SUPPORT FOR USE OF PATIENT IDENTIFIABLE INFORMATION WITHOUT CONSENT

Non-research application form

To be completed by the applicant:

SECTION 1: REGISTER DETAILS	
(a) Application Title:	National Bone and Joint Infection Registry
(b) Application Summary: *(Description of purpose of the proposed research/study/activity for which support is sought.)*	This proposal concerns the development and establishment of a national registry for Bone and Joint Infections in the United Kingdom, which is intended to be used for audit and service evaluation. Bone and joint infections are a significant cause of morbidity and mortality that affect patients of all ages. Understanding current standards for care and effectiveness of interventions and care pathways is a major challenge for surgeons, physicians, microbiologists and patients. This project seeks to capture data about affected patients and the care they receive for these debilitating and often fatal conditions. This will enable robust understanding of the current care pathways, insight into which treatments are most effective and comparisons between different units of the patient outcomes they achieve. We believe there is a strong public interest in undertaking this work.
(c) Applying Organisation:	Northumbria Healthcare NHS Foundation Trust
(d) Contact Name & Role:	Mike Reed Consultant Orthopaedic Surgeon National Bone and Joint Infection Registry
(e) Address for correspondence: Postcode: Email:	Mike Reed Consultant Orthopaedic Surgeon Northumbria Healthcare NHS Trust NE63 9JJ mikereed@nhs.net
(f) Name, role and telephone number of Information custodian * Information Custodian* in case queries: (*see Section 6 below)	Mike Reed Consultant Orthopaedic Surgeon Northumbria Healthcare NHS Trust NE63 9JJ mikereed@nhs.net
(g) Name of Sponsor Organisation: *(Sponsor's written recommendation to be attached including approval from local Caldicott guardian(s))*	Northumbria Healthcare NHS Foundation Trust
(h) Cohort/Population being studied:	All adult patients who suffer from infection involving either native bone and joint or related to medial devices in bones or joints.
(i) List/description of confidential patient information being used:	Age, sex, DoB, NHS number, date of death,, Ethnicity, Hospital Unit Identifier, Date of admission, Date and time of discharge
(j) Classes of support	☐ Specific Support required (As set out in the Regulations) ☐ **Class I Support : the process of extracting and anonymising the information** ☐ Class IV Support : To link patient identifiable information obtained from more than one source ☐ **Class V Support : for auditing, monitoring and analysing patient care and treatment** ☐ **Class VI Support : to allow access to an authorised user for one or more of the above purposes**

*** These details will appear on the Section 251 Register if the application is successful.**

SECTION 2: JUSTIFICATION OF PURPOSE & PUBLIC INTEREST

(k) Detailed Description of purpose:

(Description of purpose of the proposed research/study/activity for which support is sought?

Must also include the precise medical purpose as defined within the s251 (12) of the NHS Act 2006.

In order to better understand the problem of bone and joint infection we propose to develop a registry for recording all relevant information on native and device related bone and joint infection, including all aspects relevant to multidisciplinary team members.

We are seeking section 251 approval in order that patient information held by Trusts treating these patients can be transferred to the registry database, run by Northumbria NHS Foundation Trust.

Bone and joint infections are currently a significant cause of morbidity and mortality that affect patients of all ages, and costs the NHS considerable sums to treat. We believe that a registry of this nature would be the best way to address the challenges that bone and joint infection presents, by undertaking audit and service evaluation using the data collected.

All adult patients with the following diagnoses will be of interest to this registry:

- Long bone osteomyelitis irrespective of preceding trauma, including diabetes associated osteomyelitis
- Native joint septic arthritis
- Prosthetic joint infection of any joint replacement
- Spinal infections- both native and related to prosthesis

The registry proposed will undertake the following 'medical purposes' as outlined in the legislation:

- **Preventative medicine**-The work of the registry will inform a significant number of preventative strategies to avoid acute infection becoming a chronic infection, including antibiotic prophylaxis, and surgical techniques.
- **Medical diagnosis**-Diagnosis is a complex area of bone and joint infection. Particularly in the context of prosthetic joint infection, where little consensus exists for the accepted diagnostic criteria. Increasingly complex diagnoses are being recognised such a polymicrobial infections, and infection with microbial resistance to antibiotics.
- **The provision of care and treatment and the management of health and social care services**- Care pathways are highly complex for patients with bone and joint infection. This is due to the involvement of multiple healthcare professionals, extended lengths of treatment and complex associated wound problems requiring high levels of input. Hence the registry will act as focus to better understand how this care is being delivered currently and enable pathways to be refined, and identifying models of best practice and ways of improving outcomes for patients.

