

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)
The national musculoskeletal audit and research database (Version 1.0)

1. Is your project research?

Yes No

2. Select one category from the list below:

- Ionising Radiation for combined review of clinical trial of an investigational medicinal product
- Ionising Radiation and Devices form for combined review of combined trial of an investigational medicinal product and an investigational medical device
- Clinical investigation or other study of a 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?

- Social Care Research Ethics Committee
- 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

11. Will identifiable patient data be accessed outside the care team without prior consent at any stage of the project (including identification of potential participants)?

- Yes No

RESEARCH DATABASE



Health Research Authority

Short title and version number: (maximum 70 characters - this will be inserted as header on all forms)
The national musculoskeletal audit and research database (Version 1.0)

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

REC Name:

REC Reference Number:

Submission date:

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

The national musculoskeletal community and primary care audit and research database

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

Organisation	Keele University
Address	David Weatherall Building Keele University Stoke-on-Trent
Postcode	ST5 5BG
Telephone	01782733900
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 Forename/Initials Surname
	Prof Jonathan Hill
Address	David Weatherall Building School of Medicine Keele University Stoke-on-Trent
Postcode	ST5 5BG
E-mail	j.hill@keele.ac.uk
Telephone	01782733900
Mobile	07890299548

Date:

3

IRAS Project ID: 324885

Fax

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.

	Title Forename/Initials Surname
	Prof Kelvin Jordan
Address	David Weatherall Building
	Keele University
	Stoke-on-Trent
Postcode	ST55BG
E-mail	k.p.jordan@keele.ac.uk
Telephone	01782 733924
Mobile	
Fax	

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

Yes No

Purpose of the Database

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.

There are 4 sources of data. 1. Patient-reported surveys with musculoskeletal health outcomes and experiences, 2. Medical record data (clinician entered data on treatments provided), and 3. Provider organisational characteristics (aggregate level data about the resources, setup and system of each provider collected via an online survey to a designated lead for that service), 4. NHS digital data including HES, PLICS (patient-level information and costing system) and NHS Wales including PEDW (patient episode data for Wales).

The population base will be adult musculoskeletal consultants to primary care or community musculoskeletal services. There will be no further selection criteria other than being 18 years or over, able to provide informed consent and have an active mobile phone or email address.

Routine data is already held by individual services, however, the purpose of this database is to standardise a minimum dataset and collate data from different UK providers in one secure data repository. There is no particularly sensitive data planned and data will be anonymised before it is analysed or available for research.

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?

This database will collate routinely collected musculoskeletal (MSK) primary and community care data across MSK providers. How data is collected by services (exact question/format) will be standardised to allow for collective analysis and research. Examples of existing high-quality musculoskeletal (MSK) data collections include, the National Early Inflammatory Arthritis Audit (NEIAA) (British Society of Rheumatology (BSR) 2021), the National Hip Fracture Database (NHFD) (Royal College of Physicians, 2019), and the National PROMs Programme hip and knee arthroplasty

database (NHS Digital, 2019/20). These data collections have demonstrated how audit, evaluation and associated research projects can drive forwards quality improvement for MSK patients, with NEIAA demonstrating tangible improvements in the quality of patient care in Rheumatology including improved access to specialist services and treatment initiation for early inflammatory arthritis conditions (BSR, 2021), in line with NICE standards. At present there is no similar data collection and evaluation for the much larger group of MSK patients with non-inflammatory, non-surgical, MSK conditions such as back pain and osteoarthritis, and for patients seeking care from their GP, Physiotherapist, or wider multi-disciplinary team, in primary/community care rather than in specialist secondary care services. The Best MSK NHS England team have highlighted the need for standardised high impact metric collection including PROMs and PREMs across community and primary care services. The Keele team have developed recommendations for a core MSK outcome set in collaboration with national policy makers, have developed a case mix adjustment model to enable benchmarking across different GP practices and MSK services in respect to MSK patient outcomes, have developed MSK relevant SNOMED code lists for defining MSK patients and their care, have developed searches to pull relevant data from primary care electronic health records, and are leading projects on MSK data integration. The next step is to collect standardised routine MSK data from participating clinical services and use above methods to allow for collective analysis, benchmarking, and national audit against defined quality criteria in this area. Data will be used to highlight best practice, facilitate quality improvement, develop and answer research questions, and to develop a learning health system that supports the NHS/health system to change/improve guided by best evidence and a focus on value-based care. Data will only be released to other researchers in an anonymised format following submission of a research proposal to and approval by the MSK database research team (Professor Jonathan Hill, Professor Kelvin Jordan, and Dr Roanna Burgess).

