INFORMED CONSENT DOCUMENT

Project Title: **Wearable Bioimpedance Analyzer for Tracking Body Composition Changes: A Randomized Controlled Trial**

Principal Investigator: **Jacob Elkins, MD, PhD**

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This consent form describes the research study to help you decide if you want to participate. This form 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 as a research subject.

- If you have any questions about or do not understand something in this form, you should ask the research team for more information.
- You should discuss your participation with anyone you choose such as family or friends.
- 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 are inviting you to participate in this research study because you are a patient of the bariatric arthroplasty clinic.

The purpose of this research study is to investigate whether wearing a bioimpedance analysis (BIA) wristband has any effect on desired body composition changes. Bioimpedance is a way of measuring your body fat, muscle mass, and total body water by sending a low electrical current throughout your body. We will compare monthly progress as well as surgical outcomes for patients who wear the BIA band to those who do not. The InBody BIA wristband connects to a web-based program on a smart phone to track progress.

HOW MANY PEOPLE WILL PARTICIPATE?

Approximately 90 people will take part in this study conducted by investigators at the University of Iowa.

HOW LONG WILL I BE IN THIS STUDY?

If you agree to take part in this study, your involvement will last for up to 24 months. We will follow up with you at each of your regularly scheduled appointments to the bariatric arthroplasty as well as monthly via phone call.

WHAT WILL HAPPEN DURING THIS STUDY?

Once you consent to participate in the study, you will be randomized to one of two study groups. This means whichever study group you are assigned will be determined purely by chance (like the flip of a coin). You will have a 50/50 chance to either receive and use an InBody BIA wristband or to not wear one. The Principal Investigator will be blinded to which study group you are in.

For those randomized to the wristband group:
You will be given an InBody Band 2 Fitness Tracker. Wristbands should be worn at all times, even at night or when in water. The wristband has the ability to track many fitness data points, but the research team is mainly interested in those to do with body composition, such as body mass, fat mass, skeletal muscle mass.

At your clinic appointment, a member of the research team will provide you with the band and help complete device set up. To use the band, you will need to download the InBody app to a smartphone that can connect to the internet and has Bluetooth. You will then log in to a personal account on the app to save your data to. We expect the app to use less than 1GB of data throughout the time you will be using it. Any questions regarding how to use the InBody app and wristband will be answered. We will instruct you to initiate a BIA assessment through your band at least once per week. The band should be worn at all times throughout the day but can be removed at night when you go to bed.

We will follow up with you monthly to assess your perceived progress. We will also follow up with you at your regularly scheduled clinic appointments every 3 months. At these standard visits, you will undergo a BIA using the clinic's stationary InBody scanner as well as test your hand grip strength. You will also obtain coaching on how to optimize weight loss. If you are subsequently indicated for total joint arthroplasty (TJA) surgery, we will collect postoperative data from your clinic visits and electronic medical record such as reoperation, infection, and implant failure incidence.

For those randomized to the control group:

You will proceed with the standard in-clinic coaching on optimizing weight loss in order to eventually undergo a total joint arthroplasty (TJA). We will follow up with you at your regularly scheduled clinic appointments every 3 months. At these standard visits, you will undergo a BIA using the clinic's stationary InBody scanner as well as test your hand grip strength. If you are subsequently indicated for TJA surgery, we will collect postoperative data from your clinic visits and electronic medical record such as reoperation, infection, and implant failure incidence.

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. There are no foreseeable risks, however, there is the potential risk of falling off the stationary BIA scanner platform if you are unable to stand for longer than 90 seconds and a risk of hand fatigue and

pain from use of the hand grip strength testing. Subjects randomized to the band group have an additional risk of wrist discomfort or irritation from wearing the band.

WHAT ARE THE BENEFITS OF THIS STUDY?

We don't know if you will benefit from being in this study.

However, we hope that, in the future, other people might benefit from this study because future patients and providers will have a better understanding of the potential wearable technology has in a bariatric arthroplasty setting.

WILL IT COST ME ANYTHING TO BE IN THIS STUDY?

Study participants in the wearable wristband group may incur extra financial costs depending on their cell phone data plan.

