UOA ACLR Data Repository PRO 2026000264
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Consent to share ACL data with UOA ACLR Data Repository

SUMMARY: This form is part of an informed consent process for research, and it will provide information that will help you decide whether you want to take part in this research. It is your choice whether to take part or not.

PURPOSE:
You are being asked to share your de-identified data related to your Anterior Cruciate Ligament Reconstruction (ACLR) with the UOA ACLR Data Repository for use in future research on ACL injury, it's causes, surgical management, therapy, impact of injury on recovery, and return to sports.

If you take part in the research, there will be nothing additional for you to do. You are consenting to share your clinical, surgical and recovery data associated with your ACLR injury and it's treatment, with the UOA ACLR Data Repository.

RISKS/BENEFITS:
Physical Risks of Harm
There is no risk of physical harm that may occur with allowing us to utilize your de-identified data.
Psychological or Social Risks Associated with Loss of Privacy
Your privacy is very important to us and we will use many safety measures to protect your privacy. However, in spite of all the safety measures that we will use, we cannot guarantee that your identity will never become known.

- While the databases developed for this project will be coded with an alternate MRN and will not contain information that is traditionally used to identify you, such as your name, address, telephone number, or medical record number, people may develop ways in the future that would allow someone to link your medical information in our protected databases back to you. It is also possible that there could be violations to the security of the computer systems used to store the codes linking your medical information to you.

- There also may be other privacy risks that we have not foreseen.

ALTERNITIVES: Your alternative to taking part in the research is not to take part in it.

You do not have to share your data with the repository.

What is the Consent Process?
The consent form is part of informed consent process for the collection of de-identified data associated with ACLR for research. The form tells you important information about the research, the research procedures and information about your injury and surgery that will be collected, and will be stored on the UOA secure network (the same network your electronic health record is stored on). A member of the study staff will tell you about the research, review this form with you, and answer your questions about the research.

The form is arranged, as a series of questions we think are important to be answered for you before you make your decision. Please feel free to ask other questions. Please ask the study staff to explain any words or information provided in this document that you do not understand. You should feel free to ask questions and should expect answers that you understand. You may take home a copy of this consent form to think about or discuss with family or friends before making your decision.

After all of your questions have been answered and you determine that you want to contribute to the UOA ACLR data repository, you will be asked to sign this consent form to indicate your permission to take part in the research and allow investigators to collect and use your de-identified (with personal identifiers removed) health information. Your name will only be used to locate your medical record, but no personal data will be included in the data collection. We will give you a copy of the consent form to keep. If you do not want to allow use of your personal ACLR information, say no and do not sign the consent form. Your decision to take part or not to take part does not affect your relationship with the study staff, your medical care, or any benefits to which you are otherwise entitled.

- If you have any additional questions about the research, please contact the principal investigator **Charles J. Gatt, Jr., MD – 732-537-0909, x2500**
- If you have any questions about your rights as a subject in research, please contact the Rutgers IRB Office **732-235-2866**. You may also find information about research at Rutgers at the following website address http://www.rutgers.edu/research/research-rutgers.

Why am I being asked to take part in the Research Data Bank?

You are being asked to share your specific ACL data, which will be studied to better understand ACL injury, impact on management/recovery and return to activity. In order to gain a higher level of understanding, we need to study a large sample of ACL data in aggregate. We would like to enroll 250 prospective participants. This requires the formal establishment of an an ACLR data repository. We expect 700 people will contribute to the UOA ACLR Data repository.

What is the relationship between the Investigator and the Research Data Bank?

- **Investigator is Owner/Operator**

The PI and Co-Investigators are orthopaedic surgeons at UOA, and will be the owner and operator of the research **data** repository. The data will be maintained at UOA on a secure network that is monitored by UOA administrative staff.

What is the purpose of this research data bank?

Objectives

Establish a secure ACL data repository in order to compile significant data to study the individual factors which may influence Anterior Cruciate Ligament (ACL) injury, and ACL reconstruction (ACLR) in order to optimize management and facilitate future decision making and recovery.

The long-term goals of this data repository are to grow in number of patients who contribute data in order to better understand ACL injury. This may have an impact on ACL prevention, prediction of outcomes, improve management decision making, modify rehabilitation, improve functional assessment, and return to play decision making. There is no set limit to the number of individuals that provide data and information to this data bank. The more samples and associated information available in the data bank, the more useful the data bank will be for ACL research.

For what type of research will my data information be used?

