RESEARCH SUBJECT OVARIAN PLATELET-RICH PLASMA INJECTIONS AND TIME-LAPSE INCUBATOR WITH AI INFORMATION & CONSENT FORM

Title: OVARIAN PLATELET-RICH PLASMA (oPRP) INJECTIONS FOR IMPROVEMENT IN IVF PATIENTS BASED ON TIME-LAPSE INCUBATOR CULTURE FOR AUTOMATED TRACKING AND AI FOR EMBRYO QUALITY ASSESSMENT: A NON-RANDOMIZED PROSPECTIVE SELF-CONTROLLED INTERVENTIONAL STUDY

Sponsor: Generation Next Fertility

Investigators:

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INTRODUCTION

Before agreeing to participate in this research study, it is important that you read and

understand the following explanation of the proposed research study. This consent document describes the purpose, procedures, benefits, risks, discomforts, and precautions of the study. It also describes the alternative procedures that are available to you and your right to withdraw from the study at any time. No guarantees or assurances can be made as to the results of the study.

If you are not completely truthful with your study doctor regarding your health history, you may harm yourself by participating in this study.

The study is being conducted by Generation Next Fertility PLLC. Your study doctor is employed by Generation Next Fertility as a physician and a member of the medical staff.

Generation Next Fertility Institutional Review Board committee (GNF IRB) has approved the information in this consent document and has given approval for the study doctor to do the study. An institutional review board (IRB) is an independent committee established to help protect the rights of research subjects. This does not mean the IRB has approved your participation in the study. You must think about the information in this consent document for yourself. You must then decide if you want to be in the study.

In case of emergency, please call Dr. Jesse J. Hade or any physician employed at Generation Next Fertility LLPC at (212) 641-0906.

This consent form may contain words that you do not understand. Please ask the study doctors or the study staff to explain any word or information that you do not clearly understand. You may take home an unsigned copy of this consent form to think about or discuss with family or friends before making your decision.

IVF AND PRP HISTORICAL CONTEXT

In vitro fertilization (IVF) was first successfully employed in a human in 1978 during an unstimulated natural cycle, leading to the birth of Louise Brown, the first IVF baby. Due to the limited success of natural IVF cycles, gonadotropins were introduced as a means to stimulate

the growth and maturation of multiple antral follicles before oocyte retrieval, significantly improving the efficiency of IVF treatments. Over the years, controlled ovarian stimulation has enhanced the success of IVF by increasing the number of mature oocytes retrieved, thereby improving fertilization rates and the likelihood of achieving pregnancy and live birth.

Autologous platelet-rich plasma (PRP) was introduced as a transfusion product by hematologists in the 1970s for the treatment of thrombocytopenia. PRP is defined as plasma with a platelet concentration above that of peripheral blood and has since been widely adopted in various medical fields, including orthopedics, cardiothoracic surgery, plastic surgery, dermatology, dentistry, and diabetic wound healing, due to its regenerative properties.

The first recorded ovarian PRP (oPRP) procedure was performed in 2018, demonstrating improvements in ovarian function, folliculogenesis, and ovulation induction, particularly in patients with diminished ovarian reserve. Preliminary studies have suggested that oPRP injections may enhance ovarian reserve markers, increase the number of retrieved mature oocytes, and improve embryo quality, leading to better IVF outcomes. The mechanism behind oPRP's efficacy is believed to involve growth factors such as platelet-derived growth factor (PDGF), transforming growth factor-beta (TGF-β), and vascular endothelial growth factor (VEGF), which contribute to tissue regeneration and angiogenesis within the ovarian microenvironment.

The potential benefits of PRP for ovarian and endometrial rejuvenation have been postulated based on data extrapolated from prior medical research. However, despite promising initial findings, most of the information demonstrating the benefit of PRP on ovarian reserve, oocyte quality, and embryo development remains limited to anecdotal evidence and small-scale studies. Large-scale, well-controlled clinical trials are needed to establish definitive efficacy and safety in this domain.

PURPOSE OF THIS RESEARCH

This is a non-randomized prospective self-controlled interventional study evaluating the impact

of oPRP injections on embryo quality in patients undergoing two IVF cycles.

Participants will undergo two IVF cycles at Generation Next Fertility.

The first cycle will serve as the control (no oPRP treatment), while the second study cycle will incorporate oPRP injections.

Oocytes retrieved will undergo fertilization using one of the following methods:

Intracytoplasmic sperm injection (ICSI)

ICSI with Zymot

ICSI with Zymot and Physiological ICSI (PICSI)

Patients may opt for Preimplantation Genetic Testing for Aneuploidy (PGT-A) through Genomic Prediction LLC's LifeView™ platform, which utilizes single nucleotide polymorphism (SNP) technology to enhance accuracy in detecting chromosomal abnormalities.

All embryos from both IVF cycles will be cultured in time-lapse incubator for automated tracking and assessment.

Embryo quality will be measured by an AI software used in conjunction with the time-lapse incubators

This study aims to evaluate whether ovarian platelet-rich plasma (oPRP) injections improve embryo quality in In Vitro Fertilization (IVF) cycles. Patients will undergo two IVF cycles:

First cycle (Control cycle): A standard IVF cycle with individualized ovarian stimulation protocols based on AMH, AFC and patient history and prior IVF outcomes when applicable.