NHS England Service Specification

The 2013/14 service specification outlines the requirements for units treating patients with bone and joint infection. They specify a number of **key outcomes** necessary for the delivery of best practice care in bone and joint infection.

Clinical Outcomes

- Clinical infection recurrence rate
- Post-operative complication rate.
- Reoperation rate
- Readmission rate
- Functional outcomes with 1 and 5 year follow ups assessed by ASAMI bone and function scores.
- Amputation rate in prosthetic joint infections, chronic osteomyelitis and infected non-unions

	• Mortality (30 day and 1 year) **Process Outcomes** • Length of stay • Access to care (waiting times, failure to attend appointment rates, adherence to one- stop shop" principle). • Number of complaints and time to response/resolution • Rates of unplanned transfers to acute specialities such as general medicine, general surgery or intensive care Indeed the specification goes on to recommend the formation of a registry to study the outcomes by collecting data to provide information on epidemiology, microbiological isolates and treatment outcomes in patient-specific groups. Ultimately, as outcomes drive quality, it is likely the number of centres treating such conditions will dramatically reduce, and become more organised. This is in line with the above mentioned service specification and NHS England report, "Getting It Right First Time". **Quality** The Quality Framework seeks to put quality at the heart of NHS care. The framework goes on to set out series of steps to help achieve this: 1. Bringing clarity to quality-Currently there is no formal record of how patients with these conditions are treated. We believe this registry will be the first step in to identifying how care is given to this group of patients 2. Measuring quality and publishing quality performance- As outlined, quality cannot be measured until the nature of care is recorded. 3. Recognising and rewarding quality- Data reports will be a source to identify and report quality. 4. Raising standards and safeguarding quality- By open reporting of the outcomes for patients with bone and joint infection, it will pave the way for audit within the UK thereby contributing critically to the debate around provision of care and standards to which treating units should aspire. 5. Staying ahead- We understand this will be the first national registry for this group of patients putting the UK at the forefront of treating these conditions. The proposed registry will directly address points 2, 3, 4 and 5. In addition it will encourage recognition of quality and serve as a voice for the community of MDT members treating bone and joint infection. By contemporaneously collecting outcome data and measuring quality, it will enable those treating these conditions to be nimble in their response to evolving challenges in the field for example emergence of antibiotic resistant strains.

(l) Describe how the proposed use of patient information will improve patient care and serve the wider public interest?	Patient care Solid evidence and dedicated clinical care teams drive high quality patient care. Due to the nature of bone and joint infections-sporadically treated by non dedicated teams in many NHS units-it is difficult to estimate even basic epidemiological data and understand which treatments are employed for the various conditions. By using comprehensive patient information a realistic understanding of the burden of bone and joint infection can be generated. The data can be used to inform discussion around service provision and organisation. Low volume units with likely defer to higher volume centres; particularly those that demonstrate better outcomes. Collating patient information can expose poor and successful treatments pathways that have previously been unrecognised. Specifically outputs from the registry will drive patient care towards more successful treatments. Analysis of patient outcomes can be used to inform clinicians of best treatment modalities. Public Interest One of the principal drivers for this registry is to improve the understanding of both the prevalence and consequences of bone and joint infections. It currently falls to the remit of Public Health England (PHE) to monitor surgical site infection. This monitoring covers joint replacement of the hip and knee, hip fracture and long bone fracture. These categories will account for the most significant burden of bone and joint infections. The risk of SSI was estimated by PHE to be 4.1% in hip fracture patients undergoing arthroplasty in 2007 (1). Infection rates reported in the literature for this patient group are often higher, with some reports stating rates as high as 7% (1, 2). There is growing evidence that the surveillance system from Public Health England is providing a significant underestimate of the true incidence (3-5). Infection rates for primary hip and knee replacement are around 2%, however this makes a significance numerical contribution as around 160,000 of these operations are performed each year. The infection rates for revision (redo) joint replacement surgery is considerably higher, approximately 3 to 5%. The burden of revision continues to increase with our ageing population. However the current programme of surveillance fails to understand the pathway beyond diagnosis of surgical site infection in four specific categories of bone and joint infection. The remit of this registry is to understand care pathways and processes across England and Wales in confirmed bone and joint infection. There are multiple factors that will increase the interest in bone and joint infection in the coming years: • The rate of bone and joint infections after surgery, the primary cause, will almost double within the next 10 years due to antimicrobial resistance. • In addition the expected number of joint replacements will increase at 6% per year. • Obesity is increasing (surgery on the morbidly obese carries 5 times the risk of joint replacement infection). • Revision Joint replacement, with its higher risk for infection increases at 10% per year. Each infection costs around £100,000 to treat (Source: NHS report: Getting It Right First Time). The proposed registry will form an important tool in the strategy to both treat and prevent such infections becoming chronic. Reducing the occurrence of these infections and cost-effective-management where they do occur, has the potential to deliver significant cost-savings to the NHS

