COVER PAGE

STUDY OF OVARIAN FUNCTION FOLLOWING INTRAOVARIAN INJECTION OF PLATELET RICH PLASMA (PRP) IN WOMEN WITH EVIDENCE OF DIMINISHED OVARIAN FUNCTION

NCT – *not yet assigned*

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Informed Consent to participate in:

STUDY OF OVARIAN FUNCTION FOLLOWING INTRAOVARIAN INJECTION OF PLATELET RICH PLASMA (PRP) IN WOMEN WITH EVIDENCE OF DIMINISHED OVARIAN FUNCTION

This consent form is meant to provide you will all the necessary information that will allow you to decide whether you wish to participate in this study. If you agree to participate in this study, you will have to sign this consent form in all requires places in presence of a witness. You should not sign this consent form unless you are convinced that you do want to participate, that you know enough about this study to make an educated decision to participate and until all of your questions have been answered by CHR staff to your complete satisfaction.

All information in regard to your health is personal and CHR is obliged to protect the privacy of that information. We hereby remind you that, upon becoming a CHR patient, you gave us in writing permission to disclose your protected health information for research purposes, as long as such disclosure does not reveal your identity and or breach the confidentiality of that information. We here want to make certain that you are properly informed how this information will be used in research and/or disclosed, assuring continuous confidentiality.

By signing this consent form you reaffirm your permission. You, however, have no obligation to sign this reaffirmation and such refusal will in no way affect your clinical care at CHR."

All medical information in your medical record at CHR may be subject to review as part of this study. This means that members research team at CHR, conducting this study, may have access to your protected health information, even if they have not been part of the clinical team, providing medical care to you at CHR. Your information may also be reviewed by members of the Institutional Review Board (IRB) of CHR, which is a community board, charged with assuring that all research at CHR is conducted in accordance with generally accepted rules that protect human rights of research participants. Your information may also be shared with potential sponsors of research, conducted at CHR, and their agents, the U.S. Food and Drug Administration (FDA) and/or the U.S. Office for Human Research Protection of the U.S. Department of Health and Human Services. Finally, your data may also be shared with colleagues at other medical centers, participating and/or collaborating in CHR's research.

Your health information will be kept for at least 10 years, but possibly indefinitely, and your authorization, therefore, does not expire. You, however, can cancel your authorization at any time, though already authorized and used data cannot be withdrawn.

You may ask to see your health information used for this study, but you may have to wait until the end of the study since many study protocols do not allow interim analysis of study data.

While we make every possible effort to maintain confidentiality of your medical information and of your identity, we cannot offer an absolute guarantee that we will be successful. While all individuals, given access to this information during the study normally protect the privacy of your medical information, they may not be required to do so by law.

Once you sign, you will be given a copy of this informed consent if you so desire.

Purpose of Study
The purpose of this study is to investigate a potentially new treatment for women with a history of very poor response to ovulation induction. This study is investigating a treatment, which has been alleged to activate remaining follicles, so they start responding again to fertility drugs. Should this happen, a normal in vitro fertilization (IVF) cycle will be pursued (for which you would be billed), in the hope of obtaining one or more eggs. You, therefore, also will be asked to sign CHR's routine IVF cycle consent.

The treatment involves injection of small amounts of platelet-rich plasma. Following such injections, which, like an egg retrieval, will be performed under mild sedation administered by one of CHR's affiliated anesthesiologists, CHR physicians will follow you for up to two months in regular intervals with ultrasound and, sometimes, blood tests to determine whether your ovaries respond to the treatment. If growing follicles are seen, you will have completed the study and will be advised to begin an IVF cycle by supporting the growth of your follicles with routine fertility medications.

Risk and discomfort
The risks are similar to an egg retrieval since both procedures involve the same I.V. sedation and the same insertion of a long needle through the vagina under ultrasound control. Indeed, instrumentation is the same as in an egg retrieval, with the difference being that in a retrieval fluid is withdrawn from the ovary, while here fluid is injected into the ovary. Any time a needle is perforating skin or mucosal membranes, there is a theoretical risk of bleeding and/or infection, but those risks are very small. Since the procedure is performed under I.V. sedation, you will be asleep and will not experience pain. Following the procedure, you will be observed for ca. 20 minutes in recovery before discharge. You should experience at most minor abdominal discomfort at that stage.

Benefits
Should your treated ovary respond, you will have the potential benefit of consenting to an egg retrieval. Should that not be the case, you may not benefit from the study yourself, though others may.

Alternatives to participation
You do not have to participate in this study and your decision not to do so, will not affect your medical care at CHR. Your alternative are the use of donor eggs or no further infertility treatments at all.

Research related injury
Since this study is not funded through external grants, there is no compensation available if injury occurs. If treatment of any injury is within CHR's area of medical expertise, such treatment will be given for free. If such treatment, however, requires other specialty areas, CHR will not be able to cover the costs. In case of injury, I want _____ to be contacted at _____ .

Long-term risk(s)

Long-term risks to patients and offspring (embryo and fetus) are currently unforeseeable, though there are no theoretical concerns that would suggest such risks.

Termination of participation by CHR
Termination of participation in the study by each participant is under the purview of the Principal Investigator.

Withdrawal from study
You have the right to withdraw from the study at any point, and such withdrawal will not affect your further treatment at CHR in any way.

New findings
Should this study result in new findings of significance, you are entitled to receive this information. Please advise your Coordinator that you are interested in receiving such information, and in which way.

Study subjects
We anticipate approximately 50 patients to participate in this study.

Costs
The ovarian injection procedure for PRP will be free of charge, as CHR as the study sponsor, assumes these costs. There will, however, be anesthesia costs of $400 for the I.V. sedation administered by an affiliated anesthesiologist and a facility charge of $1,000 for the surgical facility use. Moreover, pretesting costs and medication costs will remain patient responsibility, as will be cycle stimulation costs and/or full IVF cycle costs, should there be an ovarian response following treatment with PRP. If your insurance carrier covers infertility and/or IVF costs, laboratory testing and medication costs may be covered but many insurance companies refuse payments for treatments done under a research protocol, in which case you may be responsible for such costs.

_____	_____	_____
Patient's Name (Print)	Patient's Signature	Date
_____	_____	_____
Partner's Name (Print)	Partner's Signature	Date
_____	_____	_____
Witness Name (Print)	Witness Signature	Date

WHERE APPLICABLE: NOTARY PUBLIC, stamp/signature/date