INFORMED CONSENT

Title:	Fertilo P1 Clinical Study
Protocol Version:	1
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Sponsor:	Gameto, Inc., 286 Madison Ave, 1901, New York, NY 10017
Principal investigator:	Luis Guzmán
Location:	Pranor Clinic, Av. Manuel Olguín 1045. Urb. Derby de Monterrico. Groove

INFORMED CONSENT TO PARTICIPATE IN A STUDY

You are being invited to participate in a research study. Your participation is voluntary, which means that you can choose whether or not you want to participate in this study. A person who participates in a research study is called a research subject. Before you decide to participate, you need to understand what this study is about, the possible risks and benefits of participating in this study, and your responsibilities. If you decide to participate, you must sign this form. A copy of this document will be provided to you for you to keep.

RESEARCH CONSENT SUMMARY

What should I know about this research?

- Someone will explain this research to you.
- This is a document that sums up the explanation.
- Participation in this research is voluntary. Whether you take part is up to you.
- You can choose not to participate. There will be no penalty for not participating.
- You can agree to participate and then change your mind. It will not be held against you.
- If you don't understand, ask questions.
- Ask all the questions that you want before deciding to participate.

Why is this research being done?

The purpose of this investigational research is to compare the results of assisted reproduction, both in terms of efficiency and well-being of patients. Conventional IVF and oocyte cryopreservation (commonly known as “egg freezing”) requires giving women large doses of hormones, which can have side effects in some cases. Additionally, after receiving these hormones, many of the oocytes (“eggs”) collected may be immature and cannot be used for IVF. We want to investigate a method to mature these oocytes *in vitro* to reduce the necessary doses of hormones and get more mature eggs in assisted reproduction procedures. The specific objective of this study is to evaluate the safety of the Fertilo product through the clinical evaluation of ongoing pregnancies and births.

About 80 subjects will participate in this research with the aim of observing data for about 20 births.

How long will I be in this research?

We expect that your participation in this research will last between thirteen and fifteen months. You will need to come to the clinic for the initial evaluation in the first month, three-five days in the second month for ovarian stimulation protocol and measurements, and then for embryo transfer and follow-ups depending on the result of the process, which will follow the standard protocols of the clinic.

Can I be removed from this research without my approval?

The person in charge of this research may remove you from the study without your approval. Possible reasons for this include:

- It is in your best interest
- It has a side effect that requires stopping the research.
- If the study is canceled.
- If you miss your scheduled appointments

We will tell you about any new information that may affect your health, well-being, or choice to stay in this research.

What are the interventions of the study?

This research does not include intervention in the research subjects. The protocols for ovarian stimulation, embryo transfer, and results analysis are standard in assisted fertility practice. The Fertilo research product will only be applied to the oocytes obtained after their retrieval. Your oocytes will be cultured *in vitro* (i.e. in a laboratory dish at the clinic) with the Fertilo product for 24 hours, and once they mature they will be used according to the standard procedures of the clinic. You will need to sign the clinic's specific consents for each stage of the process that are attached to this document.

What are the procedures of this study?

This investigation will be carried out in a clinic that specializes in assisted fertility treatments.

An investigator from the clinic will explain this research, the associated risks and benefits, and answer any questions you may have. If you agree to participate, you will sign this consent form. You will first be evaluated to determine your eligibility to continue in the study. In the present study, subjects will be evaluated under informed consent for inclusion and exclusion criteria by blood tests, general medical evaluation and ultrasound (for female participants) and semen analysis (for male participants). To be included in the study, both the female and male partners must meet all the inclusion criteria.

The information that will be collected for the female participants will be:

- Age
- Body Mass Index (BMI)
- Antral Follicle Count (AFC)
- Serum antimüllerian hormone (AMH) level
- Serum thyroid-stimulating hormone (TSH) level
- Serum follicle-stimulating hormone (FSH) level
- Estradiol level (E2)
- Serum prolactin level
- Total testosterone level
- Antithyroperoxidase level, sex hormone-binding globulin (SHBG)
- Bloodborne pathogen screening for HIV, HPV, Hepatitis B, Hepatitis C, Syphilis, Gonorrhea, and Chlamydia
- Universal detection of genetic carriers
- Questionnaire on the use of contraceptives or other drugs
- Normal uterine cavity assessed by hysteroscopy, hysterosalpingography, or sonohysterography within 2 months prior to screening.
- Cervical cancer screening.
- Presence of high-risk human papillomavirus.
- Presence of both ovaries without major obstructions (ovarian fibromas, ovarian cysts, endometriosis).
- medical history
- History of substance abuse and tobacco use.

