Consent of an Adult to Be in a Research Study

In this form "you" means a person 18 years of age or older who is being asked to volunteer to participate in this study.

Participant's Name_____Medical Record # _____

Principal Investigator:	Christopher R. McCartney, MD University of Virginia Center for Research in Reproduction PO Box 800391 Charlottesville, VA 22908 Telephone: (434) 243-6911
Sponsor:	University of Virginia, Department of Endocrinology and Metabolism

What is the purpose of this form?

This form will help you decide if you want to be in the research study. You need to be informed about the study, before you can decide if you want to be in it. You do not have to be in the study if you do not want to. You should have all your questions answered before you give your permission or consent to be in the study.

Please read this form carefully. If you want to be in the study, you will need to sign this form. You will get a copy of this signed form.

Who is funding this study?

This study is being funded by the University of Virginia's Department of Endocrinology and Metabolism.

Why is this research being done?

This is a study about how the normal menstrual cycle is controlled, and how the menstrual cycle can become abnormal in women with polycystic ovary syndrome (PCOS). In order to understand these things, we will study several hormones in the blood. Hormones are substances made in the body that are sent directly out into the bloodstream to increase or decrease the function of certain organs, glands, or other hormones. We will study the interactions of the luteinizing hormone (LH), gonadotropin-releasing hormone (GnRH), progesterone, and estrogen.

When progesterone and estrogen do not work normally, GnRH pulses remain fast: this occurs in PCOS and can contribute to abnormal menstrual cycles, inability to ovulate (release an egg from the ovary), and problems with fertility (ability to conceive and have children).

This study is being done to learn how quickly progesterone slows luteinizing hormone pulses. This will be done by measuring your luteinizing hormone pulses before and after you take a single dose of progesterone. For

scientific reasons, your luteinizing hormone pulses will also be measured before and after you take a single dose of an inactive cherry-flavored syrup (placebo).

During this study, you will take one dose of progesterone. This dose of progesterone will produce progesterone levels that are lower than the levels your ovaries normally produce during the second half of the menstrual cycle.

The progesterone used in this study is identical to the progesterone your body makes, and the progesterone is approved by the Food and Drug Administration (FDA). The FDA-approved progesterone is put into a cherry-flavored syrup by the research pharmacy at UVA: this formulation is not specifically approved by the FDA, although the FDA has given us permission to do this.

You will also take estrogen (i.e., estrogen patches) for a total of 8 days. The doses of estrogen will produce estrogen levels that are similar to the levels your ovaries normally produce near the middle part of the menstrual cycle (i.e., around the time of ovulation).

You are being asked to be in this study, because you are a healthy woman between the ages of 18 and 35, with normal menstrual cycles or because you are a woman with PCOS.

NOTE: All procedures noted in the consent are being done for research purposes only.

Up to 90 people will be in this study at UVA.

How long will this study take?

Most women will need to come to the Clinical Research Unit (CRU) or alternate UVA clinic for 5 visits over approximately 3 or 4 months. The overnight visits may be done at a hotel.

The first visit is a consent and screening visit and will take approximately two hours. Two visits are for single blood draws, and these visits will take approximately 15 minutes each. Two visits are overnight admissions at the Clinical Research Unit (CRU), alternate UVA hospital unit, or hotel lasting approximately 26 hours each.

NOTE: If your lab results are abnormal, we will ask you to come to the CRU to repeat this test. Therefore, the total number of visits may be greater than 5. Sometimes overnight admissions need to be delayed due to scheduling conflicts, menstrual cycle irregularities, or if your blood counts are low. Thus, the overall time for study completion can be greater than 4 months.

What will happen if you are in the study?