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?

We have had patient input into various stages of this MSK research database protocol development, including engagement with the core set of metrics to be reported on within a previous consensus study (Burgess et al, 2021), and a lay member has already supported our newly launched Community of Practice setup for the National MSK community, by giving a Patient's Perspective presentation to that national group.

We have also held a dedicated patient engagement workshop about this database development protocol involving eight patients with lived experience of MSK disorders (in October 2022). This workshop outlined the project, work to date, and current proposal. There was overwhelming support for the project with all eight patient representatives wanting to be part of the database patient advisory group. There was a strong consensus that this project was incredibly important, particularly as it would highlight areas of inequity and problems faced in current MSK primary care and provide a mechanism to evaluate and drive quality improvement. Patients told us numerous examples of why they feel there is huge inequity in current MSK care provision. They expressed a view that NHS physiotherapy is often limited, that they do not feel represented by current national audits/data, and that they do not feel supported in managing their long-term MSK conditions within the current NHS system. Several patients noted that they had never been asked for information about their MSK health or had questionnaires to monitor their symptom severity or their experiences of care. They, therefore, felt that this research would be very useful and timely. One patient commented that they particularly liked the aspect of the project which seeks to nudge clinician behaviours because they felt this would address unconscious clinician biases. Overall, they were excited that this project would begin to address many issues relating to the evaluation and quality of MSK care.

Questions raised by patients and our responses:

Whether all MSK patients could be included not just those seeing First Contact Physiotherapists (FCPs)?

We explained that this is important and we would look to extend the national MSK database to the wider GP population using a phased approach.

Whether private physiotherapists and other private MSK therapists could be included?

We agreed that this was important, and we are now exploring how to also include patients treated in private MSK services.

Why there is such inequity between orthopaedic/secondary care MSK care including amount of rehabilitation given.

We agreed that there is huge inequity and discussed how the research will only be able to highlight differences in primary and community care inequity. We also reassured patients that we are collecting organisational data including waiting times, appointment times, workforce and ratios and that these would be included in the analysis to evaluate impact of variation in these factors on MSK patient outcomes and experiences.

Why is there such inequity in waiting times for care?

As above, this will be measured as part of the organisational data submitted by NHS managers.

With regards to monitoring and proactive patient initiated follow up, will we measure this?

We agreed we could look to evaluate new policy around patient initiated follow up (PIFU) as this is implemented across MSK and FCP services.

This Patient and Public Involvement and Engagement (PPIE) input has substantially underpinned and helped to shape the project/database development to date. Many of the PPIE members who attended our dedicated workshop overlap with the PPIE members involved with the MIDAS patient advisory group. The link between the projects was highlighted as a strength by our Keele Patient User Group, who also described their involvement in that project as a great exemplar of PPIE activity.

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

We will look to produce:

- Summary reports for participating MSK services and GP practices/FCP services.
- Dependant on funding, we would like to develop interactive dashboards displaying anonymised aggregate data to different stakeholders.
- A webpage on our institutional website, and post messages on social media including Twitter
- Publications including full annual report and plain English summary, peer-reviewed journals, and local NHS and research newsletters
- Presentations at high-profile scientific and health policy conferences: British Society of Rheumatology, Chartered Society of Physiotherapy, Versus Arthritis, National PROMs Conference.

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

Funding has been secured from the British Society of Rheumatology to adapt their electronic platform (provided by Netsolving and HQIP funded) used to collect data for the National Early Inflammatory Arthritis Audit (NEIAA) and increase the breadth of the HQIP funded programme to the wider MSK patient population to include community/primary care. This gives a sustainable platform for data collection and reporting for any services that are currently finding this challenging in the current healthcare climate.

The database will be managed by the West Midlands Secure Data Environment team at University Hospitals Birmingham.

Information governance

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

- Initials
- Full name
- Address
- NHS or CHI number
- Hospital ID no.
- GP registration
- Date of birth
- Year of birth
- Date of death

Postcode District level Sector level Sub-sector level Unit level Other geographical identifiers**Purpose for which postcode/geographical identifiers required:** Deprivation scoring Lifestyle analysis Geographical analysis 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.