The information that will be collected for male participants will be:

- Age
- Volume of semen
- Sperm count
- Motility
- Morphology
- Clinic history

This information will be stored at the clinic, in accordance with applicable laws and regulations. Your information will be anonymized before being shared with the study sponsor and investigators.

Experimental Minimum Stimulation Protocol

As in any IVF cycle, participating women will undergo controlled ovarian stimulation. Women taking part in the study must stop taking the oral contraceptive pill for a minimum of 7 and a maximum of 21 days before starting stimulation. This will help achieve a more consistent, controlled patient response to stimulation, eliminate atretic follicles, and allow for timely timing of recovery.

For stimulation, female participants will undergo minimal stimulation, receiving up to 3 total doses of recombinant follicle-stimulating hormone (200 IU rFSH/day) beginning on day 5 after contraceptive cessation. Beginning on the day of the first stimulation, a thorough ultrasound will be performed on each stimulation day. Specifically, the count and size of the follicles will be recorded to monitor the response to stimulation. In addition, blood samples will be collected from the patient on the day of initiation of stimulation, the day of hCG injection, and the day of oocyte retrieval to measure serum levels of FSH, luteinizing hormone (LH), progesterone (P4), and E2. Serum hormone levels will be used to monitor follicular response, prevent premature luteinization during stimulation, and inform future study designs, which is necessary to contextualize embryological results and improve stimulation success.

After the first injection, the size of the follicles will be assessed by ultrasound the next morning. If there are no follicles ≥ 10 mm in diameter, another gonadotropin injection will be given in the evening and the follicles will be evaluated by ultrasound the next morning. This process will be repeated for a total of three injections. If three injections have been given, an injection-free coasting period of no more than 3 days can be used if no follicles reach ≥10 mm. If no follicle reaches 10mm or more during the stimulation and coasting, the cycle will be canceled.

A member of the clinic will follow up with you to check your symptoms after the injections, but **you should immediately contact the Investigator at the number listed above if you experience any serious side effects, such as pain abdominal intense, bleeding (more than can be controlled with sanitary pads), uncontrollable vomiting, or abdominal bloating or swelling associated with difficulty breathing deeply.** It is normal to experience some nausea, bloating, swelling, redness and bruising at the injection site, but in case of doubt please contact the clinic.

Once the stimulation has begun, you should limit your exercise to only walking and stay hydrated. Do not take aspirin, NSAIDs, clopidogrel, ticlopidine, or any medicine, herb, or other substance that may interfere with platelet function during your treatment cycle. Doing so will increase your risk of having a bleeding complication during egg retrieval. Consult with the investigators before starting a new medication. You should not have unprotected intercourse until your next menstrual cycle to avoid multiple pregnancies.

After the injections, an ultrasound will be performed to determine the size of your follicle. If your follicles are of an acceptable size (6-8 mm), a dose of 10,000 units of hCG hormones will be administered to trigger ovulation ("the trigger shot"). If the follicle size has not reached 6 mm, the investigator may decide to wait for one or two more days to let the follicles grow, or prescribe an additional day of medication, and then administer the trigger shot.

The clinic will schedule your retrieval procedure according to usual clinic standards. The oocytes will be placed in a laboratory dish together with the Fertilo product to induce their maturation for 24 hours. Then they will be washed, and the other procedures will follow according to the clinic's standards for IVF. Please review the clinic consents for IVF treatment, which are attached to this form.

What are my responsibilities if I participate in this research?

If you participate in this research, you will be responsible for:

- Refrain from unprotected sex during and after stimulation treatments, until your next menstrual cycle.
- Use contraceptives if indicated before stimulation protocols, up to 5 days before starting stimulation.
- During stimulation procedures, you should limit exercise to walking and stay hydrated.
- You should avoid taking aspirin or any medication, herb, or other substance that may interfere with platelet function prior to egg retrieval.
- Talk to the investigator before taking any other prescription or over-the-counter medication.
- Report your symptoms and answer the researchers' questions about your general well-being during stimulation and after recovery.
- You should report any side effects you experience during and after stimulation or retrieval to the clinic.
- You should follow instructions provided by the members from the clinic, and update any information on new medications or medical problems that arise during the research.
- You should immediately reach out to the 24-hour phone number above or seek medical attention if you experience any of the following: bleeding (more than can be controlled with sanitary pads), severe abdominal pain, uncontrollable vomiting, or abdominal bloating associated with difficulty breathing deeply.
- You must agree to undergo the PGT-A test on the embryos resulting from the procedure.
- You must attend all visits indicated by the investigators to monitor your progress during the stimulation procedure and resulting pregnancy.
- You must commit to answering the follow-up questions after your baby is born.

Could being in this investigation hurt me?

