NHS
Health Research Authority

'Section 251' Support – Annual Review

It is a standard condition of support that an annual review is supplied every 12 months, from date of the final support letter, for the duration of the support to process confidential patient information without consent. Applicants should submit this 4 weeks in advance of their annual review due date. The annual review due date is specified under the 'Next Review Date' field for each application entry in the Register of Approved Applications. Please ensure all sections are fully completed to avoid invalidation.

Notification of changes through this Annual Review submission are not permitted and will not be processed nor receive support; changes are managed via a formal separate amendment process.

PIAG/ECC/CAG reference number:	18/CAG/0064
Full application title:	National Bone and Joint Infection Registry
Application type: research or non-research	Non-research
Date annual review was due: (If the annual review has been submitted after its due date, please include an explanation)	10 May 19. In Feb 2019 we liaised with CAG and, after sending the relevant documentation, we received confirmation (2nd April 19) that our specific conditions for support had been met. We sincerely apologise for failure to send a timely annual report in May 19. We have now added this to the annual schedule for the registry workplan.

Information sharing:
Applicants should be aware that data controllers, such as NHS Digital, may wish to check whether an applicant has provided an annual review to the CAG, to ensure the applicant support to process information without consent remains active before the controller can process a request for data access. We will share confirmation with data controllers whether an annual review has been submitted or not, and whether it is valid, in order to facilitate local disclosure decisions.

1. Security arrangements

All applicants processing confidential patient information under the Regulations are required to provide evidence of suitable security arrangements via agreed routes. This must be in place before any support can come into effect, must be maintained for the duration of the support and is expected to be up to date and (in England) reviewed by NHS Digital at each annual review. Security assurance is required in relation to ALL organisations involved in processing confidential patient information. Please carefully assess where the processing is taking place, and provide security assurance based upon the jurisdiction and organisation where the information is being processed. Applicants may need to provide more than one security

assurance depending on the jurisdiction information is processed, or if processing of identifiable information is taking place in more than one organisation.

Processing takes place in:	**England**	**Wales**	**Scotland**
Security assurance provided by:	Data Security and Protection Toolkit (DSPT) – by organisation or specific function	Caldicott Principles into Practice (CPiP) report – by organisation	Review by the Public Benefit and Privacy Panel for Health & Social Care
Applicant should contact:	Exeter.Helpdesk@nhs.net	Darren.Lloyd@wales.nhs.uk	Public Benefit and Privacy Panel (PBPP) for Health & Social Care
How assurance is provided to CAG	1. Organisational self-assessed completion of relevant DSPT. 2. Applicant contacts Exeter Helpdesk to request NHS Digital to review the relevant DSPT self-assessed submissions 3. NHS Digital review the DSPT submission and confirm to CAG when 'Standards Met'	Relevant CPIP out-turn report provided directly by NWIS to CAG	An approval letter from PBPP, where processing is taking place in Scotland, is accepted as evidence of adequate security assurance.

For applicant completion:

Please list all organisations physically processing relevant information without consent for which security assurance is required. Security assurance is provided through NHs Digital reviewing the self-assessed submission. Please ensure you have contacted NHS Digital and asked them to review your submission. The annual review will not be valid until NHS Digital has reviewed the submission and confirmed its status as 'standards met'.

If confidential patient information is being processed by NHS Digital, please select this box: ☐
Security assurance has already been provided for NHS Digital so please do not complete any details below for NHS Digital.

Organisation (Full name)	**ODS Code**	**Date self-assessment submitted to NHS Digital**	**Date NHS Digital confirmed assessment reached 'Standards Met**
NORTHUMBRIA HEALTHCARE NHS FOUNDATION TRUST	RTF	19/20 Baseline – 15/10/19 18/19 – 29/3/19	2/9/19
Other NHS Trusts do submit data but only handle their own data.	Full details available on request		

Is any processing of identifiable information taking place in Wales? No
Is there any processing of identifiable information taking place in Scotland? No
If processing of confidential patient information is taking place in Wales or Scotland, please contact the Confidentiality Advice Team for advice on next steps.

2. Study progress

i. Conditions of support (if applicable)

Supported applications often have specific conditions of support, in addition to standard conditions of support. Applicants are expected to comply with all standard conditions of support by default to ensure the support remains active.

Please set out how you have met the conditions of support (expand box as required). This should include any difficulties experienced and mitigating action taken. Specific conditions of support are located in your conditional or final outcome letter

Please answer the following three questions and ensure you check the correct boxes for each question (double click on each box and select 'checked' where relevant).

1. ☒ **The application has no assigned specific conditions of support.**

On 2nd April 2019 we received notification from CAG: "I can confirm that the additional documentation has been reviewed by a sub-committee of the CAG, which confirmed that the specific conditions of support have been met. The register of approved applications will be updated to reflect this at its next publication"

2. ☐ **The following provides an update against existing specific conditions of support.**

List each specific condition (expand as necessary) and explain how it has been met

3. ☒ I can confirm the application adheres to all the standard conditions of support.

ii. Steps taken to anonymise the information or obtain consent from individuals

What steps have been taken to reduce the identifiability of the information or seek consent from the patients? If this has not been done yet, please confirm at what stage you intend to or the reasons why you are not going to.