Second cycle (Study cycle): Includes oPRP injections, administered:

1-2 weeks after the onset of menses following the first IVF cycle.

A second injection between stimulation days 2-5 of the second IVF cycle.

The protocol of the second IVF cycle will be again based on the same criteria as the first IVF cycle. Embryos from both cycles will be monitored using the a time-lapse incubator in conjunction with an AI software to analyze embryo development and assess Embryo Quality (EQ) scores. The study will determine if oPRP improves embryo quality and implantation

potential. Each embryo will be given an EQ (embryo quality) score based on the morphokinetics of the embryos during the incubation period. The Embryo Quality (EQ) Score, generated through AI analysis, will be used to assess whether oPRP improves embryo development, viability, and implantation potential. No clinical decision will be made based upon the resulting Embryo Quality (EQ) Score.

The time-lapse based AI software for embryo assessment is an investigational device, which means that it is not approved by the Food and Drugs Administration (FDA)

STUDY PROTOCOL

1. Baseline Evaluation & Enrollment

All participants will undergo a baseline ultrasound and hormonal blood workup at the start of their menstrual cycle, approximately one month or more prior to initiating the first IVF cycle. This baseline assessment will include:

Ultrasound to determine antral follicle count (AFC) and assess ovarian morphology.

Hormonal testing including Anti-Müllerian Hormone (AMH), Follicle-Stimulating Hormone (FSH), Luteinizing Hormone (LH), Estradiol (E2), Progesterone (P4), Thyroid Stimulating Hormone (TSH), Prolactin (PRL) and Beta-Human Chorionic Gonadotropin (β-hCG).

Routine infectious disease screening in compliance with IVF laboratory standards for both the patient and any male partner.

Genetic Carrier screening with NATARA will be offered to all patients and their partners

Semen Analysis for all male partners to determine if a male factor infertility is present.

Patients will then proceed with their first IVF cycle under a standardized ovarian stimulation protocol based on their ovarian reserve and history of previous IVF response when applicable.

2. First IVF Cycle (Control)

The first IVF cycle will serve as a control cycle, conducted without oPRP injections.

The ovarian stimulation protocol (natural, mild, or conventional) will be determined based on AFC and hormonal profile.

Once the lead follicle reaches the appropriate size (≥18 mm), ovulation will be induced using 10,000 IU of human chorionic gonadotropin (hCG) or 250 mcg Ovidrel®, or 80-100 IU of Leuprolide acetate or a combination of the above administered approximately 35.5 hours prior to retrieval.

Oocyte retrieval will be performed under deep intravenous (IV) sedation by a board-certified anesthesiologist, using transvaginal ultrasound guidance.

Fertilization Method Options:

Intracytoplasmic sperm injection (ICSI)

ICSI + Zymot sperm selection

ICSI + Zymot + Physiological ICSI (PICSI)

With or without PGT-A using SNP-based LifeView® technology from Genomic Prediction LLC.

Embryos will be cultured in the time-lapse incubator, which, in conjunction with AI, provides an automated embryo quality score based on morphokinetic parameters. The resulting AI Score will not be used to guide any clinical decisions.

All embryos reaching the blastocyst stage will be biopsied (if PGT-A is elected), vitrified, and stored for potential embryo transfer.

3. oPRP Treatment & Second IVF Cycle (Study Cycle)

Following the first IVF cycle, patients will undergo their first oPRP injection:

Timing: 1-2 weeks after the onset of the next menstrual cycle.

Procedure: Under IV sedation, a patient’s autologous PRP will be prepared and injected directly into both ovaries under transvaginal ultrasound guidance.

Second IVF Cycle (oPRP Study Cycle)

A similar ovarian stimulation protocol will be used for consistency.

A second oPRP injection will be performed on stimulation days 2-5 to enhance folliculogenesis.

Ovulation will be triggered at the same follicular size thresholds, and oocyte retrieval will follow identical protocols.

Fertilization methodology will be similar to the first cycle unless a poor outcome is identified.

Embryo Development Analysis: All embryos will be cultured in the time-lapse incubator, which, in conjunction with AI, provides an automated embryo quality score based on morphokinetic parameters. The resulting AI Score will not be used to guide any clinical decisions.

4. Data Collection & Outcome Measures

The primary outcome of this study is to determine if oPRP improves embryo quality by analyzing:

Number of retrieved mature (MII) oocytes

Fertilization rate (2PN stage embryos)

Blastocyst formation rate

Embryo Quality (EQ) scores assessed via a time-lapse based AI software

PGT-A results (if applicable)

Likelihood of implantation and clinical pregnancy rate per embryo transfer (if applicable)

MONITORING & SAFETY

Patients will be monitored closely throughout both IVF cycles.

Bloodwork and ultrasound assessments will track follicular development, endometrial thickness, and hormonal response.

Adverse events, including ovarian hyperstimulation syndrome (OHSS), infection, and complications from either IVF or the oPRP injections, will be documented and reported.

Inclusion & Exclusion Criteria

Inclusion Criteria:

Patients who are eligible for both In Vitro Fertilization (IVF) and ovarian Platelet-Rich Plasma

(oPRP) injections.