Visit 1: SCREENING (will take approximately 2 hours to complete):

If you agree to participate, you will sign this consent form before any study related procedures take place. Before you can start in the study, there will be a screening period. You will have tests and procedures during this time to make sure you are eligible and it is safe for you to participate. These include the following:

- A study doctor will record a family and personal medical history
- You will have a physical exam including a check of your vital signs (blood pressure, heart rate, height, weight, waist and hip circumference)
- Blood (about 3 teaspoons) will be drawn for screening laboratory tests. You should arrive in a fasting state. If you decide to participate in the study but you have eaten within the previous 8 hours, you will need to return to have the blood work completed. When you return you should not eat or drink anything except water for 8 hours prior to having your blood drawn.
- We will measure various types of hormones in your blood (including testosterone and estrogen), check your liver and kidney function, blood counts, sugar, insulin, chemistries, and perform a pregnancy test.
- Body Composition Measurements (fat and muscle):
  - Your body fat and muscle will be measured by a device called a BodPod.
  - This requires that you sit down in a fiberglass shell chamber that looks something like a giant egg with a window.
  - You will wear a bathing suit provided by the CRU while inside the Bod Pod to increase the accuracy of body fat measurement.
  - We will ask you to sit quietly in the BodPod chamber for two separate 1-minute measurements. You will simply sit still in the chamber and breathe normally. It is possible that we would ask you to do an additional measurement if the results don't match closely enough. Then we will ask you to put nose clips on your nose and breathe into a tube while we take one final measurement.
  - The entire BodPod procedure takes approximately 15 minutes.

- If you have a low red blood cell count (i.e., low hematocrit and hemoglobin), you have the option to take iron supplements for 1-2 months. After the iron treatment, we will recheck your hematocrit and hemoglobin prior to study continuation. You will not be allowed to continue with the study if your hematocrit and hemoglobin are low after two months of iron treatment.

If the screening tests show that you are eligible to participate in the study, we will work with you to schedule your first overnight admission.

STUDY TREATMENT

VISIT 2: Outpatient visit before first overnight admission (lasting about 15 minutes)
Clinical Research Unit (CRU) or clinic at the University of Virginia Hospital.

- Four to 5 days before your first overnight admission, you will have a single blood sample (less than 1 teaspoon) drawn in the CRU or clinic to measure a progesterone level and a pregnancy test.
- If it has been over 25 days since your most recent blood counts, we will also check blood counts at this time.
- If it has been about 3 months since your most recent metabolic tests (i.e., tests that help ensure good general health), we will repeat these tests at this time.
- At this visit, you will obtain estrogen patches, which you will begin to use 3 days before your first overnight admission.

***** Estrogen use before the first overnight admission**

- If you are a woman with regular menstrual cycles, you will begin to use estrogen patches on cycle day 4-8 (with cycle day 1 being the very first day of menstrual bleeding). If you are a woman with PCOS, you will begin to use estrogen patches no earlier than cycle day 4.
- You will use 2 estrogen patches at a time, and these patches are applied to the skin of the abdomen.
- The estrogen patches will produce blood estrogen levels that are normally produced by the body during parts of the menstrual cycle. The patches will be changed after 2 days; you will use the patches for a total of 4 days.

VISIT 3: First Inpatient Admission

- After being on the estrogen patches for exactly 3 days, you will be admitted to the CRU, hospital unit, or hotel for tests that will last approximately 26 hours. (Notably, the estrogen patches will be continued throughout this overnight study). You will be asked to report to the CRU, hospital unit or hotel by 6 p.m.
- You will be able to eat a normal diet (three meals per day and snacks) during the overnight admission, but we will ask that you eat only what is provided to you during the admission.
- An intravenous (IV) catheter will be placed into a vein in your arm. An IV catheter is a small flexible tube that is inserted into a vein guided by a needle. Once the catheter is in place, the needle is removed and replaced by a cap that allows blood to be drawn.
- Blood may be collected for a pregnancy test and laboratory testing. Specifically, a pregnancy test will be done only if it was not obtained 4-6 days before your overnight admission; blood counts will be checked if they have not been checked in the previous month; and metabolic tests will be checked if they have not been checked in the previous 3 months.