Your ACL Data will be used mainly to investigate questions regarding ACL injury and it's management. The long-term goals of the research are to better understand, prevent, diagnose and facilitate treatment for ACL injury. However, it is not possible to list every research project. Also, we cannot predict all of the research questions that will be important in the coming years. As we learn more, there are new research questions and the data may generate new types of research related to **ACL injury** that may be done.

____ (initial) I permit my **data/** information to be stored and used for research in the UOA ACLR Data Repository in order to learn about, prevent, or treat ACL injury.

How will my data be collected?

Individuals who have suffered an ACL injury, come to UOA for ACL evaluation/treatment/surgery/care, and have consented/agreed to undergo ACLR surgery with a UOA orthopaedic surgeon, are eligible to participate in the study. The surgeon will notify study staff of patients who will be undergoing ACLR at UOA and whom may be eligible to contribute ACL data to the repository. Study staff will inform patients of the repository and answer all questions about participation prior to receiving informed consent.

Once consent is obtained, approved study staff will collect information about your ACL injury from your patient chart. We will only utilize your name to identify your chart. Data that is collected for the repository from your chart will be de-identified and not directly link you in the repository. Once we identify your chart in our electronic health record, we will gather information about your ACL reconstruction surgery, as well as the information your doctor enters about your recovery, including

tests, and questionnaires you complete to track the progress of your recovery. The repository will also collect data about your injury that led to your ACL reconstructive surgery.

Investigators, whose studies have been approved by the Rutgers Institutional Review Board, or "IRB", may be allowed to review the aggregate ACL data within the repository. No one outside of the study team will have access to your individual medical record. UOA owns, protects and will maintain all access to the repository data. The IRB is a committee that independently reviews and approves research studies that involve people at Rutgers and other facilities that have asked them to review their repository-related research. The IRB follows state and federal laws and codes of ethics to help protect the rights and welfare of people taking part in research.

How will my data be coded and stored?

To protect your privacy, your personal health information, once your chart has been identified, you will be assigned an alternate ID by our study staff through our electronic health record (EHR). Your data will be identified only by the alternate ID. Only IRB approved study staff and UOA administrators will have the code that links to personal information traditionally used to identify you, such as your name, address, telephone number, or medical record number. The alternate ID will be stored within the UOA network and study coordinator (Eric Nussbaum) will keep a record of alternate ID utilized in a safeguarded information file. Only authorized study team members, who have agreed to protect your identity and information, will have access to this database. Once the ACL data is gathered from your chart, by the approved study staff, it will be uploaded into the data repository. It will have been de-identified with only an alternate ID linking it to your personal chart. The data repository is owned by UOA and will be maintained on a double password protected network at UOA. The security of this network also maintains the electronic health record which stores your health information as well. The data repository will be kept separate from the EHR in a secure file, on the secured UOA network. UOA will maintain control and security of the ACLR data repository.

Which researchers can use my data and what information about me can they have?

Sharing Limited to Us and Other Researchers at Rutgers:
Our own investigators and other IRB-approved investigators, who have been approved by the PI/UOA, for researching ACL injury, will use your de-identified data. The UOA ACLR data repository will be maintained by UOA, and will provide investigators only de-identified data that does not identify you. We will not provide information that is traditionally used to identify you such as your name, address, telephone number or medical record number now or in the future. While your de-identified data may be shared with other investigators, they will not be sold to them for profit. The UOA ACLR data repository is maintained for investigational purposes only.

What agencies and officials may use or share the protected health information collected about me?
The following Rutgers parties are authorized to use and share your protected health information in connection with this research study:

- The Rutgers Institutional Review Board (a committee that independently reviews and approves Rutgers research studies)
- Other Rutgers officials responsible to oversee research

The parties listed in the preceding paragraph may share your protected health information with the following persons and organizations for their use in overseeing this research:

- The Office for Human Research Protections in the U.S. Department of Health and Human Services

How long will my data be kept?

Data uploaded into the UOA ACLR data repository will be stored for be indefinitely. If you initially agree to share your ACL data, but later decide have it removed, you may request removal at any time by notifying the PI (Charles J. Gatt, MD) or Study Coordinator (Eric Nussbaum). 732-537-0909, x2500/ ericn@uognj.com. Removal of data will NOT impact your ACL care.

Will you contact me in the future with additional requests?

- We do not anticipate having to contact you for further use of your ACL data.

When will my authorization (permission) for the use of the health information traditionally used to identify me, (such as my name, address, telephone and medical record number) end?

