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.

Parents' or Guardians' Permission for Your Child to Be in a Research Study

Agreement of a Child to Be in a Research Study

In this form "you" means the child in the study *and* the parent or guardian.

- ✓ If you are the parent or guardian, you are being asked to give permission for your child to be in this study.
- ✓ If you are the child, you are being asked if you agree to be in this study.

In this form "we" means the researchers and staff involved in running this study at the University of Virginia.

Participant's Name_____

Principal Investigator:	Mark D. Miller, MD University of Virginia Box 800159 Charlottesville, VA 22904-4407 **Telephone: 434-243-0278**

What is the purpose of this form?

This form will provide you with information about this research study. You do not have to be in the study if you do not want to. You should have all your questions answered before you agree to be in this study.

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

Why is this research being done?

Anterior Cruciate Ligament (ACL) reconstruction surgery is a very common procedure in the United States, with over 100,000 being performed each year. ACL reconstruction is surgery to replace the anterior cruciate ligament — one of the major ligaments in your knee. ACL reconstruction surgery uses a graft to replace the ligament. The most common grafts are autografts using part of your own body, such as the tendon of the hamstring tendons. Another choice is allograft tissue, which is taken from a deceased donor. You and your doctor have determined which type of graft will be used for your surgery.

The purpose of this study is to determine the optimal or best placement of your anterior cruciate ligament (ACL) graft. It is unknown whether a graft placed towards the front or the back of the knee will result in a better outcome. This study will help answer that question, and improve patient outcomes.
You are being asked to be in this study, because you have had a knee injury involving your ACL, and (1) are scheduled to have your ACL surgically reconstructed as part of your clinical care, or (2) have had a previous ACL reconstruction.

Up to 100 people will be in this study at UVA, and 135 people at all sites.

How long will this study take?

Your participation in this study will require 1 to 4 study visits (depending on when you sign the research consent) over the2-year period of time after your surgery. If you are enrolled in this study before your surgery, 1 study visit will include your surgery. Each visit may last between 30 minutes and 2 hours. This study will not add any additional time to the surgical procedure you are already having, or have already had.

What will happen if you are in the study?

Note: You will sign a separate consent for your ACL reconstructive surgery that will explain the procedure and the risks involved.

SCREENING (will take about 1 hour):

Visit 1 (Pre-Operative):

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. The tests will be performed at the UVA Sports Medicine Clinic and the Exercise and Sport Injury Laboratory. These include the following:

- Review of your medical history
- An x-ray of your knee
- Physical exam of your knee:
  - During the examination, we will assess your knee function, including range of motion and how loose it is. We will also measure your thigh circumference and how far you can bend and straighten your knee
- Completion of 2 brief questionnaires that take about 10 minutes to complete. These questionnaires ask about*:
  - How does your knee feel
  - Daily physical activities

If you are eligible, you may begin participation in this study at the time of your visit, or return to the clinic at another time before your surgery to begin study procedures.

RANDOMIZATION and STUDY PROCEDURES

Visit 2 (Surgery)

You will be randomly assigned (like the flip of a coin) to 1 of 2 study groups. You have an equal chance of being assigned to any one of the groups. Neither you nor your doctor can choose which group you are assigned. You will not know which study group you will get until the study is done, however, your surgeon will. During surgery, your doctor will drill two holes (tunnels) into the upper (femur) and lower (tibia) bones of your knee. These holes are used to secure the new ACL graft that is being placed in your knee, and is considered a standard of care. The groups of this study will be different in the location of the hole placed in the lower bone of your knee (tibial tunnel).

Group assignment will be determined during surgery, before your ACL graft is secured. Your doctor will measure a distance 35% from the front to the back of the lower bone (tibia) in your knee. A sealed envelope will then be opened to determine whether the ACL graft will be placed in front (anterior) or behind (posterior) the 35% line.

Standard procedure for this surgical technique includes placement of the ACL graft near the 35% line, but may be different according to your doctor.

GROUP 1: Anterior (forward) ACL graft placement.

GROUP 2: Posterior (backward) ACL graft placement

If you have already had your ACL surgically reconstructed, you will only complete the follow up visits as appropriate below depending on the date of your surgery.

FOLLOW UP:

We would like to keep track of your condition for up to 2 years after surgery. There will be 3 scheduled follow up visits at 6, 12, and 24 months after your surgery. If you are unable to come to UVA for a follow up visit, you can contact a member of the study team to arrange a home visit to collect your outcomes. However, not all data can be collected during a home visit. The only data we can collect during a home visit are the patient subjective questionnaires, and the KT-1000 ligament laxity measurement of the knee exam.

