Welcome to the Integrated Research Application System

IRAS Project Filter

The integrated dataset required for your project will be created from the answers you give to the following questions. The system will generate only those questions and sections which (a) apply to your study type and (b) are required by the bodies reviewing your study. Please ensure you answer all the questions before proceeding with your applications.

Please complete the questions in order. If you change the response to a question, please select ‘Save’ and review all the questions as your change may have affected subsequent questions.

**Please enter a short title for this project** (maximum 70 characters)

Edinburgh Orthopaedic Research Database 2021

1. Is your project research?
   - Yes
   - No

2. Select one category from the list below:
   - Clinical trial of an investigational medicinal product
   - Clinical investigation or other study of a medical device
   - Combined trial of an investigational medicinal product and an investigational medical device
   - Other clinical trial to study a novel intervention or randomised clinical trial to compare interventions in clinical practice
   - Basic science study involving procedures with human participants
   - Study administering questionnaires/interviews for quantitative analysis, or using mixed quantitative/qualitative methodology
   - Study involving qualitative methods only
   - Study limited to working with human tissue samples (or other human biological samples) and data (specific project only)
   - Study limited to working with data (specific project only)
   - Research tissue bank
   - Research database

   If your work does not fit any of these categories, select the option below:
   - Other study

3. In which country of the United Kingdom is the database established?
   - England
   - Scotland
   - Wales
   - Northern Ireland

3a. In which countries of the United Kingdom will centres collecting and/or supplying data to the database be located?
(tick all that apply)

☐ England
☐ Wales
☑ Scotland
☐ Northern Ireland

4. Which applications do you require?

☑ Research Ethics Committee
☐ Confidentiality Advisory Group (CAG)

6. Do you plan to include any participants who are children?

☐ Yes ☐ No

7. Do you plan at any stage of the project to undertake intrusive research involving adults lacking capacity to consent for themselves?

☐ Yes ☐ No

Answer Yes if you plan to recruit living participants aged 16 or over who lack capacity, or to retain them in the study following loss of capacity. Intrusive research means any research with the living requiring consent in law. This includes use of identifiable tissue samples or personal information, except where application is being made to the Confidentiality Advisory Group to set aside the common law duty of confidentiality in England and Wales. Please consult the guidance notes for further information on the legal frameworks for research involving adults lacking capacity in the UK.

8. Do you plan to include any participants who are prisoners or young offenders in the custody of HM Prison Service or who are offenders supervised by the probation service in England or Wales?

☐ Yes ☐ No

10. Will this research be financially supported by the United States Department of Health and Human Services or any of its divisions, agencies or programs?

☐ Yes ☐ No
Short title and version number: Edinburgh Orthopaedic Research Database 2021

Please complete these details after you have booked the REC application for review.

REC Name:
Scotland B Research Ethics Committee

REC Reference Number: 20/SS/0125
Submission date: 11/11/2020

A management protocol or similar document should be enclosed with this application. This should be a comprehensive outline of the purpose, operation, methods, policies and governance of the database.

Part A: Core Information

Administrative information

1. Title of the Database
Edinburgh Orthopaedic Research Database 2021

2. Name and address of the establishment (i.e. the legal entity responsible for storage of the data)

Organisation: NHS Lothian
Address: Edinburgh Royal Infirmary
         Little France Crescent
         Edinburgh
Postcode: EH16 4SA
Telephone: 01315361000
Fax

3. Name of the Applicant
The applicant should be the person with overall responsibility for the management of the Database and will be regarded as the Data Controller.

Title: Professor
Forename/Initials: Colin
Surname: Howie
Address: Royal Infirmary of Edinburgh
         Little France Crescent
         Edinburgh
Postcode: EH16 4SA
E-mail: colin.howie@nhslothian.scot.nhs.uk
Telephone: 01312426462

Date: 11/11/2020
A copy of a current CV (maximum 2 pages) for the applicant should be enclosed.

4. Name of the Data Custodian This should be a senior person at the establishment, other than the applicant, who is independent of the research database team and able to provide assurance that appropriate information governance is in place.

