Statement of Informed Consent
And
Authorization To Use And Disclose Protected Health Information

Sponsor / Study Title:	**InnovaGyn, Inc. / "A Phase II study to evaluate the delay in ovulation following oral levonorgestrel plus meloxicam compared to placebo in obese but normal menstruating women"**
Protocol Number:	**IG-23-002**
Principal Investigator: (Study Doctor)	**Andrea Lukes, MD, MHSc, ACOG**
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Clinical studies include people who volunteer to take part in a study. Take your time to decide if you want to be part of this experimental research study. If you want to know more about this study first, ask the study doctor or study staff. We can also give you the study information written for study doctors and study staff. Your participation is voluntary.

KEY INFORMATION

You are invited to take part in a research study. This study is evaluating levonorgestrel plus meloxicam (LNG/MEL) as a possible "on-demand" contraceptive. InnovaGyn, Inc. is sponsoring this study.

This is a single-blind study. This means that you, the study doctor, study staff and the sponsor will know the study drugs and the doses that you are given. The central laboratory which analyzes the urine samples obtained from you will not be aware of this information. You will be given the placebo (inactive substance) in the first study treatment cycle, and the LNG/MEL (active study drug) in the second study treatment cycle. These study drugs will be taken by mouth at the clinic at a scheduled visit.

You will not directly benefit from participating in this study. You will receive physical and gynecological exams, laboratory assessments and the potential satisfaction of participating in the development of a new "on-demand" contraceptive option for women. You may get more information about your own health from the study. You will be able to talk with the study staff about your health and healthcare. You may feel good knowing that you are helping study doctors learn about a potential new method of female controlled birth control. This study may lead to a new form of female birth control. Because this is a research study, the study drug will be given to you only during the time you participate in this study, and not after the study is over.

It is very important that you are not planning to become pregnant while you are in the study, which is expected to last up to approximately 3 months.

You and any male partner must continue to use other effective methods of birth control throughout the study (as described later in this consent form).

Participation in this study involves a time commitment, so please consider whether it will fit into your daily schedule.

WHAT IS LEVONORGESTREL + MELOXICAM (LNG/MEL)?

On-Demand contraception is a hormonal, short acting contraceptive that can be taken at the time of intercourse. An experimental On-Demand contraceptive containing levonorgestrel (LNG) and meloxicam (MEL), also called LNG/MEL, has been developed by InnovaGyn, Inc. An experimental use is one that is not approved by the United States Food and Drug Administration (FDA)**.** LNG/MEL contains a type of hormone called a progestin, levonorgestrel (LNG), plus a non-steroidal anti-inflammatory study drug, meloxicam (MEL), and is intended to keep or delay women from releasing an egg, so they do not get pregnant. It also may work by thickening the cervical mucus to prevent the passage of sperm from the vagina and by preventing sperm from fertilizing an egg. Approved levonorgestrel birth control pills and emergency contraception (Plan B) work the same way. Meloxicam has been shown to prevent or delay ovulation in women and primates.

It is not known how well the new LNG/MEL on-demand oral contraceptive will work in preventing a woman from becoming pregnant. This study is intended to help find out what effects the hormones will have on a woman's ovulation (release of an egg from her ovary) after receiving the study drug.

This study is <u>NOT</u> intended to find out how well the study drug works to prevent pregnancy, so if you are sexually active with a male partner, you <u>must</u> use other means of birth control while you are in the study.

The LNG/MEL study drug also does <u>not</u> protect against HIV, AIDS, or other sexually transmitted infections (STIs).

WHY IS THIS STUDY BEING DONE?

The purpose of this study is to find out:

- If ovulation is delayed when using LNG/MEL compared to placebo in obese women.
- If there are any effects of the LNG/MEL study drug on menstrual periods and unanticipated and unscheduled vaginal bleeding.
- The effects the study drug has on the function of the ovaries and uterus.
- If there are side effects from this study drug that are different from what we know about side effects from other hormonal contraceptives.
- If the side effects from this study drug are more serious than the side effects from other hormonal contraceptives

In the section "What are the risks of receiving the LNG/MEL study treatment?", you can learn more about possible serious side effects that could happen to you.

