**PARTICIPANT INFORMATION SHEET**
**Total Knee Replacement**

**TITLE OF STUDY:** The Origin Study: A randomised control trial comparing functional recovery after custom or standard total knee replacement

**NAME OF RESEARCHERS**: Prof Tim Board, Dr Ben Langley, Mr Jon Barrow, Mr Adam Jones, Mr Anil Gambhir, Mr George Pavlou, Mr Hiren Divecha, Dr Axel Sylvan, Prof Matt Greig

**STUDY SPONSOR:** Wrightington, Wigan and Leigh NHS Trust

You are being invited to take part in a research study. Before you decide it is important for you to understand why the research is being done and what it will involve. Please take time to read the following information carefully and discuss it with us if you wish. Ask us if there is anything that is not clear or if you would like more information. Take time to decide whether or not you wish to take part. Thank you for reading this.

**What is the purpose of the study?**

We want to better understand how custom total knee replacements influence the recovery of movement patterns and muscle activation after surgery when compared to standard total knee replacements. A custom knee replacement is one that is made to fit a patients' knee perfectly as compared to a traditional knee replacement that comes in a range of sizes that are 'trialed' at the time of surgery and the best fitting one is chosen and implanted. A better understanding about the speed and size of functional recovery after total knee replacement between conventional and custom implants has the potential to further enhance knee replacement surgery, with a view to maximizing functional recovery. Within this study we will also look to determine how accurate and

reliable a mobile phone-based application to record joint movement patterns is. If the mobile phone-based application is valid and reliable it would provide a new way of monitoring your recovery after joint replacement surgery, potentially from your own home.

**Why have I been invited**?

You have been invited because you are awaiting a consultation about a total knee replacement. While you are eligible to participate within the study it may not be necessary for everyone who expresses an interest in completing the testing to do so, so do not worry if you do not hear back from the research team.

**Do I have to take part?**

No. It is up to you to decide whether or not to take part. If you do decide to take part, you will be given this information sheet to keep and asked to sign a consent form. If you decide to take part, you are still free to withdraw at any time. If you decide to participate and then withdraw or if you choose not to participate this will not affect the standard of care you receive in the long term.

**What will happen to me if I take part**?

You will be randomly allocated to receive either a traditional implant or a custom implant (specifically a Symbios Origin knee, designed by one of the studies funders), depending on which group you are assigned to. You will be asked to attend three testing sessions at what we refer to as our biomechanics laboratory at Edge Hill University (Ormskirk, Lancashire) to undergo movement analysis. Specifically, you will be asked to attend one testing session in the weeks leading up to your knee replacement, one 3 months after your operation, and the final testing session 12 months after your operation. Within each of the laboratory sessions you will be asked to complete some questionnaires about your pain and activities, and you will undergo an assessment of your movement patterns as you walk, walk and turn around, rise from a seated position and sit back down, walk up and down a set of stairs and if you are able, kneel down. Additionally, you will be asked to lie on a massage table and bend/straighten your knee as much as you can. The testing will be the same during each of the testing sessions. You will also be asked to undergo X-Ray and Computerized Tomography (CT) assessments prior to your total knee replacement surgery to enable the surgical team to plan your operation effectively and for your implant to be designed if you are part of the custom implant group. You would receive 2 X-

Rays and 1 CT scan pre-operatively if you participate within the study; the X-Rays are routine for all knee replacements and the CT scans routine for custom knee replacements. You will also receive 2 X-rays after the operation (usually on the day or two following surgery), which again is routine practice to ensure the alignment of the implant is correct.