<table>
<thead>
<tr>
<th>Title</th>
<th>Forename/Initials</th>
<th>Surname</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mr</td>
<td>Gavin</td>
<td>Macpherson</td>
</tr>
</tbody>
</table>

Address
Edinburgh Royal Infirmary
Little France Crescent
Edinburgh

Postcode
EH16 4SA

E-mail
gavin.macpherson@nhs.net

Telephone
01312426466

Mobile
07713626527

Fax
01312426534

5. Has this database (or any part of the database) previously been the subject of an application for ethical review?

☐ Yes  ☐ No

If Yes, was the application approved?

☐ Yes  ☐ No

Name of Research Ethics Committee: Scotland A Research Ethics Committee
Date of decision: 15/04/2016
REC reference number: 16/SS/0026

6. Summarise the types of data to be stored. Please state the population base and the selection criteria for inclusion of data in the Database. Indicate what data is already held and summarise the plans for further data collection from patients, service users or care records. Indicate whether any particularly sensitive data will be held.

Around 6000 patients undergo treatment in the Department of Orthopaedic Surgery, Royal Infirmary of Edinburgh each year. General demographic, service satisfaction and patient experience data has been routinely collected as part of service audit for the past 20 years.

As part of standard service we already collect preoperative and postoperative quality of life scores along with basic demographic and procedure data, joint and disease specific results, expectation, experience and satisfaction data.

We plan to continue collecting all of the above information. Particularly sensitive data will not be held.

Please enclose a list of all data items to be stored. Enclose a copy of any questionnaire to collect data from donors which is additional to data collected in the course of normal healthcare provision.

7. Justify the collection of this data and describe how it will be used for research. Summarise the overall policy of the establishment for use of the data, including release to other researchers or research organisations. Say what other research databases already exist in this field. What will this database add to existing resources and what will be the potential benefits?
Rationale for establishment of the Edinburgh Orthopaedic Research Database

Routine collection of demographic, procedure, general quality of life and satisfaction has been carried out for the purpose of service audit. The additional collection of disease specific Patient Reported Outcome Measures (PROMs) may count as research as it may lead to new knowledge. It will benefit hospital process design, perioperative care, implant design and long-term follow-up of patients undergoing arthroplasty. For this data to be meaningful it should encompass the highest proportion of patients as possible.

This database will allow:
1. Quantification and comparison of treatment effect across demographic groups, diseases and procedures.
2. Investigation of the links between disease severity, treatment effect and satisfaction.
3. Determination of implant survival and treatment effect related to implant type.
4. Allow post-market surveillance and recall of orthopaedic implants and provide early warning of problems relating to a particular implant.
5. Informs health economic analysis of orthopaedic procedures and implant types.
6. Provides individual surgeons with personal outcome data and patient experience information.

Due to the nature of the research is it not possible to foresee all the possible uses of the data at the start of the project. Researchers may generate hypotheses in the future based on the type and extent of the data we collect. All research will be based on the general aims of the database as stated above. Any data released will be anonymised and limited to the patients and variables required for the specified analysis. Any proposed research that will require further contact with patients or the release of patient identifiable data will be referred to a REC as part of new study protocol.

Requests for data will be considered by the Executive Database Team (EDT) and be judged on their potential benefits to patient care. The users of the database will be researchers within the Orthopaedic department and those associated with research institutions with which the department is linked (Edinburgh University and Queen Margaret University). Other organisations may be given access to certain, restricted, anonymised sections of the database if their proposed use is intended to improve patient care.

Background to PROMs and PREMs

There has been a huge expansion in the development and application of questionnaires, interview schedules and rating scales that measure states of health and illness from the patients' perspective. Patient reported outcome measures (PROMs) provide a means of gaining an insight into the way patients perceive their health and the impact that treatments or adjustments to lifestyle have on their quality of life. These instruments can be completed by a patient or individual about themselves, or by others on their behalf.

Patient Reported Outcome Measures (PROMs) are measures of health status or health-related quality of life (HRQoL) that come directly from patients. PROMs do not attempt to determine the outcome (impact) of a health care intervention but instead they assess a person's health status or HRQoL at one point in time. The impact of a health care intervention is determined by comparing the patients' self-reported health status at two points in time (in surgery, before and after the operation). PROM has become an internationally accepted term.