- Starting at 8 p.m., we will draw a blood sample every 10 minutes, and this will continue for 24 hours (that is, until 8 p.m. the following day).
- You will need to stay awake during typical waking hours (7 a.m. to 10 p.m.).
- You will be able to sleep from 10 p.m. to 7 a.m.
- At night, we will monitor your sleep.
- During your overnight admission, you will wear an actigraph. The actigraph looks like a watch, and it is worn on your wrist. The actigraph will help us know when you are awake and when you are asleep.
- In some cases, we will only use the actigraph (above) to monitor your sleep. However, in some cases, we may monitor your sleep in more detail (described below).
    - Around 8 p.m. a sleep technician will place several small button-sized sensors on your head. These sensors will tell us if you are awake or asleep.
    - You can go to the bathroom whenever you wish during this time. The sensors will remain attached to you, but the sensors will be disconnected from the recorders when you go to the restroom.
- Approximately 205 milliliters (or about 14 tablespoons) will be collected during a single inpatient admission.
- At 6 a.m., you will receive one dose by mouth of either progesterone syrup or "placebo" syrup. The placebo syrup is exactly like the progesterone syrup except that it does not contain any progesterone.
    - You will be randomly assigned (like the flip of a coin) to receive either progesterone or placebo at 6 a.m. Neither you nor your doctor can choose which treatment you are assigned for the first admission. Neither you nor your doctor will know which study treatment you will get during the first admission until the study is done. But if your doctor needs to know, the people doing this study can find out.
    - The progesterone syrup will briefly produce blood progesterone levels that are normally produced by the body during parts of the menstrual cycle.

- Blood collection (every 10 minutes) will continue until 8 p.m. The inpatient admission ends at 8 p.m., and at this time the estrogen patches will be removed.
- You will be asked to begin iron tablets to help your body rebuild blood cells.

VISIT 4: Outpatient visit before second overnight admission (lasting about 15 minutes)

Clinical Research Unit (CRU) or clinic at the University of Virginia Hospital.

- Four to 5 days before your second overnight admission, you will have a single blood sample (less than 1 teaspoon) drawn to measure a progesterone level and a pregnancy test.
- If it has been over 25 days since your most recent blood counts, we will check blood counts at this time.

- If it has been about 3 months since your most recent metabolic tests (i.e., tests that will help ensure good general health), we will repeat these tests at this time.
- At this visit, you will obtain estrogen patches, which you will begin to use 3 days before your second admission.

***** Estrogen use before the second overnight admission**

- If you are a woman with regular menstrual cycles, you again will begin to use estrogen patches on cycle day 4-8 (with cycle day 1 being the very first day of menstrual bleeding). If you are a woman with PCOS, you will again begin to use estrogen patches no earlier than cycle day 4.
- You will use 2 estrogen patches at a time, and these patches are applied to the skin of the abdomen.
- The estrogen patches will produce blood estrogen levels that are normally produced by the body during parts of the menstrual cycle. The patches will be changed after 2 days; you will use the patches for a total of 4 days.

VISIT 5: Second Inpatient Admission

- After being on the estrogen patches for exactly 3 days, you will be admitted to the CRU, hospital unit, or hotel for tests that are nearly identical to those of the first study. The only difference is that you will receive placebo syrup at 6 a.m. if you had received progesterone syrup during the first admission, and you will receive progesterone syrup at 6 a.m. if you had received placebo syrup during the first admission.
- The second admission ends at 8 p.m. The estrogen patches will be removed, and you will be asked to continue iron tablets for an additional 30 days.
- Your participation in the study is complete at the end of this inpatient admission.

NOTE: For scientific reasons, inpatient admissions should occur when progesterone levels are low, and progesterone levels are low during what is called the follicular phase of the cycle. If you have irregular periods, it can be difficult to know for sure that you are in the follicular phase of your menstrual cycle at the time of a scheduled admission. This is why we check progesterone blood levels shortly before your scheduled admission (to make sure the progesterone level is low enough to do the admission). However, in women with irregular periods, progesterone levels may rarely increase between the time that progesterone level is checked and when the inpatient admission actually occurs. Thus, women with irregular periods may rarely be studied when progesterone levels are too high. We would not know that this happened until blood samples from the inpatient admission are analyzed, which usually occurs within 1-2 months of the final inpatient admission. If it is found that your progesterone level was too high during an inpatient admission, we may ask you to consider repeating this overnight admission (along with the outpatient blood draw 1-2 days before the admission) approximately 8-12 weeks after your second overnight admission (the exact timing would depend on your menstrual cycle). In this situation, you would not be obligated to repeat the study admission, and you would

still receive $300 for completing the study (as outlined above). However, if you are asked to repeat one of the overnight study admissions, and you do so, you would be compensated an extra $100 for this extra study admission.

