Androgen Excess as a Cause for Adipogenic Dysfunction in PCOS Women

NCT01889199

Informed Consent
2-26-2020

UNIVERSITY OF CALIFORNIA LOS ANGELES
CONSENT TO PARTICIPATE IN RESEARCH

Study Title: Androgen Excess Causes Adipogenic Dysfunction in PCOS Women

Lay Title: A Study to Learn More about Polycystic Ovarian Syndrome (PCOS)

INTRODUCTION

Daniel Dumesic, MD and his associates from the Department of Obstetrics and Gynecology at the University of California, Los Angeles are conducting a research study.

The researchers will explain this study to you. **Research studies are voluntary and include only people who choose to take part.** Please take your time about deciding whether to participate in this study. Before deciding:

- You can discuss this study with friends and family.
- You can also discuss it with your health care doctor or request a second opinion.
- If you have any questions, you can ask the researchers for more information before deciding to participate.

The research team is asking you to be in this study because you are a lean woman between the ages of 18 and 35 years. For this study, women with Polycystic Ovarian Syndrome (PCOS) and women without PCOS are eligible to participate.

WHY IS THIS STUDY BEING DONE?

The purpose of this research study is to collect specimen samples and study medical information from women with PCOS and women without PCOS. The goal is to learn more about the changes that take place in the body that result in PCOS. Flutamide is a Food and Drug Administration (FDA)-approved medication used to treat prostate cancer in men, which acts by blocking the action of male hormones. The investigator of this study wants to know if flutamide will help block the male hormones found in women that may cause PCOS.

Both groups of women will undergo the same evaluations and procedures during the first 2 months. After the first 2 months, women without PCOS will have completed their participation in this study. Women with PCOS will be asked to take a pill once a day for 6 complete 28-day cycles and then continue to take the medication until all the post

treatment assessments have been completed. Participants will be asked to return to the office once a month for an exam and blood tests. The pill will either be a drug called flutamide or an inactive substance known as a placebo. Flutamide is not approved by the FDA for use in women or for the treatment of PCOS. Neither you nor your doctor will know if you are receiving the drug or placebo. At the end of the 6 complete 28-day cycles the same evaluations and tests that were performed in the first 2 months will be repeated.

The following definitions may help you understand how this research study is

designed: Randomized: assigned to a group by chance (similar to

flipping a coin)

Double Blind: neither you nor your doctor will know if you are receiving the study drug Flutatmide or a placebo

Placebo: a pill that does not contain a medication (i.e.

sugar pill) Glucose Tolerance Test: glucose is the sugar the body uses for energy. This test is done to learn how your body processes glucose.

This study is being funded by the National Institute of Child Health and Human Development.

HOW MANY PEOPLE WILL TAKE PART IN THIS STUDY?

We anticipate that 150 women will be enrolled in this study at UCLA (40 without PCOS and 110 with PCOS).

WHAT WILL HAPPEN IF I TAKE PART IN THIS STUDY?

The study procedures will take place at UCLA Westwood Campus in the 200 Medical Plaza Building, 100 Medical Plaza Building, the Clinical Translational Research Center, Ronald Reagan Medical Center, and/or Room 22-265 in the Center for Health Sciences.

Before you begin the study:

Before you begin the study, you will need to agree to use a non-hormone type of birth control for the duration of your participation in this study. If you have not undergone permanent sterilization, examples of acceptable types of birth control are an IUD (without hormones) or spermicidal jelly in combination with a diaphragm or condoms.

You will be asked to provide the name, phone number(s), and email address for someone we can contact in the event of an emergency or if we are unable to communicate directly with you.

During the study:

If you take part in this study, the researcher(s) will ask you to do the following:

All Study Participants

Appendix I at the end of this consent form provides a flow sheet of the study procedures. The order in which the procedures are performed may vary (i.e. you may have DXA before the Frequently-Sampled Intravenous Glucose Tolerance Test, etc). If you would like a copy of any of the results of the study tests or procedures, they will be provided to you free of charge.

