

Patient Information and Consent

The manufacturer of the implant that your surgeon has recommended for you, which will replace your affected joint, has chosen to include it in the **Beyond Compliance** service.

“**Beyond Compliance**” was introduced in 2012, by the Association of British Healthcare Industries (ABHI), the British Orthopaedic Association (BOA) and the Medicines & Healthcare products Regulatory Agency (MHRA), as a service available to manufacturers of implants used for joint replacements, such as total hip or total knee replacements, which supports their safe introduction.

Beyond Compliance collects information about patients who receive these implants and then tracks their post-surgical progress to make sure that each new design or design modification is performing as required. The information that is collected is reviewed by an independent group of voluntary experts, including very experienced surgeons, on a regular basis so that if any problems are noted the manufacturer is contacted and the appropriate remedial action can be instituted. For more information go to <http://www.beyondcompliance.org.uk/Home.aspx>

Beyond Compliance would like you to consent to our partner, Northgate Public Services (UK) Ltd. (“NPS”), collecting information about your surgery and link this information to other relevant information on a confidential basis. NPS are an independent company who are expert in collecting and analysing information about joint replacements. They manage the National Joint Registry data on behalf of the Healthcare Quality Improvement Partnership (HQIP) and is an accredited supplier of Patient Reported Outcome Measures (PROMs) data collections.

Personal information is treated with high standards of confidentiality in accordance with data protection laws and the duty of confidentiality. Any information that is published will always be in pseudonymised form and will not directly identify you.

Your consent for your personal information to be processed in this way is entirely voluntary. You do not have to give consent and are free to withdraw consent at any time without giving any reason, and without your medical care or legal rights being affected.

What information will be collected?

If you provide consent to Beyond Compliance (BC), information that is stored on the National Joint Registry (NJR) about your surgical procedure will be linked to and stored with information collected by your surgeon, hospital and healthcare team comprising:

- Your personal details (Your name, NHS number, home address and date of birth) and relevant clinical information (NJR Index Number, Operation Date, Procedure Type, Side, Hospital, Lead Surgeon, Consultant in Charge, Beyond Compliance implants used) about your healthcare including x-ray images, results of examinations and tests,
- We will send the following identifiers to NHS Digital: BC Index Number (Audit ID), Gender, Date of Birth, NHS Number and Postcode. If you have participated, your responses to Patient Reported Outcomes Measures (PROMs) surveys including those held by NHS Digital (for more information see <http://content.digital.nhs.uk/proms>) will be sent back to NPS, with your identifiers removed and just your BC Index Number attached.
- All information will be held until such time that the implant is no longer monitored through the Beyond Compliance Service, at which point your personal identifiers will be removed from our records.
- HQIP is the Data Controller for the National Joint Registry (NJR). NPS is the Data Controller for Beyond Compliance (BC) and, after BC consent has been recorded, will only use the information for the BC service.

If you have not provided consent to the National Joint Registry, the procedure details will be stored without any personal details. Personal details may only be added by the surgeon responsible for your care.