(m) Please list each of the data items you will hold in relation to each patient, and describe against each why the data item is required.	The database is proposed to be written in a number of modules that will allow specialist areas to input the most accurate data and prevent duplication of workload. There are six proposed modules as listed below: **Triage module** **NHS number, date of referral, referral source and location, pathway for assessment** In order to ascertain the pre-existing referral pathways that exist within the NHS **NHS number, Date of birth,** to allow accurate matching of data within the dataset **Age** Basic demographic data will enable understanding of the cohorts of patients affected **Sex** Basic demographic data will enable understanding of the cohorts of patients affected **Pre op assessment module** **Medical co-morbidities and risk factors** In order to understand which factors affect risk of infection a detailed understanding of patients' medical condition is critical. It will also allow risk stratification when considering the outcomes of units and effectiveness of treatments. The risk factors that have been identified as important in infection are as follows: Smoking, diabetes, chronic liver, lung, heart or renal disease, caner malnutrition, autoimmune disease, immunosuppression, HIV, intravenous drug user, dementia, CVA, chronic lymphedema, peripheral vascular disease, radiation, **Previous surgery** We anticipate that a significant proportion of the patients with bone and joint infection will have undergone previous surgery such as joint replacement or fracture fixation. In order to better understand which patients are most at risk, information on previous surgery will be vital. **Surgical management module** This module will capture the surgical treatments that the patient undergoes as a result of their infection. The aim is to record the site of the infection, the diagnosis (e.g. osteomyelitis / prosthetic joint infection / native joint infection) the operative procedure performed and the finding at the time of surgery, in addition the need for a number of different operations or the involvement of other specialities (e.g. plastic surgery) in the management of the patient. **Medical management module** **Microorganism** Underlying each infection is the causative organism, or organisms. Different organisms have different levels of virulence, varying antibiotic resistance and prevalence. Recording these metrics against the patient and the organism isolated will inform all aspects the registry's analysis such as effectiveness of treatment, regional variation in causative organism and resistance to antibiotic treatment. **Treatment given** Clearly one of the principal areas of interest for the registry will be studying which treatments are the most effective for bone and joint infection. As such recording treatments given will be vital. **Diagnostic test performed** Diagnosis of infection currently relies on collecting information from blood tests, tissue samples and clinical examination. Each of these is inadequate on its own. By recording diagnostic information for each patient, we will be able to better understand how bone and joint infections are diagnosed, whether people are using the same information to make these diagnoses and to stratify any comparisons. **Follow up module** This module will document the progress of the patient, the response to treatment, the need for further surgery, any complications or change in antibiotic treatments. **Outcome measures module** The module is aimed a capturing the outcome of patients from various treatments. I will allow a baseline assessment of the outcomes of patients with bone and joint infections; will allow comparisons to be made between treatments. They are in line with those used in the National Joint registry (NJR), and other infection studies

(n) Are you seeking specific support or class support? If class support, detail which of the purposes that may be covered do you need support for?	We are seeking class support, In order to be effective, this project needs to perform the following activities 1) Extract and anonymise information 2) Audit, monitoring and analysing patient care and treatment By securing class support we will be able to undertake all of the above activities and make the most of the information to the benefit of patients.

SECTION 3: CONSENT & PRACTICABLE ALTERNATIVES

(o) i. Why is it not practicable for the current holder of the information you require to seek or obtain patient consent for the proposed use of patient identifiable information on your behalf?

ii. Why is it impracticable to use anonymised or pseudonymised information?

CONSENT: The clinical syndrome found with any infection, including bone and joint infection, is often preclusive to patients giving informed consent.

Sepsis When infections are serious and systemic, as bone and joint infections often are, patients can be profoundly unwell requiring invasive monitoring and mechanical ventilation. Clearly patient in this situation are incapable or giving informed consent, however it is often at these critical early stages that long-term decisions are made about the patient's care. Additionally the mortality rates for patients with sepsis are significant. Estimates vary, according to the source and patients population under consideration, however it is thought that between 30-35% of patients with sepsis will die in hospital.
If patients who are extremely unwell due to sepsis or other
Hence any attempt to study care across the UK must capture this information to accurately reflect current practice and understand what may or may not be effective.