No known contraindications to IVF or oPRP as outlined in the exclusion criteria.

Willing to undergo two consecutive IVF cycles, with the first cycle serving as a control and the second cycle including oPRP injections.

Adequate ovarian reserve based on baseline antral follicle count (AFC) and anti-Müllerian hormone (AMH) levels.

Exclusion Criteria:

Patients will be excluded from participation if they meet any of the following conditions:

Anovulation due to perimenopause or menopause, as determined by clinical evaluation and laboratory testing

Ovarian accessibility issues, including:

Ovaries not accessible via transvaginal ultrasound

Large unresolved ovarian cysts

History of ovarian abscess or pelvic infection

Any medical condition where pregnancy is contraindicated, including but not limited to:

Severe cardiovascular disease

Uncontrolled hypertension or diabetes

Renal or hepatic insufficiency

History of malignancies, including:

Breast, gynecologic, hematologic (leukemia, lymphoma), or other cancers

Borderline ovarian tumors

Hematologic disorders, including:

Anemia (low hemoglobin/hematocrit levels)

Sickle cell disease, beta-thalassemia, or alpha-thalassemia

Polycythemia (abnormal increase in red blood cells)

Thrombocytopenia (low platelet count) or any platelet dysfunction disorder

Hypercoagulable conditions, such as:

Deep vein thrombosis (DVT)

Pulmonary embolism (PE)

History of stroke or transient ischemic attack (TIA)

Uncontrolled or poorly managed autoimmune diseases, including:

Systemic lupus erythematosus (SLE)

Sjögren’s syndrome

Uncontrolled diabetes mellitus

Severe uncontrolled thyroid dysfunction (hypothyroidism or hyperthyroidism)

Use of medications contraindicated for IVF or oPRP, including:

NSAIDs (Non-Steroidal Anti-Inflammatory Drugs)

Anticoagulants or blood thinners (oral or injectable, e.g., Lovenox, Heparin, Warfarin)

Chronic corticosteroid use

Substance use that may negatively impact IVF or oPRP response, including:

Excessive alcohol consumption

Recreational drug use

Prior oPRP treatment within the past 6 months

Patients unwilling or unable to complete two consecutive IVF cycles

NUMBER OF SUBJECTS / LENGTH OF PARTICIPATION

The study will enroll 125 patients who meet the eligibility criteria. Each patient will participate for approximately 4-6 months, covering both IVF cycles and the embryo evaluation process. The study will include multiple monitoring visits, oocyte retrievals, and time lapse videography for embryo assessment using the time-lapse incubator with AI software.

PROCEDURES & EXPECTATIONS

Initial COnsultation and Screening tests:

Prior to acceptance into the study, you will be required to have an initial consultation with Dr. Jesse Hade to review your medical history, prior fertility treatments (if applicable), and overall reproductive health. A comprehensive physical examination and ultrasound assessment will be performed to evaluate ovarian and uterine health. A pelvic vaginal ultrasound will be performed to determine a baseline AFC and ascertain if the patient meets the entry criteria for participation in the study. If the patient meets the entry criteria, then additional bloodwork for a complete blood count (CBC) and ovarian reserve testing will be performed including Anti Mullerian hormone (AMH), follicle-stimulating hormone (FSH), and estradiol (E2) levels, Thyroid stimulating hormone (TSH) and Prolactin (PRL). Both the patient and her partner will require sexually transmitted disease testing for HIV, syphilis, HBsAg, and HcAb. The patient will also have urine cultures for both Gonorrhea and Chlamydia. In addition, ABO blood group identification, Rho typing & and genetic carrier screening will be offered to both the patient and her partner.

Because some of these tests are performed on specific days of your menstrual cycle, two (2) to three (3) visits to Generation Next Fertility may be required to complete the screening process. We require that you avoid excessive alcohol, vaping, cigarette smoking, and recreational drug usage during your participation in this study.

If you meet the study requirements and do not fall under any exclusion criteria outlined below, you will be notified of your acceptance into the study.

Exclusion Criteria

Patients will be excluded from participation if they meet any of the following conditions:

Anovulation due to perimenopause or menopause, as determined by clinical evaluation and laboratory testing

Ovarian accessibility issues, including:

Ovaries not accessible via transvaginal ultrasound

Large unresolved ovarian cysts

History of ovarian abscess or pelvic infection

Any medical condition where pregnancy is contraindicated, including but not limited to:

Severe cardiovascular disease

Uncontrolled hypertension or diabetes

Renal or hepatic insufficiency

History of malignancies, including:

Breast, gynecologic, hematologic (leukemia, lymphoma), or other cancers

Borderline ovarian tumors

Hematologic disorders, including:

Anemia (low hemoglobin/hematocrit levels)

Sickle cell disease, beta-thalassemia, or alpha-thalassemia

Polycythemia (abnormal increase in red blood cells)

Thrombocytopenia (low platelet count) or any platelet dysfunction disorder

Hypercoagulable conditions, such as:

Deep vein thrombosis (DVT)

Pulmonary embolism (PE)

History of stroke or transient ischemic attack (TIA)

Uncontrolled or poorly managed autoimmune diseases, including:

Systemic lupus erythematosus (SLE)

Sjögren’s syndrome

Uncontrolled diabetes mellitus

Severe uncontrolled thyroid dysfunction (hypothyroidism or hyperthyroidism)

Use of medications contraindicated for IVF or oPRP, including:

NSAIDs (Non-Steroidal Anti-Inflammatory Drugs)

Anticoagulants or blood thinners (oral or injectable, e.g., Lovenox, Heparin, Warfarin)

Chronic corticosteroid use

Substance use that may negatively impact IVF or oPRP response, including:

Excessive alcohol consumption

Recreational drug use

Prior oPRP treatment within the past 6 months

Patients unwilling or unable to complete two consecutive IVF cycles

RISKS & SIDE EFFECTS

The treatment used in this study may cause some or none of the side effects listed. In addition, there is always the risk that some uncommon or unknown side effects may occur including death.

Risks/Side Effects Associated with Estrogen and Progesterone Supplementation:

Side effects reported in women treated with hormones such as estrogen and progesterone include nausea and vomiting, breast tenderness or enlargement, enlargement of benign tumors (“fibroids”) of the uterus, retention of excess fluid leading to worsening conditions such as asthma, epilepsy, migraine headaches, heart disease, or kidney disease. You may also experience a spotty darkening of the skin, particularly on the face. These hormones may increase your ability to form blood clots and as a result increase the chance of having a blood

clot develop in the blood vessels of your leg or pelvis. This can then lead to embolus formation (dislodging of the blood clot which then travels in the circulation) resulting in potentially serious damage to your lungs, heart or brain. Hormones may also increase your risk for developing a stroke or heart attack and even death.

Risks/Side Effects Associated with gonadotropin and hCG:

Side effects reported in women treated with gonadotropins and or menotropins (Gonal-F, Follistim, and Menopur) include ovarian hyperstimulation syndrome, pulmonary and vascular complications (such as the collapse of the lungs, acute respiratory distress syndrome, blood clots which may lead to inflammation of the veins, obstruction of blood vessels in the lungs, damage to the lung tissues, stroke, and obstruction of the arteries resulting in loss of a limb), blood in the abdominal cavity, enlarged ovaries, dizziness, increase in heart rate, shortness of breath, rapid breathing, flu-like symptoms (fever, chills, musculoskeletal aches, joint pain, nausea, headache, and fatigue), breast tenderness, and dermatological (skin) reactions (dry skin, body rash, hair loss, and hives). In rare cases, pulmonary (lung) complications and/or thromboembolic (clots in blood vessels) events have resulted in death.

There have been infrequent reports of ovarian cancer in women who have undergone multiple drug regimens for ovulation induction; however, a causal relationship has not been established.

In addition, ovulation induction medications have been used safely and without long-term adverse effects on most patients. However, the long-term safety of any one patient cannot be guaranteed. In addition, breast tenderness, mood swings, hot flashes, nausea, pain, and swelling at the injection site may occur.

The following side effects have been reported in some patients receiving Ovidrel (HCG) therapy: Headache, irritability, restlessness, depression, fatigue, swelling, and pain at the site of injection.

Risks Associated With Study Procedures:

In this study, you will be required to have blood drawn on several occasions. This may lead to

slight pain, bruising, swelling, and the possibility of local infection. You will also be required to take subcutaneous or intramuscular injection of HCG or Ovidrel (choriogonadotropin alfa). There may be risk of infection, bruising, swelling at the injection site and damage to the nerves with improper technique.

The performance of the ovarian oPRP or oS injections and the egg retrieval may be associated with infection, abscess formation, injury to abdominal organs, blood vessels, and subsequent death. All of these complications might require hospitalization and/or major surgery and/or a blood transfusion. I understand and agree that I will be given oral antibiotics to be taken by me for a period of five (5) days following the retrieval as prescribed by the physician. I understand that Generation Next Fertility cannot guarantee my future fertility. I understand that impaired fertility in the future may or may not be related to the egg retrieval process or injection of oPRP or oS. I understand that my condition may not improve or may worsen while participating in this study.

Anesthesia is required for the egg retrieval and ovarian injection procedures. The type of anesthesia administered, (I.V. deep Sedation), will be decided on an individual basis determined by the anesthesiologist physician. Side effects of anesthetic agents can include nausea, and vomiting. Allergic reactions to anesthesia agents can include skin rash and in severe cases cardiac arrest and death.

Potential Risks and Complications

As part of this study, you will undergo multiple blood draws, which may cause mild discomfort, bruising, swelling, or, in rare cases, local infection at the site of venipuncture.

You will also be required to self-administer or receive injections of fertility medications, including human chorionic gonadotropin (hCG) or Ovidrel (choriogonadotropin alfa) or Leuprolide acetate or a combination of these medications. Potential risks associated with these

injections include localized pain, bruising, swelling, and, in rare cases, nerve injury or infection if proper injection techniques are not followed.