In line with CAG approval we are seeking patient consent after the acute phase of illness when this is more feasible, with an upper limit of 18 months. Patients are asked about on-going participation, collection of patient reported outcome measures and data linkage. Those patients who do not wish to participate are asked about the use of data already collected, use of routine data or complete withdrawal from the registry.

This explicit consent is sought by post from individuals at 6 months after diagnosis of infection. For those that do not answer a further request is sent at 12 months. At 18 months we have had our software modified by the registry supplier so records without explicit patient consent are automatically anonymised, and no linkage will be performed.

iii. Projected end date

What is the expected end date for your study; **this is the date by which all confidential patient information is no longer identifiable and support is no longer required**.

There is no specified end date for this project, but patients are individually consented by 18 months.

iv. Project changes

Please provide a summary of any formal amendments made to the CAG that have been supported.

It is important to note that only those details specified in the original application (and any formal amendments) have been supported. For applications supported over 5 years ago, or where the application detail no longer reflects current activity, a new application may be required.

NA

3. Justification for ongoing support

i. Practicable alternatives/exit strategy

It is a requirement of the Regulations that applicants review the requirement to continue processing confidential patient information without consent on an annual basis. Please provide an overview of alternatives being considered or taken to remove the need for ongoing support, such as the receipt of anonymised data only or the movement towards a pseudonymised approach.

We opened the registry in January 18. Thus patient level data has been collected for just over 12 months and we believe the justification of processing patient information without consent remains on the basis that the clinical syndrome found with any infection, including bone and joint infection, is often preclusive to patients giving informed consent.
We have considered the following alternatives:
1) Use of anonymised data. Anonymised information is not a practicable alternative as it will preclude us checking for duplication of records as these patients often move between centres, and it would remove any ability to follow the long-term outcomes of these patients.
2) Early patient consent. Many of the groups of patients affected would not have capacity to consent, and it is not practicable to involve only those who do have capacity to consent because this would create an unrepresentative sample, in which significant population groups, including some in whom infection is more likely or in whom the outcomes are likely to be less favourable, would be excluded. The value of this dataset comes from the collection of data from the entire population that are affected.

After the acute phase of the illness -patients are frequently cared for in the outpatient setting. In this context, seeking patient consent is more feasible.
Therefore, we seek patient consent at six months following registration of the infection. The registry team undertake the process of seeking consent and complete this within 18 months of entry into the registry. Data from non-responding patients is anonymised at 18 months and no linkage is performed.
Those who do not wish to participate are asked about the use of data already collected, use of routine data or complete withdrawal from the registry.

This is the basis of our exit strategy from holding patient identifiable information under the section 251 legislation.

4. Patient and public feedback

Please provide details of any complaints, queries or objections that you have received from patients (which specifically relate to this application to process confidential patient information without consent) and the steps you have taken to resolve them. Have any patients requested that their data is not processed and how has it been ensured that this has been respected?

We have had no complaints for the Bone and Joint Infection Registry. We have had no requests to not process data although one patient has consented to stay on the registry but did not explicitly consent to having PROMS forms sent out, so that has been noted and respected.

5. Public benefits

To support the need for continued support, applicants should set out what public benefits have arisen since support has been in place, and from time of last annual review. Support to process confidential patient information without consent is based upon there being a public interest in the activity proceeding so applicants should consider this section carefully. Applicants should set out what public benefit has been achieved, or whether a public benefit is still anticipated.

- Since our registry launch just over a year ago we have collected data on almost 100 patients with a deliberate slow start, initially within one Trust. This has now been extended to 8 trusts and we have a further 22 Trusts undergoing internal governance processes before commencing data entry. As such we are in our early development phase. We anticipate significant public benefit and the draft NHSE service specification for bone and joint infection requested development of such a registry to provide information on epidemiology, microbiological isolates and treatment outcomes in patient-specific groups. From 2020 National guidelines (British Orthopaedic Association and British Association for Surgery of the Knee) now point surgical teams to this registry so we can develop a better understanding of these conditions.

5. Confirmation of contact details

Please confirm contact details for the publicly available register of approved applications.
☒ The contact details below are the same as those currently published in the Register of Approved Applications. ☐ The contact details below are NOT the same as those in the Register of Approved Applications. In order for this change to be processed the reason for this change must be specified here. The reason for the change to contact details is as follows: Name of controller for application: Contact Name and role: Prof Mike Reed Full address: Northumbria Healthcare NHS Foundation Trust Telephone: 01670 564154 Email: mike.reed@nhs.net

Named applicant Name: Mike Reed

Signed:  Date: 28.03.20

Please return this completed form to HRA.CAG@nhs.net. Questions over completion should be directed to HRA.CAG@nhs.net or contact the CAG general advice line on 0207 972 2557 between 9-5.

Please note this document will be assessed by the Confidentiality Advice Team in the first instance. Depending upon the content, the team might request further information, arrange a subsequent meeting to discuss the content of the annual review, or escalate to the Chair or to CAG.