Delerium/Confusion Acute cognitive impairment is a key feature of infection. This particularly affects the elderly population-who are the overwhelming proportion of patients receiving joint replacement. This cognitive impairment also precludes informed consent being given for the participation in research or data recording activity.

Pre-existing cognitive impairment Thirty seven percent of the 75 000 patients with hip fractures have dementia prior to admission with fracture. After hip fracture surgery, infection rates are much higher than for conventional joint replacement (4% vs 1%), meaning this is a particularly important group to study. Indeed there is some evidence that patients with dementia are at significantly higher risk of complications in all surgery including infection.
This means a significant proportion of the patients with implant associated bone and infection will have irreversible cognitive impairment.
If these patients are not included in the registry data, then the external validity of the finding from the data collected will be reduced.

PRACTICABLE ALTERNATIVES:

1) Using anonymised information is not a practicable alternative as it will preclude us checking for duplication of records as these patients often move between centres.
2) We articulated above that 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 creates 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 propose to seek patient consent once their treating site has advised us that the patient is suitably recovered from their acute admission and treatment. The registry team would undertake the process of seeking consent. We would aim to complete this within 18 months of entry into the registry. Patients will be asked about ongoing participation and collection of patient reported outcome measures. Those who do not wish to participate will be asked about the use of data already collected, use of routine data or complete withdrawal from the registry. This will form the basis of our exit strategy from holding patient identifiable information under the section 251 legislation.

(p) How have you involved patient and user organisations/representatives in the development of the activity for which you seek support? What safeguards have you introduced in response to their input?	<u>Patient involvement</u> We have consulted widely with patient groups: The British Orthopaedic Association (BOA) Patient Liaison Group comprises of lay members and orthopaedic surgeons. They provide invaluable advice and input from patients when the BOA is planning orthopaedic and trauma care, guidelines and when responding to changes in healthcare systems. One the representative for BAJIR met with the PLG and discussed at length the proposed work. This group of approximately 15 members reviewed a detailed 20 minute presentation about the activities of BAJIR, with deliberate focus on the process of section 251 approval and its implications. The meeting focussed heavily on the potential use of section 251 legislation to collect patient identifiable information. The group were universally supportive of the proposal and had no issues with the potential use of the legislation. They were also very positive about the importance of the project in the larger agenda of better quality information driving better services for patients. <u>All attendees at the meeting felt that bone and joint infections were important. In particular they felt that this was of value to the patients who suffer from the conditions, not just those running the service.</u> There was agreement on the range of data we proposed to collect; however a few of the PLG members raised concern about a wide range of co-morbidities such as mental and sexual health being collected. This data is not proposed to be collected routinely. However if any details related to these areas were needed for the purposes of evaluating service, then it may be collected. The PLG members were reassured by this stance. As stated above, there were no concerns about the collection of data using section 251. However the PLG did raise how the patients would be informed of the information being collected. In response to this we will develop some patient facing information with the help of a lay member. This will detail the information collected, the purpose of BAJIR, and importantly how patients can request for their information to be removed from the registry. We believe these groups are a truly independent voice for the patient as it has a lay chairperson. The group also contains representatives of carers as well as patients. <u>Direct Engagement</u> We were able to conduct several interviews with the local patient ‘Total Hip User Group’ and AgeUK; their main messages being ‘infection has a significant impact on these patients’, ‘they have to stay in for longer,’ ‘it could cause additional financial burden on the family if they need to go into a home’, ‘anything that could be done to reduce infection risk would be beneficial’. This is in line with the published qualitative literature on bone and joint infection (Moore 2015) <u>User organisations and representatives</u> The founders of the registry held a meeting attended by 20 large specialist units working in the field of bone and joint infection at the British Orthopaedic Association annual congress 2015. Along with these specialists we had a representative from the national cancer registries. This enabled full discussion about how best to gain comprehensive data coverage and whether it would be feasible to do so in patients with these infections. The Hip society and the Knee society were represented. The British Limb Reconstruction Society have a member on the steering group. In addition a separate meeting was held of 70 specialists representing 9 non specialist acute trusts in Nov 2014 and Nov 2015. The practicalities of data collection in this patient group were discussed and the urgent need for a registry agreed. As a result of these discussions at this forum and separate discussions with the National Hip Fracture Database group, we feel that the best way to achieve our aims would be through the section 251 legislation.