All of the following procedures are performed for research purposes.

Visit 3: 6 months post-surgery (will take about 30 minutes)

- Physical examination of your knee
  - Thigh Circumference
  - Range of Motion
  - KT-1000 Ligament Laxity Measurement
- Questionnaires

  - Marx Activity Scale
  - IKDC Subjective Questionnaire

Visit 4: 12 months post-surgery (will take about 1 hour)

- X-ray of your knee
- Physical examination of your knee
  - Thigh Circumference
  - Range of Motion
    KT-1000 Ligament Laxity Measurement
- Questionnaires
  - Marx Activity Scale
  - IKDC Subjective Questionnaire

Visit 5: 24 months post-surgery (will take about 2 hours)

- X-ray of your knee
- Physical examination of your knee
  - Thigh Circumference
  - Range of Motion
- KT-1000 Ligament Laxity Measurement Questionnaires
  - Marx Activity Scale
  - Including IKDC Subjective Questionnaire

- KT-1000 Ligament Laxity Measurement: You will have a device comfortably strapped on your leg while lying down, and your physician will pull the device forward, while you are relaxed to measure how much your lower leg moves. (Should only be a few millimeters). This should not painful. This measures your ligament laxity.

- Thigh muscle strength test* (optional): You will contract your thigh muscle as hard as you can when an electrical stimulus will be delivered directly to the muscle at the front of your thigh. This stimulus may cause you some minor discomfort. If it causes you an intolerable amount of discomfort, you do not have to continue with this portion of data collection. The stimulus in this experiment feels similar to the static electricity shock that is sometimes felt when you touch a doorknob or something else metal. The intensity of a static electricity shock usually ranges from 2000-4000 volts. The maximum voltage that will be delivered in this experiment is 125 volts.

- Gait analysis* (optional): Motion capture sensors will be applied to your feet, calves, thighs, and back. The skin where the sensors will be placed may need to be shaved of hair. You will be asked to walk on a treadmill at a comfortable pace. You will be given time to rest as needed. We will use a computer to record your body motions during all movements.

* Tests will be performed at the Exercise and Sport Injury Laboratory, and are optional. All other tests (review of medical history, physical examination, and x-rays) will be performed at the UVA Sports Medicine Clinic.

What are your responsibilities in the study? (Adult)

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

- 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.
- 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.

What are your/and your parent/legal guardian's responsibilities in the study? (Minor)

You and your parent/legal guardian have certain responsibilities to help ensure your safety.
These responsibilities are listed below:

- Your parent/legal guardian must bring you to each study visit.
- You and your parent/legal guardian must be completely truthful about your health history.
- You and your parent/legal guardian should follow all instructions given.
- You or your parent/legal guardian should tell the study doctor or study staff about any changes in your health or the way you feel.
- You and your parent/legal guardian should answer all of the study-related questions completely.
- You or your parent/legal guardian should 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.

If you want to know about the results before the study is done (Surgery and X-Ray):

During the study your study leader will let you know of any test results that may be important to your health. In addition, as the research moves forward, your study leader will keep you informed of any new findings 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.

If you want to know about the results before the study is done (Strength and Gait):

During the study you are having an investigational test done. The purpose of the test is NOT to diagnose any disease or abnormality you may have. Because the test is 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.

What are the risks of being in this study?

Risks and side effects related to strength testing and knee examination:

Less Likely

- Temporary skin irritation from motion capture skin preparation and sensors
- Muscle soreness from walking during motion capture or thigh muscle strength testing
- Discomfort from electrical stimulus during thigh muscle strength testing
- Slight discomfort from clinical examination of your knee

Risks from radiography (x-ray): 1-3 total
This study involves radiation exposure to your knee. As part of everyday living, everyone is exposed to a small amount of background radiation. Background radiation comes from space and naturally-occurring radioactive minerals. The maximum radiation dose you will receive from these additional views will give your body the equivalent of about 4 days' worth of this natural radiation. This radiation dose is what you will receive from this additional view only and does not include any exposure you may have received or will receive from other tests or exams. The precise risk from this dose is not known but is thought to be small. This radiation exposure is not necessary for your medical care but is necessary to obtain the research information desired. If you are pregnant, you may not participate in this research study. It is best to avoid radiation exposure to unborn children since they are more sensitive to radiation than adults.