A wide range of reliable and valid PROMs, usually administered in questionnaire format, have been developed in recent years. Some of these were developed for particular conditions or treatments (disease-specific measures) while others were developed to facilitate comparisons between conditions or treatments (generic measures). The use of PROMs will ensure that, in addition to clinical measures of outcome, patient perspectives will be taken into account. In addition, there is interest in using utility-weighted generic PROMs to determine the relative cost-utility of different interventions to inform commissioning decisions in the NHS.

While PROMs are commonly included in studies of treatment effectiveness they are less often included in assessing health care quality. Research is required to resolve a number of important issues. For example, to monitor the care of individual patients or for research.

Patient choice over treatment and care is a central feature of the NHS. Patients’ experience (PREMs) of healthcare delivery influences their outcomes and health gain following treatment and care. Patient experience is a major indicator of quality. PREMs have, not yet, settled on a definitive, validated score so we continue to rely on questions taken from the Scottish Inpatient Survey 2018.

The only other database that we are aware of in this field is that of the National Joint Registry for England, Wales,
Northern Ireland and the Isle of Man.

We are hoping to forge stronger relationships with the Scottish Arthroplasty Project (SAP) and the national Musculoskeletal (MSk) Audit and create a forum that can feed into the NHSScotland Quality Improvement programme. We feel that, after two decades we have a lot to offer. Change over time has been an important aspect of our database.

8-1. How have you actively involved, or will you involve, patients, service users, or members of the public in establishing the database and its policies?

Patients and service users have been, and will regularly be, asked to appraise the data collection process. Questionnaires and database tools will be reviewed annually to ensure that they are appropriate to meet the requirements of research and audit.

9. How will you inform data subjects and other patients, service users and members of the public of the results of research?

Regular reports and any papers produced from the Edinburgh Orthopaedic Research Database will be published on NHS Lothian's website with contact details for the authors available for further information, if required.

Departmental reports are submitted to management on an annual basis.

Annual progress reports are submitted to R&D and to the Research Ethics Service.

Individual reports with all outcomes, satisfaction and experience are created for clinicians and submitted for job appraisals and GMC revalidation.

10. How will the Database be managed, financed and sustained to ensure the potential benefits are realised?

The Database will be managed by a Research Database Manager employed by the University of Edinburgh who has an Honorary Contract with NHS Lothian and whose salary is paid from a research grant. Overall responsibility for the database will be firmly with the Data Controller, the Data Custodian and NHS Lothian.

The database will be financed primarily from endowment funds gifted to the department for research purposes.

Information governance

11. What personal identifiers will be held with the data records? Please tick all that apply.

- [x] Initials
- [x] Full name
- [x] Address
- [x] NHS or CHI number
- [x] Hospital ID no.
- [x] GP registration
- [x] Date of birth
- [x] Year of birth
- [x] Date of death
- [x] Postcode
  - District level
  - Sector level
  - Sub-sector level
  - [x] Unit level
- [ ] Other geographical identifiers
Purpose for which postcode/geographical identifiers required:

- Deprivation scoring
- Gender
- Occupation
- Ethnicity
- Other identifiers

12-1. What systems will be in place to ensure the confidentiality of personal data?

What will be your policy for limiting access to identifiable data within the establishment. Say who will have access and for what purposes, what training they will have and how the confidentiality policy will be monitored and enforced.

We are aware of and will comply with all our responsibilities under the Data Protection Act 2018 and the EU General Data Protection Regulation (GDPR).

The data will only be available to members of the research team.

The data subjects will be informed, via the information sheet, privacy notice and consent form, of those who may be given access to the data.

We will ensure that personal information is only accessible to authorised people. Our staff have a legal and contractual duty to keep personal health information secure, and confidential.

The following security measures are in place to protect personal information:

1. Training in Information Governance will be mandatory for all researchers wishing to access the database and they will be asked to complete modules for Safe Information Handling and Information Handling in Practice. The Safe Information Handling module is based on the foundation competencies published in 'Information Governance in NHSScotland: A Competency Framework'. Compliance with NHS Scotland Information Security Policy.

2. Access controls and audits of electronic systems are routinely monitored by our e-Health Research Governance Team and a Risk Assessment for the system has been completed and approved.

3. The research database has been registered on the NHS Lothian Information Asset Register.


5. We have developed a strong relationship with our local Research Governance team who have helped with training and education in this area in light of new legislation and regulation.

