Washington University in St. Louis

INFORMED CONSENT DOCUMENT

Project Title: Identification of Predictors for Clinical Outcomes in Femoroacetabular Impingement Surgery

Principal Investigator: **John Clohisy**

Research Team Contact: **Zachary Robben,**
Clinical Research Coordinator I
Office: 314-454-5345, email: zachary.robben@wustl.edu

- If you are the parent/guardian of a child under the age of 18 who is being invited to participate in this study, the word "you" in this document refers to your child. As the parent/guardian, you will be asked to read and sign this document to give permission for your child to participate.
- If you are under the age of 18 and reading this document, the word "you" in this document refers to you. You will be asked to read and sign this document to indicate your willingness to participate.

This consent form describes the research study and helps you decide if you want to participate. It provides important information about what you will be asked to do during the study, about the risks and benefits of the study, and about your rights and responsibilities as a research participant. By signing this form you are agreeing to participate in this study.

- You should read and understand the information in this document including the procedures, risks and potential benefits.
- If you have questions about anything in this form, you should ask the research team for more information before you agree to participate.
- You may also wish to talk to your family or friends about your participation in this study.
- Do not agree to participate in this study unless the research team has answered your questions and you decide that you want to be part of this study.

This is a research study conducted by Dr. John Clohisy at Washington University School of Medicine. The study is federally funded by the United States Department of Defense. This study has to do with the collection of information from patients with the diagnosis and surgical treatment of femoroacetabular impingement (FAI). You should carefully consider the information in this consent document and discuss it with the research team. You should understand why you might want to participate, or why you might not want to participate. You may choose to participate or not.

If you agree and sign this consent, you will be volunteering to participate in the research study. As a voluntary participant, you will be asked to complete study questionnaires before surgery and at postoperative clinic visits. You will spend approximately 20 minutes completing questionnaires of PROMIS measures (a set of person-centered measures that evaluates/monitors physical, mental, and social health) and hip outcomes. You may choose to skip any question(s) you would prefer not to answer. You will need to return to clinic at annual timepoints for standard of care follow-up. The main risk to you,

if you participate, is breach of confidentiality.

We don't expect this study to benefit you directly but it will help us better understand FAI in the future. By volunteering you may help someone else in the future. There are no costs for being in this research study. You do remain responsible for your regular medical expenses. Participating in this study provides you with an opportunity to be paid up to $100. All of this information will be explained and is listed in more detail in this consent document. The research team must give you a copy of this signed consent document.

What is the purpose of this study?

We invite you to participate in this research study because you have a diagnosis of femoroacetabular impingement (FAI) and have decided to undergo hip surgery.

What will happen during this study?

During this study we will collect information routinely obtained as part of your standard of care visits both pre-and-postoperatively and at annual time points. This information includes: clinical exam findings, patient reported outcomes measures, radiographic imaging, surgical findings, intra-operative images and/or videos, and photographs. Intra-operative images and/or videos are not identifiable because they are taken inside the hip joint or right outside the hip joint. No tattoos or scars can be seen because skin around the joint is covered.

All information obtained will be entered, downloaded, and stored in a secure computer database. Only collaborating PIs and IRB-approved engaged study team members will have access to your data. All information obtained will be kept indefinitely.

We will contact you by email for the purposes listed below. Some of these emails may contain health information that identifies you.

- Questionnaires
- Questionnaire Completion Reminder

Only the research team will have access to your email communications. We will only communicate by email to send you the information listed above. If you have any questions or need to contact us for an urgent or emergent situation, please contact the research team member identified at the top of this document.

You should be aware that there are risks associated with sending your health information via email.

- There is always a risk that the message could be intercepted or sent to the wrong email address. To avoid sending messages to the wrong email address, the first email we send you will be a test message to ensure we have the correct email address.
- When using any computer you should be careful to protect your username and password. Make sure you log-out before getting up from the computer.
- If you share a home computer with other family members, and do not want them to know you are participating in this study make sure you provide an email address that only you can access.

Please provide your preferred email address: _____@_____._____

Your employer will have access to any email communications sent or received on any electronic devices used for work or through a work server.

During this study we would like to follow your hip outcomes (such as pain, function, and activity) over the lifetime of your surgery. If you cannot schedule an annual clinic visit, you may be contacted by phone, mail, or email and asked to complete an outcomes packet. If we do not have your current contact information, we will try to locate you by performing an internet search, or contacting the person(s) listed as your alternate contact to ask them for your current information so that we may contact you directly.

Will you save my research data to use in future research studies?