SECTION 4: CALDICOTT	
(q) What is the justification for using patient identifiable information?	Monitoring outcomes via national clinical audit can require collation of data from multiple sources over long periods of time. This is particularly important for tracking patients across organisations, as they move between different hospitals and clinics for their care. This requires a unique patient identifier. In the absence of such cross-checking, patients could be double-counted and analyses would become unreliable. The specific requirements for patient identifiable information will be minimised wherever possible in the audit. Only the NHS Trusts providing the data and the administrative staff performing pseudonymisation will be able to access patient identifiable information. Those involved in analysing data from the registry will never have access to identifiable data. One key principle is that if there are very small numbers of a particular event it is not appropriate to report the result. Publications – either as NHS internal reports or in the peer review literature – will be based only on the central anonymised data and thus can never identify any individual. As we have outlined- patient consent would be an impractical barrier to entry for the registry. Particularly given the multiple institutions and pathways each patient may be involved with. However-once acute management has been complete, patients are likely to continue under outpatient care. We feel that this would be a good point to approach each patient and seek their explicit consent to continue to keep their patient identifiable information. We think that this should be sought within 18 months of the patient being entered into the registry. If the patient gives informed consent then their record will be kept in the same manner by Dendrite and Northumbria. If the patient does not want to give their consent to on-going data storage their record will be deleted. This will form our exit strategy for the keeping of patient level data under the approval of section 251.
(r) Does the proposed use of patient identifiable information satisfy the requirements of the Data Protection Act and other legislation? Do you have a confidentiality policy? Are confidentiality clauses included within staff contracts? Are all staff aware of their responsibilities?	The proposed use of patient identifiable information satisfies the Data Protection Act – further details of compliance with each principle is discussed below. The Northumbria Healthcare NHS Foundation Trust has a confidentiality policy that applies to all employees and confidentiality clauses are included within staff contracts. Staff are made aware of their responsibilities at their induction. The arrangement for the personal data for the joint infection registry would be that the main dataset would be pseudonymised, with the identifiable components held separately, which reduces the number of people with potential access to patient identifiable data.

Provide details of how you comply with each of the eight principles outlined in the Data Protection Act 1998:	Under <u>each</u> of the principles below, state how you achieve compliance with each in the context of this specific activity, **1. Personal data shall be processed fairly and lawfully and, in particular, shall not be processed unless at least one of the conditions in Schedule 2 is met; and in the case of sensitive personal data, at least one of the conditions in Schedule 3 is also met** The following DPA schedule 2 & 3 conditions apply. Schedule 2: 6.1) The processing is necessary for the purposes of legitimate interests pursued by the data controller or by the third party or parties to whom the data are disclosed, except where the processing is unwarranted in any particular case by reason of prejudice to the rights and freedoms or legitimate interests of the data subject. Schedule 3: 8.1) The processing is necessary for medical purposes and is undertaken by a) a health professional or (b) a person who in the circumstances owes a duty of confidentiality which is equivalent to that which would arise if that person were a health professional. **2. Personal data shall be obtained only for one or more specified and lawful purposes, and shall not be further processed in any manner incompatible with that purpose or those purposes.** Data will only be used for the purposes outlined in this application 3. **Personal data shall be adequate, relevant and not excessive in relation to the purpose or purposes for which they are processed**. The proposed dataset has been agreed following consultation a range of orthopaedic surgeons and researchers. The personal data we are including is the minimum required in order to achieve the intended aims of the project. Only data required for the purpose will be included. **4. Personal data shall be accurate and, where necessary, kept up to date** All data items will be validated as they are collected and before they are used. Locally derived datasets from HES will further validate accurate comorbidities and activity. 5. **Personal data processed for any purpose or purposes shall not be kept for longer than is necessary for that purpose or those purposes**. Given the nature of a registry, we will seek to store data long term. This will enable long term follow up of the registered cases-a critical part of studying these conditions. 6. **Personal data shall be processed in accordance with the rights of data subjects under this Act**. This regulation will be observed. All access will be role based and only authorised persons will be granted access to confidential, personal and/or sensitive data. Data will not be shared outside the terms and conditions of this programme. **7. Appropriate technical and organisational measures shall be taken against unauthorised or unlawful processing of personal data and against accidental loss or destruction of, or damage to, personal data** Confidentiality and security is of critical importance in managing these data. Security policies and procedures are in place and will be adhered to, in order to ensure unauthorised access and processing will not take place. Role based access to systems will be employed and all staff will be made fully aware of the importance of secure data processing. **8. Personal data shall not be transferred to a country or territory outside the European Economic Area, unless that country or territory ensures an adequate level of protection of the rights and freedoms of data subjects in relation to the processing of personal data.**