6. The Research Database Manager has achieved Office for National Statistics Safe Researcher status which is valid until February 2023.

7. The Edinburgh Orthopaedic Research Database Privacy Policy can be viewed at www.ed.ac.uk/clinical-sciences/orthopaedics-trauma/orthopaedics-and-trauma-projects/eordbase-privacy-policy

13. What security and audit measures will be in place to secure access to identifiable data held by the Database?

The database executive team will meet regularly to scrutinise requests for access to data and follow-up on the results of previous requests. The database will be held on a secure server controlled by the Edinburgh Royal Infirmary Information Technology (IT) department. The computer used to access the database is password protected and is located in a research room that is locked and which has key-holder only, restricted access. Researchers wishing to access the data must complete a project form which must be authorised by the supervising clinician and the Data Controller. Researchers must be in possession of an encrypted USB which has been issued by the hospital’s IT department. Researchers must sign their data request to confirm that they have completed training and will comply with NHS Data Protection and Privacy policies.
There will be a full audit trail for all data collected. The database will be internally audited on a monthly basis. This audit will be carried out by the Database Manager who is qualified to carry out internal audits.

14. What arrangements will be in place for monitoring the Database’s systems and procedures?

The Data Controller will review and report on the database systems and procedures on an annual basis. If there are any changes to policy regarding Records Management and/or security those changes will be implemented immediately.

15. Do you wish to seek generic ethical approval for research projects using the stored data, under conditions agreed with the REC, without requirement for researchers to apply individually to the REC for approval?

Yes  No

16. What types of research will be undertaken and in what field(s) of health or social care?

It is not possible to fully anticipate all future possible analysis that will result from this database. We require to collect data prospectively so that when research questions arise in future, researchers will have access to a rich database that will effectively answer clinical questions and improve patient care. The possible research aims will include:

1. Demographic, procedure, disease, implant and technique specific analysis of patient reported functional outcome, experience and satisfaction currently used in the department.
2. Health economic analysis of orthopaedic procedures.
3. Functional and quality of life benefits of arthroplasty and other orthopaedic procedures.
4. Patient reported functional impairment in musculoskeletal conditions.
5. Implant survivorship and function.
6. Implant survivorship and design.
7. Implant and surgeon operating technique.
8. The relevance and accuracy of specific PROMs and PREMs.
9. Addition of Focus Groups is new for this application although it was added to application 16/SS/0026 by substantial amendment in October of 2018. The rationale for including Focus Groups being that the analysis of patients’ subjective experiences are essential to appreciating what is working well, what needs to change, and how to go about making improvements. It is unethical to ask patients to comment on their experiences if these comments are going to be ignored. We believe a more concerted effort is now required to make better use of the evidence. On occasion, we interview a small number of our arthroplasty patients by setting up focus groups.

The purpose of the focus group is to discuss the findings from the patient satisfaction and experience comments which:
• Enrich interpretation of the data collected at one year post surgery
• Identify local issues
• Prioritise the specific areas in which there is a need for action
• Explore practical and workable improvements

Thematic analysis is used in this area and we now have a strong relationship with the Usher Institute who add their expertise to this important area of our research.

As a general principle this research will involve the data already collected. If identifiable data were required by researchers, or further contact with patients outwith the database protocol, a further REC approval would be sought.

Any researcher proposing research that wishes to investigate a new or novel implant or technique will be referred to IRAS and HRA sites so that they can obtain the appropriate approvals for their research.
17. **Give summary details of the research team.** It is not necessary to name individuals, but please give an indication of the types of researchers who are likely to be involved and the expertise available within the team, including IT and other support staff. Include any external research organisations or units you plan to collaborate with, if known.

The Research Database Team (RDT) will be led by Professor of Orthopaedics who is the Data Controller.

We will appoint a Data Custodian who will be independent of the RDT.

The day to day management of the database will be carried out by the Research Database Manager who will oversee all aspects of the database by providing efficient data collection, the safe storage and release of study and project data. The Database Manager has expertise in database development, software programming and handling of scientific data. The Database Manager is a CQI Chartered Quality Professional and has Office for National Statistics Safe Researcher status.

