

South West - Central Bristol Research Ethics Committee

2 Redman Place
Straford
LONDON
E20 1JQ

08 June 2023

Prof Jonathan Hill
Keele University
David Weatherall Building School of Medicine
Keele University
Stoke-on-Trent
ST5 5BG

Dear Prof Hill

Title of the Database: **The national musculoskeletal audit and research database (Version 1.0)**
REC reference: **23/SW/0059**
IRAS project ID: **324885**

The Research Ethics Committee reviewed the above application at the meeting held on 26 May 2023. Thank you for attending to discuss the application.

We will publish your research summary for the above study on the research summaries section of our website, together with your contact details, no earlier than three months from the date of this favourable opinion letter. Should you wish to provide a substitute contact point, make a request to defer, or require further information, please visit:

<https://www.hra.nhs.uk/planning-and-improving-research/application-summaries/research-summaries/>

Ethical opinion

The members of the Committee present gave a favourable ethical opinion of the above research database on the basis described in the application form and supporting documentation.

Recommendations

The Committee made the following recommendations:

| Number | Recommendations |
|---------------|---|
| 1 | <i>The Committee recommended that the consent form is split into two separate documents, so participants will have the opportunity to consent or not to consent to the optional statements.</i> |

| | |
|---|--|
| 2 | <i>The Committee recommended that all NHS Trusts involved in the project should standardise their processes for translating all documents that participants will need to access into different languages, including but not limited to participant information sheets, consent forms and questionnaires.</i> |
|---|--|

Publication of Your Research Summary

We will publish your research summary for the above study on the research summaries section of our website, together with your contact details, no earlier than three months from the date of this favourable opinion letter.

Should you wish to provide a substitute contact point, make a request to defer, or require further information, please visit:

<https://www.hra.nhs.uk/planning-and-improving-research/application-summaries/research-summaries/>

N.B. If your study is related to COVID-19 we will aim to publish your research summary within 3 days rather than three months.

During this public health emergency, it is vital that everyone can promptly identify all relevant research related to COVID-19 that is taking place globally. If you haven't already done so, please register your study on a public registry as soon as possible and provide the HRA with the registration detail, which will be posted alongside other information relating to your project. We are also asking sponsors not to request deferral of publication of research summary for any projects relating to COVID-19. In addition, to facilitate finding and extracting studies related to COVID-19 from public databases, please enter the WHO official acronym for the coronavirus disease (COVID-19) in the full title of your study. Approved COVID-19 studies can be found at: <https://www.hra.nhs.uk/covid-19-research/approved-covid-19-research/>

Research governance

Under the UK Policy Framework for Health and Social Care Research, there is no requirement for NHS research permission for the establishment of research databases in the NHS. Applications to NHS R&D offices through IRAS are not required as all NHS organisations are expected to have included management review in the process of establishing the database.

Research permission is also not required by collaborators at data collection centres (DCCs) who provide data under the terms of a supply agreement between the organisation and the database. DCCs are not research sites for the purposes of the RGF.

Database managers are advised to provide R&D offices at all DCCs with a copy of the REC application for information, together with a copy of the favourable opinion letter when available. All DCCs should be listed in Part C of the REC application.

NHS researchers undertaking specific research projects using data supplied by a database must apply for permission to R&D offices at all organisations where the research is conducted, whether or not the database has ethical approval.

Assessment of site suitability is not a requirement for ethical review of research databases.

Duration of ethical opinion

The favourable opinion is given for a period of five years from the date of this letter provided that you comply with the standard conditions of ethical approval for Research Databases set out in the attached document. You are advised to study the conditions carefully. The opinion may be renewed for a further period of up to five years on receipt of a fresh application. It is suggested that the fresh application is made 3-6 months before the 5 years expires, to ensure continuous approval for the research database.