Initially, all personal data will be stored at Keele University. The data will be uploaded to Keele University by participating services and initially held within a secure Microsoft SharePoint folder for data checks/cleaning. With SharePoint we have up to 25TB of storage in the Cloud and controls with permissions to granularly allow individuals into and remove out of the SharePoint permissions. Only agreed relevant users will have access to the folder and restrictions can be placed (i.e. read only) on these users depending on their involvement and data requirements. All Keele SharePoint users use 2-factor authentication to ensure data security. SharePoint ties back into the Microsoft 365 administration system which Keele University operates, so the systems can notify users of any issues. The data will then be securely transferred to the West Midlands Secure Data Environment (WMSDE).

Once the data is transferred to the West Midlands Secure Data Environment based at University Hospitals Birmingham (NHS-based) the personal data at Keele will be deleted. Data within the West Midlands Secure Data Environment will be held in a secure junction zone, where only the Data Custodian (DC) and assigned personnel will have access to the data. No data will be shared outside the environment area and processes will be put in place to ensure that only relevant individuals will have access to personal data and that this is kept separately to the anonymised research database.

A general principle of the data being made accessible should be necessary and proportionate to the purposes required i.e., there is data minimisation. Anyone requesting access to the dataset, must justify the inclusion of each data field.

Direct identifiers

The Database protocol directs the processing of data which contains direct identifiers in order to render the data pseudonymised or anonymised prior to providing access to approved researchers for an approved purpose.

Indirect identifiers

Where the database does contain NHS number, postcode, date of birth, age, gender and diagnoses including pain site and diseases etc risk will be managed proportionately when providing access to any data that might, alone or through combination, lead to the identification of an individual.

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

Data Controllers will follow a use-based access control for the purpose of audit, QA checks and reports. The SDE environment will be installed on the Microsoft Azure platform, and will have the backup and recovery tools provided by Microsoft to protect data and installations. A comprehensive audit trail is in place for the system, and the datasets record these footprints:

- who has accessed the system and when
- when data items are created and who by
- when data items are edited and who by
- when datasets have been browsed, or information (with correct permissions) has been accessed and downloaded;

downloads are highly controlled and limited to destinations that are considered to be 'safe settings'.

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

Data Handling and Record Keeping

The database will be held in a secure WMSDE owned environment. As with other health data research activities managed by the SDE, this may be held 'on premises' or on cloud or in combination, reflecting the most appropriate platform for the data use in relation to efficiency, function and cost. Regardless of location, the same standards of data security will be required, and will comply with the following standard from the International Standards Organisation (ISO): ISO 27001: An international specification for information security management. The corresponding code of practice is ISO/IEC 27002. Cloud provision will be in accordance with the UK Cyber Cloud Principles which are outlined here: <https://www.ncsc.gov.uk/collection/cloud-security/implementing-the-cloud-security-principles>. Additionally it will comply with the following standards from the ISO: ISO 27017: Code of practice for information security controls based on ISO/IEC 27002 for cloud services. ISO 27018: Code of practice for protection of Personally Identifiable Information (PII) in public clouds acting as PII processors. The database platform will comply with the Department of Health Information Governance policies and standards for secure processing of patient healthcare data, as set out in the Information Governance Toolkit of the Health and Social Care Information Centre.

Use of data by the Research Database team or other researchers

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?

Musculoskeletal primary and community care research will be undertaken using this observational dataset by established academic teams within the UK. Benchmarking methods will be tested and key quality indicators defined to help develop a learning health system. The data may also be used to support NHS policy development.

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 teams consists of a CI with experience of leading MSK studies, a PI who is currently working as a Consultant Physiotherapist within the NHS and a Professor of Biostatistics who will act as Data Custodian. Additionally trial management is provided by Keele Clinical Trials Unit, an established and accredited CTU.

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.

Data Custodian - Professor Kelvin Jordon will oversee decisions on access to the data. The Keele University MSK research database team will be the data controller and will review applications from researchers to access the MSK database data for research purposes. Any subsequent requests for access to the anonymised data from anyone outside of the study team (e.g.collaboration, joint publication, data sharing requests from publishers) will follow Keele/WMSDE Standard Operating Procedure for data sharing.

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?

Process of pseudonymisation

This is a technical process of replacing personal identifiers in a dataset with other values (pseudonyms), from which the identities of individuals cannot be intrinsically inferred. The WMSDE maintains an association between the original value and replacement value. Examples of this process are replacing an NHS number with another allocated random number curated within the SDE. For the Database the allocated number will be generated using a specific encrypted 'salt code' added to this, before the combined data is then encrypted using a SHA2-256 hashing algorithm. Some internal applicants may require access to pseudonymised data in order to support research or quality improvement which requires sequential, longitudinal data reports

Process of anonymisation

Most applicants will only access anonymised data, and will do so within the WMSDE. On receipt of an approved request, the requested data will be extracted from the pseudonymised Research Database and anonymised. The anonymised data will undergo a QC check for quality and accuracy, and to ensure adequate anonymisation of all data fields. Anonymisation means that information that identifies an individual patient has been removed. The intent of anonymisation is to turn data into a form which does not directly identify individuals, and where re-identification is not likely to take place. This is a technical process of replacing personal identifiers in a dataset with other values, from which the identities of individuals cannot be obtained. The SDE does not maintain any association between the original value and the replacement value. Examples of this process are replacing an NHS number with another allocated random number.

