[For research personnel use only] Subject Research ID#: _____

This consent form is not valid without a TTUHSC El Paso IRB stamp in the lower left corner of each page.

CONSENT TO TAKE PART IN A RESEARCH STUDY

This is a research study for people who voluntarily choose to take part. Please take your time to make a decision, and discuss the study with your personal doctor, family and friends if you wish.

STUDY TITLE: Open vs Arthroscopic Treatment of Septic Arthritis in the Adult Native Knee: A Prospective Trial

INVESTIGATOR(s): Dr. Ahmed Hagag-Thabet, MD / Dr. Adam Adler, MD / Dr. Matthew Wells, DO / Dr. Benjamin Childs, MD / Dr. Isaac Fernandez, MD

CONTACT TELEPHONE NUMBERS:

Dr. Hagag-Thabet
915-215-5400

You may contact the investigator(s) at the number(s) listed above during normal business hours if you develop any of the conditions listed in #5 or if you have any unexpected complications.

INSTITUTION: Texas Tech University Health Sciences Center El Paso

KEY INFORMATION

1. **What am I being asked to do?**
   We are asking you to take part in a research study about surgical management of septic arthritis of the knee in an adult population. Septic arthritis is an infection within your knee that can lead to accelerated wear and tear of your knee joint and, if left untreated, can also make you very sick.
   This key information is being provided to you to help you decide whether or not you should participate. Additional information is provided to you in the '**Detailed Information**' section of the document.

2. **Do I have to take part in this study?**
   You can choose to take part or you can choose not to take part in this study. You also can change your mind at any time. Whatever choice you make, you will not lose access to your medical care or give up any legal rights or benefits.
   This document has important information to help you make your choice. Take time to read it. Talk to your doctor, family, or friends about the risks and benefits of taking part in the study. It's important that you have as much information as you need and that all your questions are answered.

3. **What is this study about? How long will it last?**
   This study is being done to answer the following question: is there a difference in the number of surgeries required to treat adult patients with septic arthritis of the knee when surgically managed with open versus arthroscopic incision and drainage?
   You have been diagnosed with septic arthritis of the knee. The current clinical guidelines include surgical incision and drainage of the bacteria in your knee followed by an extended period of intravenous antibiotics. Intravenous antibiotics are provided through a peripheral catheter into your blood system and are much stronger than normal antibiotics that come in pill forms. Your overall treatment plan will not change, however you will be randomized, or randomly placed based on chance alone, into one of two groups: either a single open incision where your surgeon can directly visualize in inside of your knee or multiple smaller incisions in which a video camera (arthroscope) is used to visualize the inside of your knee. Both surgeries are accepted as appropriate surgical treatment for septic arthritis of the knee. You will have a two week follow up appointment and a six week follow up appointment.

4. **What are the key reasons I might choose to take part in this study?**
   Currently there are no clinical trials that have been performed in the United States evaluating the difference in the two surgical treatment options for septic arthritis of the knee. By participating in this study, you will be contributing to the advancement of science and potentially new clinical practice guidelines in the management of septic arthritis of the knee. At this time there is no financial reimbursement provided for patients who volunteer to participate in this study.
   For a complete description of the benefits, refer to the '**Detailed Information'** section of the consent form.

5. **What are the key reasons I might choose <u>not</u> to take part in this study?**
   You may not want to participate in the study because of personal reasons. For a complete description of the risks, refer to the '**Detailed Information'** section of the consent form. There may be some risks that the study doctors do not yet know about.
   There are no other surgical procedures recommended other than the two included in this study. You may be treated with antibiotics alone, however this has been shown to be significantly inferior in clinical outcomes compared to patients treated surgically.
   For a complete description of the alternative treatment/procedures, refer to the '**Detailed Information'** section of the consent form.

