Study Volunteer Initials

Lifespan Affiliate Site where research will be conducted

- ☒ Rhode Island Hospital
- ☐ Bradley Hospital
- ☒ The Miriam Hospital
- ☐ Newport Hospital
- ☐ Gateway Healthcare

Agreement to Participate in a Research Study And Authorization for Use and Disclosure of Information

2013-05
Committee #

Name of Study Volunteer

Effects of Initial Graft Tension on Anterior Cruciate Ligament Reconstruction Ten, Twelve and Fifteen Year Assessment
A. Anterior Cruciate Ligament Reconstructed Subjects

You are being asked to take part in a research study. All research studies at Lifespan hospitals follow the rules of the state of Rhode Island, the United States government and Lifespan. Before you decide whether to be in the study, you and the researcher will engage in the "informed consent" process. During this process, the researcher will explain the purpose of the study, how it will be carried out, and what you will be expected to do if you participate. The researcher will also explain the possible risks and benefits of being in the study, and will provide other information. You should feel free to ask any questions you might have. The purpose of these discussions is for you to decide whether participating in the study is the best decision for you.

If you decide to be in the study, you will be asked to sign and date this form in front of the person who explained the study to you. This form summarizes the information you discussed. You will be given a copy of this form to keep.

1. Nature and Purpose of the Study:

You are being asked to take part in additional follow up visits for the research project entitled "The Effects of Initial Graft Tension on ACL Reconstruction" to further evaluate the changes in your surgical knee. We would like to perform 10, 12 and 15 year follow-up visits, which will include knee examinations, x-rays, strength tests and magnetic resonance images (MRIs) of both of your knees. These visits will allow us to measure the long term mechanical and biological responses of your knee to anterior cruciate ligament reconstruction surgery.

The study is sponsored by NIH/NIAMS (National Institute of Arthritis and Musculoskeletal and Skin Diseases) and the Department of Orthopaedics at Rhode Island Hospital.

2. Explanation of Procedures:

If you take part in this study, a trained physical therapist, associated physicians and technicians will perform the following procedures to your knees. These procedures include questionnaires to assess how you are doing, X-rays, clinical examinations and mechanical measurements of your knee to assess its function and the presence of arthritis. You may also be asked to have MRIs taken to document change in knee geometry. These procedures are described in detail below.

At your 10, 12 and 15 year follow-up visits, you will be asked to fill out four questionnaires (the Tegner, Knee Osteoarthritis Outcome Score, SF-36, and Surgical Outcome form), and a contact information form. The questionnaires will be used to evaluate how your knee is doing. Second, a physical therapist or a medical doctor will perform a clinical examination. This examination will be used to determine how your surgical knee is doing. Third, the motion of your knee will be measured using a commercial device (called the KT-1000), which will be strapped to your lower leg. A physical therapist will push your knee backwards and forwards while this device measures the amount of knee movement that occurs. Fourth, you will undergo a "functional" test to assess your knee function that is commonly used to assess the progress of knee rehabilitation. This functional test is called the "one-leg hop test". You will be asked to hop as far as you can on each leg. The total distance of each hop will be measured and recorded. Next, you will allow technicians to take up to four X-rays of your normal and injured knees at each visit while you are standing.

Finally, you will allow technicians to perform MRI scans on both knees. The MRI visit will be performed at one of two sites (Brown University or at a facility run by Memorial Hospital of Rhode Island). Magnetic Resonance Imaging (MRI) uses a powerful magnet to take pictures of your knee. Because the MRI machine exposes the body to a very strong magnetic force, you will have to follow certain safety precautions to make sure you do not have any metal objects in or on your body. Thus, before you undergo your MRI scan, a researcher or technician will ask whether or not your body contains any metallic medical devices or equipment, including heart pacemakers, metal prostheses, implants or surgical clips. You also will be asked whether you have had any prior injury from shrapnel or grinding metal, and you will be asked whether your eyes have been exposed to metallic dust or metallic shavings. You or the researcher or technician will also complete a checklist that addresses issues of MRI safety.

If you have no metallic objects or particles in your body, you will be asked before entering the MRI room to remove from your person all metal objects, including jewelry, watches, hair holders or eyeglasses, and you will be asked to empty your pockets of all materials, including keys, wallets and magnetic cards such as ATM and credit cards. In addition, if your clothing has more than a minimal amount of metal content, you may be asked to change into a hospital gown or other suitable garment. Finally, you will be asked to remove any eye shadow you may be wearing, because eye shadow sometimes contains metallic substances.

After you enter the MRI room, you will be asked to lie on your back on a table that slides into a horizontal cylinder slightly wider than your body. Because the MRI machine makes loud noises while it scans, a researcher or technician will provide you with ear protection to reduce the noise level. When you and the researcher or technician, are ready to begin the MRI scan, you will be asked to lie as still as you can for up to 2 hours. During this time, multiple scans of both your knees will be performed. This will be done to allow the researchers to determine the geometry of your knee and the integrity of your cartilage (the tissue lining the end of each bone).

For the 10, 12 and 15 year follow-up visits you will receive $100 for each visit to help cover your time to participate in the research procedures. If you have MRIs performed you will also receive $100 for each MRI visit. You will receive payment after each completed visit through a check in the mail, whether or not you complete the entire study.

Study Volunteer Initials

Costs for participating in this study: The services you will receive are being performed only because you are participating in this research study. Examples of these 'research only' services include the MRI examination, x-ray examinations, clinical exam and functional testing. There will be no charge to you for any of these research related procedures.

Contact Information: Braden Fleming, PhD at Orthopedic Research; Rhode Island Hospital; Coro West, Suite 404; 1 Hoppin St.; Providence, RI 02903; (401)-444-5444 if you have any questions or concerns regarding the study.

3. Discomforts and Risks
   - *Risks due to functional testing:* There is a slight risk that you could fall when performing the one-leg hop test. The test will be performed under the guidance of a physical therapist to reduce this possibility.
   - *Risks Associated with X-ray Exposure:* No more than a total of 5 X-rays will be taken of each knee at each visit. The potential damage to subjects from exposure to these X-rays is considered minimal. The effective dose for an X-ray of the knee is estimated at approximately 0.06 mSv or approximately 6 days of the natural background radiation that an individual would be exposed to while living in New England. In a worst-case scenario, 5 X-rays are taken of each knee at each visit and there are 8 follow-up visits. Therefore up to 80 total X-rays of the knees are possible, which approximately corresponds to a cumulative effective dose estimate of about 80*0.06 mSv ≈ 5 mSv spread out over the 15 years. The American Association of Physicists in Medicine (AAPM) Position Statement on Radiation Risks from Medical Imaging Procedures states that "at the present time, epidemiological evidence supporting increased cancer incidence or mortality from radiation doses below 100 mSv is inconclusive. As diagnostic imaging doses are typically much lower than 100 mSv, when such exposures are medically appropriate, the anticipated benefits to the patient are highly likely to outweigh any small potential risks." Your torso will be shielded with a lead apron and if you are female, you will be asked if you are pregnant before the X-rays are taken. If you are pregnant or become pregnant during the course of the study, the X-rays will not be performed. If you are unsure whether or not you are pregnant, you can decline participation in the X-ray portion of the study.
   - *Risks Associated with MRI scans:* These MRI scans will be obtained only for research purposes. The FDA classifies MRI imaging as a non-significant risk. MR imaging is generally considered to be safe, but accidents, injuries, and even deaths have occurred during MRI procedures. Such adverse events are extremely rare if appropriate safety precautions are followed. Serious complications can occur in people who have metal pacemakers, metallic dust in the eyes, or certain types of metal prostheses, implants, or surgical clips. MRI is also dangerous for anyone wearing any metal objects, including jewelry, watches, hair holders, eyeglasses or metal on clothing, as well as eye shadow, which sometimes contains metallic substances. In addition, if you enter the MRI room with any magnetic cards, such as ATM and credit cards, you will risk having the data on the cards erased by the MRI machine. For these reasons, a researcher or technician will review safety information with you before the scan. **In order to determine whether it is safe for you to undergo the scanning procedure, it will be important that you tell the technician about any metallic objects or devices on or in your body.**
   - During the scan itself, you will lie on a table that slides into a horizontal cylinder slightly wider than your body. You will be asked to lie still, but you will be able to hear and speak

to the MRI personnel/research staff. Some people experience anxiety, panic or a sensation of claustrophobia when lying in the MRI machine. If you think this may happen to you, please tell the researchers before you have the scan. The scanner also makes loud noises during imaging. Ear protection will be provided to reduce the noise level. If you feel uncomfortable for any reason before or during the procedure, please tell the researchers. If for any reason during the procedure you want to stop, you may do so at any time.

- ***CAUTION:*** This study is neither designed nor intended to detect health problems in participants. The MRI scans that you will undergo do **not** substitute for an appropriate medical examination by a qualified health care provider. If you suspect that you might be suffering from injury or illness, you should **not** rely on this study as a way to determine whether or not you are well.
- **FOR WOMEN: The safety of MR imaging during pregnancy has not been proved. If you are pregnant, you cannot take part in this study. If you think you may be pregnant you cannot participate in the MRI portion of the study.**

4. Benefits

There will be no direct benefit to you for participating in this study. However, your participation may provide information that will help other people with anterior cruciate ligament injuries by improving future surgical treatment options.

5. Alternative Therapies

You can choose not to participate in the study. There are no alternative therapies.

6. Refusal/Withdrawal

It is up to you whether you want to be in the study. You are not required to enroll or participate. If you decide to participate, you can always change your mind and quit at any time. If you decide not to be in the study, or if you quit later, you will still be able to get the health care services you normally get. If you join, but later on the researcher or your doctor feels being in the study is no longer good for you, they may choose to take you out of the study before it is over. If new information becomes available that might change your mind about whether you want to stay in the study the researcher will share this information with you as soon as possible.

Follow-up after Withdrawal of Consent

If you leave the study, it would still be useful for us to know how you do over the next 5 years. We would appreciate if you would permit us to get follow-up information about your health from your doctor or your medical record.

____ If I withdraw from the study, you have my permission to collect information about my health from my doctor or medical record.

_____ I do not give my permission for you to continue to collect information about me if I stop participating in the study.

_____ _____

Signature of study volunteer Date

Study Volunteer Initials

You have the right to change your mind at any time regarding follow-up after withdrawal. If you decide to quit the study please tell the head researcher, Braden Fleming, Ph.D., Orthopedic Research; Rhode Island Hospital; Coro West, Suite 404; 1 Hoppin St.; Providence, RI 02903.

7. Medical Treatment/Payment in Case of Injury

A research injury is any physical or mental injury or illness caused by being in the study. If you are injured by a medical treatment or procedure you would have received even if you were not in the study that is not a research injury. To help avoid research injury and added medical expenses, it is very important to follow all study directions carefully. If you do experience a research injury, Lifespan or the study doctor can arrange medical treatment for you. Such treatment will be paid for as described below.

8. Rights and Complaints

Signing this form does not take away any of your lawful rights. If you have any complaints about this study, or would like more facts about the rules for research studies, or the rights of people who take part in research studies you may contact Janice Muratori in the Lifespan Office of Research Administration, at (401) 444-6246

9. Confidentiality and Research Authorization for Use and Disclosure of Your Health Care Information. Your research records will be treated as private health care records and will be protected according to Lifespan privacy practices and policies that are based on state and federal law. In particular, federal law requires us to get your permission to use or disclose (release your information to someone outside of Lifespan) your health information for research purposes. If you sign this form you agree to be in this research study and you permit the use and disclosure of your health information for the purpose of conducting the research, providing treatment, collecting payment and running the business of the hospital. This permission has no expiration date. You may withdraw from the study at any time. However, if you do not want the researchers to use or disclose any further information in this study you must cancel permission in writing and may do so at any time. If you cancel your permission, you will stop taking part in the study and no new information will be collected about you. However, if you cancel your permission, it will not apply to actions already taken or information already collected about you by the hospital or the researchers before you canceled your permission.

Generally, the entire research record and any medical records held by the hospital may be used and released for research purposes. The following people or businesses/companies/ might use, release, or receive such information:

- The researcher and their support staff;
- The study sponsor, The Miriam and Rhode Island Hospitals' Dept. of Orthopaedics, Orthopaedic Research Division.
- Doctors, nurses, laboratories and others who provide services to you or the sponsor in connection with this study;
- The company or section of the U.S. government that is paying for the study and others they hire to oversee, administer, or conduct the research;
- The United States Food and Drug Administration, the Department of Health and Human Services, the Office of Inspector General, and the Office of Civil Rights; European Medicines Agency

- People who volunteer to be patient advocates or research volunteer protectors;
- Members of the hospital's administrative staff responsible for reviewing, approving and administering clinical trials and other healthcare or research activities.
- Accrediting Organizations

There are times when the law might require or permit Lifespan to release your health information without your permission. For example, Rhode Island law requires researchers and health care workers to report abuse or neglect of children to the Department of Children, Youth and Families (DCYF) and to report abuse or neglect of people age 60 and older to the Department of Elderly Affairs.

All researchers and health care providers are required to protect the privacy of your health care information. Other people and businesses/organizations that are not health care providers are not required by law to do that so it is possible they might re-release your information.

You have the right to refuse to sign this form and not participate in the research. Your refusal would have no affect on your treatment, charges billed to you, or benefits at any Lifespan health care site. If you do not sign, you will not be able to enroll in the research study and will not receive treatment as a study participant.

