NHS
Health Research Authority

Confidentiality Advisory Group
On behalf of the Secretary of State for Health

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4 November 2013

Dear Ms Young

Study title: **National Joint Registry**
CAG reference: **PIAG 2-05(j)/2006**

Thank you for your amendment request to the above audit application, submitted for approval under the Health Service (Control of Patient Information) Regulations 2002 to process patient identifiable information without consent. Approved applications enable the data controller to provide specified information to the applicant for the purposes of the relevant activity, without being in breach of the common law duty of confidentiality, although other relevant legislative provisions will still be applicable.

The role of the Confidentiality Advisory Group (CAG) is to review applications submitted under these Regulations and to provide advice to the Secretary of State for Health on whether an application should be approved, and if so, any relevant conditions. This application was considered via proportionate review under criteria 8, amendments to approved applications.

Secretary of State for Health approval decision

The Secretary of State for Health, having considered the advice from the Confidentiality Advisory Group as set out below, has determined the following:

1. The amendment is approved, subject to compliance with the standard conditions of approval.

Context

Purpose of application

This audit application from the Healthcare Quality Improvement Partnership (HQIP) sought support for the collection of data on hip, knee, ankle, elbow, and shoulder replacement procedures carried out in England, Wales, and Northern Ireland, in both the NHS and independent healthcare sectors. The underlying aims for which this data was collected were to:

- Monitor in real time the outcomes achieved by brand of prosthesis, hospital and surgeon, and highlight where these fall below an expected performance in order to allow prompt investigation and to support follow-up action.

- Inform patients, clinicians, providers and commissioners of healthcare, regulators, and implant suppliers of the outcomes achieved in joint replacement surgery.
- Evidence variations in outcome achieved across surgical practice in order to inform best practice.
- Enhance patient awareness of joint replacement outcomes to better inform patient choice and patients' quality of experience through engagement with patients and patient organisations.
- Support evidence-based purchasing of joint replacement implants for healthcare providers to support quality and cost effectiveness.
- Support suppliers in the routine post market surveillance of implants and provide information to clinicians, patients, hospital management and the regulatory authorities.

A recommendation for class 1, 4, 5 and 6 support was requested to cover continued access to patient data where consent had not been recorded on the data collection form, and continued permission to link National Joint Registry data to Hospital Episode Statistics (HES), Patient Episode Database Wales (PEDW) and Patient Reported Outcome Measures (PROMs) datasets. It was noted that the National Joint Registry had been a mandatory data collection for the NHS since April 2011.

Confidential patient information requested

Access was requested to name, date of birth, address, postcode, NHS number and gender.

Amendment request

An amendment request was received seeking to aggregate several separate existing applications, the oldest dating from 2006, where support under the Regulations was already in place for collection of data for the purposes listed above. The request included continued linkage with the HES, PEDW and PROMs datasets.

Confidentiality Advisory Group advice

The amendment request was considered by the Chair who recommended that support under the Regulations should continue to apply only to patients where consent status was not recorded. The consolidation of a number of different amendment requests to ensure an accurate record of the approval was welcomed.

It was noted that the current consent form gave assurances that: "Data in the NJR may only be used for medical research in orthopaedic and scientifically-related studies. We do not pass on patients' personal details to researchers'" The Chair commented that this could lead to patients being unaware that their data could be shared using support under the Regulations.

The Chair also highlighted that the information sheet specified that "It is not possible for anyone other than your surgeon to identify you as an individual" and advised that this statement did not appear to reflect accurately the submission of identifiable data to the NJR, although it was noted that this was included within the consent form. In addition, the only linkage referred to was the linkage of different joint operations in order to measure time between operations to "find out problems with implants or surgeons", which did not appear to reflect the extent of data linkages and purposes described within the application form.

In line with the comments above, the Chair advised that the information sheet and consent form be revised to ensure that those patients who consented to being included on the NJR were aware of how their data would be used.

Confidentiality Advisory Group conclusion

In line with the considerations above, the Chair agreed that the minimum criteria under the Regulations appeared to have been met for this amendment, and therefore advised

recommending support to the Secretary of State for Health subject to the following conditions:

1. Confirmation of satisfactory toolkit submission. **Confirmed 22 April 2013.**

2. Please confirm that the consent form will be revised in line with the above comments and submit a revised copy once available to the CAG.

Reviewed documents

The documents reviewed by the Chair were:

Document	*Version*	*Date*
Amended Section 251 application form dated 31/08/2013		02/09/2013
Consent form v4.0 dated October 2012		18/09/2013
Data sharing agreement v4		18/09/2013
Completed query sheet		18/09/2013

Please do not hesitate to contact me if you have any queries following this letter. I would be grateful if you could quote the above reference number in all future correspondence.

Yours sincerely

Claire Edgeworth
Deputy Confidentiality Advice Manager

Email: HRA.CAG@nhs.net

Enclosures: Standard conditions of approval

Health Research Authority

Confidentiality Advisory Group

On behalf of the Secretary of State for Health

Standard conditions of approval

The approval provided by the Secretary of State is subject to the following standard conditions.

The applicant will ensure that:

1. The specified patient identifiable information is only used for the purpose(s) set out in the application.

2. Confidentiality is preserved and there are no disclosures of information in aggregate or patient level form that may inferentially identify a person, nor will any attempt be made to identify individuals, households or organisations in the data.

3. Requirements of the Statistics and Registration Services Act 2007 are adhered to regarding publication when relevant.

4. All staff with access to patient identifiable information have contractual obligations of confidentiality, enforceable through disciplinary procedures.

5. All staff with access to patient identifiable information have received appropriate ongoing training to ensure they are aware of their responsibilities.

6. Activities are consistent with the Data Protection Act 1998.

7. Audit of data processing by a designated agent is facilitated and supported.

8. The wishes of patients who have withheld or withdrawn their consent are respected.

9. The Confidentiality Advice Team is notified of any significant changes (purpose, data flows, data items, security arrangements) prior to the change occurring.

10. An annual report is provided no later than 12 months from the date of your final confirmation letter.

11. Any breaches of confidentiality / security around this particular flow of data should be reported to CAG within 10 working days, along with remedial actions taken / to be taken.