The rest of the team consists:

- Two part-time data processors - ICH GCP trained and have completed Security Essentials and Data Protection Training.
- Two data analysts - ICH-GCP trained and who have also undertaken Security Essentials and Data Protection Training. The analysts are statisticians/consultant surgeons who have wide orthopaedic knowledge and experience.

The day-to-day work of the whole team covers all aspects of data handling and management related to the collection of study data. The team ensures that this work meets the necessary data protection, consent, security and other governance requirements.

The research database team will be embedded and visible within the department of orthopaedics and trauma and will be responsible for developing and implementing the data systems that support the collection of data. The core team will provide wider support for studies carried out in our department. It will carry out and manage all of the processes that are linked to data entry and will ensure that the quality of records is accurate.

In addition we will appoint an independent Data Custodian. The main responsibility of the custodian will be to oversee progress of the database and to ensure that the data are handled in accordance with the protocol. The custodian will ensure adherence to the protocol, that data are correctly and completely recorded and reported, and will confirm that informed consent is being obtained and recorded for all patients. Any deviation from the protocol will be reported promptly to NHS Lothian and the ethics committee.

External research agencies:
Scottish Arthroplasty Project; National Musculoskeletal (MSk) Audit; Research Charities and NHS Agencies; Arthritis Research Council (ARC); British Hip Society; National Joint Registry (NJR); Other Orthopaedic units who also collect patient outcome data.

Commercial organisations: Stryker, Zimmer, DePuy as examples may request limited extracts of the data, with NHS restrictions in place to protect patient confidentiality.

We have produced a Data Sharing Agreement which is available to view here: www.ed.ac.uk/clinical-sciences/orthopaedics-trauma/orthopaedics-and-trauma-projects/eordbase-data-sharing-agreement

18. **Will any types of research or research organisation be excluded from receiving data?**

- Yes
- No

19. **What arrangements will be made to consider applications from researchers for access to the data? How will decisions on access be made and who will be involved?** Include details of arrangements for ensuring adequate scientific critique of research proposals.

Researchers will be required to complete a project form - Data Request Form (DRF) detailing the research question, scientific justification, methodology and timescale for completion of the project.

The Executive Database Team (EDT) will expect to see evidence of literature search and review in support of the application. A supervising clinician must be named on the form. The supervising clinician must be employed by NHS Lothian. Researchers and their supervisors must have undergone data protection and data security training as...
indicated in Q12-1 of this form.

The application will be reviewed and, if acceptable, approved. Approval may be revoked if the study deviates from the approved proposal and is deemed inappropriate. Regular intervals of follow up, while the project is in progress, will be undertaken by the Data Controller, Research Database Manager, the lead clinician and the researcher. These follow ups will be recorded on the DRF.

A copy of each approved DRF will be sent to our R&D department. Our R&D department will also be notified once the project has been completed and any reports or papers resulting from the study will be made available. We have been advised by R&D that a standard operating procedure (SOP) is being developed to simplify the reporting of projects to R&D.

We will ensure that each time access to patient data is granted, an appropriate audit trail is generated.

A standard procedure to evaluate requests for access to patient data exists. Such access will only be granted when this procedure has been successfully completed and signed off by the Data Controller who is authorised to do this.

Access to patient data will only be granted only for a finite period of time and, when the end of that period is reached, access revoked.

20. Please give details of how the data will be effectively anonymised or pseudonymised to protect the confidentiality of subjects. What measures will you take to prevent possible re-identification by linking to other databases?

Where datasets hold patient-identifying items a version of that dataset which has identifying data items removed will be made available. Hospital and national identifications numbers, along with dates of birth will be removed. The data will be pseudonymised. We will process personal data in such a way that the data can no longer be attributed to a specific data subject without the use of additional information.

The additional information will be kept separately and subject to technical and organisational measures to ensure non-attribute to an identified or identifiable person. Only members of the database team who have been authorised to undertake work on patient identifying data will have the ability to link the two together.

The Research Database Manager has accredited Office for National Statistics Safe Researcher status which is valid until December 2024.

21. What conditions will apply to the sharing of data with researchers? Please summarise the terms of any data access or data sharing agreement and say how these will be monitored and enforced.

To gain access to data researchers will be required to complete a Data Request Form (DRF). The application will be reviewed and, if acceptable, approved.

