



Health Research Authority

East Midlands - Derby Research Ethics Committee

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15 January 2024

Miss Sarah Mills
Imperial College London
Chelsea and Westminster Hospital
369 Fulham Road
SW10 9NH

Dear Miss Mills

Title of the Research Database:	mASCARA
REC reference:	24/EM/0002
IRAS project ID:	335443

Thank you for your letter of 12th January 2024, responding to the Committee's request for further information on the above research database and submitting revised documentation.

The further information has been considered on behalf of the Committee by the Chair and lead reviewer Esther Panek- Noble.

Confirmation of ethical opinion

On behalf of the Committee, I am pleased to confirm a favourable ethical opinion of the above research database on the basis described in the application form and supporting documentation as revised.

This application was for the renewal of a Research Database application. The previous REC Reference number for this application was **18/EM/0397 – IRAS ID: 294988**.

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/>

Duration of ethical opinion

The favourable opinion has been renewed for five years from the end of the previous five year period 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.

Research Database Renewals

The previous five year period ran from 16th January 2019 to 16th January 2024. This Research Database may be renewed for further periods of five years at a time by following the process described in the above paragraph.

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 [Cover Letter]		28 November 2023
Other [Information for Researchers]	V1.3	24 October 2023
Other [Netsolving GDPR Data Protection Policy]	V2.2	18 April 2018
Other [Netsolving Data Protection Policy]	V1.2	06 January 2022
Other [Sara Mills (Applicant)CV]	V1.00	23 November 2023
Other [Registration Form]	1.2	
Other [New Cover letter re.tracked changes]		20 December

		2023
Other [mASCARA Protocol- tracked changes]	V1.2	22 October 2023
Other [Registration Form-tracked changes]	V1.2	04 December 2023
Other [Information for Researchers- tracked changes]	V1.3	24 October 2023
Other [Cover letter after REC meeting]		12 January 2024
Other [Corrected APR]		18 January 2023
Other [Consent form- REC meeting changes]	V1.6	19 November 2023
Other [PIS- REC meeting changes]	V1.6	19 November 2023
Other [Privacy notice- REC meeting corrections]	V1.3	04 December 2023
Protocol for management of the database [mASCARA Protocol]	V1.2	22 October 2023
REC Application Form [RD_Form_01122023]		01 December 2023

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.

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 databases with a favourable opinion, including:

- Notifying substantial amendments
- Submitting Annual Progress reports

The HRA website also provides guidance on these topics, which is updated in the light of changes in reporting requirements or procedures.

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

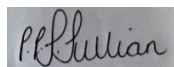
We are pleased to welcome researchers and research staff to our HRA Learning Events and online learning opportunities– see details at:

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

IRAS project ID: 335443

Please quote this number on all correspondence

Yours sincerely



Mrs Janet Mallett
Chair

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

Enclosures: (RD) Conditions of Approval

Copy to: Professor Paul Elliott Imperial College London