Initial Visit

- This consent form will be reviewed with you and anyone you wish to have present. If you choose to participate, you will sign the consent form and HIPAA Authorization form. You will be given a copy for your records.
- The doctor will ask you questions regarding your past medical history, family medical history, and lifestyle to determine if you are eligible to participate in this study.
- If you are not eligible to participate in this study, no further study related office visits or procedures will be performed.
- If you are eligible to participate, you will undergo the following:
    - Physical Exam
    - An assessment of your skin
    - Height, weight, waist and hip measurements
    - Transvaginal (Appendix II)" or abdominal ultrasound of your ovaries (if the investigator thinks the transvaginal ultrasound might be too painful for you) Blood tests - approximately 1 teaspoon (6 ml) of blood will be drawn from your vein. All of the blood samples in this study will be used to detect any abnormal hormone levels.
    - A pregnancy test will be performed.
    - Complete questionnaires regarding your feelings about various areas of your health, quality of your life, and your family history

of PCOS and/or diabetes. You have the right to refuse to answer any questions that you do not wish to answer. If your responses to the questionnaires suggest that you may be suffering from severe depression or that you may pose a risk to yourself or others, you will be referred for the appropriate follow-up care.

- It is estimated that this visit will take approximately 2 hours.

Women with and without PCOS

If you are eligible and choose to continue participation, you will undergo the following tests and procedures. You will be given separate instructions on how to prepare for the tests.

Frequently-Sampled Intravenous Glucose Tolerance Test (FSIGT) and Blood Tests

- Approximately 5 tablespoons (64 ml) of blood will be drawn from your vein for research purposes.
- The first blood draw will be sent to the laboratory f or an immediate test of your progesterone level, which indicates whether or not you are ovulating. If the progesterone test indicates that you are ovulating, the Frequently-Sampled Intravenous Glucose Tolerance Test will not be able to be performed that day and will need to be rescheduled.
- A Frequently-Sampled Intravenous Glucose Tolerance Test (FSIGT) will be performed. You will be given instructions on how to prepare for the test, which include not eating or drinking anything except water after midnight on the day of the test. A small amount of glucose will be injected into your vein. Shortly thereafter, a small amount of insulin will also be injected in your vein so that researchers can learn more about how your body reacts to glucose and insulin. Two small catheters will be attached to your veins in order to remove the blood samples so that you **will** not have to be stuck with a needle at each time interval. Your blood will be drawn 20, 15, and 5 minutes and at time 0 immediately **before** infusion of the glucose. Insulin will be injected 20 minutes after the glucose injection. Your blood will be drawn at 2, 4, 8, 19, 22, 30, 40, 50, 70, 90, and 180 minutes **after** the glucose injection. A total of approximately 2-3 tablespoons (28-42 ml's) will be removed from your vein for the FSIGT test.
- If subjects have PCOS, an additional 4Ml (approximately 1 teaspoon) of blood will be drawn for a complete blood count and comprehensive metabolic panel in order to assure that there are no abnormalities in these blood values before they begin taking flutamide or placebo.
- It is estimated that this visit will take approximately 5-6 hours.

DEXA Scan

- In order to be sure that you are not ovulating, approximately ½ teaspoon (2 ml's) of blood may be drawn and sent to the laboratory for an immediate test of your progesterone level before your DEXA scan. If the progesterone test indicates that you are ovulating, the test(s) may not be able to be performed that day and may need to be rescheduled.
- You will be asked to ingest only a clear liquid diet beginning at midnight on the day of the DEXA scan.
- Your bone density and body fat composition will be assessed by a test called a DEXA Scan.
- It is estimated that this visit will take approximately 2 hours.
- Your medical images will be performed at UCLA. The imaging studies are performed as part of this research study and will not be reviewed or interpreted by a UCLA radiologist. Any information regarding the imaging findings should be directed to the study PI.

Removal of Abdominal Fat

- In order to be sure that you are not ovulating, approximately ½ teaspoon (2 ml's) of blood may be drawn and sent to the laboratory for an immediate test of your progesterone level before the removal of fat. If the progesterone test indicates that you are ovulating, the fat removal may not be able to be performed that day and may need to be rescheduled.
- You will be asked to ingest only a clear liquid diet beginning at midnight on the day of the procedure to remove abdominal fat.
- You will be given local anesthetic and a small amount of fat approximately the size of a quarter will be removed from under the skin in your lower abdomen.
- It is estimated that this visit will take approximately 2 hours.