We will ensure that any request for access to patient data is managed by a standardised and authoritative procedure.

We will always apply the Caldicott principles:

Researchers will have to justify the purpose

Will not be given access to patient identifiable information unless it is absolutely necessary

Will be allowed access to the minimum necessary patient-identifiable information

Access to patient-identifiable information will be on a strict need to know basis

We will ensure that all researchers requesting access are aware of their responsibilities

We will ensure that all researchers requesting access understand and comply with the law

We will ensure that each time access to patient data is granted, an appropriate audit trail is generated.

A standard procedure to evaluate requests for access to patient data exists. Such access will only be granted when this procedure has been successfully completed and signed off by the Data Controller who is authorised to do this.

Access to patient data will only be granted only for a finite period of time and, when the end of that period is reached, access revoked.
We have developed an 'Edinburgh Orthopaedic Research Database Project
Data Sharing Agreement'. A copy of this protocol is available in the additional documentation accompanying this application and is available to view here: www.ed.ac.uk/clinical-sciences/orthopaedics-trauma/orthopaedics-and-trauma-projects/eordbase-data-sharing-agreement

22. Is it possible that the research could produce findings of direct clinical significance for individuals? (This may include relatives as well as data subjects.)

Yes. The only anticipated findings of clinical significance could occur if a patient enclosed further information with their questionnaire relating to their recovery. Any extra information, or information suggesting the patient has concerns or a poorer than anticipated recovery will be directed to the original clinician for clinical follow-up or where appropriate, to the unit's service management for action/resolution.

23. Where research data is of direct clinical significance for individuals, will arrangements be made to notify the individuals concerned?

| Yes | No |

If No, please justify. If Yes, say what arrangements will be made and give details of the support or counselling service. Normal clinical care will continue for patients. Feedback will be made via the Consultant and or the teams responsible for the care of that patient.

24. Will data be released to individuals/organisations conducting research outside the UK?

| Yes | No |

25. What policies will apply to further storage and use of data by researchers when studies are complete? What mechanisms will be in place for approving further studies?

The relevant documentation and data will be archived for at least five years after the conclusion of the study unless otherwise stipulated. However, gathering data is an on-going process and change over time is an important aspect of our analyses of the data. We are now in a position where we have the data, ability and processes to review patients who are at 10, 15 or 20 years following their original surgery.

The Data Controller has responsibility for organising archiving. Archiving is available via NHS Lothian R&D Department.

Applications from researchers wishing to access the Database for further studies must be made on the appropriate application form and will be reviewed on a monthly basis by members of the database team. The final decision on whether access should be allowed will be made by the Data Controller.

Any studies involving potential recontact with a patient or use of identifiable data, or linkage with other databases will be directed to REC for consideration.

Access to archived documents should be restricted to the Data Controller or the individual with responsibility for archiving within NHS Lothian R&D.

Data collection and informed consent arrangements

Question 26 applies to existing collections of data only.

26. Has informed consent already been given to use the data for research?

| Yes | No | Not applicable |

If Yes, please describe what arrangements were made to seek informed consent and for what purposes. A copy of the information sheet and consent form should be enclosed. Confirm that the consent covers the uses of personal data

Date: 11/11/2020
now proposed by the Research Database team.

If No, or if existing consent does not cover the purposes now proposed, say whether consent will now be sought. Please include details of the arrangements for seeking consent in your answer to questions 28 - 30. If consent will not be sought, please justify.

Each questionnaire that we use has an information sheet and consent form attached. We supply a telephone number and e-mail for patients to contact us if they require any further information or explanation of the forms sent or given to them. Patients can withdraw consent for the use of their data at any point.

The consent form and information sheet is incorporated into the questionnaire.

The questionnaires are in a scannable format which has both a tick box for a Yes/No response and a freetext box for a signature. Once the forms are scanned this information is automatically entered into the database. All returned questionnaires will be manually checked for a signature prior to electronic data processing.

The form and information sheet are regularly reviewed and amended to update information contained therein.

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Question 27 relates to identification of the data cohort. It applies to all new data collection from patients, service users or health records.

27-1. How and by whom will records be identified?