6. **What if I have questions?**
   For questions about this study, contact the Investigator, Matthew Wells at 973-897-4160.If you would like to speak to someone who is not involved in the study about your rights as a participant, research-related injuries, or any other matter related to the study, you can call the TTUHSC EthicsPoint Hotline: 1-866-294-9352.Or, you can file an EthicsPoint report online: https://secure.ethicspoint.com/domain/media/en/gui/44534/index.html. Please choose the "Regulatory Compliance" option when making an online report.

It is important that you understand the information in the informed consent before making your decision. Please read, or have someone read to you, the rest of this document. If there is anything you don't understand, be sure to ask your study doctor or nurse

DETAILED INFORMATION

7. What is the purpose of this study?

Surgical incision and drainage with irrigation and debridement of the knee joint is the current recommended management of septic arthritis in the adult knee. However, there has been considerable debate over the optimal surgical approach. Orthopedic surgeons perform either an open (single, larger incision) or arthroscopic (multiple smaller incisions using a small camera) approach to treat septic arthritis of the knee. While open arthrotomy has been often utilized, there have been more recent retrospective (looking into the past) studies favoring arthroscopic treatment citing lower re-infection rates and better functional outcomes. However, there has been a lack of well-designed prospective (actively following patients) studies comparing the two surgical approaches. The goals of this present study are to determine if there is a difference in the hospital length of stay and number of surgeries required to achieve clinical resolution of septic arthritis of the knee when treated with open versus arthroscopic surgical approaches. Secondary outcomes included differences in functional outcome and overall patient satisfaction.

The goal is to obtain a minimum of 40 study participants across the following sites:

University Medical Center of El Paso
4815 Alameda Ave
El Paso, Texas 79905

8. What will happen during this study?

All patients who present to the emergency department with a painful knee and clinical suspicion for septic arthritis will undergo appropriate workup by the emergency department staff members. This includes obtaining blood for basic laboratory tests and possibly obtaining fluid from the patient's knee for additional laboratory analysis. In accordance to current clinical guideline, all patients found to have septic arthritis will undergo surgical management. Each patient will be randomized into one of the following:

— open arthrotomy (single, larger incision with direct visualization of the inside of the knee)
OR
— arthroscopic arthrotomy (multiple, smaller incisions with visualization of the inside of the knee with a video camera called an arthroscope)

All patients will undergo an extended period of antibiotic therapy (4-6 weeks) with antibiotics specific to the organism found to be causing the infection. Specialized infectious disease internal medicine doctors will be managing your antibiotic therapy.

9. What will be done that is different from my usual care?

There is no difference in how you will be treated compared to patients who choose not to participate in this research study. Both open and arthroscopic treatment for septic arthritis is performed at the above listed centers. However, instead of relying on your surgeon's personal preference of surgical management, you will be randomized into one of the treatment groups. The purpose of randomization removes bias (or tendency to treat patients based on personal beliefs) from the analysis required for research purposes.

10. Are there any benefits to me if I take part in this study?

There is no additional benefit to participating in this study. Surgery would be recommended to you regardless of your choice to participate in this research study. At this time there is no financial reimbursement provided for patients who volunteer to participate in this study. Currently there are no clinical trials that have been performed in the United States evaluating the difference in the two surgical treatment options for septic arthritis of the knee. By participating in this study, you will be contributing to the advancement of science and potentially new clinical practice guidelines in the management of septic arthritis of the knee.

11. What are the risks and/or discomforts to me if I join this study?

There are retrospective (looking into the past), non-randomized studies from Europe and America suggesting that arthroscopic surgical treatment has a lower risk of reinfection when compared to open arthrotomy procedures. Additionally, arthroscopic management utilizes smaller incisions which may lead to less post-operative pain and earlier return to your normal activities of daily living. However, these possible risks are highly debated in the orthopedic surgery community. The purpose of this study is to end such debate.

12. Will there be any added risks to me from this study if I am a female/male?

There are no added risks specific to female nor male populations.

