

## Robotic Arthroplasty: a Clinical and cost Effectiveness Randomised controlled trial (RACER) Learning Effect Study Consent Form

Chief Investigators: Mr Andrew Metcalfe/Professor Edward Davis  
Local PI: <<XXXX>>

Participant ID				
L	S			

**Please read each statement and initial the box if agreed**

- |   | <i>Initials</i>   |
|---|---|
| 1. I confirm that I have read and understood the information sheet (Version..... Date.....) for the above study. I have had the opportunity to consider the information, ask questions and have had these answered satisfactorily.  | <input style="width: 100%; height: 20px;" type="text"/> |
| 2. I understand that my participation is voluntary and that I am free to withdraw at any time, without giving any reason, without my medical care or legal rights being affected.   | <input style="width: 100%; height: 20px;" type="text"/> |
| 3. I understand that relevant sections of any of my medical notes and data collected during the study may be looked at by responsible individuals from the University of Warwick, from regulatory authorities, or from the NHS Trust, where it is relevant to my taking part in this research. I give permission for these individuals to have access to my records.                                      | <input style="width: 100%; height: 20px;" type="text"/> |
| 4. I understand that appropriate personal identifying information will be collected via postal questionnaires or a mobile application and will be stored and processed by the research team and the app provider to enable the trial team to contact me to follow up my health status. This is on the understanding that any information will be treated with the strictest security and confidentiality. | <input style="width: 100%; height: 20px;" type="text"/> |
| 5. I understand that the information held and maintained by NHS Digital and other Central UK NHS bodies may be used to provide information about my health status. This will involve us linking your data (including personally identifiable data) with routine NHS datasets such as the National Joint Registry, Scottish Arthroplasty Project and NHS Digital.  | <input style="width: 100%; height: 20px;" type="text"/> |
| 6. I understand that in order to plan my surgery, CT scan images will be sent outside the European Union to the company that supplies the robot (Stryker, USA). I understand that these images will contain at least two identifiers (e.g. name, hospital number or date of birth) but these will only be seen by employees of Stryker and will not be shared with any other party.                       | <input style="width: 100%; height: 20px;" type="text"/> |
| 7. I understand that the information collected about me will be used to support other research in the future, and this anonymised data will be stored in a data repository so it may be shared with other researchers for future research, development, and learning.   | <input style="width: 100%; height: 20px;" type="text"/> |
| 8. I agree to being contacted to remind me that a questionnaire is due, to request further information, to help complete a questionnaire or to receive study results, based on the contact information I provide.   | <input style="width: 100%; height: 20px;" type="text"/> |
| 9. I agree to my GP being informed of my participation in the study.  | <input style="width: 100%; height: 20px;" type="text"/> |
| 10. I agree to take part in the RACER study.  | <input style="width: 100%; height: 20px;" type="text"/> |

**OPTIONAL DATA SHARING:** I consent to my health data being collected during the RACER study to be shared with Stryker Orthopaedics (please tick one option)

Yes	No
<input style="width: 30px; height: 20px;" type="checkbox"/>	<input style="width: 30px; height: 20px;" type="checkbox"/>

<b>Patient Name:</b>	<b>Signature:</b>	<b>Date:</b>
<b>Person taking consent (and role):</b>	<b>Signature:</b>	<b>Date:</b>
<b>For witnessed verbal consent: I witnessed accurate reading of the consent form to the patient, who could ask any questions and was happy with the responses.</b>		
<b>Person who witnessed consent (and role):</b>	<b>Signature:</b>	<b>Date:</b>