We would like to use the data we are obtaining in this study for studies going on right now as well as studies that are conducted in the future. These studies may provide additional information that will be helpful in understanding FAI, or other disease or conditions, including research to develop investigational tests, treatments, drugs or devices that are not yet approved by the U.S. Food and Drug Administration. It is unlikely that what we learn from these studies will have a direct benefit to you. There are no plans to provide financial compensation to you should this occur. By allowing us to use your data, you give up any property rights you may have in the data. We might remove identifiers from your private information and your data and then use the information and your data for future research studies or share them with other researchers for their future research. If this occurs we will not ask you for additional consent for these uses of your information or data.

If you change your mind and do not want us to store and use your data for future research, you should contact the research team member identified at the top of this document. Your data will no longer be used for research purposes. However, if some research with your data has already been completed, the information from that research may still be used. Also, if the data has been shared with other researchers, it might not be possible to withdraw the data to the extent it has been shared.

How many people will participate?

Approximately 125 participants will be enrolled in this study at Washington University. Approximately 800 participants will be enrolled at multiple sites across the U.S. and Canada.

How long will I be in this study?

If you agree to take part in this study, your study involvement will last indefinitely.

What are the risks of this study?

You may experience one or more of the risks indicated below from being in this study. In addition to these, there may be other unknown risks, or risks that we did not anticipate, associated with being in this study.

Breach of Confidentiality:

One risk of participating in this study is that confidential information about you may be accidentally disclosed. We will use our best efforts to keep the information about you secure. Please see the section in this consent form titled "*How will you keep my information confidential?*" for more information.

What are the benefits of this study?

You will not benefit from being in this study. However, we hope that, in the future, other people might benefit from this study because the information gathered will help us better understand hip disorders. Through the analysis of this data, we hope to better identify and improve: quality of life, short/long-term treatment outcomes, developmental risks and early detection, impact of hip morphology in surgical planning and outcomes, and validation of outcomes measures. This will help us educate other healthcare professionals about the care of hip disease and may identify and improve risks for disorder/disease, develop tools and protocols for earlier detection, improve surgical care and increase quality of life.

Will it cost me anything to be in this study?

You will not have any costs for being in this research study. You and/or your medical/hospital insurance provider will remain responsible for your regular medical care expenses.

Will I be paid for participating?

All participants who provide a social security number (SSN) will receive a $25 check upon full completion of each 1-year and 2-year outcome questionnaire packet which will be sent by the WU research team ($50.00 total). Participants will also be given an additional $25 check for each 1-year and 2-year in-person follow-up clinic visit ($50.00 total). If you leave the research early, or if we have to take you out of the research, you will only be paid for the questionnaires/visits you have completed.

In order to be paid for your participation, you will need to provide your SSN. If you do not wish to provide us with your SSN, you may still choose to participate without being paid. If your social security number is obtained for payment purposes only, it will not be retained for research purposes. If being paid, you will also need to provide your address so that it may be mailed to you. It may take up to a month for reimbursement.

If you are on active duty in the military, due to federal military requirements related to compensation, you will not be paid.

Who is funding this study?

The Department of Defense (DoD) is funding this study. This means that Washington University is receiving payments from the DoD to support activities that are required to conduct the study. No one on the research team will receive a direct payment or increase in salary from the DoD for conducting this study.

How will you keep my information confidential?

Other people such as those indicated below may become aware of your participation in this study and may inspect and copy records pertaining to this research. Some of these records could contain information that personally identifies you. We will keep your participation in this research study confidential to the extent permitted by law.

- Government representatives (including the Office for Human Research Protections)) to complete federal or state responsibilities
- Department of Defense representatives who are authorized to review the research records as part of its human subjects protection oversight activities.
- The U.S. Food and Drug Administration
- Hospital or University representatives, to complete Hospital or University responsibilities

- Information about your participation in this study may be documented in your health care records and be available to your health care providers who are not part of the research team.
- Washington University's Institutional Review Board (a committee that oversees the conduct of research involving human participants) and the Human Research Protection Office. The Institutional Review Board has reviewed and approved this study.
- Any report or article that we write will not include information that can directly identify you. The journals that publish these reports or articles require that we share your information that was collected for this study with others to make sure the results of this study are correct and help develop new ideas for research. Your information will be shared in a way that cannot directly identify you.

To further help protect your confidentiality, we will follow the below procedures:

- Transfer of papers containing PHI is done using a locked opaque file box and only by engaged study team members. Storage of hard copy records is kept in locked file cabinets and only engaged study team members have access.
- Electronic records (computer files, electronic databases, etc.): All data is stored in a secure database system through a 2-password entry path. Passwords to this data are only available to study team members. Research offices are located on a designated research floor with authorized ID badge access after-hours.
- If we write a report or article about this study or share the study data set with others, we will do so in such a way that you cannot be directly identified.

Are there additional protections for my health information?