**What do I have to do?**

You will be asked to walk at your preferred speed in a straight line over 7m, to walk at the same speed before turning around and walking back to where you started, to rise from a seated position and to sit back down, to walk up and down a set of stairs, lay on a massage bed and straighten/bend your knee as much as possible and if you are able to kneel down. You will be asked to complete each of these tasks a number of times to enable six good recordings to be taken. You will be able to rest whenever you require, and refreshments will be provided throughout the duration of the testing sessions. To enable the motion analysis system to track your movement patterns small reflective markers will be attached to specific locations on your legs and body. The markers will be attached using double sided tape, if you are allergic to the tape please let us know and we can make suitable arrangements. We will also use a mobile phone, which is only being used for this study and does not contain a sim card, to record a side on video of you performing the knee bending/straightening task. The video recorded on the mobile phone will not contain an image of your face (recording from shoulders down) but will be shared with myrecovery.ai, in order for them to calculate how much your knee is moving from the video file. No personal or identifiable information will be shared with myrecovery.ai; however, if you have specific distinguishing markings (scars, birthmarks or tattoos) on your legs or if you talk during the recording of the video you may be identifiable if someone at myrecovery.ai knows you. The video files will not be shared with anyone else and they will be deleted upon the completion of the study. We will use the video footage to compare the knee motion recorded on the video to that reported by our motion capture system to determine how accurate the video method is. In addition, small boxes will also be attached to the muscles on the front and back of your thighs to enable us to see which muscles are working and when during each of the movements. During each movement you will be asked to stand or step on to a plate located in the floor of our laboratory, this plate enables us to measure how much force you apply to the ground. You will be required to wear shorts for the testing sessions, and these can be provided by the research team at Edge Hill if

required. Private changing facilities are available on site. The same testing will be undertaken at each of the testing sessions you attend.

Additionally, you will have to undergo the surgical procedure aligned with the group to which you are allocated, so receive either a traditional or a custom total knee replacement. Currently, the traditional implant is used in standard practice and performs well. In contrast, the custom implant is typically used either privately or in more challenging cases where alignment of the conventional implant may be difficult. Regardless of which implant group you are aligned to you will receive the same standardized care before, during and after the operations. You will also be asked to undergo two X-Rays and a single CT scan prior to your operation regardless of which implant group you are assigned to, which will help the surgical teams plan your operation and for your implant to be designed if you are part of the custom group (this is routine practice).

**What is the procedure that is being tested?**

We are testing the custom knee replacement design against the standard, traditional design.

**What are the alternatives for treatment?**

Your surgeon will discuss treatments for your knee. You will only be entered into the trial if you and your surgeon already agree that knee replacement is the right thing for you to have.

**What are the side effects of any treatment received when taking part?**

The side effects and risks of knee replacement surgery will be discussed with you in detail by your surgeon.

If you take part in this study you will have two knee x-ray examinations and one CT scan of your knee. The CT scan of the knee will be extra to those that you would have if you did not take part. These procedures use ionising radiation to form images of your body and provide your doctor with clinical information. Ionising radiation can cause cell damage that may, after many years or decades, turn cancerous.

We are all at risk of developing cancer during our lifetime. The normal risk is that this will happen to about 50% of people at some point in their life. Taking part in this study will add only a very small chance of this happening to you.

**What are the possible disadvantages and risks of taking part?**

The disadvantages in agreeing to take part in this study are that of time commitment in attending Edge Hill University and completing our tests. We can reimburse travel costs up to £20 per visit. If you are part of the knee replacement groups you may be experiencing pain either before or after the operation which makes it uncomfortable to walk or undertake the other day to day activities, and if so you may experience some discomfort during the tests. If this is the case, the tests can be paused or stopped altogether at any time, and rest areas will be available.

There is a potential risk of falling whilst undertaking the testing, as walking aids, such as sticks and frames, cannot be used. If you cannot walk without walking aids, then unfortunately you will not be able to take part within the study. We will not ask you to do any task which you would not normally do during your day to day activities. Hand rails will be in place for all tasks to help us reduce this risk and we would ask you to tell us if you are having any problems, so we can stop the testing.

If you have any questions relating to any of the risks associated with this study and wish to discuss these further, please do so either in person with your surgical team or by using the contact information provided later in this form.

**What are the benefits of taking part?**

The research may benefit you or future patients because the findings will inform treatment in the future.

**What if new information becomes available?**

We will inform you if any new information becomes available while you are taking part in the study. However, given the nature of this project this is unlikely to be the case.

**What happens when the research study stops?**

You will continue to be cared for under standard treatment by the NHS.