13. What other choices do I have if I do not take part in the research study?

If you do not take part in the research study, you may undergo non operative management with treatment of antibiotics alone. However, this treatment modality has been shown to have significantly inferior outcomes compared to surgical management and is not recommended. If you do not participate in the research study, your doctor will recommend one of the two operative procedures. If you refuse surgery, your doctor can treat you with antibiotics.

14. What about confidentiality and the privacy of my records?

We will keep your involvement in this research study confidential to the extent permitted by law. In addition to the staff carrying out this study, others may learn that you are in the study. This might include federal regulatory agencies such as the Food and Drug Administration (FDA) and the Office for Human Research Protection (OHRP), Texas Tech University Health Sciences Center El Paso (TTUHSC EP) representatives, representatives from any hospital or site where the research takes place, and the TTUHSC EP Institutional Review Board (a committee that reviews and approves research). These people may review and copy records involving your participation in this research. A copy of this document may be placed in your medical record.

Study results that are used in publications or presentations will not use your name nor any other identifying health information.

15. Who is funding this study?

The Department of Orthopaedic Surgery and Rehabilitation is providing the space and supplies for this study. No one on the research staff will receive anything of value from other agencies, organizations, or companies to carry out this research.

16. Will it cost me anything to take part in this research study?

Any procedures that are considered standard of care are your or your insurance provider's responsibility.

You and/or your insurance provider will not have to pay for exams, tests, and procedures done for research purposes only or that are covered by the study. ***There are no exams, tests, or procedures done for research purposes only in this study.***

Talk to your insurance provider and the study staff to make sure that you understand what your insurance pays for and what it does not pay for if you take part in this study. Also, find out if you need approval from your plan before you can take part in the study.

Ask your doctor or nurse for help finding the right person to talk to if you are unsure which costs will be billed to you or your insurance provider.

17. Will I receive anything for taking part in this research study?

At this time there is no financial reimbursement provided for patients who volunteer to participate in this study.

18. Does anyone on the research staff have a personal financial interest in this study?

No one on the research staff has a financial interest in this study.

19. What if I am hurt by participating in this study?

Texas Tech University Health Sciences Center El Paso and University Medical Center of El Paso does not offer to pay for or cover the cost of medical treatment for research related illness or injury. No funds have been set aside to pay or reimburse you in the event of such injury or illness unless specifically stated.

If you have a research related illness or injury, care will be available to you as usual, but you and/or your medical or hospital insurance company will be responsible for the cost of treatment. Before entering this study, you should check whether your insurance company might limit your insurance coverage if you take part in a research study.

20. Can I stop being in the study?

Yes, you may decide to stop taking part in the study at any time. If you leave the study, we cannot remove any information we have collected to that point.

Your study doctor will tell you about new information or changes in the study that may affect your health or your willingness to continue in the study.

21. Can someone else end my participation in the study?

Under certain circumstances, the investigators, TTUHSC El Paso, or the study sponsor may decide to end your participation in this research study earlier than planned. This might happen because:

- Your health changes and the study is no longer in your best interest.
- New information becomes available and the study is no longer in your best interest.
- You do not follow the study rules.
- The study is stopped by the Institutional Review Board (a committee that reviews and approves research) or the Food and Drug Administration.

Your signature indicates that:

- **this research study has been explained to you;**
- **you have been given the opportunity to ask questions and have received answers;**
- **you accept your responsibility to follow the instructions given to you by the research team regarding study participation and, if applicable, research medication;**
- **you agree to take part in this study.**

You will be given a signed and dated copy of this form.

_____

Printed Name of Subject

Signature of Subject	Date	Time (indicate AM/PM)

If applicable, Signature of Authorized Representative *(Please print name, relationship to patient, and contact information as well)*	Date	Time (indicate AM/PM)

I have discussed this research study with the subject and, if applicable their representative, using language that is understandable and appropriate. I believe I have fully informed the subject of the possible risks and benefits, and I believe the subject understands this explanation. I have given a copy of this form to the subject.