The oPRP injection and egg retrieval procedures involve transvaginal ultrasound-guided aspiration, which carries risks including:

Infection requiring antibiotic treatment or, in rare cases, hospitalization

Pelvic abscess formation, though uncommon, may necessitate surgical intervention

Injury to nearby abdominal organs or blood vessels, which may lead to internal bleeding requiring emergency care

Ovarian trauma, potentially affecting future ovarian function

Blood loss, which in rare cases may require a blood transfusion

Adhesion formation, potentially leading to pelvic pain or fertility complications

To mitigate the risk of infection, you will be prescribed a three-day course of oral antibiotics following your oocyte retrieval and oPRP injection, as per standard clinical protocols.

While every precaution will be taken, Generation Next Fertility cannot guarantee the preservation or improvement of your future fertility. Participation in this study does not ensure improved ovarian function or pregnancy outcomes, and in some cases, ovarian response may remain unchanged or worsen.

Anesthesia Risks

For both the oocyte retrieval and the oPRP injection procedure, anesthesia will be administered via intravenous (IV) deep sedation, as determined by the attending anesthesiologist. The potential risks of anesthesia include:

Nausea and vomiting, which typically resolve within hours

Dizziness or low blood pressure, which is usually self-limited

Respiratory depression, requiring intervention in rare cases

Allergic reactions, ranging from mild skin rashes to severe, life-threatening anaphylaxis

Cardiac complications, including rare instances of heart rhythm disturbances or, in extreme

cases, cardiac arrest

Patients with a known history of anesthesia intolerance or severe allergies should inform the study team before undergoing any procedures.

Every effort will be made to ensure safe and effective anesthesia administration, and you will be closely monitored throughout the procedure. However, as with any medical intervention, complications—though rare—are possible.

BENEFITS

Participation in this study may offer personal reproductive benefits, as the use of ovarian platelet-rich plasma (oPRP) injections has been associated with enhanced ovarian function, improved folliculogenesis, and increased oocyte quality in preliminary studies. These improvements may, in turn, increase the number of mature oocytes retrieved, improve embryo development, and enhance implantation potential, potentially improving the likelihood of pregnancy.

A key component of this study is the use of a time-lapse incubator in conjunction with AI, which will provide real-time, continuous monitoring of embryo development. This advanced imaging technology allows for detailed morphokinetic analysis of embryos. By using this cutting-edge incubator, we aim to further optimize embryo selection, reduce subjectivity in grading, and potentially improve IVF outcomes.

While these potential benefits exist, it is important to acknowledge that pregnancy cannot be guaranteed, and some or all participants may not experience any improvement in their fertility outcomes. However, if oPRP proves to be beneficial, this research may have far-reaching implications for reproductive medicine, offering an innovative and less invasive alternative for women with poor ovarian response or diminished ovarian function.

Additionally, this study may contribute to advancing fertility treatments, helping future patients by providing more data on the efficacy of oPRP in IVF and refining embryo quality assessment

using AI-driven technology. By participating, you will be contributing to cutting-edge reproductive research that could enhance success rates and reduce the overall burden of fertility treatments in the future.

Compensation for Participation

The primary goal of this study is to assess the potential benefits of ovarian platelet-rich plasma (oPRP) injections in improving IVF outcomes. Participants in this study will receive a substantial reduction in the cost of specific services provided by Generation Next Fertility (GNF), including:

Two discounted IVF cycles, inclusive of ovarian stimulation monitoring and oocyte retrieval

The cost of oPRP injections (both the initial and second treatment)

Intracytoplasmic Sperm Injection (ICSI)

Zymot and PICSI sperm selection methods (if chosen)

Embryo biopsy for Preimplantation Genetic Testing for Aneuploidy (PGT-A) (if chosen)

Embryo cryopreservation for up to one year

Use of the time-lapse incubator with AI for continuous embryo monitoring and evaluation

Patient Financial Responsibility

Patients will be responsible for:

The full cost of PGT-A analysis if they choose to proceed with genetic testing of their embryos

Any additional embryo storage fees beyond the one-year complimentary period

All medical expenses related to pregnancy beyond the first pregnancy test

Any non-study-related procedures or treatments

The full cost of ovarian stimulation medications required for both IVF cycles

The full cost of the frozen embryo transfer (FET) cycle if an embryo is cryopreserved

Insurance Coverage Considerations

Patients who choose to use their insurance coverage for IVF treatments will receive a discount

on all out-of-pocket costs for procedures performed at Generation Next Fertility that are not covered by insurance. This excludes the cost of medications, PGT-A analysis of embryos, and the FET cycle, which will remain the patient's financial responsibility.

Important Considerations

No monetary compensation will be provided for participation in this study.

Participation in the study does not guarantee pregnancy or improved fertility outcomes.

The cost reduction only applies to services rendered by Generation Next Fertility and does not cover external laboratory fees, additional medical costs, medications, or the cost of the frozen embryo transfer cycle.

By participating, you will be contributing to cutting-edge fertility research while receiving access to advanced reproductive technologies at a significantly reduced cost.

Alternative Treatment Options And Participation

Participation in this study is completely voluntary, and you are under no obligation to enroll as a study participant.

If you choose not to participate, alternative fertility treatment options are available, including:

Traditional In Vitro Fertilization (IVF) with ovarian stimulation, including the option for fresh embryo transfer on Day 3 or Day 5 or a frozen embryo transfer (FET)

Artificial Intrauterine Insemination (IUI)

Oocyte donation for patients with significantly reduced ovarian function

oPRP injections outside of the study, subject to standard Generation Next Fertility (GNF) fees and charges

Use of the time-lapse incubatorfor embryo assessment, which is available outside of the study as a clinical offering.