WHAT DOES THE STUDY INVOLVE?

We expect there will be approximately 22 women participating in the study from one (1) site in the United States.

Women who join the study should be generally healthy but obese with a Body Mass Index (BMI) of greater than or equal to 30 with no chronic medical conditions, 18 through 40 years old, and have regular menstrual cycles that start every 24-32 days. They should have a uterus and both ovaries.

To join the study, you should **not** be pregnant and must **not** have had any unprotected heterosexual intercourse during the previous 10 days. If you are enrolled and agree to participate, you must not be at risk of becoming pregnant for your entire time of study participation. If you are sexually active in a heterosexual relationship, either your partner must be surgically sterile with a vasectomy, you must have previously had your tubes tied (tubal ligation) or you must use another non-hormonal method of birth control to prevent pregnancy (such as condoms, diaphragm plus spermicide, or a copper intrauterine device [IUD]). You should **not** currently be using hormonal contraception (a pill, vaginal ring, patch or injection, a hormonal implant or the levonorgestrel releasing intrauterine device). Also, you must understand what is required to take part in the study and be willing to meet the study requirements.

Your total time in the study is expected to last up to 3 months. The screening period will be approximately 2 weeks, the control cycle will be 1 month, the study treatment cycle will be 1 month, and follow up will occur approximately 3 weeks after the end of study treatment. The exact number of site visits is unknown as the study drug is given based on the largest size of the ovarian follicle (cyst) that contains the egg reaching a pre-determined size using a transvaginal ultrasound scan of your ovaries. It is estimated there will be approximately 18 visits over 3 months that will need to be completed during the study.

During screening and pre-study treatment visits, about 1-3 teaspoons of blood will be drawn. During the study, a total of approximately 100 mL of blood (about 20 teaspoons or less than one-half of a cup) will be drawn from you over 3 months. The most blood drawn in a single day will be 18mL, or less than 4 teaspoons.

Your biospecimens collected during this study may be used for commercial profit (even if identifiers are removed) and **you will not share in this profit**.

Once you have decided to participate in the study, you will first sign and date this Statement of Informed Consent Form before any study procedures are done.

WHO SHOULD NOT TAKE PART IN THE STUDY?

Your past medical history and any current medical conditions and medications or therapies will be discussed with you by the study staff to determine if you would be a qualified candidate for the study.

STUDY PROCEDURES

If you agree to be in this study, you will be asked to give your consent by signing and dating this form. The details of these visits are described below. A table of these visits has also been provided later in this form.

At most visits, study staff will collect your vital signs and review the study diary on which you will be asked to record daily occurrence of vaginal bleeding or spotting and any side effects. At pre-study treatment visits and during each menstrual cycle, you will have your blood drawn and a pelvic ultrasound (US) test will be performed. At post-study treatment visits you will drop off your daily morning urine collection.

Urine pregnancy tests will be performed at screening, at your first control cycle visit and your first study treatment cycle visit, and at the exit visit. Serum human chorionic gonadotropin [hCG] testing will be done only if the urine pregnancy test is positive. Pregnancy testing will also be performed whenever there is any question about whether you might be pregnant at any time during the study. This test must be negative for you to continue in the study.

YOUR FIRST VISITS

You will have a screening visit. This visit will occur between the twentieth and twenty-fourth day (20^{th} and 24^{th} day) of your menstrual cycle. The following will occur at the first visit:

1. Read the informed consent form and ask questions about things you do not understand. Before you sign and date the consent form, make sure you understand what this study is about and what you will be asked to do.