STUDY TIME CAPSULE:

BEFORE FIRST OVERNIGHT ADMISSION:

- 4-6 days before first overnight admission: single blood sample drawn at the CRU or clinic.
- 3 days before first overnight admission: begin estrogen patches.

FIRST OVERNIGHT ADMISSION (on menstrual cycle day 7-11 for women with regular cycles; no earlier than cycle day 7 for women with PCOS**):**

- Admit to CRU, hospital unit, or hotel (at 6 p.m.) for 26 hour study. At end of overnight study, estrogen patches are discontinued, but iron is started.

BEFORE SECOND OVERNIGHT ADMISSION:

- 4-6 days before second overnight admission: single blood sample drawn at the CRU or clinic.
- 3 days before second overnight admission: begin estrogen patches.

SECOND OVERNIGHT ADMISSION (on menstrual cycle day 7-11 for women with regular cycles; no earlier than cycle day 7 for women with PCOS**):**
Admit to CRU, hospital unit, or hotel (at 6 p.m.) for 26 hour study. At end of overnight study, estrogen patches are discontinued, but iron is continued for 30 days.

END OF STUDY:

At the conclusion of admission #2, your participation in the study is complete.

What are your responsibilities in the study?

You have certain responsibilities to help ensure your safety. These responsibilities are listed below:

- You must come to each study visit.
- You must be completely truthful about your health history.
- Follow all instructions given.
- You should tell the study doctor or study staff about any changes in your health or the way you feel.
- Ensure that the study drug is taken as instructed, keep the study drug in a safe place away from other children, return any unused study drug at each visit, and report any lost or missed tablets.
- Ensure that the study drug is taken only by you, the person for whom it has been prescribed.
- Answer all of the study-related questions completely.

- Inform the study doctor or study staff as soon as possible if you have to take any new medications, including anything prescribed by a doctor or those that you can buy without a prescription (over-the-counter), including herbal supplements and vitamins. The study doctor will let you know if you can take these medications.

Study Schedule

	Screening Visit	**(Outpatient blood draw)**	**Study medication**	**Overnight Admit #1**	**outpatient blood draw**	**Study Medication**	**Overnight Admit #2**
Study Week	0	4-6 days before overnight admission 1	3 days before first overnight admission	Menstrual day 7-11 if regularly cycling or no earlier than day 7 for women with PCOS	4-6 days before overnight admission 2	3 days before first overnight admission	Menstrual day 7-11 if regularly cycling or no earlier than day 7 for women with PCOS
Informed Consent	x						
Review study eligibility	x	x		x	x		x
Medical History	x			x (brief)			x (brief)
Vital signs	x			x			x
Physical Exam	x			x (brief)			x (brief)
Blood draw (for laboratory testing)	x	x		x	x		x
Estrogen &Progesterone Dispensed		x		x	x		x

Specimens

Blood testing

The total amount of blood we will take will be 29 tablespoons during the course of the entire study. The blood we take will be tested to measure the amount of red blood cells, how well your kidneys and liver work, and a variety of hormone levels. Approximately 29 tablespoons of blood will be drawn during the course of the entire study. When these tests are done any blood left over will be thrown away. It will not be stored for any future testing.

If you want to know about the results before the study is done:

During the study you are having an investigational procedures done. The purpose of the procedures is NOT to diagnose any disease or abnormality you may have. Because the procedures are investigational there is no way for the study leader to understand if the results are "normal" or "abnormal". However, if any test results are concerning, your study leader will let you know.

In addition, as the research moves forward, your study leader will keep you informed of any new findings about the research itself that may be important for your health or may help you decide if you want to continue in the study. The final results of the research will not be known until all the information from everyone is combined and reviewed. At that time you can ask for more information about the study results.

When these tests are done any leftover sample will be thrown away. It will not be stored for any future testing.

What are the risks of being in this study?