If you wish to pursue oPRP injections or use the time-lapse incubator independently, you may do so without enrolling in this study; however, all standard costs associated with these

procedures will apply at regular price.

Your decision not to participate in this study will not impact your ability to receive fertility treatment at Generation Next Fertility. If you would like to discuss the best treatment options for your individual case, please speak with your physician.

Confidentiality

Your participation in this study will be handled with strict confidentiality. However, there are certain circumstances in which disclosure of your study-related records may be required by law or for regulatory purposes. The study doctor, the sponsor, or individuals working on behalf of the sponsor may access your records. Additionally, the United States Food and Drug Administration (FDA), the Institutional Review Board (IRB), and other regulatory authorities may review and inspect confidential study-related documents that identify you by name to ensure compliance with ethical and medical standards. While every effort will be made to protect your privacy, absolute confidentiality cannot be guaranteed.

If the results of this study are published or presented at medical conferences or scientific meetings, your personal identity will remain anonymous and will not be disclosed.

Compensation for Injury

To participate in this study, you must have valid medical insurance and provide documentation of coverage. In the unlikely event that you experience a physical injury as a direct result of participating in this study, immediate medical care will be available, including hospitalization if necessary. Generation Next Fertility will assist in billing your insurance provider for any related expenses; however, neither Generation Next Fertility nor the study sponsor will assume financial responsibility for any medical costs related to such injuries. Any costs not covered by

your insurance will be your financial responsibility.

Sources of Funding

This research study is fully funded by Generation Next Fertility, PLLC. No external funding sources or third-party financial sponsorships are involved.

EMERGENCY CONTACT/IRB CONTACT

If, at any time during the study, you experience medical problems, adverse reactions, or a research-related injury, or if you have any questions, concerns, or complaints about your participation, please contact the study doctor or their designated representative at the phone number provided on page one of this consent document. If you require emergency medical care or hospitalization, it is critical that you inform the treating physician that you are participating in a research study conducted by the study doctor listed on page one.

For any study-related inquiries, medical concerns, or if you experience any adverse effects related to the study medication, please contact:

Dr. Hade, Dr. Luk, Dr. Nejat or Dr. Seckin at (212) 641-0906

If you have any questions about your rights as a research subject, and/or concerns or complaints regarding this research study, you should write to:

- Generation Next Fertility IRB
- 115 East 57th Street
- Suite 500
- New York, NY 10022

- Telephone: 212-641-0906

Do not Sign this consent form unless you have had a chance to ask questions and have received satisfactory answers to all of your questions.

If you do not understand any of the above risks, you may discuss them with Dr. Hade. If complications occur, Dr. Hade or his associate physicians and their team will monitor you closely and take appropriate medical action that may include stopping any or all medications and discontinuing the treatment cycle.

Voluntary Participation & Withdrawal

Your participation in this study is entirely voluntary. You have the right to decline participation, and if you choose to enroll, you may withdraw from the study at any time without penalty. Your decision to withdraw will not affect your future medical care at Generation Next Fertility.

However, you may be removed from the study without your consent under the following circumstances:

If continued participation is deemed medically unsafe. This includes any side effects or complications, such as ovarian hyperstimulation syndrome (OHSS) or hypersensitivity reactions, that, in the opinion of the study doctor or sponsor, could pose a risk to your health.

If a new medical condition arises that increases the risk of complications from the oPRP, IVF process, or related procedures.

If you require medications that are contraindicated during the study, including but not limited to certain hormones, anti-inflammatory drugs, tranquilizers, chemotherapy, or any medications deemed unsafe during pregnancy.

If you do not comply with the study requirements or fail to follow instructions provided by the study team.

If it is determined that you do not meet the eligibility criteria for participation.

If the study is discontinued for any reason.

If enrollment reaches its maximum capacity, and you are not among the selected participants.

If you choose to withdraw or are removed from the study, you will be responsible for the full cost of all treatments, procedures, and monitoring completed at Generation Next Fertility up until the point of withdrawal. Any discounts or study-related fee reductions will no longer apply, and standard rates for all services rendered will be charged to your account.

Additionally, if you withdraw, the study doctor may request that you undergo final safety assessments to ensure your well-being.

Primary Care Physician / Specialist Notification Option

Please indicate below whether you want us to notify your primary care physician or your specialist of your participation in this study.

_____ Yes, I want the study doctor to inform my primary care physician/specialist of my participation in this study.

_____ No, I do not want the study doctor to inform my primary care physician/specialist of my participation in this study.

_____ I do not have a primary care physician/specialist.

_____ The study doctor is my primary care physician/specialist

New Findings

If any new information arises during the study that may affect your willingness to continue participation, you will be promptly informed so that you can make an informed decision about your continued involvement.

CONSENT

I/we have had ample opportunity to ask questions about this study, and my/our participation is voluntary, as reflected by the signed statement below.