Approved documents

The documents reviewed and approved at the meeting were:

| <i>Document</i> | <i>Version</i> | <i>Date</i> |
|--|----------------|---------------|
| Covering letter on headed paper [Confirmation of Sponsorship] | N/A | 13 April 2023 |
| Other [Insurance] | N/A | 24 April 2023 |
| Other [CI Research CV] | N/A | 24 April 2023 |
| Other [CI GCP Certificate] | N/A | 24 April 2023 |
| Other [Privacy Statement] | 1.0 | 06 April 2023 |
| Other [Information for Services] | 1.0 | 06 April 2023 |
| Other [MSK Services Initial Questionnaire] | 1.0 | 06 April 2023 |
| Other [FCP Services Initial Questionnaire] | 1.0 | 06 April 2023 |
| Other [MSK Services 3 Month Questionnaire] | 1.0 | 06 April 2023 |
| Other [FCP Services 3 Month Questionnaire] | 1.0 | 06 April 2023 |
| Other [FCP Services Organisational Characteristics] | 1.0 | 06 April 2023 |
| Other [MSK Services Organisational Characteristics] | 1.0 | 06 April 2023 |
| Participant consent form [Consent Form] | 1.0 | 06 April 2023 |
| Participant information sheet (PIS) [Participant Information Sheet] | 1.0 | 06 April 2023 |
| Protocol for management of the database [Protocol] | 1.0 | 12 April 2023 |
| REC Application Form [RD_Form_10052023] | | 10 May 2023 |

Membership of the Committee

The members of the Ethics Committee who were present at the meeting are listed on the attached sheet.

Statement of compliance

The Committee is constituted in accordance with the Governance Arrangements for Research Ethics Committees and complies fully with the Standard Operating Procedures for Research Ethics Committees in the UK.

After ethical review: Reporting requirements

The attached standard conditions give detailed guidance on reporting requirements for research tissue banks with a favourable opinion, including:

- Notifying substantial amendments
- Submitting Annual Progress reports

The latest guidance on these topics can be found at <https://www.hra.nhs.uk/approvals-amendments/managing-your-approval/>.

User Feedback

The Health Research Authority is continually striving to provide a high quality service to all applicants and sponsors. You are invited to give your view of the service you have received and the application procedure. If you wish to make your views known please use the feedback form available on the HRA website:

<http://www.hra.nhs.uk/about-the-hra/governance/quality-assurance/>

HRA Learning

We are pleased to welcome researchers and research staff to our HRA Learning Events and online learning opportunities– see details at:

<https://www.hra.nhs.uk/planning-and-improving-research/learning/>

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| IRAS project ID: 324885 |
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| Please quote this number on all correspondence |
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Yours sincerely



Kamile Janusonyte

PP

Dr Julie Woodley

Chair

E-mail: centralbristol.rec@hra.nhs.uk

Enclosures: List of names and professions of members who were present at the meeting and those who submitted written comments

(RD) Conditions of Approval

[Research Database – Conditions of Approval](#)

Copy to: Prof Kelvin Jordan, Keele University

South West - Central Bristol Research Ethics Committee

Attendance at Committee meeting on 26 May 2023

Committee Members:

| <i>Name</i> | <i>Profession</i> | <i>Present</i> | <i>Notes</i> |
|------------------------|--|----------------|--------------|
| Christina Gale | Swine Product Manager | Yes | |
| Dr Catherine Alexander | Pharmacist | No | |
| Dr Adam Baker | Clinical Scientist | Yes | |
| Dr Chris Counsell | Head of Research Governance (Retired in 2019) | Yes | |
| Dr Stephen Daniels | Retired Research Director PET Centre | Yes | |
| Mrs Ewelina De Leon | Research Assistant | No | |
| Dr Sally Dowling | Lecturer | Yes | |
| Ms Stephanie Ellis | Retired Civil Servant | Yes | |
| Mr Andrew Harewood | Retired NHS Manager | No | |
| Dr Sarah Hissey | Senior Lecturer in Biomedical Science | Yes | |
| Mr Christian Homatas | Self Employed | Yes | |
| Dr Adrian Kendrick | Consultant Clinical Scientist | Yes | |
| Mr Christopher Queree | Boatswain | Yes | |
| Mandy Slater | Southwest Regional UTI Improvement Collaborative Lead NHS England AMS Research Pharmacist (NIHR/HEE Internship Award) RUH NHS Trust/University of Bath | Yes | |
| Dr Julie Woodley | Senior Lecturer/ Chair of Faculty Ethics Committee | Yes | |

Also in attendance:

| <i>Name</i> | <i>Position (or reason for attending)</i> |
|-------------------|---|
| Juliana Araujo | Approvals Specialist |
| Mrs Kyra Bains | Approvals Administrator |
| Kamile Janusonyte | Approvals Administrator |