2. The study staff needs to make sure the study is right for you. They need to obtain the following:
   a. Information about you, including your date of birth, ethnicity, and race.
   b. Your medical history, including all past and current medical problems, surgeries and gynecological (female reproductive) history. The information collected will include smoking history, history of alcohol or drug use (if you have used either), menstrual cycle history, pregnancy history and current sexual activity information.
   c. Your family history of certain health conditions like blood clots.
   d. Your blood pressure will be measured after you have rested by sitting for 5-10 minutes. If it is elevated, it will be measured three times with a five-minute rest period between the measurements.
   e. Your pulse, weight, and height will be recorded. The study staff will tell you what your body mass index (BMI) is, and it must be greater than or equal to 30 (obese) to qualify for the study.
   f. Tell the study staff about the medicines you are taking or have taken in the previous two weeks. This includes prescriptions, over-the-counter medicines, vitamins, and herbal products.
   g. You will have a complete physical examination, including a breast exam, a pelvic exam (internal female exam), and a cervical Pap smear (unless you have had one recently and the study doctor can obtain the results, or if you are under 21 years old). If you are having symptoms of a vaginal infection, you will also be screened for gonorrhea, chlamydia, and trichomonas.

During the pelvic exam, you will lie on your back with your feet in stirrups. Your study doctor will insert a speculum into your vagina. The speculum gently spreads apart the vaginal walls, allowing your study doctor to see the inside of the vagina and the cervix (opening to the womb). You may feel some slight discomfort when the speculum is placed. If you are due for a Pap smear (this test is used to look for changes in the cells of the cervix that show cervical cancer or conditions that may develop into cancer) or have signs of an infection, swabs will be used to collect samples from your cervix and vagina. If you have a vaginal infection, you may be prescribed medicine for it before you can enroll in the study.

h. Regular blood and urine tests, including urine pregnancy tests are scheduled throughout the study.
i. You will be given a diary to fill out and instructions and supplies for urine collection will be dispensed.

3. Tell the study doctor or study staff:
   a. If you plan to get pregnant in the next few months (you should NOT take part in this study).
   b. If you are breastfeeding, (you should NOT take part in this study. The hormones in the LNG/MEL study drug may pass to your baby through your breast milk).
   c. If you are taking medicines with hormones, medicine for seizures, or medicine for TB (tuberculosis) during the study. You may be removed from the study if you need to start these medicines during the study.
   d. If you smoke cigarettes or use electronic cigarettes ("vaping") and how much you smoke every day.
   e. If you take St. John's Wort.

DURING THE STUDY

After the screening visit is complete, you will contact your study coordinator on the first day of your next menses (menstrual period). Your study coordinator will schedule you to come in on the ninth day (9th day) of your menstrual cycle to begin the control/study treatment cycle procedures.

STUDY VISITS AND STUDY PROCEDURES

PRE-STUDY TREATMENT VISITS CONTROL AND STUDY TREATMENT CYCLES
• Prior to coming into the site for your second visit (on the 9th day of your menstrual cycle) you will begin collecting your morning urine in the provided containers, using the method described to you at the screening visit. • You will come to the study site on the ninth day (9th day) of your menstrual cycle and you will be seen every other day/every day based on the size of the follicle on your ovary and at the discretion of the study doctor. The size of the follicle will determine when you take the Placebo or LNG/MEL study drug. When the study doctor sees a follicle measuring 16-18 mm in any dimension, you will be given the Placebo or LNG/MEL. During pre-study treatment visits the following procedures will occur: The study staff will: – Ensure that you are still eligible for the study, including reviewing any medical history and physical exam findings from your earlier visits.

- Take your pulse and blood pressure.
- Perform a pelvic ultrasound. Before the study procedure, you will be asked to empty your bladder. For the ultrasound, the tip of a small, thin ultrasound instrument (probe) is lubricated with a small amount of gel and inserted in your vagina. Only two to three inches of the instrument are inserted into the vagina. Ultrasound imaging uses sound waves to produce pictures of the inside of the uterus and ovaries. The ultrasound pictures will be shown on a computer monitor. The study doctor will be looking at the thickness of the endometrium (lining of the womb) and number and size of ovarian follicles (fluid filled sacs located just beneath the ovary's surface that contain the immature eggs).
- Take blood samples for hormone tests.
- Ask you for a urine sample for a pregnancy test (only on the first Pre-Study Treatment visit of each cycle).
- Review diary cards and remind you to record your daily bleeding and spotting and any symptoms and to continue collecting your urine each morning as soon as you wake up.
- Ask about medications you have taken and any health problems you have had since your last visit.

