Washington University in St. Louis

INFORMED CONSENT DOCUMENT

Project Title: Randomized trial investigating impact of tourniquet use on functional outcomes and complications after total knee arthroplasty

Principal Investigator: Robert L. Barrack, MD

Research Team Contact: Rondek Salih (314-747-2495) or Venessa Riegler (314) 362-1721

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.

WHAT IS THE PURPOSE OF THIS STUDY?

This is a research study. We invite you to participate in this research study because you and your surgeon have decided that you need a total knee surgery. The purpose of this research study is to determine the effect of tourniquet use on pain after total knee arthroplasty (TKA). Another purpose of this study is to determine the effect of tourniquet use on functional recovery following TKA. We will be evaluating clinical and functional outcomes, including differences in pain, medication requirements, recovery, and sleep quality.

Tourniquets are commonly used during operations on the knee as they have traditionally been thought to make it easier to see the operation site. The invention of newer total knee arthroplasty systems may reduce the need to use a tourniquet. There are also possible drawbacks to use of a tourniquet during procedures on the knee, including pain after the surgery and slower quadriceps recovery.

The Zimmer A. 7'S. 4000TS Tourniquet System is approved by the U.S. Food and Drug Administration to **is a non-sterile device intended to be used by qualified medical professionals to temporarily stop blood flow in a patient's extremities during surgical procedures on those extremities.**

WHAT WILL HAPPEN DURING THIS STUDY?

You and your surgeon have already agreed for you to get total knee replacement. If you agree to be in this study, you will be screened for eligibility by reviewing your medical history. If you meet all of the

requirements to continue in the study after screening and still want to participate you will be included in the study.

We are studying pain and sleep quality after TKA. You will be provided with a wearable health tracker device (Fitbit Inspire HR), a FocusMotion knee brace, and some smartphone apps including the FocusMotion app to help collect information on pain levels, pain medication, heart rate and sleep quality. This will be collected anonymously and in an encrypted manner. You will start using the device 2 weeks prior to surgery. After 3 months post-operatively, no further data will be collected from the device.

You will be scheduled to have a total knee replacement. If you do not undergo a total knee replacement for any reason, you will not continue in the study and will not complete any additional research-related procedures. You will undergo one additional pre-operative visit to a dedicated Physical Therapy assistant to complete questionnaires and non-invasive functional testing of your knee.

You will be randomly assigned to either have the tourniquet used during surgery or to have surgery without the use of a tourniquet. This means that the study intervention you receive will be determined purely by chance, like flipping a coin. You will have a chance of receiving any one of the study treatments.
You will not know if you were part of the tourniquet group.

The use of the tourniquet does not add any extra time to the surgery.
As part of standard clinical care after surgery, you will be required to come to routinely scheduled follow-up appointments at three weeks and one year after your total knee replacement; you will have one additional post-operative visit at 3 months as part of this study. This visit will include questionnaires about your thoughts on how your knee is performing and non-invasive strength and functional testing by a dedicated study Physical Therapy assistant. Data routinely obtained as part of your normal clinical care will be collected during your visits. No additional x-rays are required as part of this study; the standard pre-operative and post-operative imaging will be obtained as part of your regular follow-up. The office visits will include the standard of care given to all surgery patients regardless of your decision to participate in the study. You are asked to join the study only if you think you may be able to return for all 3 follow up visits. We will obtain imaging and healthy information related to your surgery and follow up from your medical record. This information will be used for research purposes.

Questionnaires
For research purposes, your thoughts on how your knee is performing will be collected using questionnaires either by e-mail, phone, or at office visits. You will be asked to complete the questionnaires during this study once prior to surgery, and at 3 weeks, 3 months and 1 year after your total knee replacement. Completion of these questionnaires takes approximately 15-45 minutes.

The following schedule indicates what is done at each visit:

Evaluation	Pre-operative	Post-op: Hospital stay	Post-op: 3 weeks	Post-op: 12 weeks	Post-op: 1 Year
Standard knee surgery visits	X	X	X		X
Questionnaires	X		X	X	X
PT strength and function evaluation	X			X	
Knee measurements	X	X		X	

We will make every effort to ensure complete follow-up, including phone calls, written requests and/or email, if we are unable to reach you by phone. In the event that these approaches are not successful, you will be documented as a participant who is lost-to-follow-up and no further contact attempts will be made.

