Indiana University Informed Consent Statement and Authorization for Research

Indiana University Orthopaedic Sports Medicine Cohort Data Repository
IRB# 25155

You are being asked to participate in a research study. This consent and Authorization form will give you information about this study to help you decide whether you want to participate. It is your choice whether you want to be in this research study. Please read this form, and ask any questions you have, before agreeing to be in this study.

Important Things to Know:

The purpose of this voluntary study is to establish a data collection system for patients undergoing outpatient hip, knee, or shoulder surgery within the division of orthopaedic sports medicine in Indiana University department of orthopaedic surgery. This study involves filling out some surveys and allowing us to collect some urine, blood, joint fluid, and tissue from you today. You would fill out a survey today and at your follow-up visits planned for 2 weeks, 6 weeks, 3 months, 6 months, and 1 year after your surgery. Additionally, we would like to collect urine and venous blood samples before your surgery, and at your scheduled follow-up visits up to your 6-month visit. While you are asleep during surgery, we collect a small amount of tissue such bone, synovium, tendon, ligament, cartilage, and muscle, as well as joint fluid (synovial fluid). Synovial fluid will be collected from your non-injured joint if additional consent is provided. While the collection of synovial fluid from the joint (arthrocentesis) is a safe procedure, there are risks. The primary risks of study participation are infection, bleeding, pain, and bruising from the collection of both blood and synovial fluid. You may not benefit from this study, but it might help us better understand how to predict how well patients will do after surgery like yours today.

Please review the rest of this document for more details about this study and the things you should know before deciding whether to participate.

Why Is This Study Being Done?

The purpose of this study is to establish a data collection system for patients undergoing outpatient hip, knee, or shoulder surgery within the division of orthopaedic sports medicine in Indiana University department of orthopaedic surgery. This data will be used for future studies to help determine predictors and correlates of inflammation on the day of surgery and patient symptoms (such as pain and function) at the time points. We will assess your hip, knee, or shoulder joint symptoms and to determine if there are signs of inflammation in your body from the condition that is being treated by your orthopaedic surgeon today. We want to find out if signs of inflammation or microscopic (too small

for the naked eye to see) damage in your blood, urine, joint fluid or tissue are related to the amount of pain or symptoms you are having due to the condition you are having surgery for today. We also want to determine whether your symptoms, signs of inflammation, or signs of microscopic damage today can predict what your symptoms will be like in the future at 2 weeks, 6 weeks, 3 months, 6 months, and 1 year after surgery.

We are asking you if you want to be in this study because you are having knee, hip, or shoulder surgery today by an orthopaedic surgeon that is involved in the current research study.

The study is being conducted by Bryan Saltzman, MD and Stephen Schlecht, PhD in the Indiana University Department of Orthopaedic Surgery.

How Many People Will Take Part?

You will be one of 800 participants taking part in this study.

What Will Happen During The Study?

The study procedures will take place at IU Health Methodist Hospital or at an IU Health hospital or specialty surgery center on the day of your scheduled surgery and at IU Health offices for your follow-up visits at 2 weeks, 6 weeks, 3 months, 6 months, and 1 year after the surgery. If you agree to participate in the study, the following things will happen:

Today:

- This visit today will take approximately 10-15 minutes.
- To confirm you are eligible to participate, for women, we will confirm with you that you are not pregnant. We will also obtain a urine pregnancy test.
- You will complete several short electronic surveys before your surgery, which will contain questions about your physical and mental health, your current symptoms, your physical activity level, your demographics, and your contact information.
- A small urine sample (roughly a tablespoon) will be collected. This will be collected before you go to sleep (go under anesthesia) for surgery if you are able to produce a urine sample on your own. If you are not able to urinate before you go under anesthesia, a urine sample may be obtained by use of a urinary catheter while you are asleep. While catheters are normally placed for a variety of surgical procedures, it may not be required for your specific operation. If your surgical team places a urinary catheter for your operation, a sample of collected urine will be taken for the purposes of this study if you cannot provide a urine sample preoperatively. If catheter placement is not required for your operation and you are not able to provide a urine sample preoperatively, you will not be able to participate in this study.
- A small blood sample (roughly a tablespoon) will be collected preoperatively. This will be collected with a needle from one of your veins before you go to sleep for surgery.

