TITLE:
The Impact of Humeral Component Version on Outcomes Following Reverse Total Shoulder Arthroplasty: A Prospective, Randomized Trial

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Informed consent document

CONSENT FORM AND AUTHORIZATION FOR DISCLOSURE OF PROTECTED HEALTH INFORMATION

STUDY TITLE: **The Impact of Humeral Component Version on Outcomes Following Reverse Total Shoulder Arthroplasty: A Prospective Randomized Controlled Trial**

Principal Investigator:	**J. Michael Wiater, M.D.**
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Phone Number:	**(248) 644-3920**
Hospital:	**William Beaumont Hospital – Royal Oak**

INTRODUCTION

Why is this study being done?

You are being asked to participate in a clinical research study. The purpose of clinical research is to look at the nature of disease and try to develop improved methods to diagnose and treat disease. The doctor or clinician in charge of the study believes you meet the initial requirements to take part in the study. Before agreeing to participate, it is important for you to read and understand the following explanation of the research procedures. This Consent and Authorization form describes the purpose, procedures, benefits, risks and discomforts of the study. It also describes the alternatives available to you, and your right to withdraw (quit) from the study at any time.

Please read this information carefully and ask as many questions as you like before deciding whether or not you would like to take part in this research study.

FINANCIAL DISCLOSURE:

Dr. J. Michael Wiater, the Beaumont surgeon conducting this study, has received payments from Zimmer Biomet, the manufacturer of the product being studied, for providing teaching and consulting services.

The goal of this study is to compare the effect of different positions of the implant component that goes in the humerus (upper arm) in reverse total shoulder replacement. Some surgeons place the component in line with the native position of the ball of the humerus (retroversion), while others place it facing directly towards the body (neutral). Changing the position of the humeral component may change the amount of arm rotation after surgery for some patients. The outcomes in the published literature have been mixed, and there is currently no standard of care. Depending on the surgeon you see, you may get one or the other. This study would compare patients with "retroverted" and "neutral" humeral components to see if there are indeed any differences in range of motion or function after surgery. Patients would be randomly assigned to groups, after consenting to participate.

A total of 85 patients will take part in the study at Beaumont Hospital Royal Oak.

How long will I be in the study?
If you decide to take part in this study, your participation is expected to last approximately 2 years, and you must be undergoing a reverse total shoulder arthroplasty. You may not take part in this study if you are currently enrolled in another related research study which could alter or influence the study results.

DESCRIPTION OF THE STUDY
What will happen if I take part in the research study?
You are being asked to take part in this research study because you are undergoing a reverse total shoulder arthroplasty. The results of this study will compare patient outcomes with two different positions of the humeral component.

If you agree to take part in this study you will be randomized (like the flip of a coin) to receive either:

A. A humeral component positioned in 30 degrees of retroversion.
B. A humeral component positioned in 0 degrees of version (neutral).

You are being invited to participate because you are eligible for the study based on your information so far. None of the information collected so far will be used for research unless you agree to participate in this study by signing this Consent and Authorization Form.

Schedule of Events
After your surgery, you will be asked to follow up in the clinic at 3 months, 6 months, 1 year, and 2 years after surgery, which is standard-of-care. At each standard-of-care follow-up visit you will be asked to fill out questionnaires for the study asking about your pain and function. A physical exam and range of motion measures will also be performed at each visit, as well as standard-of-care x-rays.

PARTICIPANT RESPONSIBILITIES
You will be asked to note any side effects or medical problems you may experience while you are taking part in this study. For any illnesses or injuries, you should contact the study doctor immediately at the number listed on this consent form or in an emergency situation call 911 (or go to the nearest hospital emergency room).

RISKS, SIDE EFFECTS AND DISCOMFORTS
Ask your physician what the standard of care risks are as well as the study risks.
What side effects or risks can I expect from being in the study?

<u>Study Risks:</u>
The risks of participating in this study include the same risks normally associated with reverse total shoulder arthroplasty surgery whether you are in the study or not. Both techniques (30

degrees of humeral component retroversion versus 0 degrees of version) are standard-of-care, based on surgeon preference. There is a chance that you may have worse range-of-motion or function if one technique proves inferior. However, this has yet to be proven.