If you decide to quit the study after signing this form (as described in Section 6) no new information will be collected about you unless you gave us permission to do so. However, the hospital or the researchers may continue to use information that was collected before you quit the study to complete analysis and reports of this research.

For more detail about your privacy rights see the Lifespan Joint Privacy Notice which has or will be given to you.

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Study Volunteer Initials

SIGNATURE

I have read this informed consent and authorization form. ALL OF MY QUESTIONS HAVE BEEN ANSWERED, AND I WANT TO TAKE PART IN THIS RESEARCH STUDY.

By signing below, I give my permission to participate in this research study and for the described uses and releases of information. *I also confirm that I have been now or previously given a copy of the Lifespan Privacy Notice*

This informed consent document is approved for use with a valid IRB stamp at the top of each page. The document expires for use on the date listed within the IRB stamp. DO NOT sign this document after this expiration date. If the expiration date is blank, this document does not expire.

The Researcher is required to provide a copy of this consent to you.

Signature of study volunteer/authorized representative* Date and Time when signed

I WAS PRESENT DURING THE CONSENT PROCESS AND SIGNING OF THIS AGREEMENT BY THE STUDY VOLUNTEER OR AUTHORIZED REPRESENTATIVE

Signature of witness (required if consent is presented orally or at the request of the IRB) Date

Signature of Translator Date

Signature of researcher or designate Date and Time when signed

* If signed by agent other than study volunteer, please explain below.

Study Volunteer Initials

Lifespan Affiliate Site where research will be conducted

- ☒ Rhode Island Hospital
- ☐ Bradley Hospital
- ☒ The Miriam Hospital
- ☐ Newport Hospital
- ☐ Gateway Healthcare

Agreement to Participate in a Research Study And Authorization for Use and Disclosure of Information

2013-05
Committee #

Name of Study Volunteer

Effects of Initial Graft Tension on Anterior Cruciate Ligament Reconstruction
Ten, Twelve and 15 Year Assessment
B. Normal (control) Subjects

You are being asked to take part in a research study. All research studies at Lifespan hospitals follow the rules of the state of Rhode Island, the United States government and Lifespan. Before you decide whether to be in the study, you and the researcher will engage in the "informed consent" process. During this process, the researcher will explain the purpose of the study, how it will be carried out, and what you will be expected to do if you participate. The researcher will also explain the possible risks and benefits of being in the study, and will provide other information. You should feel free to ask any questions you might have. The purpose of these discussions is for you to decide whether participating in the study is the best decision for you.

If you decide to be in the study, you will be asked to sign and date this form in front of the person who explained the study to you. This form summarizes the information you discussed. You will be given a copy of this form to keep.

1. Nature and Purpose of the Study

You are being asked to take part in additional follow up visits for the research project "The effects of initial graft tension on ACL reconstruction" to further evaluate the articular cartilage of your normal knees. We are trying to get baseline data of normal knees ("control" group) for comparison of patients who have undergone knee surgery. We would like to perform ten, twelve and fifteen year follow-up visits, which will include knee examinations, x-rays on both knees, strength tests and Magnetic Resonance Images (MRIs) of both of your knees. The study is sponsored by NIH/NIAMS (National Institute of Arthritis and Musculoskeletal and Skin Diseases) and the Department of Orthopaedics at Rhode Island Hospital.

2. Explanation of Procedures

If you take part in this study, a trained physical therapist, associated physicians and technicians will perform the following procedures to your knees. These procedures include questionnaires to assess how you are doing, X-rays, clinical examinations and mechanical measurements of your knee to assess its function and the presence of arthritis. You may also be asked to have MRIs taken to document change in knee geometry. These procedures are described in detail below.

At your 10,12 and 15 year follow-up visits you will be asked to fill out three questionnaires (the Tegner, Knee Osteoarthritis Outcome Score, the SF-36) and a contact information form. The questionnaires will be used to evaluate how your knee is doing. Second, a physical therapist or a medical doctor will perform a clinical examination. This examination will be used to determine if your knee is normal. Third, the motion of your knee will be measured using a commercial device (called the KT-1000), which will be strapped to your lower leg. A physical therapist will push your knee backwards and forwards while this device measures the amount of knee movement that occurs. Fourth, you will also undergo a "functional" test to assess your knee function that is commonly used to assess the progress of knee rehabilitation. This functional test is called the "one-leg hop test". You will be asked to hop as far as you can on each leg. The total distance of each hop will be measured and recorded. Next, you will allow technicians to take up to four X-rays of your knees at each visit while you are standing.

Finally, you will allow technicians to perform MRI scans on both knees. The MRI visit will be performed at one of three sites (RIH, Brown University or at a facility run by Memorial Hospital of Rhode Island). Magnetic Resonance Imaging (MRI) uses a powerful magnet to take pictures of your knee. Because the MRI machine exposes the body to a very strong magnetic force, you will have to follow certain safety precautions to make sure you do not have any metal objects in or on your body. Thus, before you undergo your MRI scan, a researcher or technician will ask whether or not your body contains any metallic medical devices or equipment, including heart pacemakers, metal prostheses, implants or surgical clips. You also will be asked whether you have had any prior injury from shrapnel or grinding metal, and you will be asked whether your eyes have been exposed to metallic dust or metallic shavings. You or the researcher or technician will also complete a checklist that addresses issues of MRI safety.

If you have no metallic objects or particles in your body, you will be asked before entering the MRI room to remove from your person all metal objects, including jewelry, watches, hair holders or eyeglasses, and you will be asked to empty your pockets of all materials, including keys, wallets and magnetic cards such as ATM and credit cards. In addition, if your clothing has more than a minimal amount of metal content, you may be asked to change into a hospital gown or other suitable garment. Finally, you will be asked to remove any eye shadow you may be wearing, because eye shadow sometimes contains metallic substances.

After you enter the MRI room, you will be asked to lie on your back on a table that slides into a horizontal cylinder slightly wider than your body. Because the MRI machine makes loud noises while it scans, a researcher or technician will provide you with ear protection to reduce the noise level. When you and the researcher or technician are ready to begin the MRI scan, you will be asked to lie as still as you can for up to 2 hours. During this time, multiple scans of both your knees will be performed. This will be done to allow the researchers to determine the geometry of your knee and the integrity of your cartilage (the tissue lining the end of each bone).

For the 10, 12 and 15 year follow-up visits you will receive $100 for each visit to help cover your time to participate in the research procedures. If you have MRIs performed you will also receive $100 for each MRI visit. You will receive payment after each completed visit through a check in the mail, whether or not you complete the entire study.

Study Volunteer Initials

Costs for participating in this study:
The services you will receive are being performed only because you are participating in this research study. Examples of these 'research only' services include the MRI examination, x-ray examinations, clinical exam and functional testing. There will be no charge to you for any of these research related procedures.

Contact Information: Braden Fleming, PhD at Orthopedic Research; Rhode Island Hospital; Coro West, Suite 404; 1 Hoppin St.; Providence, RI 02903; (401)-444-5444 if you have any questions or concerns regarding the study.

3. Discomforts and Risks
   - *Risks due to functional testing:* There is a slight risk that you could fall when performing the one-leg hop test. The test will be performed under the guidance of a physical therapist to reduce this possibility.
   - *Risks Associated with X-ray Exposure:* No more than a total of 5 X-rays will be taken of each knee at each visit. The potential damage to subjects from exposure to these X-rays is considered minimal. The effective dose for an X-ray of the knee is estimated at approximately 0.06 mSv or approximately 6 days of the natural background radiation that an individual would be exposed to while living in New England. In a worst-case scenario, 5 X-rays are taken of each knee at each visit and there are 8 follow-up visits. Therefore up to 80 total X-rays of the knees are possible, which approximately corresponds to a cumulative effective dose estimate of about 80*0.06 mSv ≈ 5 mSv spread out over the 15 years. The American Association of Physicists in Medicine (AAPM) Position Statement on Radiation Risks from Medical Imaging Procedures states that "at the present time, epidemiological evidence supporting increased cancer incidence or mortality from radiation doses below 100 mSv is inconclusive. As diagnostic imaging doses are typically much lower than 100 mSv, when such exposures are medically appropriate, the anticipated benefits to the patient are highly likely to outweigh any small potential risks." Your torso will be shielded with a lead apron and if you are female, you will be asked if you are pregnant before the X-rays are taken. If you are pregnant or become pregnant during the course of the study, the X-rays will not be performed. If you are unsure whether or not you are pregnant, you can decline participation in the X-ray portion of the study.
   - *Risks Associated with MRI scans:* These MRI scans will be obtained only for research purposes. The FDA classifies MRI imaging as a non-significant risk. MR imaging is generally considered to be safe, but accidents, injuries, and even deaths have occurred during MRI procedures. Such adverse events are extremely rare if appropriate safety precautions are followed. Serious complications can occur in people who have metal pacemakers, metallic dust in the eyes, or certain types of metal prostheses, implants, or surgical clips. MRI is also dangerous for anyone wearing any metal objects, including jewelry, watches, hair holders, eyeglasses or metal on clothing, as well as eye shadow, which sometimes contains metallic substances. In addition, if you enter the MRI room with any magnetic cards, such as ATM and credit cards, you will risk having the data on the cards erased by the MRI machine. For these reasons, a researcher or technician will review safety information with you before the scan. **In order to determine whether it is safe for you to undergo the scanning procedure, it will be important that you tell the technician about any metallic objects or devices on or in your body.**

Study Volunteer Initials

- During the scan itself, you will lie on a table that slides into a horizontal cylinder slightly wider than your body. You will be asked to lie still, but you will be able to hear and speak to the MRI personnel/research staff. Some people experience anxiety, panic or a sensation of claustrophobia when lying in the MRI machine. If you think this may happen to you, please tell the researchers before you have the scan. The scanner also makes loud noises during imaging. Ear protection will be provided to reduce the noise level. If you feel uncomfortable for any reason before or during the procedure, please tell the researchers. If for any reason during the procedure you want to stop, you may do so at any time.
- ***CAUTION:*** This study is neither designed nor intended to detect health problems in participants. The MRI scans that you will undergo do **not** substitute for an appropriate medical examination by a qualified health care provider. If you suspect that you might be suffering from injury or illness, you should **not** rely on this study as a way to determine whether or not you are well.
- **FOR WOMEN: The safety of MR imaging during pregnancy has not been proved. If you are pregnant, you cannot take part in this study. If you think you may be pregnant you cannot participate in the MRI portion of the study.**

4. Benefits

There will be no direct benefit to you for participating in this study. However, your participation may provide information that will help other people with anterior cruciate ligament injuries by improving future surgical treatment options.

5. Alternative Therapies

You can choose not to participate in the study. There are no alternative therapies.

6. Refusal/Withdrawal

It is up to you whether you want to be in the study. You are not required to enroll or participate. If you decide to participate, you can always change your mind and quit at any time. If you decide not to be in the study, or if you quit later, you will still be able to get the health care services you normally get. If you join, but later on the researcher or your doctor feels being in the study is no longer good for you, they may choose to take you out of the study before it is over. If new information becomes available that might change your mind about whether you want to stay in the study the researcher will share this information with you as soon as possible.

Follow-up after Withdrawal of Consent

If you leave the study, it would still be useful for us to know how you do over the next 5 years. We would appreciate if you would permit us to get follow-up information about your health from your doctor or your medical record.

____ If I withdraw from the study, you have my permission to collect information about my health from my doctor or medical record.

_____ I do not give my permission for you to continue to collect information about me if I stop participating in the study.

Study Volunteer Initials

Signature of study volunteer Date

You have the right to change your mind at any time regarding follow-up after withdrawal. If you decide to quit the study please tell the head researcher, Braden C. Fleming, Ph.D., at Orthopedic Research; Rhode Island Hospital; Coro West, Suite 404; 1 Hoppin St.; Providence, RI 02903.

7. Medical Treatment/Payment in Case of Injury A research injury is any physical or mental injury or illness caused by being in the study. If you are injured by a medical treatment or procedure you would have received even if you were not in the study that is not a research injury. To help avoid research injury and added medical expenses, it is very important to follow all study directions carefully. If you do experience a research injury, Lifespan or the study doctor can arrange medical treatment for you. Such treatment will be paid for as described below.

If you have insurance and have a research injury that is not covered by the study, it is possible that some or all of the cost of treating you could be billed to your insurer. If your health insurance will not cover such costs, it is possible you would have to pay out of pocket. In some cases, Lifespan might be able to help you pay if you qualify for free care under Lifespan policy. However, Lifespan has no policy to cover payment for such things as lost wages, expenses other than medical care, or pain and suffering.

8. Rights and Complaints
Signing this form does not take away any of your lawful rights. If you have any complaints about this study, or would like more facts about the rules for research studies, or the rights of people who take part in research studies you may contact Janice Muratori in the Lifespan Office of Research Administration, at (401) 444-6246

9. Confidentiality and Research Authorization for Use and Disclosure of Your Health Care Information.
Your research records will be treated as private health care records and will be protected according to Lifespan privacy practices and policies that are based on state and federal law. In particular, federal law requires us to get your permission to use or disclose (release your information to someone outside of Lifespan) your health information for research purposes. If you sign this form you agree to be in this research study and you permit the use and disclosure of your health information for the purpose of conducting the research, providing treatment, collecting payment and running the business of the hospital. This permission has no expiration date. You may withdraw from the study at any time. However, if you do not want the researchers to use or disclose any further information in this study you must cancel permission in writing and may do so at any time. If you cancel your permission, you will stop taking part in the study and no new information will be collected about you. However, if you cancel your permission, it will not apply to actions already taken or information already collected about you by the hospital or the researchers before you canceled your permission.

