National Joint Registry
www.njrcentre.org.uk
Working for patients, driving forward quality

NJR Patient Consent Process

An Overview for Users

Document control

Change control table:

Version	Description	Release date	Reason for change	Authorised by
1.0	Consent process guide	July 2017	First issue	C Maskrey
2.0	Consent process guide	June 2018	Revised for MDS7 release	
3.0	Consent process guide	August 2019	New sections on children, capacity	C. Boulton

Contents

1. Introduction to patient consent

The collection of patient personal details is essential to the success of the NJR. By capturing this information the NJR is able to:

- help identify patients who have received specific implants that have been subject to a MHRA (The Medicines and Healthcare products Regulatory Agency) Field Safety Notice and /or Medical Device Alert

- link patients primary and revision procedures, so that the necessary analyses can be undertaken to improve patient outcomes and patient safety and to identify potential outlier performance at surgical, hospital, and implant levels.

- invite patients to take part in any subsequent audits and research, such as Patient Reported Outcomes (PROMs) studies.

In order to record a patient's personal details on the National Joint Registry (NJR) database, all patients must provide informed consent.

1.1 What personal details are recorded?

Patient personal details recorded by the NJR are:

- Forename(s)
- Surname
- Date of Birth
- Gender
- Postcode
- NHS number (or National Identifier)
- Local Hospital Patient identifier

Patient records are sent for subsequent tracing to either validate stored NHS numbers/national identifiers or provide them when they are missing. The tracing will also provide patient address information and, if a patient has died, the patient's date of death. The NJR's **Privacy Statement** provides details of all the processing activities undertaken using patient identifiers.

Consent is recorded differently in England and Wales than it is in Northern Ireland and the Isle of Man:

In England and Wales there are 3 consent options:
Yes
No
Not recorded

In Northern Ireland and the Isle of Man there are 2 consent options:
Yes
No (If consent status is not known, it should be entered as “No”)

In England and Wales, the NJR has support under Section 251 of the NHS Act 2006 to collect patient identifiers where consent is indicated as ‘Not Recorded’. Although Section 251 support does not ‘expire’, its continuation is dependent upon the submission of an Annual Report to the Health Research Authority’s Confidentiality Advisory Group. More information can be found at: **NJR Consent and Section 251**.

The Regulations that enable this collection are the Health Service (Control of Patient Information) Regulations 2002. Any references to ‘Section 251 support or approval’ actually refer to approval given under the authority of the Regulations.

Approximately 4% of records submitted annually have an indication of ‘Not Recorded’. This amounts to over 10,000 patients per year. Collecting patient identifiers for this significant cohort will both improve the monitoring and analysis of outcomes undertaken by the NJR and ensure that patient safety is enhanced.

Staff should also be aware that the rate of ‘Not recorded’ consent is included as an indicator in the **Best Practice Tariff**. Trusts in England and Wales will be affected financially for high rates.

All joint replacement patients must be given the opportunity to give, or decline, consent for their personal data to be recorded on the NJR for each procedure. If it is discovered subsequently that the patient consent was incorrectly recorded, or for any queries regarding patient consent, please contact your NJR Regional Coordinator (RC).

2. NJR Patient consent form

The patient consent form introduces the benefits of the NJR to the patient and, together with the patient information leaflet, explains how participation will benefit themselves and others. It also explains why consent is required and how the data will be used. All patients should be provided with a consent form. Both the consent form and an accompanying patient leaflet are available from the **NJR website**.

There is a section on the final page of the consent form, which patients are required to sign:

"**I CONSENT** to my personal details being recorded within the NJR. I understand that the NJR will not release my personalised data unless required by law or where there is a clear overriding public interest in disclosure. Where possible, I will be told if any disclosure is to take place."

OR

"**I DO NOT CONSENT** to my personal details being recorded within the NJR"

The **NJR Patient Information Leaflet** is available for all patients to take home. This should be provided to them either before, or at the time, they are provided with the consent form. Patient information leaflets can be ordered in bulk from the NJR by sending an email with the number of leaflets you require and your address to **enquiries@njrcentre.org.uk**. Large print and Welsh versions are also available.

2.1 Retaining NJR Patient Consent forms

NJR patient consent forms must be held by the hospital as part of a patient's record.

The signed form must be made available to the person inputting the procedure data for them to confirm the consent choice. Where 'Not recorded' is indicated for consent, every effort must be made to determine the patient's wishes. If it cannot be successfully determined, then a submission with 'Not recorded' is acceptable.

NJR Patient Consent forms must ***not*** be returned to the NJR Centre and are to be retained by the hospital as part of the patient record.

Patients must ***not*** send their personal details to the NJR Centre.

3. Collecting NJR Patient Consent

Some key points to remember:

- Develop a consent process as part of local policies and guidance and make staff aware of them.
    - It is important that all staff involved with the NJR process are aware of how your hospital collects NJR patient consent. Processes vary from hospital to hospital as no one process fits all.
    - Best practice is to ensure that the NJR process forms part of your Trust Policy and Procedures.

- Keep patients informed. When collecting consent you should make sure that patients:
    - understand why they are being asked to consent, what will happen to their personal information and why their consent is essential to the success of the NJR, and of benefit both to themselves and all joint replacement patients.
    - understand that consent is voluntary and that, by declining, their care will not be affected in any way.

- Patients must be asked for their written consent in respect of each operation they undergo. Consent for one operation cannot be used as consent for other joint replacement operations. This is for the following reasons:
    - the patient may have consented in the past but does not want to have any further data entered against their name.
    - the patient may have withdrawn consent (as is their right) and has asked the NJR Centre to remove their personal details from the NJR system.