Women who do not have PCOS will conclude their participation in this study at this point. No further procedures for this study will be conducted.

Women with PCOS will continue participation as described below.

Women with PCOS will be asked to do the following:

- Take one pill (either placebo or flutamide) each morning before breakfast for 6 complete 28-day cycles. The drug flutamide has not

been approved by the FDA for use in women or for the treatment of PCOS.

- Complete a short diary of 7-8 questions regarding what time you took the pill, whether you had any menstrual bleeding, any changes in your health, any medications you took, if you exercised that day, and a brief summary of your diet.
- Collect a sample of your first morning urine once a week and store it until your next clinic visit. You will be given instructions regarding the collection and storage of the samples.
- Return to the UCLA Clinic once a month for the following:
    - A brief physical exam including a measurement of your height, weight, waist, and hips. Review any symptoms you may have experienced during the past month.
    - Bring your prescription bottles so that the pills can be counted.
    - Bring your weekly urine samples.
    - Bring your completed diaries.
    - Have blood tests (pregnancy test, complete blood count, comprehensive metabolic panel) – approximately 1 teaspoon (5 ml) of blood will be drawn.
    - After the third and sixth cycle, you will be asked to complete questionnaires regarding your feelings about various areas of your health and the quality of your life. You have the right to refuse to answer any questions that you do not wish to answer. If your responses to the questionnaires suggest that you may be suffering from severe depression or that you may pose a risk to yourself or others, you will be referred for the appropriate follow-up care.
- After the third and sixth cycle, you will also have an assessment of your skin, and a transvaginal ultrasound of your ovaries.
- At the sixth cycle, approximately 1 teaspoon (5 ml) of blood will be drawn. This will be used to test for levels of testosterone, a complete blood count, and a comprehensive metabolic panel.It is estimated that each of these visits will take approximately 1 hour
- You will be asked to continue taking the flutamide or placebo until the procedures listed below are completed. Every effort will be made to complete these procedures as quickly as possible.

After completing flutamide/placebo

Frequently-Sampled Intravenous Glucose Tolerance Test and Blood Tests

- Approximately 6-7 tablespoons (90-105 ml) of blood will be drawn from your vein for research purposes.
- The first blood draw will be sent to the laboratory for an immediate test of your progesterone level, which indicates whether or not you are ovulating. If the progesterone test indicates that you are ovulating, the Frequently-Sampled Intravenous Glucose Tolerance Test will not be able to be performed that day and will need to be

rescheduled.

- A Frequently-Sampled Intravenous Glucose Tolerance Test (FSIGT) will be performed. You will be given instructions on how to prepare for the test, which include not eating or drinking anything except water after midnight on the day of the test. A small amount of glucose will be injected into your vein. Shortly thereafter, a small amount of insulin will also be injected in your vein so that researchers can learn more about how your body reacts to glucose and insulin. Two small catheters will be attached to your veins in order to remove the blood samples so that you **will** not have to be stuck with a needle at each time interval. Your blood will be drawn 20, 15, and 5 minutes and at time 0 immediately **before** infusion of the glucose. Insulin will be injected 20 minutes after the glucose injection. Your blood will be drawn at 2, 4, 8, 19, 22, 30, 40, 50, 70, 90, and 180 minutes **after** the glucose injection. Two small catheters will be attached to your veins in order to remove the blood samples so that you will not have to be stuck with a needle at each time interval. A total of approximately 3 tablespoons (45 ml's) will be removed from your vein for the FSIGT test.
- It is estimated that this visit will take approximately 5-6 hours.

DEXA Scan

- In order to be sure that you are not ovulating, approximately ½ teaspoon (2 ml's) of blood may be drawn and sent to the laboratory for an immediate test of your progesterone level before your DEXA scan. If the progesterone test indicates that you are ovulating, the test**(s) ma**y not be able to be performed that day and may need to be rescheduled.