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

As part of this study, we are obtaining data from you. We would like to use this data 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 total knee replacements, or other diseases 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 will share your data with other researchers. They may be doing research in areas similar to this research or in other unrelated areas. These researchers may be at Washington University, at other research centers and institutions, or industry sponsors of research. We may also share your research data with large data repositories (a repository is a database of information) for broad sharing with the research community. If your individual research data is placed in one of these repositories only qualified researchers, who have received prior approval from individuals that monitor the use of the data, will be able to look at your information.

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. The 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.

Please place your initials in the blank next to Yes or No for each of the questions below:

My data may be stored and used for future research as described above.

_____ Yes **_____ No**
Initials **Initials**

My data may be shared with other researchers and used by these researchers for the future research as described above.

_____ **Yes** _____ **No**
Initials **Initials**

HOW MANY PEOPLE WILL PARTICIPATE?

Approximately 144 people will take part in this study conducted by investigators at Washington University.

HOW LONG WILL I BE IN THIS STUDY?

If you agree to take part in this study, your involvement will last through your one-year follow-up visit. Visits will range from 2-3 hours in length.

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.

Some risks described in this consent document, if severe, may cause death.

Tourniquet Risks
Rare

- Skin issues(wrinkles, blisters, bruising)
- Nerve damage
- Muscle damage

The tourniquet does not add extra time to the surgery.

Women Capable of Becoming Pregnant

If you are a woman capable of becoming pregnant, we will ask you to have a pregnancy test before beginning this study. You must use effective birth control methods and try not to become pregnant while participating in this study. If you become pregnant, there may be unknown risks to your unborn child, or risks to your unborn child that we did not anticipate. There may be long-term effects of the treatment being studied that could increase the risk of harm to an unborn child. You must tell the doctor if your birth control method fails while you are on the study. If you believe or know you have become pregnant while participating in this research study, please contact the research team member identified at the top of this document as soon as possible. Please discuss with the research team how long you need to wait before becoming pregnant after completing the treatment or procedures on this study.

Questionnaires

There is a slight risk that you may feel a small amount of psychological discomfort answering the questionnaires. All questions are voluntary and if you are uncomfortable answering any question you may skip that question.

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 we will learn more about the impacts of mobile compression devices and tourniquets on post-operative pain and venous thromboembolism.

WHAT OTHER TREATMENT OPTIONS ARE THERE?

Before you decide whether or not to be in this study, your doctor will discuss the other options that are available to you. Instead of being in this study, you could receive your knee surgery without participating in the study.

WILL IT COST ME ANYTHING TO BE IN THIS STUDY?

As part of this study you will receive tests and procedures that are similar to what you would receive during routine clinical care of your condition. Your health plan/insurance company will be billed for some or all of these costs, and you will be responsible for any co-pays and deductibles that are normally required by your health plan/insurance. Not all insurance plans cover the costs associated with being in a study. Even if they do, you may be responsible for more out-of-pocket expenses, such as co-pays and deductibles, when there are more tests and procedures or more expensive tests and procedures involved in the study than if you were to receive routine clinical care outside the study.

If you wish to know whether there are more tests and procedures or more expensive tests and procedures in the study, you should ask your study doctor.
If you wish to know whether your insurance will pay, you should contact them directly, or speak with the study team about obtaining a financial pre-certification prior to enrolling in the study.

WILL I BE PAID FOR PARTICIPATING?

You will be paid for being in this research study. You will need to provide your social security number (SSN) in order for us to pay you. You may choose to participate without being paid if you do not wish to provide your social security number (SSN) for this purpose. You may also need to provide your address if a check will be mailed to you. You should receive the check in about 2-4 weeks. If your social security number is obtained for payment purposes only, it will not be retained for research purposes.

$100 will be provided following completion of evaluation at 3 months. Participants who complete their final evaluation at 1 year will be gifted the Fitbit Inspire HR device.
Participants will be offered $50 for completing the one year follow-up questionnaires.