I/we have read this consent form and have received verbal explanations of these procedures from my study doctor. I/we understand the information provided about this study. I/we freely give my consent to participate in this research. I/we understand that I/we have the right to ask questions and may withdraw from the study at any time.

During the course of the research, I/we will be informed of any significant new findings that may affect my/our willingness to continue participation.

I/we further understand that I/we may discuss any concerns with my study doctor, the study doctor's designee, or a representative of GNF Review Board, Inc. (GNF IRB) regarding my/our rights as a research participant and any potential side effects or complications.

I/we understand that by signing this consent, I/we are deciding whether to participate in this study. My/our signature(s) below confirm that I/we have made an informed decision to participate, having read (or had read to us) the information in this consent form.

I/we authorize the release of my medical records for research or regulatory purposes to the study sponsor, the FDA, DHHS agencies, governmental agencies in other countries, and GNF Review Board, Inc. (GNF IRB).

I/we acknowledge that existing laws do not fully address the legal implications of this procedure, including but not limited to its legality, the rights and responsibilities of participants, and the enforceability of any agreements regarding custody and parentage of any child conceived as a result of this procedure. I/we have been advised to seek independent legal counsel before participating. Given the evolving nature of reproductive medicine, there is limited legal precedent, and Generation Next Fertility PLLC cannot ensure the enforceability of any agreements or legal outcomes.

I/we understand and agree that all medical records related to testing and treatment as part of this study are the property of Generation Next Fertility PLLC and will not be released to me/us.

I/we acknowledge that Generation Next Fertility PLLC, its physicians, and their associates have made no guarantees regarding the outcome of this procedure. I/we release Generation Next Fertility PLLC from any liability or responsibility for the physical or mental health of any child or children conceived, as well as from any loss, damage, or complications that may result from my/our participation in this procedure or from the application of any legal regulations governing reproductive medicine.

This release applies to the fullest extent permitted by law and to any rights or claims asserted by third parties, including any children conceived as a result of this procedure.

I/we confirm that I/we have received adequate information regarding ovarian platelet-rich plasma (oPRP) injections and the in vitro fertilization (IVF) process. My/our study doctor and their associates have provided all requested information, including an explanation of the risks and potential complications. I/we understand that some risks may be unknown at this time. I/we have had the opportunity to ask all relevant questions, and these have been answered to my/our satisfaction. If I/we withdraw from the study or if the study doctor determines that continued participation is not in my/our best interest, I/we acknowledge that I/we am expected to return for a final visit.

My partner (if applicable) and I freely consent to my participation as a study patient. I/we understand that this study aims to evaluate the benefits of oPRP before undergoing IVF. I/we understand that participation requires undergoing multiple procedures, including ovarian injections of oPRP and IVF with oocyte retrieval. Following oocyte retrieval, I/we understand that the eggs will be fertilized in the laboratory with sperm from my partner or a chosen sperm donor.

I/we understand that all embryos will be cultured and monitored using the time-lapse incubator with AI. This advanced system provides continuous, non-invasive embryo assessment, allowing

for precise tracking of embryo development. The Embryo Quality (EQ) score generated will be used as an additional measure to assess whether oPRP has an impact on embryo quality and implantation potential; but not for making any clinical decision.

I/we understand that the time-lapse based AI software for embryo assessment is an investigational device, which means that it is not approved by the Food and Drug Administration (FDA).

I/we understand that I/we will undergo Intracytoplasmic Sperm Injection (ICSI) for fertilization. Additionally, I/we have the option to enhance sperm selection using Zymot sperm separation technology and/or Physiological Intracytoplasmic Sperm Injection (PICSI), which may improve embryo quality by selecting higher-quality sperm for fertilization.

I/we understand that if I/we elect to undergo Preimplantation Genetic Testing for Aneuploidy (PGT-A), embryo biopsy will be performed to determine chromosomal normalcy before transfer. However, I/we acknowledge that PGT-A analysis is not covered as part of this study, and I/we will be responsible for the full cost of testing and analysis. Only embryos deemed suitable for transfer based on standard embryology criteria and, if applicable, PGT-A results, will be transferred to my uterus, while embryos ineligible for transfer will be discarded.

I/we understand and consent to micromanipulation procedures, such as ICSI, on all mature eggs retrieved during IVF. I/we acknowledge that ICSI, Zymot, and PICSI involve some risk to the oocyte and embryo. While these procedures are designed to reduce abnormal fertilization, they do not eliminate the possibility of creating abnormal embryos. Any embryos identified as abnormal will be discarded and not used for transfer.

I/we understand that I/we are fully responsible for any and all offspring, regardless of pregnancy outcomes.

I/we acknowledge that once the eggs are retrieved and fertilized, the resulting embryos become my/our sole responsibility. I/we understand that I/we are legally responsible for the resulting embryos.

I/we acknowledge that no guarantees can be made regarding the success of this procedure. I/we understand that the physician may cancel the procedure at any time based on their clinical judgment. I/we also understand that there is a possibility that no eggs will be retrieved, that retrieved eggs may not fertilize, or that fertilized eggs may not develop into blastocyst-stage embryos. Additionally, I/we recognize that some blastocyst embryos may not be eligible for biopsy or transfer and may fail to implant after embryo transfer.