- The study staff will discuss the times for your next visits.

DOSING VISIT 1
CONTROL AND STUDY TREATMENT CYCLES

- Your initial dose will occur when the largest (dominant) ovarian follicle measures 16-18mm in any diameter. When the ovarian follicle reaches this dimension, you will take the first dose of the study drug by mouth. You will then be instructed to come back to the site in 48 hours to receive the second dose.
- This will occur during the first, or control, cycle, and again in the second, or study treatment, cycle. You will collect your urine daily for ten (10) more calendar days after your first dose of study drug in each cycle.

DOSING VISIT 2 (48 hours after first dose)
CONTROL AND STUDY TREATMENT CYCLES

- You will be asked to return to the study site 48 hours after your first dose of study drug to receive a second dose given to you by the study staff. Additionally, the following procedures will be performed:
  - Return the daily urine collections
  - Take your pulse and blood pressure.
  - Review diary cards and remind you to record your daily bleeding and spotting and to continue collecting your first morning urine sample

MID CYCLE URINE COLLECTION (Approximately 4 Days after first study drug dose)
CONTROL AND STUDY TREATMENT CYCLES

- You will be asked to return to the study site at approximately the eighteenth day (18^{th} day) of your cycle to drop off your collected urine. Additionally, the following procedures will be performed:
  - Take your pulse and blood pressure.
  - Review diary cards and remind you to record your daily bleeding and spotting and to continue collecting your urine each morning.
  - Ask about medications you have taken and any health problems you have had since your last visit

END OF CYCLE URINE COLLECTION (Approximately 10 Days after first study drug dose) **CONTROL AND STUDY TREATMENT CYCLES**
• You will be asked to return to the study site at approximately the twenty-second day (22nd day) of your cycle to drop off the reminder of your collected urine for each cycle. Additionally, the following procedures will be performed: - Take your pulse and blood pressure. - Review diary cards and remind you to record your daily bleeding and spotting and to stop collecting your urine each morning. - Ask about medications you have taken and any health problems you have had since your last visit
STUDY EXIT
• You will have the study exit visit after the onset of your menses. This will occur approximately 5-10 days after your first menstrual bleed after the Study Treatment (LNG/MEL) Cycle of the study. The following procedures will take place: - Take your pulse and blood pressure. - Review diary cards. - Ask about medications you have taken and any health problems you have had since your last visit. - Ask you for a urine sample for a pregnancy test. - Your diary will be collected. - An Acceptability Questionnaire regarding the study drug taken will be administered.

WILL I STILL HAVE PERIODS?

- It is expected that your period may be delayed after taking the LNG/MEL study treatment.
- If you do have bleeding or spotting after the study treatment, please record the bleeding and/or spotting on the study diary. If you have heavy bleeding after the study treatment, please contact the study staff.
- It is expected that your normal periods should return within a month after receiving the study treatment.

WHAT IF I BECOME PREGNANT DURING THE STUDY?

The LNG/MEL study treatment must not be relied upon as a method of birth control. To take part in this study, you must not be at risk of becoming pregnant. You do not have to be sexually active to take part in this study. If you are sexually active in a heterosexual relationship, either your partner must be surgically sterile with a vasectomy, you must have previously had your tubes tied (tubal ligation) or you must use another non-hormonal method of birth control to prevent pregnancy (such as condoms, diaphragm plus spermicide, or copper IUD.). You will have to use one of these methods the whole time you are in this study. You should consider this before you decide to take part in this study.

Talk to the study doctor or study nurse about what you might do if you become pregnant and do not wish to continue the pregnancy. You should understand what you could do before you give consent to take part in this study.

If you become pregnant during the study, you will be discontinued from the study and complete the study procedures for the Exit Visit. You will be informed about pregnancy options and referral for appropriate care. The study staff will monitor the pregnancy until the pregnancy outcome is known or by a 6- or 12-month follow-up after delivery. The study staff will attempt to estimate the date of conception by performing a pelvic ultrasound and/or pelvic and/or abdominal examination and by looking at your diary information and blood hormone levels.