Generally, the entire research record and any medical records held by the hospital may be used and released for research purposes. The following people or businesses/companies/ might use, release, or receive such information:

- The researcher and their support staff;

- The study sponsor: NIH/NIAMS (National Institute of Arthritis and Musculoskeletal and Skin Diseases)
- Doctors, nurses, laboratories and others who provide services to you or the sponsor in connection with this study;
- The company or section of the U.S. government that is paying for the study and others they hire to oversee, administer, or conduct the research;
- The United States Food and Drug Administration, the Department of Health and Human Services, the Office of Inspector General, and the Office of Civil Rights; European Medicines Agency
- People who volunteer to be patient advocates or research volunteer protectors;
- Members of the hospital's administrative staff responsible for reviewing, approving and administering clinical trials and other healthcare or research activities.
- Accrediting Organizations

There are times when the law might require or permit Lifespan to release your health information without your permission. For example, Rhode Island law requires researchers and health care workers to report abuse or neglect of children to the Department of Children, Youth and Families (DCYF) and to report abuse or neglect of people age 60 and older to the Department of Elderly Affairs.

All researchers and health care providers are required to protect the privacy of your health care information. Other people and businesses/organizations that are not health care providers are not required by law to do that so it is possible they might re-release your information.

You have the right to refuse to sign this form and not participate in the research. Your refusal would have no affect on your treatment, charges billed to you, or benefits at any Lifespan health care site. If you do not sign, you will not be able to enroll in the research study and will not receive treatment as a study participant.

If you decide to quit the study after signing this form (as described in Section 6) no new information will be collected about you unless you gave us permission to do so. However, the hospital or the researchers may continue to use information that was collected before you quit the study to complete analysis and reports of this research.

Additionally, 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.

For more detail about your privacy rights see the Lifespan Joint Privacy Notice which has or will be given to you.

Study Volunteer Initials

SIGNATURE

I have read this informed consent and authorization form. ALL OF MY QUESTIONS HAVE BEEN ANSWERED, AND I WANT TO TAKE PART IN THIS RESEARCH STUDY.

By signing below, I give my permission to participate in this research study and for the described uses and releases of information. *I also confirm that I have been now or previously given a copy of the Lifespan Privacy Notice*

This informed consent document is approved for use with a valid IRB stamp at the top of each page. The document expires for use on the date listed within the IRB stamp. DO NOT sign this document after this expiration date. If the expiration date is blank, this document does not expire.

The Researcher is required to provide a copy of this consent to you.

Signature of study volunteer/authorized representative* Date and Time when signed

I WAS PRESENT DURING THE CONSENT PROCESS AND SIGNING OF THIS AGREEMENT BY THE STUDY VOLUNTEER OR AUTHORIZED REPRESENTATIVE

Signature of witness (required if consent is presented orally or at the request of the IRB) Date

Signature of Translator Date

Signature of researcher or designate Date and Time when signed

* If signed by agent other than study volunteer, please explain below.

IRB approval 11/17/2016
IRB accepted: 12/14/2016
IRB expiration: 11/16/2017

Study Volunteer Initials

Lifespan Affiliate Site where research will be conducted

- ☒ Rhode Island Hospital
- ☐ Bradley Hospital
- ☒ The Miriam Hospital
- ☐ Newport Hospital
- ☐ Gateway Healthcare

Agreement to Participate in a Research Study And Authorization for Use and Disclosure of Information

2013-05
Committee #

Name of Study Volunteer

Effects of Initial Graft Tension on Anterior Cruciate Ligament Reconstruction Ten and Twelve Year Assessment
A. Anterior Cruciate Ligament Reconstructed Subjects

You are being asked to take part in a research study. All research studies at Lifespan hospitals follow the rules of the state of Rhode Island, the United States government and Lifespan. Before you decide whether to be in the study, you and the researcher will engage in the "informed consent" process. During this process, the researcher will explain the purpose of the study, how it will be carried out, and what you will be expected to do if you participate. The researcher will also explain the possible risks and benefits of being in the study, and will provide other information. You should feel free to ask any questions you might have. The purpose of these discussions is for you to decide whether participating in the study is the best decision for you.

If you decide to be in the study, you will be asked to sign and date this form in front of the person who explained the study to you. This form summarizes the information you discussed. You will be given a copy of this form to keep.

1. Nature and Purpose of the Study:

You are being asked to take part in additional follow up visits for the research project entitled "The Effects of Initial Graft Tension on ACL Reconstruction" to further evaluate the changes in your surgical knee. We would like to perform 10 and 12 year follow-up visits, which will include knee examinations, x-rays, strength tests and magnetic resonance images (MRIs) of both of your knees. These visits will allow us to measure the long term mechanical and biological responses of your knee to anterior cruciate ligament reconstruction surgery.

The study is sponsored by NIH/NIAMS (National Institute of Arthritis and Musculoskeletal and Skin Diseases) and the Department of Orthopaedics at Rhode Island Hospital.

2. Explanation of Procedures:

If you take part in this study, a trained physical therapist, associated physicians and technicians will perform the following procedures to your knees. These procedures include questionnaires to assess how you are doing, X-rays, clinical examinations and mechanical measurements of your knee to assess its function and the presence of arthritis. You may also be asked to have MRIs taken to document change in knee geometry. These procedures are described in detail below.

At your 10 and 12 year follow-up visits you will be asked to fill out four questionnaires (the Tegner, Knee Osteoarthritis Outcome Score, SF-36, and Surgical Outcome form), and a contact information form. The questionnaires will be used to evaluate how your knee is doing. Second, a physical therapist or a medical doctor will perform a clinical examination. This examination will be used to determine how your surgical knee is doing. Third, the motion of your knee will be measured using a commercial device (called the KT-1000), which will be strapped to your lower leg. A physical therapist will push your knee backwards and forwards while this device measures the amount of knee movement that occurs. Fourth, you will undergo a "functional" test to assess your knee function that is commonly used to assess the progress of knee rehabilitation. This functional test is called the "one-leg hop test". You will be asked to hop as far as you can on each leg. The total distance of each hop will be measured and recorded. Next, you will allow technicians to take up to four X-rays of your normal and injured knees at each visit while you are standing.

Finally, you will allow technicians to perform MRI scans on both knees. The MRI visit will be performed at one of two sites (Brown University or at a facility run by Memorial Hospital of Rhode Island). Magnetic Resonance Imaging (MRI) uses a powerful magnet to take pictures of your knee. Because the MRI machine exposes the body to a very strong magnetic force, you will have to follow certain safety precautions to make sure you do not have any metal objects in or on your body. Thus, before you undergo your MRI scan, a researcher or technician will ask whether or not your body contains any metallic medical devices or equipment, including heart pacemakers, metal prostheses, implants or surgical clips. You also will be asked whether you have had any prior injury from shrapnel or grinding metal, and you will be asked whether your eyes have been exposed to metallic dust or metallic shavings. You or the researcher or technician will also complete a checklist that addresses issues of MRI safety.

If you have no metallic objects or particles in your body, you will be asked before entering the MRI room to remove from your person all metal objects, including jewelry, watches, hair holders or eyeglasses, and you will be asked to empty your pockets of all materials, including keys, wallets and magnetic cards such as ATM and credit cards. In addition, if your clothing has more than a minimal amount of metal content, you may be asked to change into a hospital gown or other suitable garment. Finally, you will be asked to remove any eye shadow you may be wearing, because eye shadow sometimes contains metallic substances.

After you enter the MRI room, you will be asked to lie on your back on a table that slides into a horizontal cylinder slightly wider than your body. Because the MRI machine makes loud noises while it scans, a researcher or technician will provide you with ear protection to reduce the noise level. When you and the researcher or technician, are ready to begin the MRI scan, you will be asked to lie as still as you can for up to 2 hours. During this time, multiple scans of both your knees will be performed. This will be done to allow the researchers to determine the geometry of your knee and the integrity of your cartilage (the tissue lining the end of each bone).

For the 10 and 12 year follow-up visits you will receive $100 for each visit to help cover your time to participate in the research procedures. If you have MRIs performed you will also receive $100 for each MRI visit. You will receive payment approximately 4 weeks after each completed visit through a check in the mail, whether or not you complete the entire study.

Study Volunteer Initials

Costs for participating in this study: The services you will receive are being performed only because you are participating in this research study. Examples of these 'research only' services include the MRI examination, x-ray examinations, clinical exam and functional testing. There will be no charge to you for any of these research related procedures.

Contact Information: Braden Fleming, PhD at Orthopedic Research; Rhode Island Hospital; Coro West, Suite 404; 1 Hoppin St.; Providence, RI 02903; (401)-444-54440 if you have any questions or concerns regarding the study.

3. Discomforts and Risks
   - *Risks due to functional testing:* There is a slight risk that you could fall when performing the one-leg hop test. The test will be performed under the guidance of a physical therapist to reduce this possibility.
   - *Risks Associated with X-ray Exposure:* No more than a total of 4 X-rays will be taken of each knee for research purposes at each visit. The potential damage to subjects from exposure to these X-rays is considered insignificant. The total X-ray exposure for the additional research is estimated at approximately 3%, or 10 days, of the background radiation that an individual would be exposed to living in New England over one year. Your torso will be shielded with a lead apron to further reduce your risk. If you are female, you will be asked if you are pregnant before the X-rays are taken. If you are pregnant or become pregnant during the course of the study, the X-rays will not be performed. If you are unsure whether or not you are pregnant, you can decline participation in the X-ray portion of the study.
   - *Risks Associated with MRI scans:* These MRI scans will be obtained only for research purposes. The FDA classifies MRI imaging as a non-significant risk. MR imaging is generally considered to be safe, but accidents, injuries, and even deaths have occurred during MRI procedures. Such adverse events are extremely rare if appropriate safety precautions are followed. Serious complications can occur in people who have metal pacemakers, metallic dust in the eyes, or certain types of metal prostheses, implants, or surgical clips. MRI is also dangerous for anyone wearing any metal objects, including jewelry, watches, hair holders, eyeglasses or metal on clothing, as well as eye shadow, which sometimes contains metallic substances. In addition, if you enter the MRI room with any magnetic cards, such as ATM and credit cards, you will risk having the data on the cards erased by the MRI machine. For these reasons, a researcher or technician will review safety information with you before the scan. **In order to determine whether it is safe for you to undergo the scanning procedure, it will be important that you tell the technician about any metallic objects or devices on or in your body.**
   - During the scan itself, you will lie on a table that slides into a horizontal cylinder slightly wider than your body. You will be asked to lie still, but you will be able to hear and speak to the MRI personnel/research staff. Some people experience anxiety, panic or a sensation of claustrophobia when lying in the MRI machine. If you think this may happen to you, please tell the researchers before you have the scan. The scanner also makes loud noises during imaging. Ear protection will be provided to reduce the noise level. If you feel uncomfortable for any reason before or during the procedure, please tell the researchers. If for any reason during the procedure you want to stop, you may do so at any time.
   - ***CAUTION:*** This study is neither designed nor intended to detect health problems in participants. The MRI scans that you will undergo do **not** substitute for an appropriate

Study Volunteer Initials

medical examination by a qualified health care provider. If you suspect that you might be suffering from injury or illness, you should **not** rely on this study as a way to determine whether or not you are well.

- **FOR WOMEN: The safety of MR imaging during pregnancy has not been proved. If you are pregnant, you cannot take part in this study. If you think you may be pregnant you cannot participate in the MRI portion of the study.**

4. Benefits

There will be no direct benefit to you for participating in this study. However, your participation may provide information that will help other people with anterior cruciate ligament injuries by improving future surgical treatment options.

5. Alternative Therapies

You can choose not to participate in the study. There are no alternative therapies.

6. Refusal/Withdrawal

It is up to you whether you want to be in the study. You are not required to enroll or participate. If you decide to participate, you can always change your mind and quit at any time. If you decide not to be in the study, or if you quit later, you will still be able to get the health care services you normally get. If you join, but later on the researcher or your doctor feels being in the study is no longer good for you, they may choose to take you out of the study before it is over. If new information becomes available that might change your mind about whether you want to stay in the study the researcher will share this information with you as soon as possible.

Follow-up after Withdrawal of Consent

If you leave the study, it would still be useful for us to know how you do over the next 5 years. We would appreciate if you would permit us to get follow-up information about your health from your doctor or your medical record.

____ If I withdraw from the study, you have my permission to collect information about my health from my doctor or medical record.

_____ I do not give my permission for you to continue to collect information about me if I stop participating in the study.

_____ _____

Signature of study volunteer Date

You have the right to change your mind at any time regarding follow-up after withdrawal. If you decide to quit the study please tell the head researcher, Braden Fleming, Ph.D., Orthopedic Research; Rhode Island Hospital; Coro West, Suite 404; 1 Hoppin St.; Providence, RI 02903 at Orthopedic Research; Rhode Island Hospital; Coro West, Suite 404; 1 Hoppin St.; Providence, RI 02903.