Risks and side effects related to the study procedures and drugs (estrogen, progesterone, iron) include:

Likely

- Dark bowel movements with iron supplements (temporary and not serious)

Less Likely

- The estrogen skin patch can cause local skin irritation. This would be temporary and not serious. Mild skin irritation is expected to occur in one out of ten people using the estrogen patches. We reduce the possibility of this by changing the patch every 2 days to a new location on the abdomen.
- You may experience mild nausea, swelling or breast tenderness, headache, dizziness, and changes in bleeding patterns. These symptoms are usually minor and will disappear after stopping the estrogen skin patch. One or more of these symptoms are expected to occur in fewer than one out of ten people using the estrogen patches for four days.
- Withdrawal of the estrogen treatment does not usually produce symptoms, but you may have mild hot flashes. This is expected to occur in fewer than one out of ten people using the estrogen patches for four days.
- When taking progesterone, you may experience stomach pain and bloating, skin rash, acne, itching, unusual vaginal bleeding or discharge, and muscle or joint pain (these effects would be temporary and not serious). However, these symptoms are very unlikely to occur since you will take only one dose of progesterone.

- Longer-term use of progesterone has been associated with depression, irritability, and emotional changes. These symptoms are not expected since only one dose of progesterone is given.
- You may feel tired, particularly when exercising, because of mildly low red blood cell count related to blood withdrawal (this would be temporary and not serious).
- Iron supplements can cause stomach upset or constipation (these effects would be temporary and not serious). You should take your iron tablets with food and a full glass of water. You should also have 8 glasses of water a day and plenty of whole grains, fruits and vegetables for fiber to help prevent these side effects.

Rare but serious

- There are no long-term risks associated with the doses of estrogen and progesterone given during the study. The levels of these hormones in the blood will be similar to those that occur during normal menstrual cycles.
- Higher doses of estrogens can produce or increase hypertension in some women. Long term (over months to years) administration of estrogen has been reported to be associated with the formation of blood clots in the deep veins of the body, similar to the risk of taking birth control pills.

Risks of Sharing the Drug

Do not share the study drug with anyone. It is prescribed only for you and could hurt someone else. Keep it out of reach of children and people not able to read or understand the label.

Blood Donation

If you participate in this study it may affect your ability to donate blood. This study involves a drug that is not approved by the FDA. The American Red Cross guidelines state that, if you take a drug that is not approved by the FDA, you will not be able to donate blood for one year after you take your last dose of study drug. If you have any questions call the organization where you donate blood and talk to one of their nurses.

Risks of having your blood drawn:

Having blood drawn may cause:

- ✓ pain (common),
- ✓ a bruise (sometimes),
- ✓ fainting or passing out (not very often), and
- ✓ infection (rare).

If the people doing the study are exposed to your blood or body fluids in a way that could give them a disease, your blood may be tested. The tests might check for:

- ✓ hepatitis,

- ✓ HIV (Human Immunodeficiency Virus), or
- ✓ other infections.

You and the person exposed would be told the test results. However, your name would be kept private. If your test is positive for hepatitis or HIV or any other infection that may affect your clinical care, we will tell you the results and help you understand what the results mean for you.

Risks of taking blood from an IV catheter:

Risk of Repeated Sticks

Sometimes the catheter stops working. In order to get the blood we need, we may have to stick you again with another needle.

Risk of Heparin Lock Flush: Heparin works by preventing blood clots from forming in IV catheters when they are not in use. Allergic reactions and side effects are rare. You should not use heparin lock flushes if you are allergic to heparin or pork products. Symptoms of allergic reaction may include, rash, itching or swelling at the IV catheter site severe dizziness or trouble breathing. Side effects though very unlikely may include, unusual bleeding or bruising and mild pain at the I.V. site.

Risk of Saline Lock Flush: Saline works by preventing blood clots from forming in IV catheters when they are not in use. Saline is a salt solution. There are no known risks to saline lock flush other than mild pain at the injection site.

A caution about giving too much blood:

Because of the amount of blood being taken, you should not give blood for other reasons for ***3 months***. For example, avoid giving blood at a blood bank or in another research study.

Risks for women:

Subjects are not expected to have any decrease in fertility as a result of study medications. Therefore, sexually active subjects may get pregnant during this protocol. If you become pregnant, the study and all study medications will be discontinued.