- You will be asked to ingest only a clear liquid diet beginning at midnight on the day of your DEXA scan.
- Your bone density and body fat composition will be assessed by a test called a DEXA Scan.
- It is estimated that this visit will take approximately 2 hours.
- Your medical images will be performed at UCLA. The imaging studies are performed as part of this research study and will not be reviewed or interpreted by a UCLA radiologist. Any information regarding the imaging findings should be directed to the study PI.

Removal of Abdominal Fat

- In order to be sure that you are not ovulating, approximately ½ teaspoon (2 ml's) of blood may be drawn and sent to the laboratory for an immediate test of your progesterone level before the removal

of fat. If the progesterone test indicates that you are ovulating, the fat removal may not be able to be performed that day and may need to be rescheduled

- You will be given local anesthesia and a small amount of fat approximately the size of a quarter will be removed from under the skin in your lower abdomen on the opposite side from where the first biopsy was taken.
- You will be asked to ingest only a clear liquid diet beginning at midnight on the day of the procedure to remove abdominal fat.
- It is estimated that this visit will take approximately 2 hours.

30 days after last pill

- Physical Exam
- Blood tests (pregnancy test, complete blood count, comprehensive metabolic panel) - approximately 1 teaspoon (6 ml) of blood will be drawn from your vein.
- It is estimated that this visit will take approximately ½ - 1 hour.

6 months after completion of the study procedures

Participants who have received the flutamide or placebo will be contacted by phone 6 months after the study procedures have been completed. You will be asked if you have experienced any health problems or become pregnant since you completed the study procedures. There will be no compensation for the phone call. It is estimated that this phone call will take approximately ¼ - ½ hour.

HOW LONG WILL I BE IN THIS STUDY?

If you have PCOS, this study will last approximately 10 months with a follow-up phone call 6 months after completion of the study procedures. If you do not have PCOS, your participation will last approximately two months. There will be no long-term follow-up review of medical records, telephone follow-up or physical exam.

WHAT KINDS OF RISKS OR DISCOMFORTS COULD I EXPECT?

Known risks and discomforts:

The possible risks and/or discomforts associated with the procedures described in this consent form include:

Flutamide:

Symptoms of liver injury, including loss of appetite, nausea and vomiting, fatigue, stomach or abdominal pain, flu-like symptoms and jaundice (yellowing of the skin or whiteness of the eyes), have occasionally been reported with the use of flutamide. Such liver injury, however, is related to the dose of flutamide and is reversible following discontinuation of the drug. For this reason, the flutamide dose chosen for this study is below the dose previously reported to harm the liver, with long-term (>1 year) flutamide studies showing no harmful liver effects at 125 mg orally on a daily basis. Additional risks of flutamide therapy include anemia, photosensitivity, breast tenderness, retention of fluid, discharge of fluid from your nipples, rash, hypertension, hot flashes, central nervous system reactions, decreased interest in having sexual relations, diarrhea, and anorexia. For these reasons, monthly blood tests will be done to monitor the safety of flutamide and this medication will be discontinued if there are any temporary changes in blood or liver function. Brownish urine also can occur and is due to a metabolite of flutamide. Call the study doctor immediately if you notice any yellowing of skin or eyes.

Placebo Pills

There are no known risks from taking a placebo pill.

Risks of a Transvaginal Ultrasound:

You may experience some discomfort from having the ultrasound probe placed in your vagina and moved during the exam.

Ultrasound imaging has been used for over 20 years and has an excellent safety record. It is non-ionizing radiation, so it does not have the same risks as x-rays or other types of ionizing radiation.

Even though there are no known risks of ultrasound imaging, it can produce effects on the body. When ultrasound enters the body, it heats the tissues slightly. In some cases, it can also produce small pockets of gas in body fluids or tissues (cavitation), although this is extremely rare. The long-term effects of tissue heating and cavitation are not known.

Risks of Blood Draw:

Drawing blood may cause temporary pain from the needle stick, bruising or swelling at the site, and rarely, infection or fainting.

Risks of Procedure to Remove Fat from Under the Skin:

Potential problems during the collection of the subcutaneous abdominal fat specimens include a temporary discomfort from the local injection of anesthetic

and/or pain, bleeding, and infection at the site of the lower abdominal incision. In very rare circumstances, local injection of anesthetic and/or the removal of abdominal fat may be associated with fainting with or without convulsions. Only experienced surgeons will perform the procedure to remove the small amount of fat, which should not significantly distort the contour of the abdominal skin.

