Key Information for:
Prosthetic Joint Infection Distress Thermometer Study

You are being asked to participate in the research described below. This page provides key information that may help you to make this decision; more detailed information can be found after this section.

Why is this research being done, and what is involved?

This study is being conducted to determine whether patients being treated for prosthetic joint infections (PJI) experience distress during the course of their treatment and how distress influences various aspects of their lives. This project is being conducted by Allison Lastinger, MD, in the Department of Internal Medicine at WVU.

To participate in this study, you must be undergoing a revision surgery to your hip or knee with or without a diagnosis of a prosthetic joint infection. You must be enrolled in the host study, "Treating the Whole Patient: Measuring Distress in Prosthetic Joint Infection Using a Standardized Metric". Your participation in this project will take approximately 30 minutes. You must be 18 years of age or older to participate.

Do I have to participate, and what are the risks?

Participation in this research study is entirely voluntary; you are free to withdraw from the research at any time. If you do not wish to participate, please discuss alternatives with the study doctor or refer to the "Alternatives" section in the consent form. You may or may not directly benefit from participating in this research.

Risks from participation in this study include the possibility of mild frustration of answering several questions for the study.

Who can I talk to if I have questions or concerns?

If you have any questions or concerns about this research or would want to withdrawal from the study, you can contact Jennifer Eicher, Monday-Fridays from 8a-430p at 304-285-7445 or jeicher@hsc.wvu.edu from the Dept. of Orthopaedics at West Virginia University.

For more information, please see the Informed Consent Form.

Informed Consent for Research | Minimal Risk

Principal Investigator (PI) |	Allison Lastinger, MD
Department |	Department of Internal Medicine
Co-Investigator(s) |	Matthew J. Dietz, MD; Nathan Pearson, MD
WVU IRB Protocol # |	2101221058
Study Title |	Treating the Whole Patient: Measuring Distress in Prosthetic Joint Infection Using a Standardized Metric. CRUTCH Pathway Pilot Study.

Introduction

You, _____, have been asked to participate in this research study, which has been explained to you by _____. This study is being conducted by Allison Lastinger, MD in the Department of Internal Medicine at West Virginia University, along with Matthew J. Dietz, MD in the Department of Orthopaedics at WVU

Purpose

The purpose of this study is to determine whether patients being treated for prosthetic joint infections (PJI) experience distress during the course of their treatment and how distress influences various aspects of their lives. WVU expects to enroll approximately 12 subjects. Patients identified as scoring ≥4 on the Distress Thermometer at the two-week follow-up visit will be offered the opportunity to participate in the novel CRUTCH Pathway. Once enrolled, you will meet virtually with psychiatrist Dr. Nathan Pearson. Dr. Pearson will complete a 30-minute intake visit where he will review your distress thermometer scoring, discuss contributing factors to current distress level, and discuss other problems like depression or anxiety. You will also be asked to complete a 4 question survey regarding your time in the study. This should take no more than five minutes to complete.

Description of Procedures

To participate in this study, you must be undergoing a revision surgery to your hip or knee with or without a diagnosis of a prosthetic joint infection and willing to answer three questionnaires. You must be 18 years of age or older to participate. You must be enrolled in the mother study, "Treating the Whole Patient: Measuring Distress in Prosthetic Joint Infection Using a Standardized Metric". Your participation in this project will take approximately 30 minutes.

You will be asked to meet virtually with psychiatrist Dr. Nathan Pearson. Dr. Pearson will complete a 30-minute intake visit where he will review your distress thermometer scoring, discuss contributing factors to current distress level, and and discuss other problems like depression or anxiety. Following this assessment, psychotherapy, psychotropic medication, and referral for social work/financial services will be offered as indicated.

You will not be asked any questions that could lead back to your identity as a participant. You may skip any question that you do not wish to answer and you may discontinue at any time.

Risks and Discomforts

You may become mildly frustrated from answering the questions regarding your distress related to your prosthetic joint infection.

The research may involve risks that are currently unforeseeable.

Also, there is always the risk of uncommon or previously unknown side effect(s) or events.

Alternatives

The alternative is not to participate in the study.

Participation in this study is voluntary; you do not have to participate.

Benefits

You may or may not directly benefit from participating in this research. The knowledge gained from this study may eventually benefit others.

Financial Considerations

Your information, if obtained, may be provided to the appropriate parties for billing and/or payment processing. Please be advised that any compensation received for participation in a research study, including a gift card, is considered taxable income and must be reported to the Internal Revenue Service (IRS).

Your data, health information, research results, specimens, or other information related to this research study may contribute to a discovery or treatment. In some instances, your data, your health information, your research results, your specimens, the discoveries or treatments, or other information related to this research study, even if identifiers are removed, may be of commercial value. This information may be sold, patented, or licensed by the principal investigators and West Virginia University for use in other research or the development of new products. You are not entitled to retain any property rights or share in any money or commercial profit that the principal investigators, West Virginia University, or their agents may realize.