If you are pregnant now, or get pregnant during the study, please tell us. Although the drugs and procedures in this study would not be expected to have an adverse effect on a pregnancy or your unborn baby, we cannot guarantee this. Also, you should be sure you do not get pregnant for 4 weeks after the study. Use an effective method of birth control (that does not involve hormones) during this time. Examples of birth control you may use include:

- Condoms
- Jellies or foam
- Withdrawal
- Diaphragm
- Rhythm
- Cervical cap

- Sponge
- Copper IUD (intrauterine device)
- Abstinence

Ask your doctor for more details about the proper birth control method for you. If you become pregnant during this study, you must tell your doctor right away. Your doctor will discuss your treatment and the effect on the pregnancy.

We will be monitoring for pregnancy throughout the course of the study, and it is important that you avoid getting pregnant until the study is completed. If you should become pregnant in spite of taking precautions, please immediately contact the investigator whose phone number is listed on this form and he will provide you with information and/or resources for your consideration.

Other unexpected risks:
You may have side effects that we do not expect or know to watch for now. Call the study leader if you have any symptoms or problems.

Could you be helped by being in this study?

You will not benefit from being in this study. However the information researchers get from this study may help others in the future.

What are your other choices if you do not join this study?

The only other choice is not to be in this study.
If you are an employee of UVa your job will not be affected if you decide not to participate in this study.
If you are a student at UVa, your grades will not be affected if you decide not to participate in this study.

Will you be paid for being in this study?

You will receive up to $300 for participating in and completing this study. You will receive $100 for each completed inpatient admission, and an additional $100 incentive for completing all the admissions and outpatient visits in the study. You should expect to receive your payment approximately 2-4 weeks after the completion of the study. If you are asked by the study team to repeat a study admission after you complete the main part of the study, you will be compensated an extra $100.

If you do not finish the study, you will be paid $ 100 for completing the first admission.

You may be reimbursed for some of your travel expenses. Specifically, if you must drive 50 miles or more (one-way trip) to get to UVa, you will be eligible for travel reimbursement at $25 per trip for up to three trips (total travel reimbursement for the entire study cannot exceed $75).
If you are driving to Charlottesville for other reasons as well (e.g., for work), you will not be reimbursed. You will also not be reimbursed for the cost of lodging.

If you owe money to the University of Virginia or the University of Virginia Medical Center, the money to be paid to you in this study can be withheld to pay what you owe. And if a court has issued a judgment against you, the money may also be withheld to pay the judgment creditor for such things as taxes, fines, or child support that you owe.

By agreeing to be in this study, you are donating your ***blood samples*** for research, and giving up any property rights you may have in them. The results of this research using your donated materials may have commercial value. However, you will not receive any payments.

Will being in this study cost you any money?

The following procedures/tests, which are being done for research purposes, will be provided at no cost to you or your health insurance: ***lab tests, Bod Pod, all study medication (estrogen, progesterone, iron), physician visits***.

You and/or your insurance company must pay for any tests or care given beyond what is required in this study. In addition, you and/or your health insurance may also have to pay for other drugs or treatments that are given to help you control any side effects. You will have to pay for any costs not covered by your health plan. You may be responsible for any co-payments or deductibles. You may wish to ask your insurance company for an estimate of what these costs might be or if pre-approval is required.

Your travel and parking costs will also be reimbursed. See the "Will you be paid for being in this study?" section of this form for more information.

What if you are hurt in this study?

You do not give up any legal rights, such as seeking compensation for injury, by signing this form. If you feel you have been injured as a result of this study you may contact the Principal Investigator or the IRB (phone numbers are located near the end of this form). If you are hurt as a result of being in this study, there are no plans to pay you for medical expenses, lost wages, disability, or discomfort. The charges for any medical treatment you receive will be billed to your insurance. You will be responsible for any amount your insurance does not cover.

What happens if you leave the study early?

You can change your mind about being in the study any time. You can agree to be in the study now and change your mind later. If you decide to stop, please tell us right away. You do not have to be in this study to get services you can normally get at the University of Virginia.

Even if you do not change your mind, the study leader can take you out of the study. Some of the reasons for doing so may include

a) Your study physician is concerned about your health
b) The side effects of the investigational procedures are too dangerous for you
c) You do not follow your doctor's instructions
d) The study sponsor closes the study for safety, administrative or other reasons

How will your personal information be shared?