Risks of Frequently-Sampled Intravenous Glucose Tolerance Test:

Insulin (introduced into your body during the intravenous glucose tolerance test) is the body's natural hormone for lowering blood sugars. If your blood sugars fall rapidly, you may experience mild dizziness, nausea, vomiting, shortness of breath, increased heart rate or sweating. If these effects occur, they are easily detected and treated with administration of supplemental sugar through the indwelling catheter, thereby raising the blood sugar. This condition is only temporary and has no known long-term health impact. The glucose (commonly called sugar) infused through the catheter as part of the intravenous glucose tolerance test may cause an initial feeling of warmth and flushing of the face, which are both transient symptoms that rapidly resolve. You will be asked to arrive for your testing after having fasted from midnight the night before. In light of the prolonged fast, you may feel hungry during the testing.

Risks of Radiation from DEXA Scans:

Since the radiation procedures are all standard of care, the amount of radiation you will receive is the same as that for similar patients who are not participating in this study.
Therefore, you will not be exposed to any additional radiation by participating in this study.

Known Reproductive Risks:

You should not become pregnant while on this study because the drugs in this study and the DEXA testing can affect an unborn baby. Women should not breastfeed a baby while on this study. Therefore, you need to use effective birth control while on this study. If you have not undergone permanent sterilization, examples of acceptable types of birth control are an IUD (without hormones) or spermicidal jelly in combination with a diaphragm or condoms. You must use birth control starting at the beginning of your participation in this study and for one month after.

Unknown Risks to Women of Child Bearing Potential and Pregnant Women:

Women formerly thought to be infertile may ovulate and become pregnant when taking flutamide. This drug may cause abnormalities in a fetus. For

this reason, if you believe

that you are pregnant or have a chance of becoming pregnant you should not participate in this study. A serum pregnancy test will be performed before the start of study procedures and monthly throughout your participation in this study. If you are pregnant, you will not be allowed to participate in the study. If you do participate in this study, you must use a medically effective form of birth control before entering the study, while participating in the study, and for at least one month after stopping the study. If you become pregnant during the study, tell the researchers right away.

***Unknown Risks to Infants**:*

The side effects of flutamide on infants are not known, therefore if you are currently breastfeeding you cannot participate in this study.

Loss of Confidentiality:

As this study involves the use of your identifiable, personal information, there is a chance that a loss of confidentiality will occur. The researchers have procedures in place to lessen the possibility of this happening (see "How will my information about me and my participation be kept confidential?" section below).

Unknown Risks and Discomforts:

The experimental treatments may have side effects that no one knows about yet. The researchers will let you know if they learn anything that might make you change your mind about participating in the study.

ARE THERE ANY BENEFITS IF I PARTICIPATE?

Possible benefits to me or others in society:

There will be no direct benefit to you from participating in this study. However, this study will help the researchers learn more about the differences between women with and without PCOS and the role of the drug flutamide in patients with PCOS. Hopefully this information will help in the treatment of future patients PCOS.

The possible benefits you may experience from being in this study include the additional knowledge about your health from undergoing the exams, blood tests and procedures. If you would like a copy of any of the results of the study tests or procedures, they will be provided to you free of charge.

WHAT OTHER CHOICES DO I HAVE IF I DON'T WANT TO PARTICIPATE?

If you decide not to take part in this study, or if you withdraw from this study before it is completed, the following alternative procedures or courses of treatment are available:

- Standard care for women with and without PCOS

CAN THE RESEARCHERS REMOVE ME FROM THIS STUDY?

The researchers may end your participation in this study for a number of reasons, such as if your safety and welfare are at risk, if you do not follow instructions or if you miss scheduled visits. If you become pregnant, you will be removed from the study. The researchers or the study sponsor might also decide to stop the study at any time.

If you decide to stop being in the study, or are removed from the study, or the study is stopped the researcher will ask you to return for a final close-out visit or evaluation and return unused study medication.