Once we have located your chart within our EHR, your name, formal link to your chart, will no longer be utilized. We will maintain your de-identified data within the UOA ACLR Data repository for a period of 5 years or until you notify the PI that you no longer with to share your ACLR data with the repository.

What are the risks of harm to me?

Physical Risks of Harm

There is no risk of physical harm that may occur with allowing us to utilize your de-identified data.

Psychological or Social Risks Associated with Loss of Privacy

Your privacy is very important to us and we will use many safety measures to protect your privacy. However, in spite of all the safety measures that we will use, we cannot guarantee that your identity will never become known.

- While the databases developed for this project will be coded with an alternate MRN and will not contain information that is traditionally used to identify you, such as your name, address, telephone number, or medical record number, people may develop ways in the future that would allow someone to link your medical information in our protected databases back to you. It is also possible that there could be violations to the security of the computer systems used to store the codes linking your medical information to you.

- There also may be other privacy risks that we have not foreseen.

What are the benefits to me?

You will not benefit personally from providing data for this project because research usually takes a long time to produce meaningful results. However, your participation may help investigators understand, prevent, or treat ACL injuries in the future. Should you suffer a contra-lateral injury or re-tear of your graft, the information generated from the repository, may positively impact your future care.

What are my alternatives if I do not want to take part in the Research Data Bank?

Your alternative is not to consent to release your ACL related data to this research UOA ACLR Data repository.

Will I get results of the research done using my data?

No. The research we are doing is only a stepping-stone in understanding ACL injury**.** It may take a long time for this project and related research to produce health-related information that we will know how to interpret accurately. Therefore, your data may not be useful in directing your immediate medical care. Immediate information from this research will not be returned to you, your family members, your doctor, or outside parties.

However, you can choose to receive the UOA newsletter that will update you about the research studies we are doing. This newsletter will not announce your results or anyone else's, but it will tell you what we are learning from the data you share with the UOA ACLR Data Repository. We also hope to publish what we learn in medical journals and/or present our findings at medical conferences.

What are the costs to me to take part in the research data bank?

Data Storage and Research Activities:

- ❖ There is no cost to you to share your data with the UOA ACLR Data repository or for the research utilizing the aggregate information.

Will I be paid for providing my data?

You will not be paid to participate. Your ACL data will utilized only for research purposes and will not be sold for profit. It is possible that some of the research conducted using aggregate data, may lead to the development of new medical tests and techniques, or other commercial products. Should this occur, there is no plan to provide you with any part of the profits generated from such products.

Can I still get medical care if I do not my data with the repository or if I decide to discontinue taking part?
Yes. Your decision to participate or not to participate does not affect your relationship with the study staff, your medical care, or any benefits to which you are otherwise entitled. Sharing your data to the

repository is up to you. You can decide not to allow your data to be stored in the research repository. If you decide to participate now, you can change your mind and withdraw from participation later.

Whom do I call to ask questions about the research Data bank?

You may ask more questions about the research repository at any time. The staff is available to answer your questions about the research, your participation in it, or if you feel you have suffered a research – related injury. They may be contacted at **732-537-0909, x2600.** The best time to reach them is **M-F, 9-4pm.** You may also contact the Principal Investigator whose name, address and telephone number are listed on the first page of this consent form.

Whom do I call to ask questions about my rights as a research subject?
You may ask more questions about your rights as a research subject at any time. The Rutgers IRB Administrator is available to answer your questions. She or he may be contacted in New Brunswick @ 732-235-2866. The best time to reach them in person is Monday through Friday, 8:30am through 4:30p. Otherwise, call any time to leave a voice message for them.

Do I have to sign this form?
Your participation in this research is voluntary.

- If you **do not** want to participate in this research or do not want to authorize use of your personal or private health information, do not sign this consent form.

- If you **do** want to participate in this research and do want to authorize use of your personal or private health information, you must sign this consent form to do so.

ASSENT TO TAKE PART IN THIS RESEARCH

Participant's Signature:

I have read this form, or it has been read to me, and I believe I understand what has been talked about. My questions about this research have been answered. I agree to take part in this research.

Name (Print) _____

Signature _____ Date _____

Consenting Parent/ Adult: (if applicable)

Name (Print) _____

Signature _____ Date _____

Signature of Investigator/Person Obtaining Consent:

To the best of my ability, I have explained and discussed the important details about the research including all information contained in this assent form. All questions have been accurately answered.

Investigator/Person Obtaining Consent Name (Print): _____

Signature _____ Date _____