7. Medical Treatment/Payment in Case of Injury A research injury is any physical or mental injury or illness caused by being in the study. If you are injured by a medical treatment or procedure you would have received even if you were not in the study that is not a research injury. To help avoid research injury and added medical expenses, it is very important to follow all study directions

carefully. If you do experience a research injury, Lifespan or the study doctor can arrange medical treatment for you. Such treatment will be paid for as described below.

8. Rights and Complaints

Signing this form does not take away any of your lawful rights. If you have any complaints about this study, or would like more facts about the rules for research studies, or the rights of people who take part in research studies you may contact Janice Muratori in the Lifespan Office of Research Administration, at (401) 444-6246

9. Confidentiality and Research Authorization for Use and Disclosure of Your Health Care Information. Your research records will be treated as private health care records and will be protected according to Lifespan privacy practices and policies that are based on state and federal law. In particular, federal law requires us to get your permission to use or disclose (release your information to someone outside of Lifespan) your health information for research purposes. If you sign this form you agree to be in this research study and you permit the use and disclosure of your health information for the purpose of conducting the research, providing treatment, collecting payment and running the business of the hospital. This permission has no expiration date. You may withdraw from the study at any time. However, if you do not want the researchers to use or disclose any further information in this study you must cancel permission in writing and may do so at any time. If you cancel your permission, you will stop taking part in the study and no new information will be collected about you. However, if you cancel your permission, it will not apply to actions already taken or information already collected about you by the hospital or the researchers before you canceled your permission.

Generally, the entire research record and any medical records held by the hospital may be used and released for research purposes. The following people or businesses/companies/ might use, release, or receive such information:

- The researcher and their support staff;
- The study sponsor, The Miriam and Rhode Island Hospitals' Dept. of Orthopaedics, Orthopaedic Research Division.
- Doctors, nurses, laboratories and others who provide services to you or the sponsor in connection with this study;
- The company or section of the U.S. government that is paying for the study and others they hire to oversee, administer, or conduct the research;
- The United States Food and Drug Administration, the Department of Health and Human Services, the Office of Inspector General, and the Office of Civil Rights; European Medicines Agency
- People who volunteer to be patient advocates or research volunteer protectors;
- Members of the hospital's administrative staff responsible for reviewing, approving and administering clinical trials and other healthcare or research activities.
- Accrediting Organizations

There are times when the law might require or permit Lifespan to release your health information without your permission. For example, Rhode Island law requires researchers and health care workers to report abuse or neglect of children to the Department of Children, Youth and Families

(DCYF) and to report abuse or neglect of people age 60 and older to the Department of Elderly Affairs.

All researchers and health care providers are required to protect the privacy of your health care information. Other people and businesses/organizations that are not health care providers are not required by law to do that so it is possible they might re-release your information.

You have the right to refuse to sign this form and not participate in the research. Your refusal would have no affect on your treatment, charges billed to you, or benefits at any Lifespan health care site. If you do not sign, you will not be able to enroll in the research study and will not receive treatment as a study participant.

If you decide to quit the study after signing this form (as described in Section 6) no new information will be collected about you unless you gave us permission to do so. However, the hospital or the researchers may continue to use information that was collected before you quit the study to complete analysis and reports of this research.

For more detail about your privacy rights see the Lifespan Joint Privacy Notice which has or will be given to you.

For more detail about your privacy rights see the Lifespan Joint Privacy Notice which has or will be given to you.

Study Volunteer Initials

SIGNATURE

I have read this informed consent and authorization form. ALL OF MY QUESTIONS HAVE BEEN ANSWERED, AND I WANT TO TAKE PART IN THIS RESEARCH STUDY.

By signing below, I give my permission to participate in this research study and for the described uses and releases of information. *I also confirm that I have been now or previously given a copy of the Lifespan Privacy Notice*

This informed consent document expires on 11/16/2017.
DO NOT sign this document after this expiration date

The Researcher is required to provide a copy of this consent to you.

Signature of study volunteer/authorized representative* Date and Time when signed

I WAS PRESENT DURING THE CONSENT PROCESS AND SIGNING OF THIS AGREEMENT BY THE STUDY VOLUNTEER OR AUTHORIZED REPRESENTATIVE

Signature of witness (required if consent is presented orally or at the request of the IRB) Date

Signature of Translator Date

Signature of researcher or designate Date and Time when signed

* If signed by agent other than study volunteer, please explain below.

IRB approval 11/17/2016
IRB accepted: 12/14/2016
IRB expiration: 11/16/2017

Study Volunteer Initials

Lifespan Affiliate Site where research will be conducted

- ☒ Rhode Island Hospital
- ☐ Bradley Hospital
- ☒ The Miriam Hospital
- ☐ Newport Hospital
- ☐ Gateway Healthcare

Agreement to Participate in a Research Study And Authorization for Use and Disclosure of Information

2013-05
Committee #

Name of Study Volunteer

Effects of Initial Graft Tension on Anterior Cruciate Ligament Reconstruction
Ten and Twelve Year Assessment
B. Normal (control) Subjects

You are being asked to take part in a research study. All research studies at Lifespan hospitals follow the rules of the state of Rhode Island, the United States government and Lifespan. Before you decide whether to be in the study, you and the researcher will engage in the "informed consent" process. During this process, the researcher will explain the purpose of the study, how it will be carried out, and what you will be expected to do if you participate. The researcher will also explain the possible risks and benefits of being in the study, and will provide other information. You should feel free to ask any questions you might have. The purpose of these discussions is for you to decide whether participating in the study is the best decision for you.

If you decide to be in the study, you will be asked to sign and date this form in front of the person who explained the study to you. This form summarizes the information you discussed. You will be given a copy of this form to keep.

1. Nature and Purpose of the Study

You are being asked to take part in additional follow up visits for the research project "The effects of initial graft tension on ACL reconstruction" to further evaluate the articular cartilage of your normal knees. We are trying to get baseline data of normal knees ("control" group) for comparison of patients who have undergone knee surgery. We would like to perform ten, and twelve year follow-up visits, which will include knee examinations, x-rays on both knees, strength tests and Magnetic Resonance Images (MRIs) of both of your knees. The study is sponsored by NIH/NIAMS (National Institute of Arthritis and Musculoskeletal and Skin Diseases) and the Department of Orthopaedics at Rhode Island Hospital.

2. Explanation of Procedures

If you take part in this study, a trained physical therapist, associated physicians and technicians will perform the following procedures to your knees. These procedures include questionnaires to assess how you are doing, X-rays, clinical examinations and mechanical measurements of your knee to assess its function and the presence of arthritis. You may also be asked to have MRIs taken to document change in knee geometry. These procedures are described in detail below.

At your 10 and 12 year follow-up visits you will be asked to fill out three questionnaires (the Tegner, Knee Osteoarthritis Outcome Score, the SF-36) and a contact information form. The questionnaires will be used to evaluate how your knee is doing. Second, a physical therapist or a medical doctor will perform a clinical examination. This examination will be used to determine if your knee is normal. Third, the motion of your knee will be measured using a commercial device (called the KT-1000), which will be strapped to your lower leg. A physical therapist will push your knee backwards and forwards while this device measures the amount of knee movement that occurs. Fourth, you will also undergo a "functional" test to assess your knee function that is commonly used to assess the progress of knee rehabilitation. This functional test is called the "one-leg hop test". You will be asked to hop as far as you can on each leg. The total distance of each hop will be measured and recorded. Next, you will allow technicians to take up to four X-rays of your knees at each visit while you are standing.

Finally, you will allow technicians to perform MRI scans on both knees. The MRI visit will be performed at one of three sites (RIH, Brown University or at a facility run by Memorial Hospital of Rhode Island). Magnetic Resonance Imaging (MRI) uses a powerful magnet to take pictures of your knee. Because the MRI machine exposes the body to a very strong magnetic force, you will have to follow certain safety precautions to make sure you do not have any metal objects in or on your body. Thus, before you undergo your MRI scan, a researcher or technician will ask whether or not your body contains any metallic medical devices or equipment, including heart pacemakers, metal prostheses, implants or surgical clips. You also will be asked whether you have had any prior injury from shrapnel or grinding metal, and you will be asked whether your eyes have been exposed to metallic dust or metallic shavings. You or the researcher or technician will also complete a checklist that addresses issues of MRI safety.

If you have no metallic objects or particles in your body, you will be asked before entering the MRI room to remove from your person all metal objects, including jewelry, watches, hair holders or eyeglasses, and you will be asked to empty your pockets of all materials, including keys, wallets and magnetic cards such as ATM and credit cards. In addition, if your clothing has more than a minimal amount of metal content, you may be asked to change into a hospital gown or other suitable garment. Finally, you will be asked to remove any eye shadow you may be wearing, because eye shadow sometimes contains metallic substances.

After you enter the MRI room, you will be asked to lie on your back on a table that slides into a horizontal cylinder slightly wider than your body. Because the MRI machine makes loud noises while it scans, a researcher or technician will provide you with ear protection to reduce the noise level. When you and the researcher or technician are ready to begin the MRI scan, you will be asked to lie as still as you can for up to 2 hours. During this time, multiple scans of both your knees will be performed. This will be done to allow the researchers to determine the geometry of your knee and the integrity of your cartilage (the tissue lining the end of each bone).

For the 10 and 12 year follow-up visits you will receive $100 for each visit to help cover your time to participate in the research procedures. If you have MRIs performed you will also receive $100 for each MRI visit. You will receive payment approximately 4 weeks after each completed visit through a check in the mail, whether or not you complete the entire study.

Costs for participating in this study:

The services you will receive are being performed only because you are participating in this research study. Examples of these 'research only' services include the MRI examination, x-ray examinations, clinical exam and functional testing. There will be no charge to you for any of these research related procedures.

Contact Information: Braden Fleming, PhD at Orthopedic Research; Rhode Island Hospital; Coro West, Suite 404; 1 Hoppin St.; Providence, RI 02903; (401)-444-54440 if you have any questions or concerns regarding the study.

3. Discomforts and Risks
   - *Risks due to functional testing:* There is a slight risk that you could fall when performing the one-leg hop test. The test will be performed under the guidance of a physical therapist to reduce this possibility.
   - *Risks Associated with X-ray Exposure:* No more than a total of 4 X-rays will be taken of each knee for research purposes at each visit. The potential damage to subjects from exposure to these X-rays is considered insignificant. The total X-ray exposure for the additional research is estimated at approximately 3%, or 10 days, of the background radiation that an individual would be exposed to living in New England over one year. Your torso will be shielded with a lead apron to further reduce your risk. If you are female, you will be asked if you are pregnant before the X-rays are taken. If you are pregnant or become pregnant during the course of the study, the X-rays will not be performed. If you are unsure whether or not you are pregnant, you can decline participation in the X-ray portion of the study.
   - *Risks Associated with MRI scans:* These MRI scans will be obtained only for research purposes. The FDA classifies MRI imaging as a non-significant risk. MR imaging is generally considered to be safe, but accidents, injuries, and even deaths have occurred during MRI procedures. Such adverse events are extremely rare if appropriate safety precautions are followed. Serious complications can occur in people who have metal pacemakers, metallic dust in the eyes, or certain types of metal prostheses, implants, or surgical clips. MRI is also dangerous for anyone wearing any metal objects, including jewelry, watches, hair holders, eyeglasses or metal on clothing, as well as eye shadow, which sometimes contains metallic substances. In addition, if you enter the MRI room with any magnetic cards, such as ATM and credit cards, you will risk having the data on the cards erased by the MRI machine. For these reasons, a researcher or technician will review safety information with you before the scan. **In order to determine whether it is safe for you to undergo the scanning procedure, it will be important that you tell the technician about any metallic objects or devices on or in your body.**
   - During the scan itself, you will lie on a table that slides into a horizontal cylinder slightly wider than your body. You will be asked to lie still, but you will be able to hear and speak to the MRI personnel/research staff. Some people experience anxiety, panic or a sensation of claustrophobia when lying in the MRI machine. If you think this may happen to you, please tell the researchers before you have the scan. The scanner also makes loud noises during imaging. Ear protection will be provided to reduce the noise level. If you feel uncomfortable for any reason before or during the procedure, please tell the researchers. If for any reason during the procedure you want to stop, you may do so at any time.
   - ***CAUTION:*** This study is neither designed nor intended to detect health problems in participants. The MRI scans that you will undergo do **not** substitute for an appropriate

medical examination by a qualified health care provider. If you suspect that you might be suffering from injury or illness, you should **not** rely on this study as a way to determine whether or not you are well.

- **FOR WOMEN: The safety of MR imaging during pregnancy has not been proved. If you are pregnant, you cannot take part in this study. If you think you may be pregnant you cannot participate in the MRI portion of the study.**

4. Benefits

There will be no direct benefit to you for participating in this study. However, your participation may provide information that will help other people with anterior cruciate ligament injuries by improving future surgical treatment options.

5. Alternative Therapies

You can choose not to participate in the study. There are no alternative therapies.

6. Refusal/Withdrawal

It is up to you whether you want to be in the study. You are not required to enroll or participate. If you decide to participate, you can always change your mind and quit at any time. If you decide not to be in the study, or if you quit later, you will still be able to get the health care services you normally get. If you join, but later on the researcher or your doctor feels being in the study is no longer good for you, they may choose to take you out of the study before it is over. If new information becomes available that might change your mind about whether you want to stay in the study the researcher will share this information with you as soon as possible.