Data Quality Management Data will be cleansed and matched on the UHB servers, as per usual data controllership activities. Data cleansing is the process of detecting and correcting (or removing) corrupt or duplicate or inaccurate records from a record set, table or database. It refers to identifying incomplete, incorrect, inaccurate or irrelevant parts of the data, and then replacing, modifying, or deleting the dirty or coarse data. Secondly, the data will be normalised. This is the systematic process to ensure the data structure is suitable or serves the purpose. Here, the undesirable characteristics of the data are eliminated or updated to improve the consistency and the quality. The goal of this process is to reduce redundancy, inaccuracy, and to organise the data. The data will only be pseudonymised when these processes are complete.

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.

The MSK Research Database will have a group to review applications of the requests from researchers to use data. This group will review each application and whether it is suitable which will determine whether they are then granted access. No data will leave the environment when sharing.

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.)

We do not anticipate any immediate benefits for patients, although some people find it rewarding to take part in health research, as we do not expect the research could produce findings of direct clinical significance for individuals.

Participation may help to improve services and develop policy for people with common MSK conditions.

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.
The data will not provide direct clinical significance for individuals.

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?

Datasets created on demand will be timestamped and made available under contractual arrangements for prespecified time periods in line with the nature of the projects.

Most requests, reviews and release documentation will be stored for 5 years to allow audit and scrutiny of decision

making procedures. Data on any deviations/breaches may be kept indefinitely to allow for assessments of corrective and preventative actions. For certain research records, there will have to be a regard to the Public Records Act 1958 which requires organisations to select records for permanent preservation. Records for preservation must be selected in accordance with the guidance contained in the Records Management Code of Practice 2021.

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 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.

The National MSK Audit team will provide services with a standardised consent statement that needs to be embedded within their own data collection processes in order to participate in the National Audit. This will enable participants completing provider-commissioned online patient surveys to be asked for their consent to use their data for the research database. This will include, retaining and analysing their survey responses, and accessing relevant information from their medical records held at their general practice/community MSK service (through a standardised pre-determined EHR data extraction search) and linking this to their survey responses.

Prior to seeking consent to include their data within the research database, all potential participants will have had the opportunity to access our standardised data privacy and information statements about how the data will be used.

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?

Records will only be exported to the National research database if the patient has provided the relevant consent, has an appropriate MSK health condition, and is over the age of 18 years. The process of identification of records to be uploaded will be agreed and checked by both the National Audit team and individuals within participating providers responsible for local governance sign-off (e.g. data sharing agreements in place). There will be a named lead for the National MSK Audit who is a member of the direct healthcare team at each participating service who has the authority to review patient records within that organisation.

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?

Every 6 months the National Audit team will send a notification to invite participating services to upload data to the research database. An individual from each organisation who is a member of the direct healthcare team and a data controller, will review the file prior to export to ensure that all patients included are eligible (e.g. have consented, have an appropriate MSK condition, and are over the age of 18 years), or ensure their data processor has the approval to do this on their behalf.

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

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?

This will be in the course of healthcare provision. Patient outcome and experience data will be collected using the participating services' online patient surveys that have been standardised to meet the National MSK Audit requirements (e.g. minimum dataset aligned to national policy on routine data collection, and consent statements).

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 children in Part B Section 7.

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.

Consent will be obtained from patients using a standardised consent statement embedded into all participating service data collection procedures. The statements ask if the patient understands the information about how the data will be used, that participation is voluntary and they can withdraw at any time, their personal details will not be shared beyond the data controllers and approved data processors, agree for their de-identified information to be used for research purposes, consent to their data being matched to other national health databases, and for their information to be held by Keele University for the purposes of the research database only. A written information sheet and privacy statement will be made available to services to embed into their data collection processes to allow for an informed decision to be made by patients. Only patients that provide consent for data to be used for research purposes and have data shared to the MSK research database.