Patients will be identified at the time of their procedure. All patients attend a pre-operative assessment clinic one to two weeks prior to surgery. All patients receive an information pack with this appointment which includes a questionnaire appropriate to the surgery they are about to undergo. The questionnaire is included by the NHS Lothian Waiting List Office and sent or given to all patients attending for surgery.

27-2. Will this involve reviewing or screening identifiable personal information of potential data subjects?

- [ ] Yes
- [ ] No

27-3. Please give details of how identification will be carried out and what resources will be used?

Identification will be carried out using the NHS Lothian's Orthopaedic Waiting List Office to determine the procedure being undertaken and insert the appropriate questionnaire into their pre-surgery documentation pack.

27-4. Will individuals other than the direct healthcare team have access to identifiable personal information of potential data subjects for this purpose?

- [ ] Yes
- [ ] No

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Questions 28 - 30 apply in all cases except where the application relates to an existing data collection and consent has already been obtained.

28. How and by whom will data subjects first be approached? Indicate whether this will be in the course of healthcare provision or whether additional procedures will be involved. In the case of additional procedures, what burdens could arise for participants?

Data subjects are approached in the course of their healthcare provision. Questionnaires will be either sent with their clinic appointment letters or will be given to patients when they attend for their clinic appointment.

29-1. Will you obtain informed consent from or on behalf of data subjects?

- [ ] Yes
- [ ] No

If you will be obtaining consent from adult data subjects, please give details of who will take consent and how it will be done, with details of any steps to provide information (a written information sheet, videos or interactive material). Arrangements for adults unable to consent for themselves should be described separately in Part B Section 6, and for

Date: 11/11/2020
If you plan to seek informed consent from vulnerable groups, say how you will ensure that consent is voluntary and fully informed.

If you will not be obtaining informed consent, please complete question 29-3.

The consent form and information sheet is incorporated into the questionnaire. Completion of the questionnaire is entirely voluntary.

The questionnaires are in a scannable format which has both a tick box for a Yes/No response, date boxes for recording the date of consent and a freetext area for the patient's signature. Once the forms are scanned this information is automatically entered into the database. All returned questionnaires will be manually checked for a signature prior to electronic data processing. Any unsigned consent forms will not be processed. Any patient form which has been completed but the 'No' to details being recorded will be processed but their data will not go forward for any analysis other than that which would be routinely collected for audit.

Please enclose a copy of the information sheet(s) and consent form(s).

29-2. Will you record informed consent in writing?

- Yes  - No  - Not applicable

30-1. What arrangements have been made for persons who might not adequately understand verbal explanations or written information in English, or who have special communication needs? (e.g. translations, use of interpreters)

The questionnaires we will be using are published and validated and are available in many different language and large print formats. Data subjects requiring such formats will be accommodated.

Although we would like to supply Braille versions of the questionnaire the costs for producing these are prohibitive and we would request that a trusted family member or carer aid a visually impaired patient to complete the form by reading the questions and noting the answers.

Questions 31 - 32 apply to all applications:

31. Will any financial or other incentives be offered to data subjects?

No.

32. What steps will be taken where data subjects subsequently withdraw consent to the use of their data? What information will data subjects be given about this?

Data subjects are informed on the information sheet provided that they may withdraw their consent to the use of their data at any time. If a data subject withdraws their consent their information will be removed from the database immediately.

Questionnaires received from any data subject who ticks 'No' on the consent form will not be included in a dataset.

If a data subject contacts the Research Database Team and requests their data to be removed, the data will be removed immediately and the request logged.

Summary of the application

33. Please provide a brief summary of the application in a form suitable for publication, using language easily understood by patients and public. The summary will be published on the website of the National Research Ethics Service following the ethical review. You may cut and paste from answers to other questions.

Title of the database: Edinburgh Orthopaedic Research Database 2021

Establishment responsible for management of the database:

Date: 11/11/2020
Data to be stored and data collection arrangements (maximum 200 words): Around 6000 patients undergo treatment in the Department of Orthopaedic Surgery, Royal Infirmary of Edinburgh, each year. General demographic and service satisfaction data has been routinely collected as part of service audit.

As part of standard service audit we collect preoperative and postoperative quality of life scores along with basic demographic and procedure data. Current data: EQ-5D Quality of Life Health Measures; comorbidities; joint and disease specific questionnaire results; expectation, satisfaction and experience data. Particularly sensitive data will not be held.