Follow-up after Withdrawal of Consent

If you leave the study, it would still be useful for us to know how you do over the next 5 years. We would appreciate if you would permit us to get follow-up information about your health from your doctor or your medical record.

____ If I withdraw from the study, you have my permission to collect information about my health from my doctor or medical record.

_____ I do not give my permission for you to continue to collect information about me if I stop participating in the study.

_____ _____

Signature of study volunteer Date

You have the right to change your mind at any time regarding follow-up after withdrawal. If you decide to quit the study please tell the head researcher, Braden C. Fleming, Ph.D., at Orthopedic Research; Rhode Island Hospital; Coro West, Suite 404; 1 Hoppin St.; Providence, RI 02903.

7. Medical Treatment/Payment in Case of Injury A research injury is any physical or mental injury or illness caused by being in the study. If you are injured by a medical treatment or procedure you would have received even if you were not in the study that is not a research injury. To help avoid research injury and added medical expenses, it is very important to follow all study directions

carefully. If you do experience a research injury, Lifespan or the study doctor can arrange medical treatment for you. Such treatment will be paid for as described below.

If you have insurance and have a research injury that is not covered by the study, it is possible that some or all of the cost of treating you could be billed to your insurer. If your health insurance will not cover such costs, it is possible you would have to pay out of pocket. In some cases, Lifespan might be able to help you pay if you qualify for free care under Lifespan policy. However, Lifespan has no policy to cover payment for such things as lost wages, expenses other than medical care, or pain and suffering.

8. Rights and Complaints

Signing this form does not take away any of your lawful rights. If you have any complaints about this study, or would like more facts about the rules for research studies, or the rights of people who take part in research studies you may contact Janice Muratori in the Lifespan Office of Research Administration, at (401) 444-6246

9. Confidentiality and Research Authorization for Use and Disclosure of Your Health Care Information.

Your research records will be treated as private health care records and will be protected according to Lifespan privacy practices and policies that are based on state and federal law. In particular, federal law requires us to get your permission to use or disclose (release your information to someone outside of Lifespan) your health information for research purposes. If you sign this form you agree to be in this research study and you permit the use and disclosure of your health information for the purpose of conducting the research, providing treatment, collecting payment and running the business of the hospital. This permission has no expiration date. You may withdraw from the study at any time. However, if you do not want the researchers to use or disclose any further information in this study you must cancel permission in writing and may do so at any time. If you cancel your permission, you will stop taking part in the study and no new information will be collected about you. However, if you cancel your permission, it will not apply to actions already taken or information already collected about you by the hospital or the researchers before you canceled your permission.

Generally, the entire research record and any medical records held by the hospital may be used and released for research purposes. The following people or businesses/companies/ might use, release, or receive such information:

- The researcher and their support staff;
- The study sponsor: NIH/NIAMS (National Institute of Arthritis and Musculoskeletal and Skin Diseases)
- Doctors, nurses, laboratories and others who provide services to you or the sponsor in connection with this study;
- The company or section of the U.S. government that is paying for the study and others they hire to oversee, administer, or conduct the research;
- The United States Food and Drug Administration, the Department of Health and Human Services, the Office of Inspector General, and the Office of Civil Rights; European Medicines Agency
- People who volunteer to be patient advocates or research volunteer protectors;

- Members of the hospital's administrative staff responsible for reviewing, approving and administering clinical trials and other healthcare or research activities.
- Accrediting Organizations

There are times when the law might require or permit Lifespan to release your health information without your permission. For example, Rhode Island law requires researchers and health care workers to report abuse or neglect of children to the Department of Children, Youth and Families (DCYF) and to report abuse or neglect of people age 60 and older to the Department of Elderly Affairs.

All researchers and health care providers are required to protect the privacy of your health care information. Other people and businesses/organizations that are not health care providers are not required by law to do that so it is possible they might re-release your information.

You have the right to refuse to sign this form and not participate in the research. Your refusal would have no affect on your treatment, charges billed to you, or benefits at any Lifespan health care site. If you do not sign, you will not be able to enroll in the research study and will not receive treatment as a study participant.

If you decide to quit the study after signing this form (as described in Section 6) no new information will be collected about you unless you gave us permission to do so. However, the hospital or the researchers may continue to use information that was collected before you quit the study to complete analysis and reports of this research.

Additionally, 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.

For more detail about your privacy rights see the Lifespan Joint Privacy Notice which has or will be given to you.

Study Volunteer Initials

SIGNATURE

I have read this informed consent and authorization form. ALL OF MY QUESTIONS HAVE BEEN ANSWERED, AND I WANT TO TAKE PART IN THIS RESEARCH STUDY.

By signing below, I give my permission to participate in this research study and for the described uses and releases of information. *I also confirm that I have been now or previously given a copy of the Lifespan Privacy Notice*

This informed consent document expires on 11/16/2017.
DO NOT sign this document after this expiration date

The Researcher is required to provide a copy of this consent to you.

Signature of study volunteer/authorized representative* Date and Time when signed

I WAS PRESENT DURING THE CONSENT PROCESS AND SIGNING OF THIS AGREEMENT BY THE STUDY VOLUNTEER OR AUTHORIZED REPRESENTATIVE

Signature of witness (required if consent is presented orally or at the request of the IRB) Date

Signature of Translator Date

Signature of researcher or designate Date and Time when signed

* If signed by agent other than study volunteer, please explain below.

The Miriam Hospital
IRB Approved
6/8/16
Expiration Date
6/7/17

Study Volunteer Initials

Affiliate		
	☒ Rhode Island Hospital	☒ The Miriam Hospital
	☐ Bradley Hospital	☐ Newport Hospital

Agreement to Participate in a Research Study
And Authorization for Use and Disclosure of Information

Committee #

Name of Study Volunteer

Effects of Initial Graft Tension on Anterior Cruciate Ligament Reconstruction
Five and Seven year follow ups

A. ACL-Deficient Patients

You are being asked to take part in a research study. All research studies carried out at Lifespan institutions are covered by rules of the Federal government as well as rules of the State and Lifespan. Under these rules, the researcher will first explain the study, and then he or she will ask you to participate. You will be asked to sign this agreement which states that the study has been explained, that your questions have been answered, and that you agree to participate.

The researcher will explain the purpose of the study. He or she will explain how the study will be carried out and what you will be expected to do. The researcher will also explain the possible risks and possible benefits of being in the study. You should ask the researcher any questions you have about any of these things before you decide whether you wish to take part in the study. This process is called informed consent.

This form also explains the research study. Please read the form and talk to the researcher about any questions you may have. Then, if you decide to be in the study, please sign and date this form in front of the person who explained the study to you. You will be given a copy of this form to keep.

1. Nature and Purpose of the Study
   You are being asked to take part in additional follow up visits for the research project "The effects of initial graft tension on ACL reconstruction" to further evaluate the changes in your surgical knee. We would like to perform five and seven year follow-up visits, which will include knee examinations, x-rays on both knees, strength tests and Magnetic Resonance Images (MRIs) of both of your knees. These visits will allow us to measure the long term mechanical and biological responses of your knee to anterior cruciate ligament reconstruction surgery.

2. Explanation of Procedures

If you take part in this study, a trained physical therapist, associated physicians and technicians will perform the following procedures to your knees. These procedures include questionnaires to assess how you are doing, X-rays, clinical examinations and mechanical measurements of your knee to assess its function and the presence of arthritis. You may also be asked to have MRIs taken to document change in knee geometry. These procedures are described in detail below.

At the 5 year and 7 year follow-up visits you will be asked to fill out three questionnaires (the Tegner, Knee Osteoarthritis Outcome Score, and the SF-36). The questionnaires will be used to evaluate how your knee is doing. Second, a physical therapist or a medical doctor will perform a clinical examination. This examination will be used to determine how your surgical knee is doing. Third, the motion of your knee will be measured using a commercial device (called the KT-1000), which will be strapped to your lower leg. A physical therapist will push your knee backwards and forwards while this device measures the amount of knee movement that occurs. Fourth, you will also undergo two additional "functional" tests to assess your knee function that are commonly used to assess the progress of knee rehabilitation. The first functional test is performed on a device (the "Biodex") that is frequently used when weight training the lower leg muscles. When seated on the Biodex, you will be asked to flex (bend) and extend (straighten) your knee against a resistance force. The second functional test is called the "one-leg hop test". You will be asked to hop as far as you can on each leg. The total distance of each hop will be measured and recorded. Next, you will allow technicians to take up to four X-rays of your normal and injured knees while you are standing.

Finally, you will allow technicians to perform MRI scans on both knees. The MRI visit will be performed at one of three sites (RIH, Brown University or at a facility run by Memorial Hospital of Rhode Island). Magnetic Resonance Imaging (MRI) uses a powerful magnet to take pictures of your knee. Because the MRI machine exposes the body to a very strong magnetic force, you will have to follow certain safety precautions to make sure you do not have any metal objects in or on your body. Thus, before you undergo your MRI scan, a researcher or technician will ask whether or not your body contains any metallic medical devices or equipment, including heart pacemakers, metal prostheses, implants or surgical clips. You also will be asked whether you have had any prior injury from shrapnel or grinding metal, and you will be asked whether your eyes have been exposed to metallic dust or metallic shavings. You or the researcher or technician will also complete a checklist that addresses issues of MRI safety.

If you have no metallic objects or particles in your body, you will be asked before entering the MRI room to remove from your person all metal objects, including jewelry, watches, hair holders or eyeglasses, and you will be asked to empty your pockets of all materials, including keys, wallets and magnetic cards such as ATM and credit cards. In addition, if your clothing has more than a minimal amount of metal content, you may be asked to change into a hospital gown or other suitable garment. Finally, you will be asked to remove any eye shadow you may be wearing, because eye shadow sometimes contains metallic substances.

After you enter the MRI room, you will be asked to lie on your back on a table that slides into a horizontal cylinder slightly wider than your body. Because the MRI machine makes loud noises while it scans, a researcher or technician will provide you with ear protection to reduce the noise level. When you and the researcher or technician are ready to begin the MRI scan, you will be asked to lie as still as you can for up to 2 hours. During this time, multiple scans of both your knees will be performed. This will be done to allow the researchers to determine the geometry of your knee and the integrity of your cartilage (the tissue lining the end of each bone).

For the 5 and 7 year follow-up visits you will receive $100 for each visit to help cover your time to participate in the research procedures. If you have MRIs performed you will also receive $100 for each MRI visit. You will receive payment approximately 4 weeks after each completed visit through a check in the mail, whether or not you complete the entire study.

3. Discomforts and Risks

Risks due to functional testing: There is a risk that the patient could fall when performing the one-leg hop test that could possibly result in a graft rupture or other injury. The test will be performed by a physical therapist to reduce this possibility.

Risks Associated with X-ray Exposure: No more than a total of 8 X-rays will be taken of each knee for research purposes. The potential damage to subjects from exposure to these X-rays is considered insignificant. The total X-ray exposure for the research is estimated at approximately 60% of the background radiation that an individual would be exposed to living in New England over one year. Your torso will be shielded with a lead apron to further reduce your risk. If you are female, you will be asked if you are pregnant before the X-rays are taken. If you are pregnant or become pregnant during the course of the study, the X-rays will not be performed. If you are unsure whether or not you are pregnant, you can decline participation in the X-ray portion of the study.

Risks Associated with MRI scans: These MRI scans will be obtained only for research purposes. The FDA classifies MRI imaging as a non-significant risk. MR imaging is generally considered to be safe, but accidents, injuries, and even deaths have occurred during MRI procedures. Such adverse events are extremely rare if appropriate safety precautions are followed. Serious complications can occur in people who have metal pacemakers, metallic dust in the eyes, or certain types of metal prostheses, implants, or surgical clips. MRI is also dangerous for anyone wearing any metal objects, including jewelry, watches, hair holders, eyeglasses or metal on clothing, as well as eye shadow, which sometimes contains metallic substances. In addition, if you enter the MRI room with any magnetic cards, such as ATM and credit cards, you will risk having the data on the cards erased by the MRI machine. For these reasons, a researcher or technician will review safety information with you before the scan. **In order to determine whether it is safe for you to undergo the scanning procedure, it will be important that you tell the technician about any metallic objects or devices on or in your body.**

During the scan itself, you will lie on a table that slides into a horizontal cylinder slightly wider than your body. You will be asked to lie still, but you will be able to hear and speak to the MRI

personnel/research staff. Some people experience anxiety, panic or a sensation of claustrophobia when lying in the MRI machine. If you think this may happen to you, please tell the researchers before you have the scan. The scanner also makes loud noises during imaging. Ear protection will be provided to reduce the noise level. If you feel uncomfortable for any reason before or during the procedure, please tell the researchers. If for any reason during the procedure you want to stop, you may do so at any time.

CAUTION: This study is neither designed nor intended to detect health problems in participants. The MRI scans that you will undergo do **not** substitute for an appropriate medical examination by a qualified health care provider. If you suspect that you might be suffering from injury or illness, you should **not** rely on this study as a way to determine whether or not you are well.

FOR WOMEN: The safety of MR imaging during pregnancy has not been proved. If you are pregnant, you cannot take part in this study. If you think you may be pregnant you cannot participate in the MRI portion of the study.