There is a rare risk of breach of confidentiality (release of information which personally identifies you). Every research study involves some risk to your confidentiality. It is possible that other people could find out you are in the study or see your study information. But we will take every step to keep this from happening.

Pregnancy Warning

If you are a woman who is pregnant or becomes pregnant during the research study, there could be harmful effects to you or your unborn child. It is important you not be pregnant or breast-feeding at the time of surgery. If you are a woman of childbearing potential you must confirm that you are not pregnant before entering the study.

BENEFITS

What are the benefits of taking part in this study?

There may be no direct benefit to you from taking part in this study. However, you may have better motion or function if one technique proves superior. It is hoped that the results of this study will help doctors learn which treatment is most effective for maximizing outcomes after reverse total shoulder arthroplasty.

ALTERNATIVE OPTIONS

What are my choices other than taking part in this study?

You do not have to take part in this study to receive treatment for your condition. Your alternative is to not participate in this study and receive standard medical care as prescribed by your doctor (which may include one of the study treatments).

ECONOMIC CONSIDERATIONS

What are the costs of taking part in this study?

There will be no additional cost to you for the study participation. Routine procedures you would have had done even if you were not taking part in this study, such as your surgery, hospitalization, anesthesia, and pain medications will be billed to your health insurance company and/or group health plans as usual. If these routine care costs are not covered by your health insurance/group health plan, the cost will be your responsibility. The study will cover the cost of the questionnaires.

You will be reimbursed for your time and travel (etc.) for the final visit of the study (2-year follow-up). A $100 check will be mailed to your home approximately 4 weeks after your visit.

COMPENSATION

What happens if I am injured because I took part in this study?

Your involvement in this study is voluntary. The possible risks and side effects which might occur during the course of the research study have been described in this Consent and Authorization form. A research injury is any physical injury or illness caused by your participation in this study.

Should you experience a research injury, there are no designated funds provided for subsequent medical care or compensation by either the study doctor/clinician or William Beaumont Hospital.

Every effort to prevent any injury resulting from this study will be taken by your study doctor and William Beaumont Hospital. Immediate necessary care, emergency treatment, and professional services will be available to you, just as they are to the general community. You and/or your insurance company will be responsible for the costs. Compensation (such as for lost wages and/or pain and suffering) is not available.

What are my rights if I take part in this study?
You are not giving up any of your legal rights by signing this form.

CONFIDENTIALITY, DISCLOSURE AND USE OF YOUR INFORMATION
Will my medical information be kept private?
In order for this research study to take place, you must also authorize the researchers to access and use some of your protected health information (PHI). PHI is information which could identify you as an individual such as name, address, date of birth, etc. By signing this Consent and Authorization Form, you give William Beaumont Hospital permission to use and/or disclose (release) your health information related to this research. Your medical and billing records collected for the purpose of the study will remain confidential, but may be disclosed (released) or used by the following and/or their representatives:

- The investigators (study doctor/clinician, research staff)
- William Beaumont Hospital
- The Food and Drug Administration
- Other governmental regulatory agencies (domestic and/or foreign)
- Your health insurance company and/or group health plans and their intermediaries (companies contracted to process claims) may also have access to your medical and billing records of the study.

The purpose for this disclosure (release) or use is, for example, to assure compliance with the study protocol, to evaluate the effectiveness of the study, and/or to provide protection to you as a research study participant. The disclosure and use of your information will continue after your involvement in the study has ended. There is no expiration date for the use of your medical and billing records from the study. Any information about you disclosed to the parties identified above may be re-disclosed by them; however, such re-disclosure is not under the protections of this Consent and Authorization.

You will not be identified in any publication or other release of study results, data, and other information (such as in professional writings or at professional meetings).

If you decide to withdraw your authorization for the researchers to access and use your personal health information before the end of the study, you will be withdrawn from the research study. However, where the study relied on your Consent and Authorization for the time you participated

in the study, your Consent and Authorization cannot be withdrawn and the information already collected may still be used and disclosed as you previously authorized.