The UVa researchers are asking for your permission to gather, use and share information about you for this study. If you decide not to give your permission, you cannot be in this study, but you can continue to receive regular medical care at UVA.

If you sign this form, we may collect any or all of the following information about you:

- Personal information such as name, address and date of birth
- Social Security number ONLY IF you are being paid to be in this study
- Your UVA medical records and test results from before and during the study from any of your doctors or health care providers (accessing these records is not usually required)
- NOTE: If we decide that medical records from outside UVA are needed, we will ask your specific permission at that time.

Who will see your private information?

- The researchers to make sure they can conduct the study the right way, observe the effects of the study and understand its results
- People or groups that oversee the study to make sure it is done correctly
- People who pay for this study
- Tax reporting offices (if you are paid for being in the study)
- People who evaluate study results, which can include government agencies that provide oversight such as the Food and Drug Administration (FDA) if the study is regulated by the FDA.
- If you tell us that someone is hurting you, or that you might hurt yourself or someone else, the law may require us to let people in authority know so they can protect you and others.

Some of the people outside of UVa who will see your information may not have to follow the same privacy laws that we follow. We ask them to protect your privacy. However, they may release your information to others, and it may no longer be protected by those laws.

The information collected from you might be published in a medical journal. This would be done in a way that protects your privacy. No one will be able to find out from the article that you were in the study.

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.

What if you sign the form but then decide you don't want your private information shared?

You can change your mind at any time. Your permission does not end unless you cancel it. To cancel it, please send a letter to the researchers listed on this form. Then you will no longer be in the study. The researchers will still use information about you that was collected before you ended your participation. Uva researchers will do everything possible to protect your privacy.

A copy of this consent form will be put in your medical record. (This is not the same as the record of this research study.) This means that everyone who is allowed to see your medical records will be able to find out that you are in this study. This is done so your regular doctors will know what you receive as part of this study. If you have other health problems during the study, they will be able to treat you properly.

Please contact the researchers listed below to:

- Obtain more information about the study
- Ask a question about the study procedures or treatments
- Report an illness, injury, or other problem (you may also need to tell your regular doctors)
- Leave the study before it is finished
- Express a concern about the study

Principal Investigator: Christopher McCartney, MD
Department of Medicine, School of Medicine
PO Box 800391
University of Virginia Health System
Charlottesville, VA 22908
Telephone: (434) 243-6911

What if you have a concern about this study?

You may also report a concern about this study or ask questions about your rights as a research subject by contacting the Institutional Review Board listed below.

University of Virginia Institutional Review Board for Health Sciences Research
PO Box 800483
Charlottesville, Virginia 22908
Telephone: 434-924-9634

When you call or write about a concern, please give as much information as you can. Include the name of the study leader, the IRB-HSR Number (at the top of this form), and details about the problem. This will help officials look into your concern. When reporting a concern, you do not have to give your name.

Signatures

What does your signature mean?

Before you sign this form, please ask questions about any part of this study that is not clear to you. Your signature below means that you have received this information and all your questions have been answered. If you sign the form it means that you agree to join the study. You will receive a copy of this signed document.

Consent From Adult

_____	_____	_____
PARTICIPANT (SIGNATURE)	PARTICIPANT (PRINT)	DATE

To be completed by participant if 18 years of age or older.

Person Obtaining Consent

By signing below you confirm that you have fully explained this study to the potential subject, allowed them time to read the consent or have the consent read to them, and have answered all their questions.

_____	_____	_____
PERSON OBTAINING CONSENT (SIGNATURE)	PERSON OBTAINING CONSENT (PRINT)	DATE

Consent from Impartial Witness

If this consent form is read to the subject because the subject is blind or illiterate, an impartial witness not affiliated with the research or study doctor must be present for the consenting process and sign the following statement. The subject may place an X on the Participant Signature line above.

I agree the information in this informed consent form was presented orally in my presence to the **identified individual(s)** who has had the opportunity to ask any questions he/she had about the study. I also agree that the **identified individual(s)** freely gave their informed consent to participate in this trial.

Please indicate with check box the identified individual(s):

☐ Subject

_____	_____	_____
IMPARTIAL WITNESS (SIGNATURE)	IMPARTIAL WITNESS (PRINT)	DATE