	This regulation will be observed

SECTION 5: MEASURES TO PREVENT DISCLOSURE OF PATIENT IDENTIFIABLE INFORMATION

(s) What security and audit measures have been implemented to secure access to, and limit use of, patient identifiable information within your organisation?	The National registry applications are hosted on secure N3 servers (Carelink) with access from the internet and the NHS N3 network using Internet browsers and authenticated user accounts and passwords. Clinicians and database administrators only have access to the registry via an internet browser using authenticated usernames and passwords. Each user account profile ensures that the users will only view patient records associated with their hospital (may be individual consultants in some cases). Dendrite has direct access to these servers and the database using secure virtual private network (vpn) connections from our two offices in the UK, and three senior members of staff from their offices at home. Access is restricted to staff that directly support or manage the database application. Access to the server is logged and audited using best practice guidelines. **Carelink Server Hosting** **Server Security** The e-dendrite services are hosted within the Telehouse data centre in London. This is a tier 4 data centre which meets the highest levels of building security including constant security by trained security staff 24x7, electronic access management, proximity access control systems and CCTV. The service platform is held within a secure enclosed suite (TFM20) where access requests are managed via the Piksel Service Desk and restricted to Piksel engineers and trusted 3rd party support. Piksel managed CCTV is also installed within the suite and managed 24/7. Hardened base Operating System images are created as templates to ensure all virtual machines are created with a known baseline level of security and the images are incorporated within our patching policy. The planned monthly maintenance schedule is centred around the release of patches. Patches are released on the 2nd Tuesday of every month and reviewed by the operations team before issuing email notification of when your servers will be patched (during the 3rd week of the month), where they are patched automatically, rebooted and tested on each occasion. All servers have Forefront Endpoint Protection AV installed and is configured to use real-time scanning on all file-systems specific file types excluded (e.g. db & log files). Dendrite's service delivery and information governance complies with ISO 20000 & ISO 9001 accreditation and the security structure is aligned alongside ISO27001 for continuous assurance and compliance. Internal audits are completed approximately every 3 months and external audits every 6 months. **Access via Intellect web application** Dendrite will store the patient demographic data in the same way that is done for a standard hospital system. That is, data is stored unencrypted, but access to that data will be controlled on the basis of user accounts and User Application Flags (UAFs). There will be three levels of user: ***Super Administrator*** Restricted to Dendrite personnel only and used to administer other users accounts. Primarily used to create Administrator accounts as follows. ***Administrator*** Administrators will have permission to create and administer user accounts. They will be able to assign rights to Standard Users that allow those users to see demographics for their patients, but will not be able to set those permissions for their own account(s). Administrators will not be able to enter data into registries. Administrators will have the ability to export data extracts for all data in all registries, but such extracts would not contain any patient identifiable data. ***Standard User*** A Standard User is one who is associated with a specific site (or sites) and can enter data into registries. The set of registries visible to Standard Users will be limited by permission setting. Standard Users can create new patients, but only for a site with which they are associated. The ability to create new patients (or to edit the demographics of existing patients) can be controlled if necessary on a user-by-user basis. Standard Users will have the ability to export data extracts for only those registries for which they have permission to enter data. (Currently, restriction will be by assigned hospital) These extracts could contain selected patient demographic data from the patient table. **Access via Database Environment** The database itself will be hosted on a secure hosting environment in either Rackspace (UK) or Kit Digital (formerly IOKO / Carelink) who host servers within the N3 NHS Network. Kit Digital servers are only accessible from the Dendrite locations connected by permanent secure VPNs. This currently includes the offices at Raynes Park and Henley, and the home-offices of two Dendrite directors and the Software Development Manager . The hosted environments are typical high-security, restricted access hosting facilities. Further details of the individual site policies is available if required. ***Backup Resilience*** When a server is first commissioned, a complete backup of the system and data is taken. Then on subsequent days, incremental delta copies are taken using a disc based backup system running Asigra Televaulting software. The backups are held for a defined retention period after which the oldest backups are overwritten. The delta's can be subtracted sequentially from the latest up-to-date backup in order to roll the system back to any daily state within the defined retention period. All backed up data stored is compressed, de-duplicated and encrypted within a secure off-site vault. Dendrite manage two backup vaults; the primary one is hosted within our Telehouse DataCentre which is then backed up to our secure secondary off-site vault hosted within a separate IX Europe datacentre located at Heathrow. To provide vault level resilience for backup service, Dendrite maintain two completely separate agentless backup and restore platforms across two data centres. To maintain consistency, replication synchronisation occurs across the primary and secondary vault. Within the Asigra Televaulting software itself a considerable amount of checks and data corrections are conducted on an on-going basis. The DS-Client runs a "verify backup set" every day and as part of its weekly checks, a file comparison of the backed up copy and what's stored in the backend on the ds-system is completed. The DS-System also runs a task called "Autonomic healing" which means the computer system repairs itself without human intervention. The Autonomic healing process addresses the problems of file corruption and increases the integrity of DS-