4. Benefits
   There will be no direct benefit to you for participating in this study. However, your participation may provide information that will help other people with anterior cruciate ligament injuries by improving future surgical treatment options.

5. Alternative Therapies
   You can choose not to participate in the study.

6. Refusal/Withdrawal
   You decide whether or not you want to be in the study. Participation is voluntary. If you decide now to participate, you can change your mind later and quit the study.
   If you decide not to participate, or if you quit the study, it will not affect the health care services that you normally receive. If the researcher or your doctor feels it is in your best interest, they may choose to take you out of the study at any time before you complete the study.

   As soon as it becomes available, the researcher will give you new information about the study that may or may not affect your decision to stay in the research study

   Follow-up after Withdrawal of Consent
   If you decide to stop your participation in the study, it would still be useful to us to know how you do over the next five years. We'd appreciate it if you'd give your permission for us to continue to obtain follow-up information about your health status from your doctor or from your medical record.

   ____ If I withdraw from the study, you have my permission to collect information about my health from my doctor or medical record.

Study Volunteer Initials

_____ I do not give my permission for you to continue to collect information about me if I stop participating in the study.

Signature of study volunteer _____ Date _____

You have the right to change your mind at any time, regarding follow-up after withdrawal.

7. Medical Treatment/Payment in Case of Injury

If you experience a research injury Lifespan, or the study doctor, will arrange for medical treatment at no cost to you. The cost of your treatment will be paid for as described below. A research injury is any physical injury or illness caused by your participation in the study. If you are injured by a medical treatment or procedure that you would have received even if you were not in the study, that is not a research injury. To help avoid injury, it is very important to follow all study directions.

If you suffer a research injury and you are covered by insurance, it is possible that some or all of the costs of treating your condition could appropriately be billed to your insurance company. If such costs are not covered either by health insurance or the study Sponsor, Lifespan will pay for what it considers fair and proper treatment. Lifespan has no policy to cover payment for such things as lost wages, expenses other than medical care, or pain and suffering.

Signing this form does not lessen or take away any of your lawful rights. For more facts, please contact Patricia E. Houser in the Office of Research Administration at 401-444-6246.

8. Rights and Complaints

If you have any complaints about your taking part in this study, or would like more facts about the rules for research studies, or the rights of people who take part in research studies, you may contact Patricia E. Houser, in the Lifespan Office of Research Administration, at (401) 444-6246

9. Confidentiality

The section at the end of this document called "Research Authorization for Use and Disclosure of Information" provides detailed information about how the information learned about you during this study will be used and shared. More generally, all of your records from this study will be treated as private health care records. The records will be protected according to the rules of Lifespan. The Lifespan privacy practices and policies are based on the rules about protection of private health care information contained in Rhode Island law and in the Federal Health Insurance Portability and Accountability Act of 1996 and its regulations ("HIPAA"). The privacy practices of Lifespan and of the people who provide services at or with Lifespan are explained in more detail in the Lifespan Joint Privacy Notice (the "Privacy Notice') which will be given to you.

You should also know that there are times when the law might require or permit Lifespan to release your health information without your permission. The Privacy Notice explains when this might happen. To give you some examples, State law requires health care workers to

report abuse or neglect of children to the Department of Children, Youth and Families (DCYF). State law also requires health care workers to report abuse or neglect of people age 60 and older to the Department of Elderly Affairs.

10. Research authorization for use and disclosure of information.

The purpose of this section of the document is to provide you with some more information about how the information learned about you during the study will be used and shared.

We understand that your medical information is very personal and we will work hard to keep it private. **If you sign this form you consent to participate in this research study and are giving us permission to use and share your personal health information in the ways described in this form.**

Understandings and notifications

The main purpose of permitting the use and release of your information is to allow the research project to be conducted and to ensure that the information relating to that research is available to all parties who may need it for research purposes. Your information may also be used as necessary for your research-related treatment, to collect payment for your research-related treatment (when applicable), and to run the business operations of the hospital.

All health care providers are required to protect the privacy of your information. However, most persons or entities (i.e., businesses, organizations) that are not health care providers are not bound by law to protect the privacy of your information. You understand that if the person or entity that receives your information is not a health care provider bound to protect your privacy, such person or entity might re-release your health information.

You have the right to refuse to sign this form. If you do not sign this form, none of your health care outside the study, or the payment for your health care, or your health care benefits will be affected. However, if you do not sign this form, you will not be able to enroll in the research study described in this form, and you will not receive treatment as a study participant.

If you sign this consent form, you may withdraw from the study at any time. However, if you do not want the researchers to use or disclose any further information in this study you must cancel permission in writing and may do so at any time. If you cancel your permission, you will stop taking part in the study and no new information will be collected about you. However, if you cancel your permission, it will not apply to actions already taken or information already collected about you by the hospital or the researchers before you canceled your permission. This information or action may be needed to complete analysis and reports of this research. This permission will never expire unless you cancel it. To cancel this permission, please write to Braden Fleming, PhD at Orthopedic Research; Rhode Island Hospital; Coro West, Suite 404; 1 Hoppin St.; Providence, RI 02903

You will not be allowed to see or copy the information described in this form as long as the research is in progress. You may see and copy the information upon completion of the research in accordance with Lifespan policies.

If after you have signed this form you have any questions relating to your rights, please contact Patricia E. Houser, RN, MSJ in the Office of Research Administration, 401-444-6246.

Uses and releases covered by this authorization (permission)
Who will release, receive, and/or use your information? This form will allow the following person(s), class(es) of persons, and/or organization(s)* to release, use, and receive the information listed below in connection with this Study, or as required by law:

- ☒ Every research site for this study, including this hospital, and including each site's research staff and medical staff
- ☒ Health care providers who provide services to you in connection with this study
- ☒ Laboratories and other individuals and organizations that analyze your health information in connection with this study, in accordance with the study's protocol
- ☐ The following research sponsors and the people and companies that they use to oversee, administer, or conduct the research: _____
- ☒ The United States Food and Drug Administration, the Department of Health and Human Services, the Office of Inspector General, and the Office of Civil Rights.
- ☒ The members and staff of the Institutional Review Board(s) or Ethics Committee(s) that approves this study
- ☒ Principal Investigator and other Investigators
- ☒ Study Coordinator
- ☒ Additional members of the Research Team
- ☐ The Patient Advocate or Research Volunteer Protector: _____
- ☒ Members of the hospital's administrative staff responsible for administering clinical trials and other research activities
- ☐ Contract Research Organization (A contract research organization is an independent organization that agrees to oversee and make possible, various aspects of the clinical research process for the research sponsor.)
- ☐ Data and Safety Monitoring Boards and others that monitor the conduct of the Study, for example a Clinical Events Committee
- ☐ The members and staff of the hospitals affiliated Privacy Board (if such a board is used)
- ☐ Others (as described below)_____

* If, during the course of the research, one of the companies or institutions listed above merges with or is purchased by another company or institution, this permission to use or release protected health information in the research will extend to the new company or institution.

- ☐ The entire research record and any medical records held by the hospital may be used and released.

- ☒ The following information:

Study Volunteer Initials

All pre- or post-operative knee x-rays (and/or MRIs); All pre-operative, post-operative and follow up records relating to the knee injury; Biochemical analyses of blood and synovial fluid; Questionnaire data; Clinical examination data; Functional test results.

SIGNATURE

I have read this informed consent and authorization form. ALL OF MY QUESTIONS HAVE BEEN SATISFACTORILY ANSWERED, AND I WANT TO TAKE PART IN THIS RESEARCH STUDY.

By signing below, I give my permission to participate in this research study and for the described uses and releases of information. *I also confirm that I have been now or previously given a copy of the Lifespan Privacy notice*

This informed consent document expires on 6/7/11 .
DO NOT sign this document after this expiration date

Signature of study volunteer/authorized representative* Date and Time when signed

I WAS PRESENT DURING THE CONSENT PROCESS AND SIGNING OF THIS AGREEMENT ABOVE BY THE STUDY VOLUNTEER OR AUTHORIZED REPRESENTATIVE

Signature of witness (required if consent is presented orally or at the request of the IRB) Date

I ASSURE THAT I HAVE FULLY EXPLAINED TO THE ABOVE STUDY VOLUNTEER/AUTHORIZED REPRESENTATIVE, THE NATURE AND PURPOSE, PROCEDURES AND THE POSSIBLE RISK AND POTENTIAL BENEFITS OF THIS RESEARCH STUDY.

Signature of researcher or designate Date and Time when signed

Study Volunteer Initials

* If signed by agent other than study volunteer, please explain below.

_____

_____

Documentation that a copy of this Informed Consent was given to the research participant is a Federal requirement. Prior to making a copy of the signed and dated Informed Consent please check appropriate box(es) as applicable to indicate copy provided to:

☐ Study Volunteer ☐ Medical Record ☐ Researcher ☐ Other (Specify)

The Miriam Hospital
IRB Approved
6/8/10
Expiration Date
6/7/11

Study Volunteer Initials

Affiliate	☒ Rhode Island Hospital	☒ The Miriam Hospital
	☐ Bradley Hospital	☐ Newport Hospital

Agreement to Participate in a Research Study
And Authorization for Use and Disclosure of Information

Committee #

Name of Study Volunteer

Effects of Initial Graft Tension on Anterior Cruciate Ligament Reconstruction
Five and Seven year follow ups

B. Normal (control) Subjects

You are being asked to take part in a research study. All research studies carried out at Lifespan institutions are covered by rules of the Federal government as well as rules of the State and Lifespan. Under these rules, the researcher will first explain the study, and then he or she will ask you to participate. You will be asked to sign this agreement which states that the study has been explained, that your questions have been answered, and that you agree to participate.

The researcher will explain the purpose of the study. He or she will explain how the study will be carried out and what you will be expected to do. The researcher will also explain the possible risks and possible benefits of being in the study. You should ask the researcher any questions you have about any of these things before you decide whether you wish to take part in the study. This process is called informed consent.

This form also explains the research study. Please read the form and talk to the researcher about any questions you may have. Then, if you decide to be in the study, please sign and date this form in front of the person who explained the study to you. You will be given a copy of this form to keep.

1. Nature and Purpose of the Study
   You are being asked to take part in additional follow up visits for the research project "The effects of initial graft tension on ACL reconstruction" to further evaluate the articular cartilage of your normal knees. We are trying to get baseline data of normal knees ("control" group) for comparison of patients who have undergone knee surgery. We would like to perform five and seven year follow-up visits, which will include knee examinations, x-rays on both knees, strength tests and Magnetic Resonance Images (MRIs) of both of your knees.

2. Explanation of Procedures

If you take part in this study, a trained physical therapist, associated physicians and technicians will perform the following procedures to your knees. These procedures include questionnaires to assess how you are doing, X-rays, clinical examinations and mechanical measurements of your knee to assess its function and the presence of arthritis. You may also be asked to have MRIs taken to document change in knee geometry. These procedures are described in detail below.

At the 5 year and 7 year follow-up visits you will be asked to fill out three questionnaires (the Tegner, Knee Osteoarthritis Outcome Score, and the SF-36). The questionnaires will be used to evaluate how your knee is doing. Second, a physical therapist or a medical doctor will perform a clinical examination. This examination will be used to determine if your knee is normal. Third, the motion of your knee will be measured using a commercial device (called the KT-1000), which will be strapped to your lower leg. A physical therapist will push your knee backwards and forwards while this device measures the amount of knee movement that occurs. Fourth, you will also undergo two additional "functional" tests to assess your knee function that are commonly used to assess the progress of knee rehabilitation. The first functional test is performed on a device (the "Biodex") that is frequently used when weight training the lower leg muscles. When seated on the Biodex, you will be asked to flex (bend) and extend (straighten) your knee against a resistance force. The second functional test is called the "one-leg hop test". You will be asked to hop as far as you can on each leg. The total distance of each hop will be measured and recorded. Next, you will allow technicians to take up to four X-rays of your knees while you are standing.

Finally, you will allow technicians to perform MRI scans on both knees. The MRI visit will be performed at one of three sites (RIH, Brown University or at a facility run by Memorial Hospital of Rhode Island). Magnetic Resonance Imaging (MRI) uses a powerful magnet to take pictures of your knee. Because the MRI machine exposes the body to a very strong magnetic force, you will have to follow certain safety precautions to make sure you do not have any metal objects in or on your body. Thus, before you undergo your MRI scan, a researcher or technician will ask whether or not your body contains any metallic medical devices or equipment, including heart pacemakers, metal prostheses, implants or surgical clips. You also will be asked whether you have had any prior injury from shrapnel or grinding metal, and you will be asked whether your eyes have been exposed to metallic dust or metallic shavings. You or the researcher or technician will also complete a checklist that addresses issues of MRI safety.

If you have no metallic objects or particles in your body, you will be asked before entering the MRI room to remove from your person all metal objects, including jewelry, watches, hair holders or eyeglasses, and you will be asked to empty your pockets of all materials, including keys, wallets and magnetic cards such as ATM and credit cards. In addition, if your clothing has more than a minimal amount of metal content, you may be asked to change into a hospital gown or other suitable garment. Finally, you will be asked to remove any eye shadow you may be wearing, because eye shadow sometimes contains metallic substances.

