Washington University in St.Louis

INFORMED CONSENT DOCUMENT

Project Title: Prospective study investigating antibiotic elution from free intra-articular vancomycin and tobramycin after cementless total knee arthroplasty

Principal Investigator: Charles Lawrie

Research Team Contact: 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 are scheduled for a total knee arthroplasty (TKA).
The purpose of this research study is to learn about intra-articular antibiotic use in primary cementless total knee arthroplasty. Two types of commonly used antibiotics will be used as part of this study. Vancomycin and Tobramycin will be administered into the joint during surgery.

The findings from this study will provide evidence for optimal antibiotic choice in cementless total knee arthroplasties.

Tobramycin and vancomycin are approved by the U.S. Food and Drug Administration to treat serious bacterial infections caused by microorganism strains that are susceptible to these drugs. However, the use of tobramycin and vancomycin are considered investigational in this study.

WHAT WILL HAPPEN DURING THIS STUDY?

If you agree to participate you will have the standard procedure of receiving vancomycin and tobramycin powder administered to your knee during surgery. As part of routine care, a drain will be placed into your knee during surgery. We will then collect and test the fluid that is drained from your knee on the day after surgery. This fluid is usually discarded. The study will collect 3 samples of

postoperative intra-articular drain fluid from the total knee arthroplasty, and 3 postoperative serum samples the day after surgery. The total amount of drain fluid and blood to be drawn will be 15milliliters fluid (3 teaspoonfuls) and 15 milliliters blood (3 teaspoonfuls), respectively.

We will also collect data from your medical records including demographic information (age, gender, BMI), implant and surgical information, other medical conditions you might have and joint-related findings.

Will you save my research information/samples to use in future research studies?

We would like to use the fluid samples and 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 **antibiotics used in total knee arthroplasties in knee joint fluid immediately following TKA** 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 and samples you give up any property rights you may have in the data and samples.

We will share your data and samples 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 knee fluid 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 knee fluid has already been completed, the information from that research may still be used. Also, if data has been shared with other researchers it might not be possible to withdraw 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 and samples may be stored and used for future research as described above.

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

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

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

- Identifiers may be removed from your private information including fluid samples and data and used for future research or shared with others. If this occurs, we will not ask you for additional consent.

HOW MANY PEOPLE WILL PARTICIPATE?

Approximately 20 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 for the completion of the collection of your fluid samples (which will be done on the day after surgery).

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.

Risk of Blood samples
bruising, pain, bleeding, and infection

Risk of Tobramycin

Likely/ Common
Mild

- Renal function changes (which can indicate kidney damage)

Less Likely / Less Common

Mild

- Anemia
- Decrease/increase in white blood cells
- Low blood platelet count
- Fever
- Rash
- Dermatitis (skin inflammation)
- Itching
- Nausea

- Vomiting
- Diarrhea
- Headache
- Lethargy (sleepiness)
- Abnormal labs(increased ALT and AST, increased serum LDH and bilirubin, decreased serum calcium, magnesium, sodium, and potassium) which could indicate liver damage

Rare

Mild

- Disorientation
- Dizziness
- Vertigo (feeling off balance)
- Tinnitus (ringing in the ears)
- Roaring in ears
- Hearing loss

Risk of Vancomycin

Likely/ Common

Mild

- Renal function changes

Rare

Mild

- Hearing loss
- Vertigo
- Dizziness
- Tinnitus
- Low blood platelet count
- Decrease in white blood cells

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 findings will provide evidence for optimal antibiotic choice in antibiotic cement used in total knee arthroplasty, as well as determine the effect of using intra-articular antibiotics in cementless total knees**.**

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 choose not to be in the study. You will still be getting a total knee arthroplasty regardless if you are in the study or not.

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 not be paid for being in this research study.

WHO IS FUNDING THIS STUDY?

The University and the research team are not receiving payment from other agencies, organizations, or companies to conduct this research 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 at 314- 747-2508 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. 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
- 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.
- 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 help protect your confidentiality, we will password protect computer and files containing your information. Your study data and samples will be labeled with a code that does not identify you. Data that does identify you will be kept separately from the code.

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 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?

Valid enrollment is not granted until after surgery, once it has been verified that the participant has had total knee surgery.

Under certain circumstances, the investigator **[or the study sponsor]** might decide to end your participation in this research study earlier than planned. This might happen for no reason or because in our judgement it would not be safe for you to continue, or if your condition has become worse.

WHAT IF I HAVE QUESTIONS?

We encourage you to ask questions. If you have any questions about the research study itself, please contact: Venessa Riegler at 314-362-1721. If you experience a research-related injury, please contact Dr. Charles Lawrie, at 314-747-2508.

If you have questions, concerns, or complaints about your rights a 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: 12/15/20.

_____ _____
(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)