	System. It continually monitors DS-System Online Storage for data corruption and if found, corrects it, removes it, or reports that a correction is made. could contain selected patient demographic data from the patient table. **Access via Database Environment** The database itself will be hosted on a secure hosting environment in either Rackspace (UK) or Kit Digital (formerly IOKO / Carelink) who host servers within the N3 NHS Network. Kit Digital servers are only accessible from the Dendrite locations connected by permanent secure VPNs. This currently includes the offices at Raynes Park and Henley, and the home-offices of two Dendrite directors and the Software Development Manager . The hosted environments are typical high-security, restricted access hosting facilities. Further details of the individual site policies is available if required. ***Backup Resilience*** When a server is first commissioned, a complete backup of the system and data is taken. Then on subsequent days, incremental delta copies are taken using a disc based backup system running Asigra Televaulting software. The backups are held for a defined retention period after which the oldest backups are overwritten. The delta's can be subtracted sequentially from the latest up-to-date backup in order to roll the system back to any daily state within the defined retention period. All backed up data stored is compressed, de-duplicated and encrypted within a secure off-site vault. Dendrite manage two backup vaults; the primary one is hosted within our Telehouse DataCentre which is then backed up to our secure secondary off-site vault hosted within a separate IX Europe datacentre located at Heathrow. To provide vault level resilience for backup service, Dendrite maintain two completely separate agentless backup and restore platforms across two data centres. To maintain consistency, replication synchronisation occurs across the primary and secondary vault. Within the Asigra Televaulting software itself a considerable amount of checks and data corrections are conducted on an on-going basis. The DS-Client runs a "verify backup set" every day and as part of its weekly checks, a file comparison of the backed up copy and what's stored in the backend on the ds-system is completed. The DS-System also runs a task called "Autonomic healing" which means the computer system repairs itself without human intervention. The Autonomic healing process addresses the problems of file corruption and increases the integrity of DS-System. It continually monitors DS-System Online Storage for data corruption and if found, corrects it, removes it, or reports that a correction is made.
(t) Provide details of the data security policy to be used by all organisations party to this application. Please provide copies of the data security policies for each organisation, together with details of officers responsible for their implementation. (u) Please provide details of your Information Governance Toolkit score	Northumbria security policies are all aligned to the 2700 series of standards and IG toolkit requirements. IG TOOLKIT SCORE: 92% Fully compliant at level 2 or above against all requirements Dendrite's Information Security Policy provided as a separate document. IG TOOLKIT SCORE: Dendrite's IG toolkit Score provided as a separate document
(v) Provide written confirmation that the organisation's data security policy is fully implemented (and complies with the management and control guidelines contained in the ISO/IEC 17799:2005 & ISO/IEC 27001:2005, as replacements for Parts 1 & 2 of the BS7799 "Code of Practice for Information Security Management"	Northumbria security policies are all aligned to the 2700 series of standards and IG toolkit requirements. Dendrite's Data Security Policy is fully implemented and complies with current management and control guidelines described in ISO 27001/2 standards.

