how they may differ from participating in the research study;

3. to be told what will happen to me and whether any of the procedures, drugs or devices used in the study will be different from the routine care I could expect;

4. to be told about any risks, side effects or discomforts that may occur that are due to my research participation and how these may differ from routine care;

5. to be told whether I can expect any personal benefit from participating in the research study and the likelihood of such a benefit;

6. to ask any questions I have before consenting to participate and throughout my time in the study;

7. to know what medical treatments are available to me and how they will be paid for, if any complications arise due to my participation in this study;

8. to have all records bearing any information that could identify me held in confidence by the researcher(s) and revealed only if necessary for review by appropriate governmental oversight authorities such as the Federal Food and Drug Administration, authorized representatives of the Advocate Health Care Institutional Review Board.

9. to be kept informed of any new medical or technical developments that may affect my condition or my willingness to participate in the research;

10. to refuse to participate or to withdraw from the study at any time without affecting my regular medical care;

11. to receive a copy of the complete consent form;

12. to be free of pressure while considering whether I wish to agree to be in this study.

CONSENT

By signing this form, I acknowledge that this study has been explained to me, including the procedures, and potential risks and discomforts. I have read this consent form in its entirety and have spoken to the investigator or his/her representative and have had all questions answered to my satisfaction. I will receive a completed signed copy of this document. My signature indicates my agreement to voluntarily participate in this study.

_____ _____

Signature of Patient/ *Legal Representative* Date

_____

Printed Name of Patient/Legal Representative

If Signed by Legal Representative (legally authorized medical decision maker), describe the relationship to Patient:

Patient's Name: _____

Relationship of Signatory: _____

_____

Research Representative's Statement
I have explained this research study to the subject and have answered any questions he/she had.

_____ _____

Signature of Research Representative Date

_____ AHCIRB #xxxx

Printed Name and Title of Research Representative Protocol Number

Witness Statement
I acknowledge that I witnessed the Research Representative named above discuss participation in this research study with the subject, that the subject had opportunity to ask questions about the research, and the subject agreed to participate in the research and signed to consent to that effect.

_____ _____

Witness Signature Date

_____

Witness Name *(Please print)*