HOW DO I USE THE DIARY CARDS?

You will get diary cards for the study treatment period and should use the cards every day to record any bleeding or spotting. **Every day, please record if you are having any bleeding or spotting or if you are having none.**

The study staff will review your study diary with you at each visit. Be sure to ask questions if you are not sure how to use your study diary.

HOW DO I COLLECT URINE?

You will be provided paper cups, a large medicine dropper and collection tubes at the screening visit. Your study coordinator will go over instructions on how to properly collect and store your urine samples. You will also be given a copy of the instructions to take home with you. It is very important that you follow these instructions closely.

WHAT ARE THE RISKS OF RECEIVING THE LNG/MEL STUDY TREATMENT?

You may have some side effects we do not expect because we are still learning about this study drug. Because the LNG is the active component of LNG/MEL in the body, we expect that the side effects from LNG/MEL will be like those seen in women using LNG alone. Levonorgestrel is available in combination hormonal oral contraceptives, a progestin only oral pill, subcutaneous (underneath the skin) implant, emergency contraceptive pill and a medicated intrauterine device. The side effects listed below have been reported in people who used LNG (levonorgestrel) in pills, implants, or IUDs (intrauterine devices). Levonorgestrel has a long history as a safe and effective progestin without significant side effects.

Possible side effects of the study drug LNG taken over prolonged periods may include:

- Changes in menstrual bleeding patterns.
- Unanticipated or unscheduled bleeding or spotting.
- Headache
- Dizziness
- Breast tenderness or pain
- Abdominal cramping
- Mood change
- Nausea or vomiting
- Increased vaginal discharge.
- Weight gain

- Flu-like symptoms
- Depression
- Acne

Less likely side effects of the study drug LNG taken over prolonged periods may include:

- Constipation or diarrhea
- Migraine headache
- Hair loss
- Abnormal hair growth (increased hair growth and/or hair loss)
- Weight loss

Rare side effects of the study drug LNG taken over prolonged periods may include:

- Severe allergic reactions - Symptoms may include:
  - Rash
  - Hives
  - Itching
  - Difficulty breathing
  - Tightness in the chest
  - Swelling of the mouth, face, lips, or tongue

MEL (Meloxicam) is a well-known non-steroidal anti-inflammatory study drug (NSAID) used to treat and reduce the pain of arthritis. It is principally taken daily by older men and women for chronic arthritic or muscular pain. There is an increased risk of cardiovascular disease such as deep vein thrombosis (blood clot) and myocardial infarction (heart attack) with chronic daily administration of non-steroidal anti-inflammatory drugs that is also age related. Gastric ulcers and gastrointestinal bleeding are associated with chronic administration of a NSAID at any age. A rare but potentially fatal skin inflammation could occur with meloxicam use. The side effects listed below have been reported in people who used MEL consistently over longer periods of time.

Possible side effects of the study drug MEL taken over prolonged periods may include:

- Diarrhea
- Upper respiratory tract infection
- Influenza-like symptoms.
- Indigestion
- Nausea/vomiting

Less likely side effects of the study drug MEL taken over prolonged periods may include:

- Bleeding from the bowel

Uncommon side effects of the study drug MEL taken over prolonged periods may include:

- Heart attacks
- Blood clots in the leg
- Stroke

Rare side effects of the study drug MEL taken over prolonged periods may include:

- Skin reactions

There may be other unknown side effects of the LNG/MEL study treatment.

It is not known if a woman using this LNG/MEL study treatment is at a higher risk of serious side effects than she would be if she used an FDA approved birth control.

You should contact your study staff and study doctor listed on the first page of this form immediately if any events occur. If your study doctor cannot be reached, and you have significant problems then you should seek medical treatment at the nearest medical facility available to you.

Study Drug Interactions

There are some drugs (prescription and non-prescription) that may cause problems when taken with the LNG/MEL study drug. The study staff will carefully review all the drugs you are taking before allowing you to use the study drug. If any other health care provider prescribes any new drug(s) for you while you are in this study, please tell the study doctor before you take the new drug. You could also have that provider talk to the study doctor before prescribing the new drug. Do not take any new over-the-counter drugs or dietary supplements while you are in this study unless you first check with the study doctor.