In addition we plan to collect disease and procedure specific functional data through validated questionnaires. The scores administered will be tailored to the particular procedure to minimise the size of the questionnaire and time taken to complete.

Research programme/community supported by the database (maximum 200 words): Internally NHS Lothian and the University of Edinburgh: Consultant Surgeons, Specialist Registrars, orthopaedic trainees and medical students. External research agencies: Scottish Arthroplasty Project; the national Musculoskeletal (MSk) Audit; Research Charities and NHS Agencies; Arthritis Research Council (ARC); British Hip Society; National Joint Registry (NJR); Other Orthopaedic units who also collect patient outcome data.

Commercial organisations: Stryker, Zimmer, DePuy, as examples, may request limited extracts of the data with NHS restrictions in place to protect patient confidentiality.

We have produced a Data Sharing Agreement which is available to view here: www.ed.ac.uk/clinical-sciences/orthopaedics-trauma/orthopaedics-and-trauma-projects/eordbase-data-sharing-agreement.
### Part C: Data Collection Centres

Please enter details of the organisations (NHS or other) in the UK that will act as data collection centres for this research database.

<table>
<thead>
<tr>
<th>Data collection centre</th>
<th>Local collaborator</th>
</tr>
</thead>
<tbody>
<tr>
<td>Edinburgh Royal Infirmary</td>
<td>Professor Colin Howie</td>
</tr>
</tbody>
</table>
D1. Declaration by the applicant:

1. The information in this form is accurate to the best of my knowledge and belief and I take full responsibility for it.
2. If the application is approved I undertake to adhere to the terms of the application of which the REC has given a favourable opinion and any conditions set out by the REC in giving its opinion.
3. I undertake to seek an ethical opinion before implementing substantial amendments to the terms of the application of which the REC has given a favourable opinion.
4. I undertake to submit annual progress reports to the REC.
5. I understand that the information contained in this application, any supporting documentation and all correspondence with NHS Research Ethics Committees or their operational managers relating to the application:
   ○ Will be held by the main REC indefinitely (or until 3 years after the closure of the Database).
   ○ May be disclosed to the operational managers or the appointing body for the REC in order to check that the application has been processed correctly or to investigate any complaint.
   ○ May be seen by auditors appointed by the National Research Ethics Service to undertake accreditation of the REC.
   ○ Will be subject to the provisions of the Freedom of Information Acts and may be disclosed in response to requests made under the Acts except where statutory exemptions apply.
   ○ May be sent by email to REC members.
6. I understand that a summary of this application will be published on the website of the National Research Ethics Service (NRES), together with the contact point for enquiries named below. Publication will take place no earlier than 3 months after issue of the ethics committee’s final opinion or the withdrawal of the application.

Contact point for publication

NRES would like to include a contact point with the published summary of the application for those wishing to seek further information. We would be grateful if you would indicate one of the contact points below.

- Applicant named at A3
- Other – please give details
- None

Optional – please tick as appropriate:

- I would be content for members of other RECs to have access to the information in the application in confidence for training purposes. All personal identifiers and references to the establishment and other research units and collaborators would be removed.

This section was signed electronically by COLIN HOWIE on 11/11/2020 19:20.

Job Title/Post: Cons Orthop Surgeon
Organisation: nhs Lothian
Email: colin.howie@nhslothian.scot.nhs.uk
**Part D: Declarations**

**D2. Declaration by Data Custodian**

1. I confirm that the information in this application is accurate to the best of my knowledge and belief and I approve the application.
2. I confirm that the establishment has Data Protection Registration appropriate to the purposes described in this application.
3. I confirm that the establishment has an appropriate System Level Security Policy in place for the systems used by the Database.
4. If the application is approved, I confirm that I will take responsibility for ensuring that the arrangements described in the application are adhered to and any agreed conditions of ethical approval are complied with.

This section was signed electronically by Mr Gavin Macpherson on 11/11/2020 20:40.

Job Title/Post: Clinical Lead for Elective Orthopaedic Surgery

Organisation: NHS Lothian

Email: gavin.macpherson@nhslothian.scot.nhs.uk