**What if something goes wrong?**

In the unlikely event that something may go wrong within the study, for instance if you slipped and got injured during testing, then insurance and indemnity cover is provided by both Edge Hill Universities insurance policy when on site and/or by the insurance policies of Wrightington, Wigan and Leigh NHS Trust. The Trust insurance and indemnity policies will cover all aspects of surgery related to the study. Should you feel uncomfortable, in any pain or uneasy at any stage during the data collection at please let the research team know immediately. Similarly, if you feel uncomfortable, in any pain or uneasy during your surgical procedures please let the surgical team know immediately.

If you wish to complain or have any concerns about any aspect of the way you have been approached or treated during the course of this study, the normal NHS complaints mechanism should be available to you.

**Will my taking part in this study be kept confidential?**

All information, which is collected, about you during the course of this research will be kept strictly confidential. Any information about you, which leaves the hospital, will have your name and address removed so that you cannot be recognized from it. The only exception to this rule will be the passing on of your contact details to the research team at Edge Hill University in order for them to arrange testing sessions with you directly.

If a scientific paper is written about the results your name and details will be removed completely.

If you are happy we will also contact your GP to inform them that you are taking part within this study and to provide them with some background to the work. If you do not wish your GP to be contacted then please let the research team know when you sign the consent forms.

**What will happen to the results of the research study?**

We hope to publish the results of this study in scientific journals, conferences and at meetings in order to help all doctors treating patients with this condition. The results will also be used as part of one of the research teams PhD Thesis. Data collected using both the motion analysis system and the phone application will be shared in an anonymised manner with myrecoevery.ai, who have developed the software to calculate how much your knee moves from the video files. We will also send you a basic summary of the study's findings, should you so wish, to help us do this we will keep your contact details on file at WWL NHS Trust.

Additionally, if you agree to take part in this study, you will have the option to take part in future research using your data saved from this study.

**Who is funding this study?**

This study is part funded by Symbios Orthopedics, The John Charnley Trust and The Wrightington Wish Foundation. Symbios Orthopedics are the manufacturer of the custom total knee replacement implant being assessed within this study.

**Who has reviewed this study?**

The study has been reviewed by the North of Scotland Research Ethics Committee (1).

**Contact for further information**.

If you would like to discuss the study further please either raise the study with your surgical team at your next outpatient appointment or contact Emma Robinson (phone: 01257 256564; email: Emma.Robinson@wwl.nhs.uk).

**General Data Protection Regulations Information**

**How will we use information about you?**

We will need to use information from you and if you are part of the knee replacement group information from your medical records for this research project.

This information will include your;

- NHS number (Wrightington Hospital)
- Name and contact details (Wrightington Hospital and Edge Hill University)

- Reason for your total knee replacement surgery [total knee replacement participants] (Wrightington Hospital)
- Background health information, such as pervious lower limb surgery or musculoskeletal conditions [total knee replacement participants] (Wrightington Hospital)

People will use this information to do the research or to check your records to make sure that the research is being done properly.

People who do not need to know who you are will not be able to see your name or contact details. Your data will have a code number instead.

We will keep all information about you safe and secure.

Once we have finished the study, we will keep some of the data so we can check the results. We will write our reports in a way that no-one can work out that you took part in the study.

**What are your choices about how your information is used?**

You can stop being part of the study at any time, without giving a reason, but we will keep information about you that we already have.

We need to manage your records in specific ways for the research to be reliable. This means that we won't be able to let you see or change the data we hold about you.

**Where can you find out more about how your information is used?**

You can find out more about how we use your information from the following sources;

- www.hra.nhs.uk/information-about-patients/
- https://www.wwl.nhs.uk/information/IG_Data_Protection.aspx
- by asking one of the research team
- or by contacting Natalie Baxter by phone on 01257 256277 or email at Natalie.Baxter@wwl.nhs.uk who is the Data Protection Officer at Wrightington, Wigan and Leigh NHS Trust

If you would like some general information about being involved in a research project please contact your local Research & Development Department on 01257 256465 or see www.nres.org.uk or www.involve.org.uk

**Thank you for taking the time to read about this study, if you have any questions please do not hesitate to ask. If you agree to take part you will be given a copy of this information sheet as well as the consent form for taking part in the study.**