Printed name of authorized research personnel who conducted the informed consent discussion

Signature of authorized research personnel who conducted the informed consent discussion	Date	Time (indicate AM/PM)

[For research personnel use only, if applicable] Subject Research ID#: _____

TEXAS TECH UNIVERSITY HEALTH SCIENCES CENTER EL PASO
AUTHORIZATION TO USE AND/OR DISCLOSE YOUR PROTECTED HEALTH INFORMATION for a RESEARCH STUDY

STUDY TITLE: Open vs Arthroscopic Treatment of Septic Arthritis in the Adult Native Knee: A Prospective Trial

This form is intended to tell you about the use and/or disclosure (sharing) of your personal **Protected Health Information** (PHI) if you decide to participate in the research study described on the previous pages. The health information about you that may be used or disclosed is described below. This information is usually found in your medical records. Only the health information about you that is needed for this research study will be used or disclosed. When you consider taking part in this research study, you are also being asked to give your permission for your Protected Health Information to be released from your doctors, clinics, and hospitals to the research personnel approved for this research study. This Authorization specifically relates to the research study described in the attached Informed Consent document.

1. This Authorization is valid indefinitely or until such time as legal requirements will allow this Authorization to be destroyed.

2. If you choose to cancel this Authorization, please give notice in writing to:

TTUHSC-El Paso Privacy Officer
Office of Institutional Compliance
5001 El Paso Drive
El Paso, TX 79905

If you sign this Authorization, the following persons, groups or organizations may rely on this Authorization to disclose your Protected Health Information to the Principal Investigator and other research personnel who are conducting this Study:

- your treating physicians and healthcare providers and their staff,
- associated healthcare institutions and hospitals where you have or may receive care.

While this research study is in progress, the Principal Investigator or research personnel working on this study will inform you whether or not you will be allowed to see the research related health information that is created about you or collected by the research personnel prior to the end of the study. After the study is finished you may request this information as allowed by the TTUHSC EP Notice of Privacy Practices.
The Protected Health Information that you authorize to be used or disclosed for research purposes may include your current or future health information from some or all of your health records, including:

- hospital records and reports
- admission history, and physical examination
- X-ray films and reports; operative reports

- laboratory reports, treatment and test results (including sexually transmitted diseases, HIV or AIDS)
- any other Protected Health Information needed by the research personnel listed above.

(* use separate form for disclosure of psychotherapy notes)
- immunizations
- allergy reports
- prescriptions
- consultations
- clinic notes
- mental health records
- alcohol / substance abuse records

For the purposes of this study, your Protected Health Information may need to be reviewed or disclosed to individuals or organizations within and/or outside of TTUHSC EP who sponsor, approve, assist with, monitor or oversee the conduct of research studies. This includes, but is not limited to, the TTUHSC EP Institutional Review Board, TTUHSC EP compliance reviews, the US Food and Drug Administration (FDA) or governmental agencies in other countries. Some of these individuals or organizations may share your health information further, and your health information may not be protected by the same privacy standards that TTUHSC EP is required to meet.

If you choose to sign this Authorization form, you can change your mind about this later. If you change your mind, send a letter to the person identified above telling us to stop collecting and sharing your Protected Health Information. When we receive your request, you may be asked to leave the research study if all the necessary information has not been collected. We may still use the information about you that we have already collected. We need to know what happens to everyone who starts a research study, not just those people who stay in it.

You have the right to refuse to sign this form. If you choose not to sign this form, your regular health care will not be affected. However, not signing this form will prevent you from participating in this research study and prevent you from receiving research related health care services provided under this study.

I have had the opportunity to review and ask questions regarding this Authorization to use or disclose my personal health information, and I will receive a copy of this form. By signing this Authorization, I am confirming that it reflects my wishes.

Printed Name of Subject

Signature of Subject | Date | Time (indicate AM/PM)

If applicable, Signature of Authorized Representative. *(Please print name, relationship to patient, and contact information as well)* | Date | Time (indicate AM/PM)