HOW WILL INFORMATION ABOUT ME AND MY PARTICIPATION BE KEPT CONFIDENTIAL?

The researchers will do their best to make sure that your private information is kept confidential. Information about you will be handled as confidentially as possible, but participating in research may involve a loss of privacy and the potential for a breach in confidentiality. Study data will be physically and electronically secured. As with any use of electronic means to store data, there is a risk of breach of data security.

Use of personal information that can identify you:

You will be assigned a study code number that will be linked to your personal information.

How information about you will be stored:

Information about you will be stored in password-protected computers and locked offices.

People and agencies that will have access to your information:

Dr. Dumesic and the research team will have access to the research

data/records/specimens and will share information through secured electronic files and/or or study charts that are kept in locked offices.

The research team, authorized UCLA personnel, and regulatory agencies such as the Food and Drug Administration (FDA), may have access to study data and records to monitor the study. Research records provided to authorized, non-UCLA personnel will not contain identifiable information about you. Publications and/or presentations that result from this study will not identify you by name.

To help us protect your privacy, we have received a Certificate of Confidentiality from the National Institutes of Health. The researchers can use this Certificate to legally

refuse to disclose information that may identify you in any federal, state, or local civil, criminal, administrative, legislative, or other proceedings, for example, if there is a court subpoena. The researchers will use the Certificate to resist any demands for information that would identify you, except as explained below.

The Certificate cannot be used to resist a demand for information from personnel of the United States Government that is used for auditing or evaluation of Federally funded projects or for information that must be disclosed in order to meet the requirements of the federal Food and Drug Administration (FDA).

You should understand that a Certificate of Confidentiality does not prevent you or a member of your family from voluntarily releasing information about yourself or your involvement in this research. If an insurer, employer, or other person obtains your written consent to receive research information, then the researchers may not use the Certificate to withhold that information.

The Certificate of Confidentiality will not be used to prevent disclosure to state or local authorities if there are concerns about harm to you or others. You should understand that a Certificate of Confidentiality does not prevent you or a member of your family from voluntarily releasing information about yourself or your involvement in this research. If an insurer, employer, or other person obtains your written consent to receive research information, then the researchers may not use the Certificate to withhold that information.

How long information from the study will be kept:

Information will be kept for an indefinite period of time.

ARE THERE ANY COSTS FOR TAKING PART IN THIS STUDY?

The study sponsor will supply and pay for the cost of supplying and

administering the study drug and the extra-related laboratory tests. However, you and your insurer will be billed for the costs of all other study procedures as these are considered standard of care.

You or your insurer will be billed for the costs of any standard medical care you receive during your participation in the study and you will be responsible for any associated co- payments and deductibles. There is a possibility that your medical insurance company may not cover these costs because you are in a research study. If this happens you might have unexpected expenses from being in this study, such as the costs associated with treating side effects. Financial counseling and itemized cost estimates are available upon request.

WILL I BE PAID FOR MY PARTICIPATION?

Personal information about you, including your name, address, and social security number will be released to the UCLA Accounting Office for the purpose of payment.

Women who are found to be not eligible after completing the history and questionnaires will receive $15. Women who are found to be not eligible after completing the history, questionnaires, physical exam and blood tests will be paid $20.

Women without PCOS may receive up to $200 for their participation in this study. If you are in this group, you will receive 2 payments as follows:

1) $20 after the eligibility visit is completed
2) $165 after the FSIGT, DXA, and Fat Removal, visits are completed.

Women with PCOS may receive up to $605 for their participation in this study. If you are in this group, you will receive 4 payments as follows:

1) $20 after the eligibility visit is completed
2) $165 after the FSIGT, DXA and Fat Removal, visits are completed.
3) $255 after completion of all 6 of the 28 day cycles when you will be taking flutamide or a placebo
4) $165 after the repeat FSIGT, DXA, Fat Removal and the 30 day after last pill visits are completed.

Women who are found to be ovulating on the day of the study procedure will be paid
$15 and the procedure will be rescheduled.

You will be asked to complete a form so that a check can be mailed to you within 2 months of completing the intervals described above. If you are paid $600 or more for participation in this study, your payment will be reported to

the IRS.