Unknown Risks

There may be other side effects that are unknown and that we cannot predict.

Risks related to study procedures:

- **Blood Collection (Venipuncture):** Venipuncture is taking blood from a vein by needle. Risks associated with drawing blood from your arm include momentary discomfort and/or bruising. Infection, inflammation of a vein, excess bleeding, clotting, or fainting are also possible, although unlikely. Blood samples will be taken with each ultrasound visit. Fasting (avoiding food and drink except water) blood samples will be taken at the screening visit.
- **Gynecological Exams and Pap Smears:** Gynecological exams and pap smears may cause some slight pain or cramping. Some women may experience temporary spotting or bleeding afterward.
- **Diary, Acceptability Questionnaire and Medical History Questions:** Some of the questions you will be asked may seem personal or embarrassing. They may upset you. You may refuse to answer any of the questions that you do not wish to answer.

IS MY PARTICIPATION IN THIS STUDY VOLUNTARY?

Participation in this study is voluntary. If you do not want to be in this study, you will still receive any of the services otherwise available to you at this study site.

WHEN SHOULD I CONTACT MY STUDY DOCTOR?

You should contact the study doctor or study staff whenever you have any concerns or questions about the study or your health.

HOW WILL THE STUDY HELP ME OR OTHERS?

There are no direct benefits for the women participating in the study. This study may lead to a new form of female birth control.

HOW LONG DOES THE STUDY LAST?

We expect that your participation in the study will last approximately 3 months, but the exact time is not known. Ask the study doctor for your estimated recovery time from the study treatment or procedures done during your participation in this study.

WHO IS WORKING ON THIS STUDY?

The study is supported by contributions from InnovaGyn Inc. InnovaGyn Inc. is involved with the conduct of the study and is the sponsor. If the LNG/MEL study drug is approved by the health authorities such as the U.S. Food and Drug Administration for sale and is sold as a female birth control, InnovaGyn Inc. may earn money from it.

The study doctor and the study staff will not earn any money from the LNG/MEL study drug if it is sold as birth control. InnovaGyn Inc. pays the study staff during the study.

The Principal Investigator of the Research Grant from the National Institutes of Health for this study has stock in InnovaGyn, Inc., and is a co-Patent holder on the investigational product. The site's study doctor and study staff who manage the study do not have any conflicts of interest.

ALTERNATIVES TO PARTICIPATION

This study is for research purposes only. The only alternative is to not participate in this study.

COSTS OF BEING IN THE STUDY

The study drug and all tests, study procedures and visits required by the study are provided at no cost to you.

WILL I BE PAID FOR THE STUDY?

You could receive up to $960.00 if all study visits are completed according to the following schedule:

Screening - $100
Control cycle Enroll -pre-study treatment visits- $150.
Control cycle – Dose 1 - $75
Control cycle – Dose 2 - $55
End of cycle urine collection - $100.
Study Treatment cycle – pre-study treatment visits - $150.
Study Treatment cycle – Dose 1 - $75

Study Treatment cycle – Dose 2 - $55
End of cycle urine collection - $100.
Exit Visit - $100.

You will be paid following each completed cycle visit or at the end of your participation in the research study. If you do not finish the study, you will only be paid for the visits you completed.

If the amount exceeds $600 within a calendar year, an IRS Form 1099 will be filed with the Internal Revenue Service, with a copy going to you.

If any new products, tests, or discoveries resulting from the research have potential commercial value, you will not be compensated or benefit financially.

WHAT HAPPENS IF I NEED MEDICAL TREATMENT?

If you become ill or are hurt while you are in the study, get the medical care that you need right away. You should inform the healthcare professional treating you that you are participating in this study.

The study doctor will talk with you about any medical problems you may have. She or he may send you to other doctors for medical care. If you have questions, talk with your study doctor at the telephone number listed on the first page of this form.