- During your surgery, we will collect biospecimens (samples from your body like tissues, fluids, and bone) that will let us look for signs of inflammation or microscopic injury. We will collect the samples after you go to sleep for surgery.
    - This will include a small piece of tissue (roughly the size of a pea) such as synovium (joint capsule tissue) ligament, tendon, bone, cartilage, muscle, or joint lining that is either normally removed as part of your surgery or is from an area in the surgical site that will not affect the health of your joint.
    - We will also collect up to a tablespoon of synovial fluid (joint fluid). The joint fluid will come from your affected joint AND we will collect fluid from a your other joint (hip/knee/shoulder) for comparison. This will be collected with a needle. Sometimes this requires injecting and pulling out a small amount (up to a tablespoon) of sterile salt water (saline) to gently 'rinse' the inside of your joint.
- The surgeon will complete a form detailing various findings during your surgery.
    - This will include the appearance of the inside of your joint, including the appearance of your joint surfaces (cartilage), joint lining (synovium), and any surrounding tissues visible during the surgery.

2 weeks, 6 weeks, 3 months, 6 months, and 1 year After Your Surgery:

- We will see you again at 2 weeks, 6 weeks, 3 months, 6 months, and 1 year after surgery for your scheduled postoperative visits to fill out similar short surveys, and to provide blood and urine samples. Venous blood and urine samples will be collected up to the 6 month visit. Survey completion will be done at your respective postoperative visits.

What happens after sample collection:

- Samples collected on the day of surgery and at each of your respective postoperative visits will be transported to the Schlecht Lab at the Indiana University School of Medicine to be stored.
- Future analysis on samples will be conducted at Purdue University in the Veterinary Clinical Sciences Research Laboratory, PUCL Biotechnology Lab, and/or the Bindley Biosciences Proteomics facility in accordance with an institutional agreement between IU and Purdue.
- Samples to be analyzed will be transported from the Schlecht Lab to Purdue.

You will be in this study for about one year. The last survey will be about one year after your surgery today.

We will not share the results of these tests or procedures with you because they are being done only for research purposes.

In the future and even after completion of the current study, you may be asked by our research team to participate in additional research (for example, if you undergo another surgery). If our research team asks you whether you want to participate in additional testing and you are willing to do so, you

will then be asked to complete a new consent form that describes the additional research. You may choose to accept or decline participation in additional research and this will not affect your participation in the current study.

What Are The Risks Of Taking Part In The Study?

- You may be uncomfortable while answering the survey questions. While completing the survey, you can skip any questions that make you uncomfortable or that you do not want to answer.
- If possible, a portion of the urine you may need to provide as part of your medical assessment before your surgery will be used for the study so that you do not need to provide a second urine sample.
- There is a risk someone outside the study team could get access to your research or medical information from this study. There are measures in place to maintain confidentiality.
- The risks of drawing blood include pain, bruising, and, rarely, infection. Blood will be drawn by experienced staff members both preoperatively before you go to sleep, and at your scheduled postoperative visits up to your 6-month visit.
- The risks of collecting joint fluid (synovial fluid) or tissue biopsy include pain, bruising, and, rarely, infection or bleeding. There may also be swelling or soreness at the site of joint fluid collection. Joint fluid and tissue will be collected by your surgeon in the affected and non-affected joints for comparative purposes. For your comfort, synovial fluid and tissue will be collected once you are under anesthesia for your surgery.

Who Will Pay For My Treatment If I Am Injured?

If you have an injury or illness as a result of participating in this study, necessary medical treatment will be provided to you and billed as part of your medical expenses. Any costs not covered by your medical insurance will be your responsibility. We don't have money set aside to pay for these types of injuries. However, signing this form won't take away any of your legal rights if you are injured.

What Are The Benefits Of Taking Part In The Study?