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 receiving no payments from other agencies, organizations, or companies to conduct this research study.

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

- If you are injured or become ill from taking part in this study, medical treatment is available at the University of Iowa Hospitals and Clinics.
- The University of Iowa does not plan to provide free medical care or payment for treatment of any illness or injury resulting from this study unless it is the direct result of proven negligence by a University employee.
- If you experience a research-related illness or injury, you and/or your medical or hospital insurance carrier will be responsible for the cost of treatment.

WHAT ABOUT CONFIDENTIALITY?

We will keep your participation in this research study confidential to the extent permitted by law. However, it is possible that 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.

- federal government regulatory agencies,
- auditing departments of the University of Iowa, and
- the University of Iowa Institutional Review Board (a committee that reviews and approves research studies)
- InBody Co., Ltd. may receive information regarding this study

To help protect your confidentiality, only the minimum necessary data will be collected. All electronic data will be stored on University of Iowa's password protected servers. All physical information and data will be stored in the locked offices of the research team. 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.

A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. A copy of the informed consent document will be available on this website. This website will not include information that can identify you. At most, the website will include a summary of the results. You can search this website at any time.

WILL MY HEALTH INFORMATION BE USED DURING THIS STUDY?

The Federal Health Insurance Portability and Accountability Act (HIPAA) requires University of Iowa Hospitals and Clinics to obtain your permission for the research team to access or create "protected health information" about you for purposes of this research study. Protected health information is information that personally identifies you and relates to your past, present, or future physical or mental health condition or care. We will access or create health information about you, as described in this document, for purposes of this research study. Once University of Iowa Hospitals and Clinics has disclosed your protected health information to us, it may no longer be protected by the Federal HIPAA privacy regulations, but we will continue to protect your confidentiality as described under "Confidentiality."

We may share your health information related to this study with other parties including federal government regulatory agencies, the University of Iowa Institutional Review Boards and support staff.

You cannot participate in this study unless you permit us to use your protected health information. If you choose *not* to allow us to use your protected health information, we will discuss any non-research alternatives available to you. Your decision will not affect your right to medical care that is not research-related. Your signature on this Consent Document authorizes University of Iowa Hospitals and Clinics to give us permission to use or create health information about you.

Although you may not be allowed to see study information until after this study is over, you may be given access to your health care records by contacting your health care provider. Your permission for us to access or create protected health information about you for purposes of this study has no expiration date. You may withdraw your permission for us to use your health information for this research study by sending a written notice to Dr. Elkins at 01071 JPP, 200 Hawkins Drive, Iowa City, IA 52242. However, we may still use your health information that was collected before withdrawing your permission. Also, if we have sent your health information to a third party, such as the study sponsor, or we have removed your identifying information, it may not be possible to prevent its future use. You will receive a copy of this signed document.

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. 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 HAVE QUESTIONS?

We encourage you to ask questions. If you have any questions about the research study itself, please contact: Silvana Velasquez Marin at (319) 384-6072, or Lauren Crowe at (319) 467-7128, or Victoria Tappa at (319) 384-6136. If you experience a research-related injury, please contact: Dr. Elkins at (319) 678-7945.

If you have questions, concerns, or complaints about your rights as a research subject or about research related injury, please contact the Human Subjects Office, 105 Hardin Library for the Health Sciences, 600 Newton Rd, The University of Iowa, Iowa City, IA 52242-1098, (319) 335-6564, or e-mail irb@uiowa.edu. General information about being a research subject can be found by clicking "Info for Public" on the Human Subjects Office web site, http://hso.research.uiowa.edu/. To offer input about your experiences as a research subject or to speak to someone other than the research staff, call the Human Subjects Office at the number above.

This Informed Consent Document 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 signing this Informed Consent Document. 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 copy of this form.

Subject's Name (printed): _____

_____ _____
(Signature of Subject) (Date)

Statement of Person Who Obtained Consent

I have discussed the above points with the subject or, where appropriate, with the subject's legally authorized representative. It is my opinion that the subject understands the risks, benefits, and procedures involved with participation in this research study.

_____ _____

(Signature of Person who Obtained Consent) (Date)