Protected Health Information (PHI) is health information that identifies you. PHI is protected by federal law under HIPAA (the Health Insurance Portability and Accountability Act). To take part in this research, you must give the research team permission to use and disclose (share) your PHI for the study as explained in this consent form. The research team will follow state and federal laws and may share your health information with the agencies and people listed under the previous section titled, "How will you keep my information confidential?"

Once your health information is shared with someone outside of the research team, it may no longer be protected by HIPAA.

The research team will only use and share your information as talked about in this form or as permitted or required by law. When possible, the research team will make sure information cannot be linked to you (de-identified). Once information is de-identified, it may be used and shared for other purposes not discussed in this consent form. If you have questions or concerns about your privacy and the use of your PHI, please contact the University's Privacy Officer at 866-747-4975.

Although you will not be allowed to see the study information, you may be given access to your health care records by contacting your health care provider.

If you decide not to sign this form, it will not affect

- your treatment or the care given by your health provider.
- your insurance payment or enrollment in any health plans.
- any benefits to which you are entitled.

However, it will not be possible for you to take part in the study.

If you sign this form:

- You authorize the use of your PHI for this research
- This authorization does not expire.
- You may later change your mind and not let the research team use or share your information (you may revoke your authorization).
  - To revoke your authorization, complete the withdrawal letter, found in the Participant section of the Human Research Protection Office website at https://hrpo.wustl.edu/participants/withdrawing-from-a-study/ or you may request that the investigator send you a copy of the letter.
    - **If you revoke your authorization:**
      - The research team may only use and share information already collected for the study.
      - Your information may still be used and shared as necessary to maintain the integrity of the research, for example, to account for a participant's withdrawal from the research study or for safety reasons.
      - You will not be allowed to continue to participate in the study.

Is being in this study voluntary?

Taking part in this research study is completely voluntary. You may choose not to take part at all. If you decide to be in this study, you may stop participating at any time. Any data that was collected as part of your participation in the study will remain as part of the study records and cannot be removed.

If you decide not to be in this study, or if you stop participating at any time, you won't be penalized or lose any benefits for which you otherwise qualify.

What if I decide to withdraw from the study?

You may withdraw by telling the study team you are no longer interested in participating in the study or you may send in a withdrawal letter. A sample withdrawal letter can be found at http://hrpo.wustl.edu/participants under Withdrawing from a Research Study.

Will I receive new information about the study while participating?

If we obtain any new information during this study that might affect your willingness to continue participating in the study, we'll promptly provide you with that information.

Can someone else end my participation in this study?

Under certain circumstances, the investigator might decide to end your participation in this research study earlier than planned. This might happen for no reason or because your condition has changed or you are no longer able to fill out the questionnaires.

What if i have questions?

We encourage you to ask questions. If you have any questions about the research study itself, please contact: Zachary Robben (314) 454 5345 (office), zachary.robben.wustl.edu. If you experience a research-related injury, please contact: Dr. Clohisy 314-747-2566 (office). If you have questions, concerns, or complaints about your rights as a research participant, please contact the Human Research Protection

Office 1-(800)-438-0445, or email hrpo@wustl.edu. General information about being a research participant can be found on the Human Research Protection Office web site, http://hrpo.wustl.edu. To offer input about your experiences as a research participant or to speak to someone other than the research staff, call the Human Research Protection Office at the number above.

This consent form is not a contract. It is a written explanation of what will happen during the study if you decide to participate. You are not waiving any legal rights by agreeing to participate in this study. As a participant you have rights and responsibilities as described in this document and including:

- To be given enough time before signing below to weigh the risks and potential benefits and decide if you want to participate without any pressure from the research team or others.
- To understand all of the information included in the document, have your questions answered, and receive an explanation of anything you do not understand.
- To follow the procedures described in this document and the instructions of the research team to the best of your ability unless you choose to stop your participation in the research study.
- To give the research team accurate and complete information.
- To tell the research team promptly about any problems you have related to your participation, or if you are unable to continue and wish to stop participating in the research study.
- Your signature indicates that this research study has been explained to you, that your questions have been answered, and that you agree to take part in this study. You will receive a signed and dated copy of this form.

Do not sign this form if today's date is after EXPIRATION DATE: N/A.

_____ _____
(Signature of Participant) (Date)

_____
(Participant's name – printed)

Parent/Guardian Name and Relationship to Participant:

Do not sign this form if today's date is after EXPIRATION DATE: N/A.

_____
(Child's name – printed)

_____ _____
(Signature of Parent/Guardian) (Date)

_____ _____
(Name of Parent/Guardian- printed) (Relationship to participant – printed)

Statement of Person Who Obtained Consent

The information in this document has been discussed with the participant or, where appropriate, with the participant's legally authorized representative. The participant has indicated that they understand the risks, benefits, and procedures involved with participation in this research study.

_____ _____
(Signature of Person who Obtained Consent) (Date)

_____
(Name of Person who Obtained Consent - printed)