You will be be reimbursed for your parking expenses for each study visit. You will not be reimbursed for any other out of pocket expenses, such as transportation fees.

WHAT OTHER THINGS SHOULD I CONSIDER BEFORE PARTICIPATION?

Use of my specimens:

Any specimens (e.g., tissue, blood, urine) obtained for the purposes of this study will become the property of the University of California. Once you provide the specimens you will not have access to them. The University may share your specimens in the future with other researchers or outside institutions. Information that identifies you will not be shared with anyone outside of UCLA. The specimens will be used for research and such use may result in inventions or discoveries that could become the basis for new products or diagnostic or therapeutic agents. In some instances, these inventions and discoveries may be of potential commercial value and may be patented and licensed by the University. You will not receive any money or other benefits derived from any commercial or other products that may be developed from use of the specimens.

MAKING YOUR CHOICES ABOUT FUTURE RESEARCH

UCLA researchers may contact me in the future to ask me to take part in other research studies. Please circle your answer in the boxes below.

YES	NO

UCLA researchers may share my coded specimens and medical record information with other researchers who are studying conditions including but not limited to PCOS.
These researchers will not have access to my personal identity.

YES	NO

_____ _____
Signature of Participant Date/Time

_____ _____
Signature of Investigator Date/Time

Researcher Financial Interests in this Study

The study team has no personal financial interest in any outside entity funding this study or other personal financial interests in entities that might reasonably be affected by the research.

WHO CAN I CONTACT IF I HAVE QUESTIONS ABOUT THIS STUDY?

The Research Team:

You may contact Dr. Daniel Dumesic at (310) 794-5542 with any questions or concerns about the research or your participation in this study. You can also call the UCLA Page Operator at (310) 825-6301 to reach Dr. Dumesic 24 hours a day, 7 days week.

UCLA Office of the Human Research Protection Program (OHRPP):

If you have questions about your rights while taking part in this study, or you have concerns or suggestions and you want to talk to someone other than the researchers about the study, you may contact the UCLA OHRPP by phone: (310) 825-5344; by email: mirb@research.ucla.edu or U.S. mail: UCLA OHRPP, 11000 Kinross Ave., Suite 211, Box 951694, Los Angeles, CA 90095-1694.

Public Information about this Study:

ClinicalTrials.gov is a website that provides information about federally and privately supported clinical trials. A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. This website will not include information that can identify you. At most, the website will include a summary of the results. You can search this website at any time.

WHAT HAPPENS IF I BELIEVE I AM INJURED BECAUSE I TOOK PART IN THIS STUDY?

It is important that you promptly tell the researchers if you believe that you have been injured because of taking part in this study. You can tell the

researcher in person or call him/her at the number listed above.

If you are injured as a result of being in this study, UCLA will provide necessary medical treatment. The costs of the treatment may be covered by the University of California or billed to you or your insurer just like other medical costs, depending on a number of factors. The University and the study sponsor do not normally provide any other form of compensation for injury. For more information about this, you may call the UCLA Office of the Human Research Protection Program at 310-825-5344 or send an email to mirb@research.ucla.edu.

WHAT ARE MY RIGHTS IF I TAKE PART IN THIS STUDY?

Taking part in this study is your choice. You can choose whether or not you want to participate. Whatever decision you make, there will be no penalty to you and you will not lose any of your regular benefits.

- You have a right to have all of your questions answered before deciding whether to take part.
- Your decision will not affect the medical care you receive from UCLA.
- If you decide to take part, you can leave the study at anytime.
- If you decide to stop being in this study you should notify the research team right away. The researchers may ask you to complete some procedures in order to protect your safety.
- If you decide not to take part, you can still get medical care from UCLA.

HOW DO I INDICATE MY AGREEMENT TO PARTICIPATE?

If you agree to participate in this study you should sign and date below. You have been given a copy of this consent form and the Research Participant's Bill of Rights to keep. You will be asked to sign a separate form authorizing access, use, creation, or disclosure of health information about you.

