Patient Information Sheet and Consent Form

The manufacturer of the Joint Replacement that your surgeon has recommended for you, to replace your affected joint, has chosen to include it in the **Beyond Compliance** Service.

"**Beyond Compliance**" was introduced in 2012, by the manufacturers (ABHI), the British Orthopaedic Association (BOA) and the Medicines & Healthcare products Regulatory Agency (MHRA), as a service available to manufacturers of joint replacements, such as Total Hip and Total Knee Replacements, to support their safe introduction. In Beyond Compliance we collect information about patients receiving these implants and then track their post-surgical progress to make sure that this 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 and if any problems are noted the manufacturer is contacted and the appropriate remedial action can be instituted.

Thus Beyond Compliance would like you to consent to our partner, Northgate Public Services (UK) Ltd. ("NPS"), to collect information about your surgery and link this to other information held in NHS databases. Most of this data will come via the National Joint Registry, which is also managed by NPS, to whom you will have (or about to) give your consent for data collection. NPS are an independent company who are expert in collecting and analysing information about Joint Replacements. They manage the National Joint Registry and are an accredited supplier of Patient Recorded Outcome Measures (PROMs) data collections.

Follow-up Questionnaires
To help us monitor and report upon the outcomes achieved following surgery we may, from time to time, send you a questionnaire asking about your recovery and health outcomes. Your participation in these surveys is optional, but all answers will be for the benefit of future patients and help us to assure the safety and effectiveness of implants. If you have e-mail address it will be much easier for us to contact you and for you to reply!

Confidentiality
Your personal information will be handled securely, and will only be shared with professionals directly involved in your health care. NPS will not release your personal information unless in the unlikely event it is required by law or where there is a clear overriding public interest. We think the likelihood of this ever being required is remote.
Information about your joint replacement surgery, **with your personal details removed**, will be made available to the manufacturer of your implant, to independent advisors to the Beyond Compliance Service, and to other healthcare professionals using the same implant.

By signing this form you are giving your consent to:

- Your personal details, your procedure details and your responses to any PROMs surveys (and relevant clinical information including x-ray images, results of examinations and tests) being held for the lifetime of your prosthesis and used by NPS for the Beyond Compliance Service.
- Linking and storing relevant information held about you by the National Joint Registry (NJR) and other NHS data sets including Hospital Episodes Statistics and Patient Reported Outcomes Measures (PROMs).
- Allowing your personal details to be used for the purpose of sending you follow-up questionnaires for the lifetime of your prosthesis.

Your participation is voluntary. If you do not want to take part, do not complete this form. You may withdraw your consent at any time, by notifying us using the contact details listed, at which point your personal details will be removed from our records. If you have any queries about this questionnaire please discuss them with your surgeon or call the Beyond Compliance helpline on 0845 263 6376 or go to www.beyondcompliance.org.uk

YOUR CONSENT- I confirm that:

- **I understand the information provided above and I agree to my details being used as described,**
- **Should my joint replacement ever be removed, I agree to it being sent for analysis by a retrieval-centre.**
- **If I provide an electronic mail address below, I agree that NPS may contact me by email:**

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Printed Name of Patient Date Signature