I/we acknowledge the risks of pregnancy complications, potential congenital anomalies, hereditary conditions, or other adverse outcomes. I/we agree not to hold Generation Next Fertility PLLC or any of its employees liable for such complications. Generation Next Fertility PLLC cannot guarantee future fertility or reproductive outcomes. I/we understand that future fertility may be affected by participation in this study, though it is unclear whether it will be related to the egg retrieval process or oPRP injections.

Considering all the information provided, I/we release Generation Next Fertility PLLC and its employees from any liability related to the physical or mental health of any resulting child or children, as well as any loss or damage related to this procedure. This release applies to any complications arising from participation in this study and any legal agreements between participants.

This release applies to the fullest extent permitted by law and extends to any third parties, including any children conceived as a result of this procedure. I/we release Generation Next Fertility PLLC and its employees from any financial responsibility due to complications that may arise for me/us or my/our offspring due to this procedure. I/we also understand that if pregnancy occurs, additional genetic testing, such as amniocentesis or chorionic villous sampling (CVS), may be recommended to assess fetal chromosomal abnormalities.

If I/we or my/our offspring require medical treatment due to participation in this study, I/we acknowledge that the financial responsibility for such care will be solely mine/ours.

CONSENT

I/we have read and understand the information in this informed consent document. I/we have had an opportunity to ask questions and all of my questions have been answered to my satisfaction. I/we voluntarily agree to participate in this study until I/we decide otherwise. I/we do not give up any of my legal rights by signing this consent document. I/we will receive a copy of this signed consent document.

_____□□□

Subject's Printed Name

_____□□□_____

Subject's Signature□□□□□□□Date

_____□□□

Subject Partner's Printed Name (if applicable)

_____□□□_____

Subject Partner's Signature (if applicable)□□□□Date□□□Date

_____□□□

Printed Name of the Person Conducting the □□□

Consent Discussion □

_____□□_____

Signature of the Person Conducting the □□□□Date□

Consent Discussion □□□□□□

CONSENT FOR SUBJECTS WHO CAN NOT READ

The study subject has indicated that he/she is unable to read. The consent document has been read to the subject by a member of the study staff, discussed with the subject by a member of the study staff, and the subject has been allowed to ask questions of the study staff.

_____

Printed Name of Impartial Witness

_____□□□_____

Signature of Impartial Witness* □□□□Date

*Impartial Witness: A person, who is independent of the trial, who cannot be unfairly influenced by people involved with the trial, who attends the informed consent process if the subject or the subject's legally acceptable representative cannot read, and who reads the informed consent

and any other written information supplied to the subject. Guidance for Industry E6 Good Clinical Practice: Consolidated Guidance

AUTHORIZATION TO USE AND DISCLOSE

PROTECTED HEALTH INFORMATION

During your participation in this research study, the study doctor Jesse Hade, M.D., Janelle Luk, MD, Edward Nejat, MD, Serin Seckin, MD or another designated physician 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 doctor will keep this personal health information in your study-related records (that we will refer to as "your study records"). In addition, the study doctor may obtain and include information regarding your past, present, and/or future physical or mental health and/or condition in your records. Your study doctor 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 numbers, 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). Other PHI that may be used includes; laboratory data, photos, and images of ultrasounds, oocytes, and embryos. Information regarding test results for a resulting pregnancy, including but not limited to birth date, gestational age of delivery, birth weight, size, complications of pregnancy and delivery, fetal malformations if it occurs, and method of delivery applies as well.

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 agree to allow the study doctor Jesse Hade, M.D. or another GNF physician and staff to use your PHI to conduct this study.

By signing this Authorization, you also are agreeing to allow the study doctor Jesse Hade, M.D. or another GNF physician 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 participant records, meaning they will not ordinarily be identified in the records sent to the sponsor. The sponsor may, however, look at complete study records that identify participants. In addition, the sponsor may visit the study site to oversee how the study is being conducted and may review participants' PHI during these visits to ensure 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.

Your medical insurance company, another third-party payer, legal boards, and other legal representatives of your choosing may request access to your PHI.

The study doctor 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 others who are not required to comply with federal law, your PHI will no longer be protected by this law and could be used or disclosed in ways other than those listed here.

You have a right to see and make copies of your PHI. You agree, 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 complete records.

This Authorization 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 doctor, Jesse Hade, M.D., or another designated GNF physician, stating that you are revoking your Authorization to Use and Disclose Protected Health Information. If you revoke this Authorization, you will not be allowed to continue 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□□□□Date

Authorization□

_____

Printed Name of the Person Obtaining the

Authorization

FOR SUBJECTS WHO CAN NOT READ

The study subject has indicated that he/she is unable to read. This Authorization document has been read to the subject by a member of the study staff, discussed with the subject by a member of the study staff, and the subject has been allowed to ask questions of the study staff.

_____

Printed Name of Impartial Witness

_____□□□_____

Signature of Impartial Witness* □□□□Date

*Impartial Witness: A person, who is independent of the trial, who cannot be unfairly influenced by people involved with the trial, who attends the informed consent process if the subject or the subject's legally acceptable representative cannot read, and who reads the informed consent and any other written information supplied to the subject. Guidance for Industry E6 Good Clinical Practice: Consolidated Guidance