After you enter the MRI room, you will be asked to lie on your back on a table that slides into a horizontal cylinder slightly wider than your body. Because the MRI machine makes loud noises while it scans, a researcher or technician will provide you with ear protection to reduce the noise level. When you and the researcher or technician are ready to begin the MRI scan, you will be asked to lie as still as you can for up to 2 hours. During this time, multiple scans of both your knees will be performed. This will be done to allow the researchers to determine the geometry of your knee and the integrity of your cartilage (the tissue lining the end of each bone).

For the 5 and 7 year follow-up visits you will receive $100 for each visit to help cover your time to participate in the research procedures. If you have MRIs performed you will also receive $100 for each MRI visit. You will receive payment approximately 4 weeks after each completed visit through a check in the mail, whether or not you complete the entire study.

3. Discomforts and Risks

Risks due to functional testing: There is a slight risk that you could fall when performing the one-leg hop test. The test will be performed under the guidance of a physical therapist to reduce this possibility.

Risks Associated with X-ray Exposure: No more than a total of 8 X-rays will be taken of each knee for research purposes. The potential damage to subjects from exposure to these X-rays is considered insignificant. The total X-ray exposure for the research is estimated at approximately 60% of the background radiation that an individual would be exposed to living in New England over one year. Your torso will be shielded with a lead apron to further reduce your risk. If you are female, you will be asked if you are pregnant before the X-rays are taken. If you are pregnant or become pregnant during the course of the study, the X-rays will not be performed. If you are unsure whether or not you are pregnant, you can decline participation in the X-ray portion of the study.

Risks Associated with MRI scans: These MRI scans will be obtained only for research purposes. The FDA classifies MRI imaging as a non-significant risk. MR imaging is generally considered to be safe, but accidents, injuries, and even deaths have occurred during MRI procedures. Such adverse events are extremely rare if appropriate safety precautions are followed. Serious complications can occur in people who have metal pacemakers, metallic dust in the eyes, or certain types of metal prostheses, implants, or surgical clips. MRI is also dangerous for anyone wearing any metal objects, including jewelry, watches, hair holders, eyeglasses or metal on clothing, as well as eye shadow, which sometimes contains metallic substances. In addition, if you enter the MRI room with any magnetic cards, such as ATM and credit cards, you will risk having the data on the cards erased by the MRI machine. For these reasons, a researcher or technician will review safety information with you before the scan. **In order to determine whether it is safe for you to undergo the scanning procedure, it will be important that you tell the technician about any metallic objects or devices on or in your body.**

During the scan itself, you will lie on a table that slides into a horizontal cylinder slightly wider than your body. You will be asked to lie still, but you will be able to hear and speak to the MRI personnel/research staff. Some people experience anxiety, panic or a sensation of claustrophobia when lying in the MRI machine. If you think this may happen to you, please tell the researchers before you have the scan. The scanner also makes loud noises during imaging. Ear protection will be provided to reduce the noise level. If you feel uncomfortable for any reason before or during the procedure, please tell the researchers. If for any reason during the procedure you want to stop, you may do so at any time.

CAUTION: This study is neither designed nor intended to detect health problems in participants. The MRI scans that you will undergo do **not** substitute for an appropriate medical examination by a qualified health care provider. If you suspect that you might be suffering from injury or illness, you should **not** rely on this study as a way to determine whether or not you are well.

FOR WOMEN: The safety of MR imaging during pregnancy has not been proved. If you are pregnant, you cannot take part in this study. If you think you may be pregnant you cannot participate in the MRI portion of the study.

4. Benefits
   There will be no direct benefit to you for participating in this study. However, your participation may provide information that will help other people with anterior cruciate ligament injuries by improving future surgical treatment options.

5. Alternative Therapies
   You can choose not to participate in the study.

6. Refusal/Withdrawal
   You decide whether or not you want to be in the study. Participation is voluntary. If you decide now to participate, you can change your mind later and quit the study.
   If you decide not to participate, or if you quit the study, it will not affect the health care services that you normally receive. If the researcher or your doctor feels it is in your best interest, they may choose to take you out of the study at any time before you complete the study.

   As soon as it becomes available, the researcher will give you new information about the study that may or may not affect your decision to stay in the research study

   Follow-up after Withdrawal of Consent
   If you decide to stop your participation in the study, it would still be useful to us to know how you do over the next five years. We'd appreciate it if you'd give your permission for us to continue to obtain follow-up information about your health status from your doctor or from your medical record.

   ____ If I withdraw from the study, you have my permission to collect information about my health from my doctor or medical record.

Study Volunteer Initials

_____ I do not give my permission for you to continue to collect information about me if I stop participating in the study.

_____ _____

Signature of study volunteer Date

You have the right to change your mind at any time, regarding follow-up after withdrawal.

7. Medical Treatment/Payment in Case of Injury

If you experience a research injury Lifespan, or the study doctor, will arrange for medical treatment at no cost to you. The cost of your treatment will be paid for as described below. A research injury is any physical injury or illness caused by your participation in the study. If you are injured by a medical treatment or procedure that you would have received even if you were not in the study, that is not a research injury. To help avoid injury, it is very important to follow all study directions.

If you suffer a research injury and you are covered by insurance, it is possible that some or all of the costs of treating your condition could appropriately be billed to your insurance company. If such costs are not covered either by health insurance or the study Sponsor, Lifespan will pay for what it considers fair and proper treatment. Lifespan has no policy to cover payment for such things as lost wages, expenses other than medical care, or pain and suffering.

Signing this form does not lessen or take away any of your lawful rights. For more facts, please contact Patricia E. Houser in the Office of Research Administration at 401-444-6246.

8. Rights and Complaints

If you have any complaints about your taking part in this study, or would like more facts about the rules for research studies, or the rights of people who take part in research studies, you may contact Patricia E. Houser, in the Lifespan Office of Research Administration, at (401) 444-6246

9. Confidentiality

The section at the end of this document called "Research Authorization for Use and Disclosure of Information" provides detailed information about how the information learned about you during this study will be used and shared. More generally, all of your records from this study will be treated as private health care records. The records will be protected according to the rules of Lifespan. The Lifespan privacy practices and policies are based on the rules about protection of private health care information contained in Rhode Island law and in the Federal Health Insurance Portability and Accountability Act of 1996 and its regulations ("HIPAA"). The privacy practices of Lifespan and of the people who provide services at or with Lifespan are explained in more detail in the Lifespan Joint Privacy Notice (the "Privacy Notice') which will be given to you.

You should also know that there are times when the law might require or permit Lifespan to release your health information without your permission. The Privacy Notice explains when

this might happen. To give you some examples, State law requires health care workers to report abuse or neglect of children to the Department of Children, Youth and Families (DCYF). State law also requires health care workers to report abuse or neglect of people age 60 and older to the Department of Elderly Affairs.

10. Research authorization for use and disclosure of information.

The purpose of this section of the document is to provide you with some more information about how the information learned about you during the study will be used and shared.

We understand that your medical information is very personal and we will work hard to keep it private. **If you sign this form you consent to participate in this research study and are giving us permission to use and share your personal health information in the ways described in this form.**

Understandings and notifications

The main purpose of permitting the use and release of your information is to allow the research project to be conducted and to ensure that the information relating to that research is available to all parties who may need it for research purposes. Your information may also be used as necessary for your research-related treatment, to collect payment for your research-related treatment (when applicable), and to run the business operations of the hospital.

All health care providers are required to protect the privacy of your information. However, most persons or entities (i.e., businesses, organizations) that are not health care providers are not bound by law to protect the privacy of your information. You understand that if the person or entity that receives your information is not a health care provider bound to protect your privacy, such person or entity might re-release your health information.

You have the right to refuse to sign this form. If you do not sign this form, none of your health care outside the study, or the payment for your health care, or your health care benefits will be affected. However, if you do not sign this form, you will not be able to enroll in the research study described in this form, and you will not receive treatment as a study participant.

If you sign this consent form, you may withdraw from the study at any time. However, if you do not want the researchers to use or disclose any further information in this study you must cancel permission in writing and may do so at any time. If you cancel your permission, you will stop taking part in the study and no new information will be collected about you. However, if you cancel your permission, it will not apply to actions already taken or information already collected about you by the hospital or the researchers before you canceled your permission. This information or action may be needed to complete analysis and reports of this research. This permission will never expire unless you cancel it. To cancel this permission, please write to Braden Fleming, PhD at Orthopedic Research; Rhode Island Hospital; Coro West, Suite 404; 1 Hoppin St.; Providence, RI 02903

You will not be allowed to see or copy the information described in this form as long as the research is in progress. You may see and copy the information upon completion of the research in accordance with Lifespan policies.

If after you have signed this form you have any questions relating to your rights, please contact Patricia E. Houser, RN, MSJ in the Office of Research Administration, 401-444-6246.

Uses and releases covered by this authorization (permission)
Who will release, receive, and/or use your information? This form will allow the following person(s), class(es) of persons, and/or organization(s)* to release, use, and receive the information listed below in connection with this Study, or as required by law:

- ☒ Every research site for this study, including this hospital, and including each site's research staff and medical staff
- ☒ Health care providers who provide services to you in connection with this study
- ☒ Laboratories and other individuals and organizations that analyze your health information in connection with this study, in accordance with the study's protocol
- ☐ The following research sponsors and the people and companies that they use to oversee, administer, or conduct the research: _____
- ☒ The United States Food and Drug Administration, the Department of Health and Human Services, the Office of Inspector General, and the Office of Civil Rights.
- ☒ The members and staff of the Institutional Review Board(s) or Ethics Committee(s) that approves this study
- ☒ Principal Investigator and other Investigators
- ☒ Study Coordinator
- ☒ Additional members of the Research Team
- ☐ The Patient Advocate or Research Volunteer Protector: _____
- ☒ Members of the hospital's administrative staff responsible for administering clinical trials and other research activities
- ☐ Contract Research Organization (A contract research organization is an independent organization that agrees to oversee and make possible, various aspects of the clinical research process for the research sponsor.)
- ☐ Data and Safety Monitoring Boards and others that monitor the conduct of the Study, for example a Clinical Events Committee
- ☐ The members and staff of the hospitals affiliated Privacy Board (if such a board is used)
- ☐ Others (as described below)_____

* If, during the course of the research, one of the companies or institutions listed above merges with or is purchased by another company or institution, this permission to use or release protected health information in the research will extend to the new company or institution.

- ☐ The entire research record and any medical records held by the hospital may be used and released.

- ☒ The following information:

Study Volunteer Initials

All pre- or post-operative knee x-rays (and/or MRIs); All pre-operative, post-operative and follow up records relating to the knee injury; Biochemical analyses of blood and synovial fluid; Questionnaire data; Clinical examination data; Functional test results.

SIGNATURE

I have read this informed consent and authorization form. ALL OF MY QUESTIONS HAVE BEEN SATISFACTORILY ANSWERED, AND I WANT TO TAKE PART IN THIS RESEARCH STUDY.

By signing below, I give my permission to participate in this research study and for the described uses and releases of information. *I also confirm that I have been now or previously given a copy of the Lifespan Privacy notice*

This informed consent document expires on 6/7/11 .
DO NOT sign this document after this expiration date

Signature of study volunteer/authorized representative* Date and Time when signed

I WAS PRESENT DURING THE CONSENT PROCESS AND SIGNING OF THIS AGREEMENT ABOVE BY THE STUDY VOLUNTEER OR AUTHORIZED REPRESENTATIVE

Signature of witness (required if consent is presented orally or at the request of the IRB) Date

I ASSURE THAT I HAVE FULLY EXPLAINED TO THE ABOVE STUDY VOLUNTEER/AUTHORIZED REPRESENTATIVE, THE NATURE AND PURPOSE, PROCEDURES AND THE POSSIBLE RISK AND POTENTIAL BENEFITS OF THIS RESEARCH STUDY.

Signature of researcher or designate Date and Time when signed

Study Volunteer Initials

* If signed by agent other than study volunteer, please explain below.

_____

_____

Documentation that a copy of this Informed Consent was given to the research participant is a Federal requirement. Prior to making a copy of the signed and dated Informed Consent please check appropriate box(es) as applicable to indicate copy provided to:

☐ Study Volunteer ☐ Medical Record ☐ Researcher ☐ Other (Specify)

Affiliate	☒ Rhode Island Hospital	☒ The Miriam Hospital
	☐ Bradley Hospital	☒ Newport Hospital

Agreement to Participate in a Research Study

Committee # _____ Name of Study Volunteer _____

Effects of Initial Graft Tension on Anterior Cruciate Ligament Reconstruction

A. ACL-Deficient Patients

You are being asked to take part in a research study. All research studies carried out at Lifespan institutions are covered by rules of the Federal government as well as rules of the State and Lifespan. Under these rules, the researcher will first explain the study, and then he or she will ask you to participate. You will be asked to sign this agreement which states that the study has been explained, that your questions have been answered, and that you agree to participate.

The researcher will explain the purpose of the study. He or she will explain how the study will be carried out and what you will be expected to do. The researcher will also explain the possible risks and possible benefits of being in the study. You should ask the researcher any questions you have about any of these things before you decide whether you wish to take part in the study. This process is called informed consent.

This form also explains the research study. Please read the form and talk to the researcher about any questions you may have. Then, if you decide to be in the study, please sign and date this form in front of the person who explained the study to you. You will be given a copy of this form to keep.

1. Nature and Purpose of the Study

You are invited to participate in this research study that is funded by the National Institutes of Health. One hundred and four patients who have an anterior cruciate ligament injury will be asked to participate in this study. Fifty-four subjects who have not injured their knees will also be asked to participate in the non-surgical aspects of the study.