DOES THE INVESTIGATOR OR OTHER RESEARCH TEAM MEMBER HAVE A PERSONAL FINANCIAL INTEREST IN THIS STUDY?

Dr. Charles Lawrie, a co-investigator on this study, is a paid consultant for, receives royalties from, and receives other financial or material support from Zimmer Biomet, Inc. Washington University's Conflict of Interest Review Committee and Institutional Review Board have reviewed Dr. Lawrie's financial

interest. A plan has been developed and implemented to ensure that the research is conducted objectively. These committees believe that the financial interest is not likely to affect your safety or the scientific quality of the study.

WHO IS FUNDING THIS STUDY?

Zimmer USA, Inc. is funding this research study. This means that Washington University is receiving payments from Zimmer to support the activities that are required to conduct the study. No one on the research team will receive a direct payment or increase in salary from Zimmer for conducting this study.

WHAT IF I AM INJURED AS A RESULT OF THIS STUDY?

Washington University investigators and staff will try to reduce, control, and treat any complications from this research. If you feel you are injured because of the study, please contact the investigator, Dr. Barrack, at (314) 747-2562 and/ or the Human Research Protection Office at 1-(800)-438-0445.

Decisions about whether payment for medical treatment for injuries relating to your participation in research will be made by Washington University and Zimmer. If you need to seek medical care for a research-related injury, please notify the investigator as soon as possible.

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
- The U.S. Food and Drug Administration
- Zimmer
- Zimmer may also inspect any part of your medical record for the purposes of auditing the conduct of the study
- Your primary care physician if a medical condition that needs urgent attention is discovered
- 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 will be available to anyone with access to your health care record, including your health insurance company. This information may also be released as part of a release of information request.
- The last four digits of your social security number may be used in hospital or University systems to track billing information for research procedures
- 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.

The research team will send study results to Zimmer. Information sent to Zimmer will not contain any information that could identify you. Zimmer will use the data to reduce the incidence of venous thromboembolism (VTE) after total knee arthroplasty (TKA) with and without the use of mobile compression device and to determine if they need to use tourniquets with and without using a mobile

compression device (MCD) following TKA. Zimmer may also use this information for development and training of new and existing products, instruments and software, such as knee replacement parts. In the future, Zimmer may continue to use your health information that is collected as part of this study. For example, Zimmer may combine information from this study with the results of other studies to re-analyze the safety and effectiveness of the study devices, to evaluate other products or therapies, to develop a better understanding of a disease, or to improve the design of future research studies. Zimmer may also share information from the study with regulatory agencies in foreign countries.

If you receive Medicare benefits, are injured as part of your participation in this research study and medical treatment relating to this injury is paid by anyone other than you or your insurance company, that payer will need to collect personal information about you. This information includes your name, date of birth, gender, social security number, Medicare identification number and information related to this research study. The payer will report this information to the Centers for Medicare & Medicaid Services (CMS), the federal agency that oversees the Medicare program, during your participation in the study and for as long as the payer is required by CMS to report this information. If you do not want to release your personal or treatment related information you have the right to refuse reimbursement by the payer for any research injury. The payer will not use this information for any other purpose.

To help protect your confidentiality, we will password protect computers and files containing your information. The office suite and cabinets used to store your information are locked and/or passcode protected. 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. Sharing this information will allow 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.

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.

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.

Can we contact you by email?

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

- Schedule follow-up visits and send appointment information

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

Do you agree to allow us to send your health information via email?

_____ Yes **_____ No**
Initials **Initials**

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 https://hrpo.wustl.edu/participants/withdrawing-from-a-study/ 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 or Zimmer might decide to end your participation in this research study earlier than planned. This might happen for no reason or if it would not be safe for you to continue, or because you are or became pregnant.

WHAT IF I HAVE QUESTIONS?
We encourage you to ask questions. If you have any questions about the research study itself, please contact: Rondek Salih, MPH, 314-747-2495. If you experience a research-related injury, please contact: Robert Barrack, MD, 314-747-2562.

If you have questions, concerns, or complaints about your rights as a research participant, please contact the Human Research Protection Office at 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: 06/29/21.

_____ _____
(Signature of Participant) (Date)

_____
(Participant's name – 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)