Emergency contact: If you are having a serious medical problem such as needing to go to the emergency room or have surgery, get the medical care you need right away and call the study doctor at their 24-hour telephone number listed on the first page of this form. The study doctor needs to know you had a serious medical problem.

If you get hurt <u>because of the study</u> and you need medical care, the study doctor will help you. You will not have to pay for any emergency care expenses that are directly related to conditions caused by the study and provided by the study care doctor. The study will not be obligated to pay for any other medical care.

To pay these medical expenses, the sponsor will need to know some information about you like your name, date of birth, and social security number or Medicare Health Insurance Claim Number. This is because the sponsor must check to see if you receive Medicare and if you do, report the payment it makes to Medicare.

You or your insurance company will be billed for any medical care, as medical care at no cost is not available. Financial compensation for research related injury or illness, lost wages, disability, or discomfort is not available from Carolina Women's Research and Wellness Center. In no way does signing and dating this consent form waive your legal rights nor does it relieve the study doctors, Sponsor or involved institutions from their legal and professional responsibilities.

PROTECTING THE PRIVACY OF YOUR HEALTH DATA

Your signature on this form will authorize (give permission for) the study staff to collect and use information that can identify you. You are also giving permission for study staff to disclose (share) your identifiable information with others as described below.

Certain people and organizations will need to see, copy, and use your health data so that they can do their part in the study. They are called 'authorized users.' Authorized users will be given access to and may make copies of your health data. This health data may or may not include your name. It may be traced back to you even if it does not include your name.

Authorized users may include:

- Representatives of InnovaGyn Inc.
- Representatives of Advarra IRB (an Institutional Review Board that reviews this study).
- Representatives of Carolina Women's Research and Wellness Center
- The Food and Drug Administration (FDA) and other US governmental agencies.
- Government agencies to whom certain diseases (like HIV, hepatitis, and STDs) must be reported.
- Governmental agencies of other countries.
- Labs working with the sponsor on this study.
- Other authorized users.

To ensure that your information collected for this study will be kept private, your name will not be used whenever possible. A code will be used instead of your name. All your study data will be kept in a secure location.

Your health data needs to be shared for research and other reasons. Therefore, complete privacy of your health data cannot be promised. However, sharing your health data will be guided by professional standards and the law.

Information from this study may be presented at meetings or published in medical journals. The information included at meetings or in journals will not include your name or information that can easily be traced back to you.

For your safety, you should tell your regular health care provider that you are in this study.

If you decide to be in this study, the study doctor and study staff will use and share health data about you to conduct the study. Health data may include:

- Your name
- Address
- Phone number
- Date of birth
- Medical history
- Information from your study visits, including all test results.

Health data may come from your study records or from existing records kept by your doctor or other health care workers.

For this study, the study staff may share health data about you with authorized users. The sponsor and those working for the sponsor may use the health data sent to them:

- To see if the study drug works and is safe.
- To compare the study drug to other drugs.
- For other research activities related to the study drug.

Once your health data has been shared with authorized users, it may no longer be protected by federal privacy law and could possibly be used or disclosed in ways other than those listed here.

Identifiers might be removed from your identifiable private information or identifiable biospecimens collected during this study and could then be used for future research studies or distributed to another investigator for future research studies without additional informed consent.

Researchers can look closely at large amounts of your genetic information by sequencing, or "reading," every letter in your DNA (your genome). Reading a person's entire genetic code is called whole genome sequencing. The research will not include whole genome sequencing (for example, sequencing of a human germline or somatic specimen with the intent to generate the genome or exome sequence of that specimen).

Your permission to use and share health data collected during this study about you will not end when you exit the study. However, you may take back your permission to use and share health data about you at any time by writing to the study doctor at the address listed on the first page of this form. If you do this, you will not be able to stay in this study. No new health data that identifies you will be gathered after your written request is received. However, health data about you that has already been gathered may still be used and given to others as described in this form.

Research results that are clinically relevant, including individual research results, will be disclosed to you under these conditions: Your right to access your health data in the study records will be suspended during the study to keep from changing the study results. When the study is over, you can access your study health data. If it is medically necessary during this study, your study records will be made available to you or to others who are treating you.