Anterior cruciate ligament reconstruction is a surgical procedure that is frequently used to treat an anterior cruciate ligament disruption. During surgery, the ligament is replaced with a substitute (typically a tendon graft). However, little is known about the best means of applying force (tension) to the graft after it is inserted in the knee. Some surgeons feel that it is best to apply force to the graft to recreate normal knee motion at the time of surgery while others feel that it is best to use a greater force to compensate for any stretching that may occur in the graft during the healing process. Although both methods are commonly used, it is not known which tensioning procedure is the best for the long-term. This study will help answer this question and will be accomplished by measuring the mechanical and biological responses of your knee before, during, and at specific time points following your surgery. Your results will also be compared to the subjects who do not have a knee injury. We hope that this study may lead to improvements in anterior cruciate ligament reconstruction surgery.

2. Explanation of Procedures

Drs. Paul Fadale, Michael Hulstyn, Robert Shalvoy, James Maher, associated physicians, and technicians will perform the following procedures to your knee. These procedures include questionnaires to assess how you are doing, X-rays, clinical examinations and mechanical measurements of your knee to assess its function and the presence of arthritis. You may also be asked to have MRIs taken to document change in knee geometry, but you do not have to have MRIs taken to be a part of the study. These procedures are described in detail below.

Pre-operative Procedures

Prior to your surgery, you will undergo a complete medical evaluation of your knee injury. First, you will be asked to fill out three questionnaires (the Tegner, Knee Osteoarthritis Outcome Score, and the SF-36). The questionnaires will be used to evaluate how your knee is doing and how you are coping with your injury and treatment. Second, a medical doctor (that is not your surgeon) will

perform a clinical examination. This examination will be used to determine the extent of your injury and how your injury is responding to treatment. Third, the motion of your knee will be measured using a commercial device (called the KT-1000), which will be strapped to your lower leg. A physical therapist will push your knee backwards and forwards while this device measures the amount of knee movement that occurs. Fourth, you will also undergo two additional "functional" tests to assess your knee function and are commonly used to assess the progress of knee rehabilitation. The first functional test is performed on a device (the "Biodex") that is frequently used when weight training the lower leg muscles. When seated on the Biodex, you will be asked to flex (bend) and extend (straighten) your knee against a resistance force. The second functional test is called the "one-leg hop test". You will be asked to hop as far as you can on each leg. The total distance of each hop will be measured and recorded. Next, you will allow technicians to take up to four X-rays of your normal and injured knees while you are standing. Finally, you will allow technicians to perform MRI scans on both knees (if you choose to participate in this part of the study). This will be done to allow the researchers to determine the geometry of your knee and the integrity of your cartilage (the tissue lining the end of each bone).

1. *Operative Procedures*

Just prior to making the surgical incisions, but after your leg has been anesthetized, a small amount of fluid (approximately 1 teaspoon) will be removed from your normal and injured knees by a medical doctor using a hypodermic needle. The needle will be inserted next to your kneecap. The fluid in your knee will be analyzed to determine if arthritis is present. A blood sample (approximately 1 tablespoon) will also be taken using a hypodermic needle from a vein in your arm. The motion of your knee will then be re-measured using the "KT-1000" as described above.

You will then be randomly assigned to either the "low-tension" or "high-tension" treatment group. You will have an equal chance of being assigned to either group and you will not be able to choose which treatment you will receive. You will not be told which group you have been assigned to until after the study is complete. If you are placed in the "low-tension" group, forces will be applied to your graft that will produce knee motions similar to that of your uninjured knee at the time of surgery. If you are placed in the "high-tension" group, forces will be applied to your graft at the time of surgery that will initially produce less motion in your knee. Both the "high-tension" and "low-tension" techniques are commonly used for this surgical procedure.

A common surgical procedure that is routinely used at Rhode Island Hospital, The Miriam Hospital and Newport Hospital for the reconstruction of the anterior cruciate ligament will be performed. A portion of your patellar tendon (a tendon located between your knee cap and lower leg) or your hamstring tendons (located on the back and inner portion of your thigh) will be removed to make the graft. The graft will then be placed in your knee through tunnels drilled in the bones. One end of the graft will be fixed with a screw as is routine. The other end will be attached to a surgical device that will be used to apply the tension to the graft before it is permanently attached. For the experiment, the force in the graft will be adjusted until the motion of your knee meets the "low-tension" standard (where the motion of the operated knee is similar to that of the non-operated knee) or the "high-tension" standard (where the motion of the operated knee is approximately $1/10^{th}$ of an inch less than that of the non-operated knee), depending on which group you are assigned to. The KT-1000 will be used to measure your knee motion during this procedure. Once the appropriate tension has been achieved, this end of the graft will be permanently fixed in your knee using a screw as is routine. The surgery will then be completed following routine procedures. The additional time required by the research steps will be less than 5 minutes.

2. *Follow-up Procedures*

Your post-operative care will not be different if you participate in this study. After surgery, you will be instructed how to rehabilitate your knee. You will then visit your surgeon for your routine follow-up visits. Research follow-up visits will also be required by the study. These will occur at 6-, 12-, and 36-months after your surgery. The 6- and 12-month visits will coincide with one of your routine clinical visits. The 36-month visits will be for research purposes only. You will also be contacted by phone at 24-months to see how you are doing. These visits can be held in the Providence, East Greenwich or Newport clinics.

At the 6-month follow-up visit, you will be asked to fill out two of the questionnaires that you filled out prior to your surgery (the Knee Osteoarthritis Outcome Score and the SF-36). A doctor (that is not your surgeon) will perform a clinical examination. The KT-1000 will be used to measure your knee motion. The total research time for each of these visits will be approximately one hour.

At the 12- and 36-month follow-up visits, the same tests that were performed at your 6-month visit will be repeated. In addition, you will be asked to perform the two functional tests that were described for your pre-operative visit (the "Biodex" and "one-legged hop test"). Up to four additional x-rays will be taken of your injured and

normal knees following the same procedure that was described for the pre-operative visit at each visit. At the 36-month visit MRI scans will be repeated if obtained at the initial visit. The 12-month visits should take less than 1 hour to complete. The 36-month visit will take two to three hours, if you have MRIs performed.

For the initial, 6-, 12- and 36-month follow-up visits you will receive $100.00 for each visit to help cover your time to participate in the research procedures. If you have MRIs performed you will also receive $100 for each MRI visit. You will receive payment approximately 4 weeks after each completed visit whether or not you complete the entire study.

If you have any questions at any time regarding the study you are free to contact the Primary Investigator, Dr. Braden Fleming at 401-444-4164.

3. Discomforts and Risks

Complications due to Knee Surgery: Complications of knee surgery are not common, but do occasionally occur. Some of the possible surgical complications include infection, blood clots, increased swelling and irritation to the lining of the joints. These complications are very rare. For example, the infection rate is less than 1%.

Complications due to Graft Tension: Both graft-tensioning techniques are commonly used. It is unknown which is the better for the long-term. There is a possibility that the knees with the "high-tension" grafts may result in a joint that is initially too tight, potentially limiting your knee motion. It is also possible that a "low-tension" graft could become excessively loose once the graft heals. We may also find that there is no difference between the two treatments after healing takes place.

Risks Associated with the Removal of Joint Fluid & Blood: The risks associated with the removal of joint fluid (and blood) are considered minimal. Redness, bruising or soreness may occur where the needle was inserted into your knee or vein. This should not last more than a couple of days. There is also a slight risk of infection when obtaining synovial fluid. However, no infections have occurred when removing joint fluid for similar research studies at other institutions in over 3000 patients.

Risks due to functional testing: There is a slight risk that the graft could be damaged if the functional tests are performed during the initial healing phases. These activities are known to load the anterior cruciate ligament graft and are commonly used to determine if a patient is ready to go back to sports. They are also used to assess the

progress of rehabilitation. The functional tests will be performed by a physical therapist that is trained in rehabilitation following ACL reconstruction. The tests will not be administered during the first 6-months following surgery to ensure that the graft will not be damaged when it is weak. There is also a risk that the patient could fall when performing the one-leg hop test that could possibly result in a graft rupture or other injury. The test will be performed by a physical therapist to reduce this possibility.

Risks Associated with X-ray Exposure: No more than a total of 8 X-rays will be taken of each knee for research purposes. The potential damage to subjects from exposure to these X-rays is considered insignificant. The total X-ray exposure for the research is estimated at approximately 60% of the background radiation that an individual would be exposed to living in New England over one year. Your torso will be shielded with a lead apron to further reduce your risk. If you are female, you will be asked if you are pregnant before the X-rays are taken. If you are pregnant or become pregnant during the course of the study, the X-rays will not be performed. If you are unsure whether or not you are pregnant, you can decline participation in the X-ray portion of the study.

Risks Associated with MRI scans: MRI scans will be obtained two times for research purposes. The FDA classifies MRI imaging as a non-significant risk. You will be screened for metal objects before scans are performed because the strong magnetic field used by the MRI will pull on any metal object implanted in the body the MRI staff will ask whether you have a any metal plates, pins, screws or surgical staples in your body. Other potential risks include elevated noise from the MRI machine; discomfort associated with lying in an MRI gantry and finally the risks of MR imaging on a developing fetus are not fully understood. If you are pregnant or become pregnant during the course of the study, the MRIs will not be performed.

Your participation in this study will require additional time over and above your regularly scheduled visits to the clinic. The research portions of the 6-, and 12-month follow-up visits will be less than 90 minutes. The initial visit and 36-month visit will be two to three hours if MRI time is included.

4. Benefits

There will be no direct benefit to you for participating in this study. However, your participation may provide information that will help other people with anterior cruciate ligament injuries by improving future surgical treatment options.

5. Alternative Therapies

Disruption of the anterior cruciate ligament can be treated with physical therapy in some patients. The choice is dependent on a number of factors that have been discussed with your doctor. Also, the surgical procedure can be performed using other graft types. The decision to undergo anterior cruciate ligament reconstruction using a patellar tendon graft was not based on your participation in the study.

6 Confidentiality

All of your records from this study will be treated as private health care records. The records will be protected according to the rules of Lifespan. The Lifespan privacy practices and policies are based on the rules about protection of private health care information contained in Rhode Island law and in the Federal Health Insurance Portability and Accountability Act of 1996 and its regulations ("HIPAA"). The privacy practices of Lifespan and of the people who provide services at or with Lifespan are explained in more detail in the Lifespan Joint Privacy Notice (the "Privacy Notice') which will be given to you.

As required by HIPAA, you will be given a separate Research Authorization Form that will tell you the people and organizations that may use, receive and share information learned about you during the Study. Signing the Authorization Form means you give permission for your health care information to be used and shared for the Study purposes.

You should also know that there are times when the law might require or permit Lifespan to release your health information without your permission. The Privacy Notice explains when this might happen. To give you some examples, State law requires health care workers to report abuse or neglect of children to the Department of Children, Youth and Families (DCYF). State law also requires health care workers to report abuse or neglect of people age 60 and older to the Department of Elderly Affairs.

7. Refusal/Withdrawal

You decide whether or not, you want to be in the study. Participation is voluntary. If you decide now to participate, you can change your mind later and quit the study.

If you decide not to participate, or if you quit the study, it will not affect the health care services that you normally receive. If the researcher or your doctor feels it is in your best interest, they may

choose to take you out of the study at any time before you complete the study.

As soon as it becomes available, the researcher will give you new information about the study that may or may not affect your decision to stay in the research study

8. Medical Treatment/Payment in Case of Injury

We do not expect that you will be hurt by taking part in this research study. However, if you are hurt as a result of taking part in this study, Lifespan will provide without charge to you, what it feels is fair and proper treatment. Lifespan does not however, have any plan or money set aside to pay you (for "pain or suffering") if you are hurt. Signing this agreement does not lessen or take away any of your lawful rights. For more facts about these terms, please contact Patricia E. Houser in the Office of Research Administration at 401-444-6246.

9. Rights and Complaints

If you have any complaints about your taking part in this study, or would like more facts about the rules for research studies, or the rights of people who take part in research studies, you may contact Patricia E. Houser, in the Lifespan Office of Research Administration, at (401) 444-6246

I HAVE READ THE ABOVE DESCRIPTION OF THIS STUDY. ALL OF MY QUESTIONS HAVE BEEN SATISFACTORILY ANSWERED, AND I WANT TO TAKE PART IN THIS RESEARCH STUDY.

Signature of study volunteer/authorized representative* Date

I WAS PRESENT DURING THE CONSENT PROCESS ANDSIGNING OF THIS AGREEMENT ABOVE BY THE STUDY VOLUNTEER OR AUTHORIZED REPRESENTATIVE

Signature of witness (required if consent is presented orally or at the Date

Study Volunteer Initials

request of the IRB)

I ASSURE THAT I HAVE FULLY EXPLAINED TO THE ABOVE STUDY VOLUNTEER/AUTHORIZED REPRESENTATIVE, THE NATURE AND PURPOSE, PROCEDURES AND THE POSSIBLE RISK AND POTENTIAL BENEFITS OF THIS RESEARCH STUDY.

Signature of researcher or designate

Date

Consent form copy: ☐ study volunteer ☐ medical record ☐ researcher ☐ other(specify)

*If signed by agent other than study volunteer, please explain below.