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)

This will be the responsibility of participating MSK services that provide data to the MSK research database. The central database team will encourage participating services to ensure inclusive policies that promote alternative language options for patient self-report questionnaires where possible. For example, we are looking to include Welsh providers so will work with providers and the national Welsh team for MSK to meet language requirements for their population.

30-2. What arrangements will you make to comply with the principles of the Welsh Language Act in the provision of information to data subjects in Wales?

As above.

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?

It is recognised that patients may choose to opt-out after their data has entered the WMSDE. Within the WMSDE personal identifiers such as NHS numbers will be held in a separate database that is not accessible for research analysis. Within this personal database patient's will be given a Unique Identifier and this unique identifier alone will be available in the anonymised dataset. This is to enable the re-identification of patients in the eventuality that they withdraw their consent.

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: The national musculoskeletal community and primary care audit and research database

Establishment responsible for management of the database:

Organisation	Keele University
Address	David Weatherall Building Keele University Stoke-on-Trent
Postcode	ST5 5BG
Telephone	01782733900
Fax	

Data to be stored and data collection arrangements (maximum 200 words): Participating MSK services will register to be part of the national MSK audit. Using a standard process, each service will need to ensure it has the appropriate process, permissions, and agreements in place to take part. This will include each MSK service having their existing data collection process audited, to ensure they are using the National MSK Audit's standardised dataset (including patient reported outcome and experience data collected via patient survey and coded health record data providing information on management/treatments), and, consent, data privacy and participant information statements about why and how the data is being used. In addition, a set of dummy data from each service will be sent for checking by the central research database team.

Every 6 months, participating services will be asked to upload their routinely collected MSK data and to complete a form with up-to-date information about their organisation (e.g. waiting times and staffing levels). The data will initially be reviewed by the central Keele team to check the quality of the data, ensure patient consent is evident, and that the data is in the right format. Once checked, the data will be transferred to the NHS Secure Data Environment.

Research programme/community supported by the database (maximum 200 words): Publicly available information about the quality and consistency of primary care treatment of musculoskeletal (MSK) conditions including back, neck, joint, and muscle pain problems, is close to becoming a reality, with this database due to start collecting data in June 2023. This national database will collect information from Providers of NHS MSK services across the UK, including data from physiotherapists working in community and primary care as well as their patients via online questionnaires. First Contact Physiotherapists (FCPs) are a rapidly expanding new role in GP practices, designed to help reduce GP's heavy workload and waiting times by assessing and managing MSK conditions instead of patients needing to see a GP.

The target population for the national MSK audit and research database is, adults aged 18+ years consulting with an MSK pain condition from a participating community MSK service or a GP practice/FCP service. The project aims to involve a minimum of 10 MSK community services (outpatient physiotherapy) and a minimum of 10 primary care MSK services (GP Practices/FCP Services) within the first year from across the UK

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.

Data collection centre	Local collaborator
University Hospital Sussex	
Healthshare Limited	
Doncaster and Bassetlaw Teaching Hospitals	
Northumbria Healthcare NHS Foundation Trust	
Mid and South Essex NHS Foundation Trust	
Provide	
Connect Health	
Allied Health Professionals Suffolk CIC	
University Hospitals of Leicester NHS Trust/ LLR ICS	
ESNEFT (East Suffolk and North East Essex Foundation Trust)	
East Coast Community Healthcare	
Dudley Group Foundation Trust	
Solent NHS Trust	
Midlands Foundation Partnership Trust	
Southport & Ormskirk Hospitals NHS Trust	
Sandwell and West Birmingham NHS Trust	
The Queen Elizabeth Hospital King's Lynn	
Mersey Care NHS Foundation Trust	
University Hospital Coventry & Warwickshire NHS Trust	
Cambridge University Hospital	
George Eliot Hospital	
Circle Integrated Care	
North Tees and Hartlepool NHS Foundation Trust	
King's College Hospital NHS Foundation Trust	
Derbyshire Community Health Services NHS Foundation Trust	
Sutton Health and Care	
Cardiff and Vale UHB	
University Hospitals of Derby and Burton	
Northern Care Alliance NHS FT Rochdale Care Organisation	
NHS Ayrshire and Arran	
Hampshire Hospitals NHS Trust	

Part D: Declarations**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 Jonathan Hill on 03/05/2023 16:35.

Job Title/Post:

Organisation:

Email:

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 Prof Danielle van der Windt on 03/05/2023 10:17.

Job Title/Post: Professor of Primary Care Epidemiology

Organisation: Keele University

Email: d.van.der.windt@keele.ac.uk

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