Confidentiality

Personal information that is obtained as a result of your participation in this research will be kept as confidential as legally possible. Your research records and test results, just like hospital records, could be subpoenaed by court order or may be inspected by the study sponsor or federal regulatory authorities, including the Food and Drug Administration (FDA), without your additional consent.

Also, there are certain instances where the researcher is legally required to provide information to the appropriate authorities. The situations include mandatory reporting of infectious diseases, mandatory reporting of information about behavior that is imminently dangerous to you or others, such as suicide, child abuse, etc.

Your name or other identifying information will not be included in research-related publications without your consent.

Identifiers will be removed from the you private information and after removal, that information could be used for future research or distributed to another PI for future research without additional informed consent.

HIPAA Authorization

We know that information about your health is private. We are dedicated to protecting the privacy of your information. Because of this promise, we must obtain your written authorization (permission) before we may use or disclose your protected health information (PHI) or share it with others for research purposes.

You can decide to sign or not to sign this authorization. However, if you choose not to sign, you will not be able to take part in the research study. Whatever choice you make about this research study will not affect your access to medical care.

Persons/Organizations Providing the Information

Patient/West Virginia University Hospitals/ WVU Medicine/ WVUHS

Persons/Organizations Receiving the Information

- The research site(s) carrying out this study. This includes UHA or UHA Affiliates, WVU, WVU Hospitals, West Virginia University Health System (WVUHS). It also includes each site's research and medical staff.
- Health care providers who provide services to you as part of this research study.
- Laboratories and other people and groups that look into your health information as part of this study in agreement with the study protocol.
- WVCTSI and the people and companies that they use to oversee, manage, or conduct the research.
- The members and staff of any institutional review board that oversees this research study.
- The West Virginia University Office of Human Research Protection and the West Virginia University Office of Sponsored Programs.
- Department of Internal Medicine, Department of Orthopaedics and Department of Behavioral Health.

The Following Information Will Be Used

Information from your existing medical records, and new information about you that is created or collected during this study, such as: history and physicals, clinic visit notes, nursing and staff notes, laboratory results, x-rays, EKG results, demographic data, pulmonary tests, imaging scans, and study forms.

The Information is Being Disclosed for the Following Reasons

- Review of your data for quality assurance purposes
- Publication of study results (without identifying you)
- Evaluating other therapies for patients and developing a better understanding of the disease.

You may Cancel this Authorization at Any Time by Writing to the Principal Investigator

Allison Lastinger, M.D.
West Virginia University Medicine
Department of Internal Medicine, Section of Infectious Diseases
PO Box 9163
Morgantown, WV 26506

If you cancel this authorization, any information that was collected already for this study cannot be withdrawn. Once information is disclosed, according to this authorization, the recipient may re-disclose it, and then the information may no longer be protected by federal regulations.

You have a right to see and make copies of your medical records. You will not be able to see or copy your records related to the study until the sponsor has completed the study. At that time, you may ask for the study doctor's files related to your participation and request that information be corrected.

This authorization will expire at the end of the study unless you cancel it before that time.

Voluntary Participation

Participation in this study is voluntary. You are free to withdraw your consent to participate in this study at any time. If you choose to withdraw your participation from the study, the data collected on you up until that time remains a part of the study database and may not be removed. No additional information will be added to the study database after your withdrawal.

Refusal to participate or withdraw will not affect your future care or status at West Virginia University.

In the event new information becomes available that may affect your willingness to participate in this study, this information will be given to you so that you can make an informed decision about whether or not to continue your participation.

Contact Persons

If you have any questions, concerns, or complaints about this research, you can contact Jenn Eicher at 304-285-7445 or jeicher@hsc.wvu.edu between the hours of 7a – 4p, Monday – Thursday.

If you are hurt from being in this research, you should contact Allison Lastinger, MD at 304-598-4855. If an injury occurs outside of business hours and is related to your participation in this research, please contact 304-598-4855 to be directed to the on-call provider.

For information regarding your rights as a participant in research or to talk about the research, contact the WVU Office of Human Research Protections (OHRP) at (304) 293-7073 or by email at IRB@mail.wvu.edu.

Future Contact

Future research may be conducted for which you are eligible. If you are interested in being contacted for future research, please indicate so by completing this section.

☐ Yes, I want to be contacted if future research studies, for which I am qualified, become available.

☐ No, I **do not** want to be contacted.

Signatures and Authorization

You have been given the opportunity to ask questions about the research and your authorization of HIPAA, and you have received answers concerning areas you did not understand. Upon signing this form, you will receive a copy.

Participant Signature

I willingly consent to participate in this research.

Signature of Subject or Subject's Legal Representative

Printed Name Date

Consenting Individual Signature

The participant has had the opportunity to have questions addressed. The participant willingly agrees to be in the study.

Signature of Person Obtaining Informed Consent

Printed Name Date