We don't think you will have any personal benefits from taking part in this study, but we hope to learn things that will help other people in the future.

Will I Be Paid For Participation?

You will not be paid for participating in this study.

How Will My Information And Specimens Be Used?

The study team will collect information about you from your medical records. This may include information that can identify you, such as your name, contact information, and medical record number. Information from your medical records will be used to make sure you meet the criteria to be

in this study, gather information about your medical history to include in the research data, review results of your medical tests for safety purposes, check on your health in the future to help answer our research question, or to inspect and/or copy your research records for quality assurance and data analysis.

The information released and used for this research will include all of your medical records. This may include information about mental health, alcohol or substance abuse, HIV/AIDS, sexually transmitted diseases, and/or results of genetic testing.

If you agree to participate, you authorize the following to disclose your medical record information:

- Indiana University Health
- Indiana University Health Physicians Orthopedics & Sports Medicine

The following individuals and organizations may receive or use your identifiable health information:

- The researchers and research staff conducting the study
- The Institutional Review Boards (IRB) or its designees that review this study
- Indiana University
    - The Indiana Clinical Research Center (ICRC)
- State and Federal government agencies as permitted by law
- Data safety monitoring boards and others authorized to monitor the conduct of the study

After your medical record information is released for purposes of this research study, your information may no longer be protected under federal privacy laws, such as HIPAA. However, your identifiable information will still be stored securely and only used as described in this consent.

Information and specimens collected for this study may be used for other research studies or shared with other researchers who are conducting their own research studies. This may include sharing with researchers outside Indiana University and sharing with private companies. It may also include making the information available in public and private databases of research data so that other researchers can use the information to answer research questions.

If we share your information or specimens in this way, we will remove information that could identify you, such as your name and contact information, before any information or specimens are shared. Since identifying information will be removed, we will not ask for your additional consent for this sharing.

Your specimens will be labeled with a study ID number. This is the same ID number that will be used to link your study information in a secure electronic server (REDCap and IU Microsoft Secure Storage). Your specimens will NOT be labeled with any other identifiers and the only way to link your specimens to your personal information will be through information stored in REDCap. Access to the information stored in REDCap is the only way to link your ID number back to your personal health information. Specimens will be stored in a secure building, and only members of the research team will have access to your samples. Specimens will be used for studies examining predictors and correlates of patient outcomes. This may include a wide variety of topics including predicting patients at risk of common complications and determining markers indicative of positive patient outcomes.

After completion of the current study, information that could identify you, such as your name and other identifiers, will be maintained on a secure electronic server (REDCap and IU Microsoft Secure Storage). REDCap is the same secure, research-compliant server that is being used to administer and store the electronic surveys for the current study. The purpose of storing this information is to be able to identify you for future research studies related to the current study in which you may be interested in participating. As an example, if the current research team obtains funding to perform blood testing at 5 years after surgery and compare this to your blood testing results on the day of surgery, your stored information may be used to contact you in 5 years to determine if you are interested in participating in the additional testing. To protect confidentiality, only members of the current study staff will have access to information that could identify you.

Specimens collected from you for this research may be used to develop products which could be sold in the future. Any profits or losses from the sale of those products will not be shared with you.

Further information about withdrawing from study participation is described later in this form.

How Will My Information Be Protected?

We will do our best to keep your personal information private, but we cannot promise complete confidentiality. We won't share any information that we think could be used to identify you in publications about this study. However, your personal information may be shared outside the research study as described above and/or if required by law.

What Will You Do With My Genetic Information?

The specimens collected in this study will be used for genetic studies which may include taking your DNA from the specimens. We will not use the specimens collected as a part of this study for whole genome sequencing, which involves mapping all of your DNA. Every person's DNA is unique; therefore, it may be possible for someone to find out who you are just from knowing your DNA sequence.

We may send your DNA information or de-identified specimens to a government database, such as the National Institutes of Health's Database for Genotypes and Phenotypes (dbGaP). These databases allow researchers from around the world who have received approval to use the samples or data for future research. These databases will not contain any identifying information about you. However, we cannot guarantee that no one will ever be able to use your genetic information to identify you.