STOPPING STUDY PARTICIPATION

What if I decide to stop taking part in the study?

Taking part in this research study is completely voluntary. You may choose not to take part or to stop being in the study (withdraw) at any time without penalty or loss of benefits to which you are otherwise entitled, or without jeopardizing your medical care by your physician at William Beaumont Hospital. However, if you do not agree to sign this Consent and Authorization Form, you will not be able to take part in this study.

If you decide to withdraw from the study you will need to notify the study doctor/clinician of your decision to stop taking part in the study. Written notification is preferred. This notice may be sent to Dr. J. Michael Wiater at Beaumont, 3601 West Thirteen Mile Road, 111 MOB-RO, Royal Oak, MI 48073.

Your participation in this study may be stopped by the study doctor/clinician, without your consent, for any reason, which will be explained to you. Examples include:

- The study procedures appear to be medically harmful to you.
- You fail to follow directions for participating in the study.
- It is discovered you do not meet the study requirements.
- The study is canceled.
- It is determined to be in your best interest.

CONTACTS

Who can answer my questions about the study?

You may talk to the study doctor/clinicians about any questions or concerns regarding your study participation, or if you think you may have suffered a research-related injury. The doctor in charge of the study, Dr. J. Michael Wiater, may be reached at (248) 644-3920 to answer your questions. Your contact person is Lauren Davey. You may contact her at (248) 551-2313.

If you have questions regarding your rights as a research participant, or have problems, concerns, complaints, want information or would like to offer input, you may contact the Institutional Review Board Chairperson at (248) 551-0662. The Institutional Review Board is charged with the oversight of all human participant research conducted at William Beaumont Hospital facilities.

STATEMENT OF VOLUNTARY PARTICIPATION

I have read the above, have asked questions and have received answers about this study to my satisfaction. I understand what I have read and willingly give my consent to participate in: **The Impact of Humeral Component Version on Outcomes Following Reverse Total Shoulder Arthroplasty: A Prospective Randomized Controlled Trial.** I understand I will receive a signed copy of this document and will be promptly informed of any new findings regarding this study. I further authorize the use or disclosure of my health and personal information contained in records as described above.

_____
RESEARCH PARTICIPANT NAME (PLEASE PRINT)

_____ _____ _____
RESEARCH PARTICIPANT SIGNATURE DATE TIME

ALTERNATIVE SIGNATURE (IF RESEARCH PARTICIPANT UNABLE TO SIGN)

AS THE PERSONAL/LEGAL REPRESENTATIVE OF THE STUDY PARTICIPANT, PLEASE PRINT PARTICIPANTS NAME ABOVE IN THE RESEARCH PARTICIPANT SECTION, AND CHECK ONE OF THE BOXES BELOW AS THE BASIS FOR YOUR AUTHORITY TO SIGN THIS CONSENT AND AUTHORIZATION:

☐ COURT-APPOINTED GUARDIAN
*COURT LETTER IS REQUIRED

☐ DURABLE POWER OF ATTORNEY
*ATTORNEY LETTER MUST BE PRESENT & VERIFIED BY 2 PHYSICIANS

☐ NEXT OF KIN

_____ _____
NAME (PLEASE PRINT) RELATIONSHIP TO PARTICIPANT

_____ _____ _____
SIGNATURE DATE TIME

***WITNESS TO THE ENTIRE CONSENT PROCESS AND SIGNATURE ARE REQUIRED IF THE PARTICIPANT IS VISUALLY IMPAIRED, ILLITERATE OR NON-ENGLISH SPEAKING ONLY**

_____
WITNESS NAME (PLEASE PRINT)

_____ _____ _____
WITNESS SIGNATURE DATE TIME

AUTHORIZED CONSENT PROVIDER STATEMENT:

I have explained this study and have offered the study participant an opportunity for any further discussion or clarification.

_____ _____ _____
NAME (PLEASE PRINT) CREDENTIALS PHONE NUMBER

_____ _____ _____
SIGNATURE DATE TIME

IRB NUMBER: 2017-057
IRB APPROVAL DATE 02/16/2022
EXPIRATION DATE 02/15/2023