(w) Provide confirm that your organisation has Data Protection Registration for purposes of analysis and classes of data requested. Please provide a copy of your Data Protection Registration.	DPA NOTIFICATION REFERENCE: Z691260X Details available via ICO website. Dendrite's Data Protection Registration is provided as a separate document. DPA NOTIFICATION REFERENCE: **Z8855307**
(x) Describe the physical security arrangements for the location where patient identifiable data is to be: i) Processed; and ii) Stored (if these are different)	All internal Trust servers are in secure locations with controlled access to the physical equipment. Client workstations provide access to data only when this has been through an approval process. Access to the system via logon is subject to a robust authorisation process. Any data processing would be within the requirements of the DPA 1998 and have Trust Caldicott approval. Key systems are subject to annual risk reviews. External Any external system would be subject to full contract and agreement with IG clauses included with if necessary a data processing agreement. The e-dendrite services are hosted within the Telehouse data centre in London. This is a tier 4 data centre which meets the highest levels of building security including constant security by trained security staff 24x7, electronic access management, proximity access control systems and CCTV. The service platform is held within a secure enclosed suite (TFM20) where access requests are managed via the Piksel Service Desk and restricted to Piksel engineers and trusted 3rd party support. Piksel managed CCTV is also installed within the suite and managed 24/7. Data is stored and processed in the same hosted environment
(y) System Information: Identify the type of system and application to be used for information processing including product version numbers where known (e.g. desktop PC, Laptop PC, MS Access, etc)	***Carelink Server*** Operating System: Virtual servers running Windows server 2008 Database server: InterSystems Cache Application: Dendrite Intellect
Confirm if the computer system will be entirely standalone or connected to a LAN or WAN network, or be otherwise accessible remotely by another means such as dial-up modem. If so please confirm which networks these are and what they are used for, and provide a copy of the Network Security Policy.	The servers are stand-alone but can be connected to remotely using a secure vpn.
Provide details of access and/or firewall controls implemented on: i) This system; and ii) Any LAN or WAN to which it is connected Please also identify who is responsible for the management of these arrangements.	We are currently undergoing changes to our Firewall arrangements which will shortly be managed by BT.

(z) System-level Security: Is there a system level security policy for this system? If yes, please supply a reference copy and confirm its status.	A SLSP would be developed for both internal or external system and this will be subject to an annual review.
Has the system ever been the subject of a security risk review? If so, please provide details and confirm whether all the necessary recommendations have been implemented.	The SLSP requires a risk review annually for key systems There is no system level security policy for this system. Dendrite is commissioning an independent system security risk assessment to assure ourselves and the data controllers that its risk assessment and security systems are in line with best practice principles. Any findings from this risk assessment will be incorporated into the policies, systems and practices used to manage the system.
Please provide details of the arrangements you have implemented to routinely monitor and audit the security of this system for potential misuse or abuse.	The SLSP provides audit details and a site visit would be held annualyy for a system held externally.
(aa) Data Retention & Destruction: How long will the information be retained? If longer than 12 months please provide justification.	One of the important uses of the data collected will be ongoing monitoring of the outcomes for patients and any future episodes of care that relate to the bone or joint infection. In order to do this effectively it will be critical to retain data for the long term. Bone and joint infection can persist for decades and ay become an incurable but chronic condition. Hence there would be enormous value on extended holding of data. Patients will be able to find out about the use of their data as we will be setting up a registry website to provide information about the project, which would be signposted by those units that participate. The information provided would include mechanisms for objecting to the use of their personal data, which would result in that data being removed from the registry. Dendrite will delete confidential data at the request of the data controller, BAJIR. Consultant Outcomes publication for bone and joint infection will involve the first iteration to include collation of 3 years of data to avoid problems with low denominators for individual surgeons. Thereafter, it is anticipated that annual outcomes will be published. To identify trends and allow comparison, the information will be retained for 5 years.
Describe the method of data destruction you will employ when you have completed your work using patient identifiable data.	The Trust has policies that cover the destruction of data be it electronic or paper. No electronic data is allowed to be removed from the site and hard drives are physically destroyed. Paper records are shredded both would be subject to retention schedules The destruction of data processes would apply to any third party under any contractual arrangements. Since data recovery software could be used "undelete" deleted files, the disk-space previously used by deleted files needs to be overwritten with new, meaningless data - either some fixed pattern (e.g. binary zeroes) or random data. Similarly, reformatting the whole hard disk may not in itself prevent the recovery of old data as it is possible for disks to be "unformatted". Dendrite policy is to use Kaspersky File Shredder.

SECTION 6 INFORMATION CUSTODIAN

This form should be signed and dated by the Information Custodian.

SIGNED:	DATE:

Return completed application and supporting information to:
HRA.CAG@nhs.net

Confidentiality Advisory Group
Health Research Authority
Ground floor, Skipton House
80 London Road
London SE1 6LH

The Confidentiality Advice Team can be contacted via 020 7972 2557 in the first instance

Annex A

Application Checklist

- ❑ Have you had a colleague check through your application form so that it is complete and conforms with actual practice?

Have you included the following with your Application Form:

- ❑ Written recommendation from the Caldicott Guardian of the sponsoring NHS organisation
- ❑ A data flow diagram
- ❑ Copy of your organisation's Confidentiality Policy, including staff information leaflets and example(s) of confidentiality clauses in relevant staff contracts
- ❑ Copy of your organisation's Security Policy, covering physical and system security
- ❑ Copy of your organisation's Data Protection Notification including registered uses
- ❑ Examples of Patient Information Leaflets provided to the public