If you decide not to sign this form, you will not be able to take part in the study.

We will do everything we can to keep others from learning about your participation in this study. To further help us protect your privacy, the study is covered by a Certificate of Confidentiality from the National Institutes of Health. With this Certificate, the study doctors may not disclose study information that may identify you in any Federal, State, or local civil, criminal, administrative, legislative, or other proceedings, or be used as evidence, for example, if there is a court subpoena.

Study information protected by this Certificate cannot be disclosed to anyone else who is not connected with the study unless:

1. There is a law that requires disclosure (such as to report child abuse or communicable diseases but not for legal proceedings).
2. You have consented to the disclosure, including for your medical treatment; or
3. The study information is used for other scientific research, as allowed by federal regulations protecting research subjects.

Disclosure is required, however, for audit or study evaluation requested by the agency that is funding this study or for information that is required by the Food and Drug Administration (FDA).

You should understand that a Confidentiality Certificate does not prevent you or a member of your family from voluntarily releasing information about yourself or your involvement in this study. If you want your study information released to an insurer, medical care provider, or any other person not connected with the study, you must provide consent to allow the study doctors to release it. This means that you and your family must also actively protect your own privacy.

Finally, you should understand that the study doctor is not prevented from taking steps, including reporting to authorities, to prevent serious harm to yourself or others.

WHOM TO CONTACT ABOUT THIS STUDY

During the study, if you experience any medical problems, suffer a research-related injury, or have questions, concerns, or complaints about the study, please contact the Study doctor at the telephone number listed on the first page of this consent document. If you seek emergency care, or hospitalization is required, alert the treating physician that you are participating in this research study.

An institutional review board (IRB) is an independent committee established to help protect the rights of research subjects. If you have any questions about your rights as a research subject, and/or concerns or complaints regarding this research study, contact**:**

- By **mail**:
  Study Subject Adviser
  Advarra IRB
  6100 Merriweather Dr., Suite 600
  Columbia, MD 21044
- or call **toll free**: 877-992-4724
- or by **email**: adviser@advarra.com

Please reference the following number when contacting the Study Subject Adviser: Pro00070907.

A description of this clinical trial will be available on http://www.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 Web site at any time.

BEING A STUDY VOLUNTEER

Entering a research study is voluntary.

- You may always say no. You do not have to take part in the study.
- If you start a study, you may stop at any time. You do not need to give a reason.
- If you do not want to be in a study or stop the study at a later time, you will not be penalized or lose any benefits.
- If you stop, you should tell the study staff and follow the instructions they may give you.

Your part in the research may stop at any time for any reason, such as:

- The sponsor or the study doctor decides to stop the study.
- The sponsor or the study doctor decides to stop your part in the study for your safety.

- You need additional medicine.
- You do not follow the study rules.
- You have a new injury or illness.
- You decide to stop.

You may be asked to stop the study even if you do not want to stop.

NEW INFORMATION ABOUT THE STUDY

You will be told about any new information found during the study that may affect whether you want to continue to take part.

STATEMENT OF CONSENT AND AUTHORIZATION

I have read this form and its contents were explained. I agree to be in this research study. I also give permission to the study staff to use and share my health data for the purposes listed above. All my questions were answered to my satisfaction. I will receive a signed and dated copy of this form for my records.

I am not giving up any of my legal rights by signing this form. Nothing in this form is intended to change applicable federal, state, or local laws.

_____ ____/____/____
Signature of Research Subject Date

_____
Printed Name of Research Subject

STATEMENT OF PERSON EXPLAINING CONSENT AND AUTHORIZATION

I have carefully explained to the subject the nature and purpose of the above study. There has been an opportunity for the subject to ask questions about this research study and this form. I am available to answer any questions that the subject has about this study and this form.

_____ ____/____/____
Signature of Person Explaining Consent and Authorization Date

_____
Printed Name of Person Explaining Consent and Authorization

_____ ____/____/____
Signature of Study doctor Date
(If Not Person Explaining Consent)

_____
Printed Name of Study doctor
(If Not Person Explaining Consent)