SIGNATURE OF THE PARTICIPANT

_____
Name of Participant

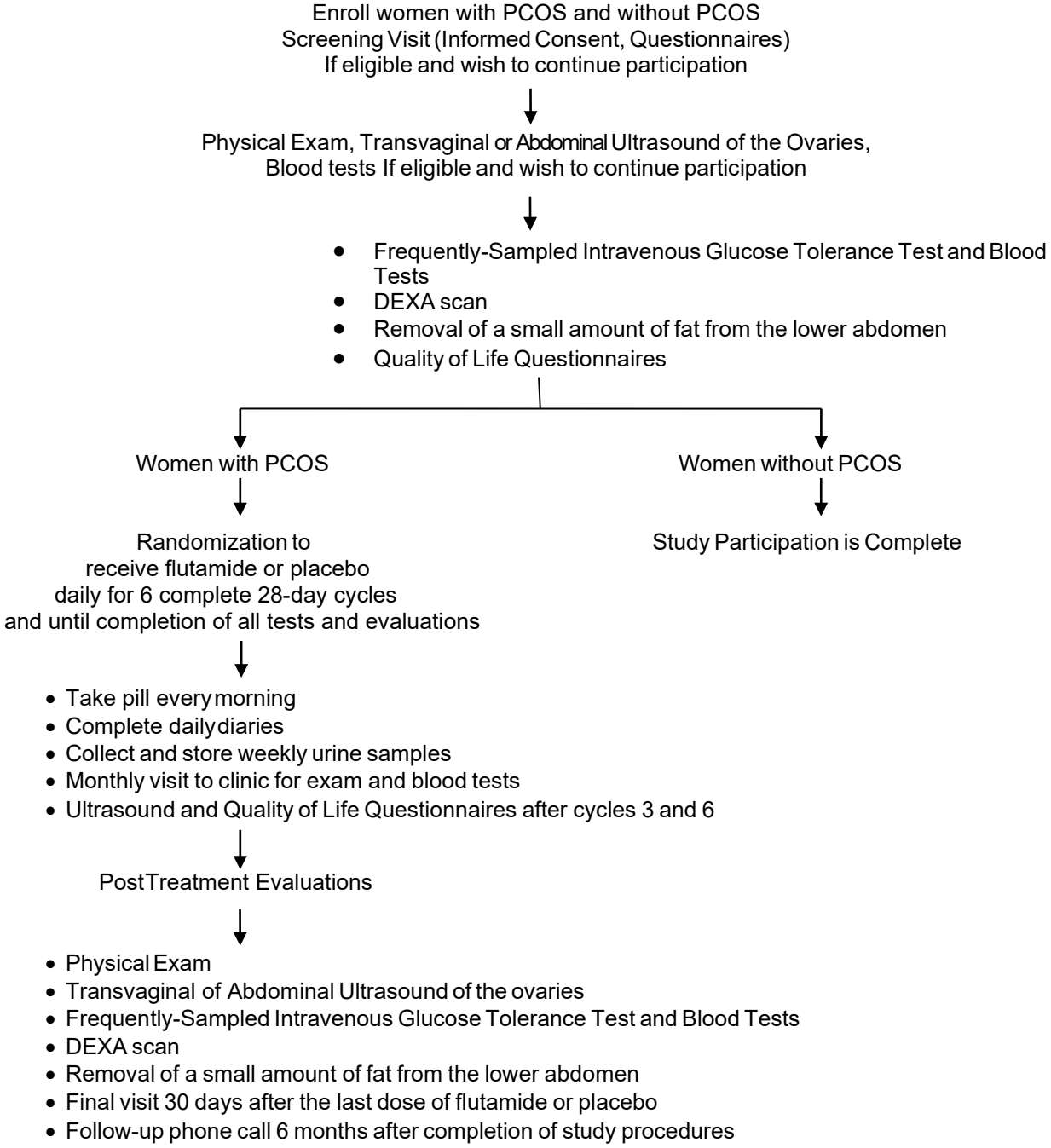
_____ _____
Signature of Participant Date/Time

SIGNATURE OF PERSON OBTAINING CONSENT

_____ _____
Name of Person Obtaining Consent Contact Number

_____ _____
Signature of Person Obtaining Consent Date/Time

Appendix I - Study Flow Sheet



Appendix II

Transvaginal Ultrasound