Who Should I Call With Questions Or Problems?

For questions about the study or a research-related injury, contact the researcher, Bryan Saltzman, at 317-944-9400 or by email at bsaltzman@iuhealth.org. After business hours, please contact the hospital operator at 317-944-5000 and ask for Bryan Saltzman or email bsaltzman@iuhealth.org.

In the event of an emergency, you may contact Bryan Saltzman by phone at 317-944-9400 (if after business hours, call 317-944-5000) or by email at bsaltzman@iuhealth.org. If you are having a medical emergency and do not received a prompt reply, call 9-1-1 or go to your local Emergency Room.

For questions about your rights as a research participant, to discuss problems, complaints, or concerns about a research study, or to obtain information or to offer input, please contact the IU Human Research Protection Program office at 800-696-2949 or at irb@iu.edu.

What If I Do Not Participate Or Change My Mind?

After reviewing this form and having your questions answered, you may decide to sign this form and participate in the study. Or, you may choose not to participate in the study. This decision is up to you. If you choose not to participate in this study or change your mind after signing this document, it will not affect your relationship with Indiana University or the medical care you receive from IU Health.

As mentioned above, in the future and even after completion of the current study, you may be asked by our research team to participate in additional research. You may choose to accept or decline participation in additional research and this will not affect your participation in the current study. If you want to continue participating in the current study and you do not want to be contacted by our team about future research studies, contact Bryan Saltzman by phone at 317-944-9400 or by email at bsaltzman@iuhealth.org stating your desire to not be contacted by our team for additional research studies. You will receive a verbal or written reply confirming this, and further communications by our research team will only be related to the current study.

If you change your mind and decide to leave the study in the future, the study team will help you withdraw from the study safely. If you decide to withdraw, contact Bryan Saltzman by phone at 317-944-9400 or by email at bsaltzman@iuhealth.org stating your desire to withdraw. You will receive a verbal or written reply confirming your withdrawal. You will not be contacted in the future by the study staff once you have withdrawn from the study.

If you choose to withdraw your authorization for use and disclosure of your protected health information, you must do so in writing by notifying Bryan Saltzman at 1801 N Senate Blvd, Suite 400, Indianapolis, IN, 46202. If you withdraw your authorization, you will not be able to continue in this study. However, even if you cancel this authorization, the research team, research sponsor(s), and/or the research organizations may still use information about you that was collected as part of the research project between the date you signed this document and the date you cancelled this authorization. This is to protect the quality of the research results. Otherwise, this authorization remains valid until the research ends and required monitoring of the study has been completed.

Agreement to be Contacted by Text and/or Email

We would like to communicate with you about this study by text message and/or email. We might use text or email to communicate reminders about upcoming appointments and check on how you are doing after your surgery.

Text messaging and email are not secure methods of communication. The information sent over text or email, which may include sensitive or personal information, such as protected health information, could be accessed or read by someone other than you. If you would like us to communicate with you via text or email, please initial the lines below and provide the phone number(s) and/or email address(es) you would like us to use.

_____ I authorize the researchers to send me emails related to this research study

Email address for this communication: _____

_____ I authorize the researchers to send me text messages related to this research study

Phone number for this communication: _____

You can still participate in this study even if you do not want us to contact you by text or email.

Participant's Consent and Authorization

I agree to participate in this research study and **for obtaining a specimen from the affected joint**.

Participant's Printed Name **Participant's Signature** **Date** **Participant's Address (include street address, city, state, and zip code)**	**Printed Name of Person Obtaining Consent** **Signature of Person Obtaining Consent** **Date**

I agree to participate in this research study and for **obtaining a specimen from the contralateral (non-affected) joint for comparison purposes**.

Participant's Printed Name **Participant's Signature** **Date** **Participant's Address (include street address, city, state, and zip code)**	**Printed Name of Person Obtaining Consent** **Signature of Person Obtaining Consent** **Date**