The risks associated with this study are those that result from participation in an assisted fertilization process. Please refer to the attached documents for details of each stage of the process and the inconvenience and risks that may result from each stage.

Although your information will be anonymized before being shared with the sponsor or researchers outside the clinic, there is a slight risk of loss of confidentiality.

In addition to these risks, participating in this research may cause damages in unknown ways.

Will it cost me money to participate in this research?

There will be no additional cost to you to participate in this research. However, if you want to store your frozen embryos for more than three months, or later than the completion of the study, you will have to pay the storage costs.

Will being in this research benefit me?

We cannot promise any benefits to you or others from your participation in this research. However the study sponsor will cover the cost of one IVF cycle for your benefit, including storage of the embryos for three months and up to two embryo transfers.We cannot promise that mature eggs will be recovered from the procedure, or that the procedure will result in a pregnancy, or that the procedure will result in the birth of a baby, or that the baby will be free of birth defects.

Potential benefits to others include all women undergoing IVF or egg freezing in the future, as this research will help develop a method that will hopefully require less time, fewer injections, and better outcomes from the process. Additionally, this research will benefit women with conditions that are incapable of receiving a longer stimulation treatment, such as women with polycystic ovarian syndrome or cancer patients.

You will not be paid to participate in this research.

This research may have commercial value. Participation in the study does not confer a right to such commercial value or profit.

What other options do I have besides participating in this research?

This research is not designed to diagnose, treat, or prevent any disease. Participation in this research is completely voluntary. Your alternative is to not participate in the research.

What happens to the information collected for this research?

All specimens and related health information provided to the sponsor will be anonymized and assigned a unique identifier number. The participant's name, medical record number or other easily identifiable information will not be stored with research data. All medical data will be kept by the clinic, along with a unique number key so that the clinic can identify your specimens, if

necessary. The clinic and the sponsor will use all reasonable means to protect your privacy. Research related publications will not identify participants.

Your health information and research record may be shared with people and organizations that conduct or oversee this research, including:

- The research sponsor
- People who work with the research sponsor.
- Governmental agencies
- The IRB that approved this study.

The clinic will protect your information to the extent required by law. We cannot promise complete secrecy.

You will have access to your record of participation in the research and the data that arises directly from it.

Your data will not be deleted in case you change your mind and withdraw the informed consent.

The data collected in this research is anonymized and can be used for future research or distributed to another researcher for future research without further consent.

What if I am injured by participating in this research?

If you are injured or become ill as a result of your participation in this research, call the study doctor immediately. The study doctor will provide emergency medical treatment, or refer you for treatment.

What happens if I agree to participate in this research, but then change my mind later?

If you decide that you no longer want to participate in this research, please inform the clinic as soon as possible. You may change your mind and withdraw from the research without explanation and without penalty or loss of benefits to which you would be entitled. However, the sponsor will not cover the cost of any IVF procedures you choose to perform on your own that are not part of the research.

Who can answer my questions about this research?

If you have questions, concerns, complaints, or feel you have been hurt by this research, please contact the research team at the phone number above on the first page.

You can also contact the CIEI: Address, email and telephone.

If you believe that your rights have been violated or in the event of any complaint, you can contact the INS (General Office for Research and Technology Transfer, OGITT), the regulatory entity for clinical trials, through the following telephone number: 748-1111 ext. 2191 or by communication written through the following email: consultaensayos@ins.gob.pe, or through a formal document presented through the institution's parties' table or go in person to the OGITT at the following address: Cápac Yupanqui 1400, Jesus Maria, Lima 11.

Informed Consent Signature

Please read the statements below, think about your choice, and sign when you are ready. You may also take this form home and discuss it with whomever you wish and then return it to us later if you decide to participate in this research project.

I _____ (Name and surname)

- I have read (or someone has read to me) the information provided in this document.
- I have been informed about the objectives of this study, the procedures, the risks, what is expected of me, and my rights.
- I have been able to ask questions about the study and they have all been answered appropriately. I believe that I understand all the information provided about this clinical trial.
- I understand that my participation is voluntary.
- I understand that I can withdraw from the study at any time, without explanation and without affecting my medical care.
- By signing this document, I agree to participate in this research. I am not giving up any rights.
- I understand that I will receive a signed and dated copy of this document.

Full name of the research subject: _____

_____

Signature of research subject: _____

Date and Time: _____

Staff Obtaining Consent: I spoke with the patient and explained the purpose of this research. I have explained the benefits and risks involved with the experimental stimulation protocol. All

the questions raised have been answered to the satisfaction of the patient. The patient has signed the consent and was given a copy.

Signature of the person obtaining consent	Date and time