Risks from Completing Questionnaires:
Some of the questions asked may make you angry, emotionally upset or stressed out now or at a later time. If this occurs, you can contact the following person for help Joe Hart at 434-924-6187 or jmf3zh@virginia.edu. If you do not wish to answer a question, you may skip it and go to the next question

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 may or may not benefit from being in this study. Possible benefits include: improved outcomes related to the function of your knee. In addition, information researchers get from this study may help others in the future.

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

You do not have to be in this study to be treated for your illness or condition. You can get the usual treatment even if you choose not to be in this study. The usual treatment would include:

- Standard ACL surgery with no randomization of graft placement.

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 be paid $100.00 for finishing this study by check, or $50.00 after completing the 12 month and 24 month visits. If the study leader says you cannot continue, you will be paid the full amount for the study.

You will not receive any compensation for home visits at the 12 and 24 month time points. Compensation is granted for travel expenses and the additional time it takes to perform gait and strength tests during clinic visits for the 12 and 24 month follow up. These additional measures are not done during home visits; therefore you will not receive compensation unless you complete the visits in clinic.

You should get your payment about 3-4 weeks after finishing each visit. The income may be reported to the IRS as income.

If you owe money to any Virginia state agency, the state can use the money you earn in this study to pay those debts. These state agencies include the UVa Medical Center, VCU Medical Center or a college or university. The money may be withheld to pay back debt for such things as unpaid medical bills, taxes, fines, child support. Even if this happens, the money you earn may be reported to the IRS as taxable income.

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:

- X-ray (12 and 24 month only)
- Physician visit (12 and 24 month only)
- Physical examination: knee laxity, range of motion, thigh circumference
- Thigh strength test
- Gait analysis

You will be responsible for all tests or care that are considered standard of care. 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 for an estimate of your financial costs. You may also wish to check with your insurance company before the study starts. Ask what they will cover and if they require you to get their permission before you decide to be in the study.

You will be responsible for the cost of travel to come to any study visit and for any parking costs.

What if you are hurt in this study?

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. You do not give up any legal rights, such as seeking compensation for injury, by signing this form.

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) Your condition gets worse
c) Your physician feels the side effects of study procedures are too dangerous for you
d) New information shows the treatment will not work or is not safe for you
e) You do not follow your doctor's instructions

If you decide to stop being in the study, we will ask you to:

- Contact the study leader

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 health information if required for this study. This may include a review of your medical records and test results from before, during and after the study from any of your doctors or health care providers. This may include mental health care records, substance abuse records, and/or HIV/AIDS records.

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
- Insurance companies or other organizations that may need the information in order to pay your medical bills or other costs of your participation in the study

- Tax reporting offices (if you are paid for being in the study)
- People who evaluate study results, which can include sponsors and other companies that make the drug or device being studied, researchers at other sites conducting the same study, and government agencies that provide oversight such as the Food and Drug Administration (FDA) if the study is regulated by the FDA.

Some of the people outside of UVa who will see your information may not have to follow the same privacy laws that we follow. 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.

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:

Mark Miller, MD
Orthopaedic Surgery, School of Medicine, Box 800159
Charlottesville, VA 22904-4407
Telephone: (434) 243-0278

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

Assent from Child (16-17 years of age)

Consent from the parent/guardian MUST be obtained before approaching the child for their assent.

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

Person Obtaining Assent of the Child (less than 18 years of age)

Consent from the parent/guardian MUST be obtained before approaching the child for their assent.

By signing below you confirm that the study has been explained to the child (less than 18 years of age), all questions have been answered and the child has voluntarily agreed to participate.

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

Parental/ Guardian Permission

By signing below you confirm you have the legal authority to sign for this child.

PARENT/GUARDIAN (SIGNATURE)	PARENT/GUARDIAN (PRINT NAME)	DATE

PARENT/GUARDIAN (SIGNATURE)	PARENT/GUARDIAN (PRINT NAME)	DATE

Person Obtaining Parental/Guardian Permission

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

PERSON OBTAINING PARENTAL/ GUARDIAN PERMISSION (SIGNATURE)	PERSON OBTAINING PARENTAL/GUARDIAN PERMISSION (PRINT NAME)	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
☐ Parent(s)/Guardian of the subject

IMPARTIAL WITNESS (SIGNATURE)	IMPARTIAL WITNESS (PRINT)	DATE