Most hospitals collect NJR Patient Consent during the Pre-operative Assessment appointment. However there are instances where this is not possible – for example, those patients who have unplanned or emergency surgery. Processes for obtaining consent, therefore, should cover all possible eventualities.

NJR consent may be obtained at any point during the patient journey. If a record of signed, written consent cannot be found and if clinically appropriate, consent can be sought post-operatively, either while the patient is still in hospital or contacted at home. Under the new General Data Protection Requirements (GDPR), proof of patient consent is required: if verbal consent is obtained from a patient, all details (date, time, location, staff name, etc.) should be recorded and included in the patient record.

If a patient lacks the mental capacity to make an informed choice about consent, it should not be made on their behalf by any member of the clinical staff. For a child,

consent can be provided by a parent or legal guardian, but for an adult the decision to consent can only be provided by an individual with Lasting Power of Attorney for the individual. If you are unsure, you should contact the NJR Service Desk to seek advice. In England and Wales, recording consent as unknown may be appropriate: patients for whom consent is indicated as 'Not recorded' are not contacted by the NJR under any circumstance.

4. NJR consent for children

Although very small numbers of children have joint replacement procedures (fewer than 500 out of >2.5 million records on the NJR, it remains important that NJR is able to capture data on the quality and outcomes of surgery in this cohort of patient. It is also important that the ability to recall patients in the event of identified concerns with an implant is available. The value of these data is also important for researchers to be able to understand the implications of joint replacement surgery in young patients.

Patients under 18 should consented by an adult with parental responsibility by the hospital carrying out the joint replacement surgery using the standard NJR consent form. Patient information leaflets directed at young people have been developed and are made available routinely to the specialist centres that would carry out paediatric joint replacement surgery. Others sites carrying out procedures occasionally can download materials form the NJR website.

Currently the very low numbers of patients under 18 mean that developing bespoke processes for different age ranges is impractical. However, consent to the NJR should always be sought by the clinical team carrying out the surgery and as such take place in the context of an appropriate discussion with the patient and their family. The information leaflet has been developed to be as broad as possible to accommodate the needs of children of a range of ages.

5. NJR consent for patients that lack capacity

The NJR wish to ensure that patients who lack capacity to consent to participate in the NJR - for the core purposes of patient safety and for secondary research, are able to be included in the registry. Excluding this cohort of patients is undesirable for a number of reasons. It risks introducing biases into the NJR as a whole as patients with potentially poor outcomes are systematically excluded, thus artificially inflating performance metrics. It also excludes these patients from standard surveillance of their implant performance. This places them at a disadvantage to their peers with mental capacity, as they would be unable to be recalled in the event of a clinical concern. From a research perspective, this cohort of patients is often excluded from studies and so knowledge on how best to treat these patients is limited.

Best efforts should be made to involve participants who, temporarily or permanently, lack

capacity in the decision to be involved in the study. The clinical team should make a judgement about the amount and complexity of the information that the participant is able to understand and retain on an individual basis. Appropriate information should be communicated to the participant and updated as their understanding changes. In the event that a patient has temporary loss of capacity, clinical teams should follow best practice and ask the patient for consent as soon as they are able to do so.

In accordance with the section 32 subsection 9b of the Mental Capacity Act 2005, where a patient does not have capacity to consent for themselves, clinical teams should seek agreement from an appropriate consultee.

Where a Personal Consultee is available, they should be provided with the NJR information – a patient information leaflet prepared specifically for consultees is available from the NJR website. The Personal Consultee should be given the opportunity to ask questions and discuss the NJR after which the Personal Consultee will be asked to sign a consultee declaration form. The Personal Consultee may complete the outcome questionnaires on behalf of the participant.

Where a Personal Consultee is not available, then a Nominated Consultee will be identified to advise the clinical team. The Nominated Consultee could be the participant's treating Surgeon and/or their treating General Practitioner. The Nominated Consultee will be asked, after reviewing the NJR documentation and in light of the individual's overall condition, to provide advice that the patient participate fully in the NJR. Data collection, including linkage to routine NHS datasets, will commence as soon as advice from Personal/Nominated Consultee has been obtained. Nominated consultees should also sign the consultee declaration form.

At all times the clinical team and the NJR will act in accordance with the participants' best interests. Any new information that arises during the study that may affect participants' willingness to take part will be reviewed by the hospital clinical lead; if necessary this will be communicated to all participants and a revised consent form completed. If the patient withdraws from the NJR, data collected up until the point of withdrawal will be included in NJR analysis.

5. Further information and support

In addition to the Patient Information Leaflet, A3 posters for display in waiting areas can be requested from the NJR Centre. The contact details for the NJR centre are shown below.

For NJR advice and guidance establishing best practice processes in you hospital, please contact your local NJR RC. To find out who your RC is, please visit the **NJR website** or contact the NJR Service Desk.

If you have queries about the legal aspects of consent or what constitutes acceptable practice, please contact the NJR Service Desk and your query will forwarded to the

appropriate individual.

Finally, please share this guide with your colleagues and help raise awareness of the importance of the collection and recording of patient consent: without patient identifiers, the NJR cannot meet its goals.

6. Contact Details

The contact details for the NJR Centre are:

- Email: **enquiries@njrcentre.org.uk**
- Telephone: 0845 345 9991

Further information is available from the NJR website at **www.njrcentre.org.uk**.