

# 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, NEC Software Solutions (UK) Ltd. (“NECSWS”), collecting information about your surgery and link this information to other relevant information on a confidential basis. NECSWS 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 are an accredited supplier of Patient Reported Outcome Measures (PROMs) data collections.

Your 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, Beyond Compliance (BC) will collect the following information about you and your operation: Your name, NHS number, home address, date of birth, operation date, operation type, operation side, Hospital, Lead Surgeon, Consultant in Charge, Beyond Compliance implants used, x-ray images and results of examinations and tests. We will also link this information to all information stored about you for this operation or any subsequent operation or outcome held on the National Joint Registry (NJR). For more information about NJR please go to [njr.org.uk](http://njr.org.uk).

We will also send the following identifiers to NHS England ([www.england.nhs.uk](http://www.england.nhs.uk)): Your BC Index Number, gender, date of birth, NHS Number and postcode. If you have chosen to participate in the national NHS PROMs survey your responses, held by NHS England, will be sent back to NECSWS, with all these identifiers, except your BC Index Number, removed (for more information see [www.england.nhs.uk/ourwork/insight/proms/](http://www.england.nhs.uk/ourwork/insight/proms/)).

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. NECSWS is the Data Controller for Beyond Compliance and, after BC consent has been recorded, we 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.

