05 December 2023

Professor Laura Shallcross
University College London
Institute of Health Informatics
University College London
222 Euston Rd
NW1 2DA

Dear Professor Shallcross,

Title of the Research Database:	**VIVALDI SOCIAL CARE DATABASE**
REC reference:	**23/SW/0105**
IRAS project ID:	**330194**

Thank you for your letter of the 29/09/2023, 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.

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.

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 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:

Document	Version	Date
Covering letter on headed paper [Cover letter - REC]	1	16 August 2023
Covering letter on headed paper [Cover Letter]	1	29 September 2023
Other [Glossary]	1	18 July 2023
Other [Appendix 1: Inventory of engagement activities]	1	18 July 2023
Other [Appendix 2: Letter of Support Care Rights UK]	1	17 July 2023
Other [Appendix 3: DACHA NAPA Toolkit]		
Other [Appendix 4: VIVALDI Working Group ToR]		
Other [Appendix 4: VIVALDI Working Group Membership]		
Other [Appendix 5: Engagement Workstream ToR]		
Other [Appendix 6: Governance and Oversight Workstream ToR]		
Other [Chief Investigator CV]	1	15 August 2023
Other [Data Protection Registration]	1	31 July 2023
Other [Data Custodian Letter of Recommendation (CAG)]	1	14 August 2023

Other [Research CAG Pilot Application]	1	18 July 2023
Other [Information Leaflet for Relatives]	2	22 September 2023
Other [Information Leaflet for Residents]	2	22 September 2023
Other [Poster]	2	22 September 2023
Other [Animation Story Map]		02 October 2023
Other [Animation Script]	3	02 October 2023
Other [Animation illustration sample]		
Participant information sheet (PIS) [Detailed Information Sheet]	2	22 September 2023
Protocol for management of the database [Protocol]	1	16 August 2023
REC Application Form [RD_Form_16082023]		16 August 2023
Summary of research programme(s) [Data Flow Diagram]	1	18 July 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:
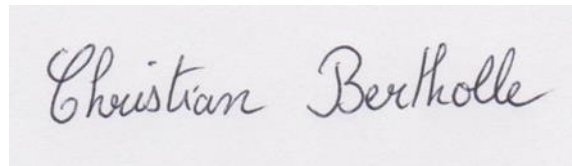https://www.hra.nhs.uk/planning-and-improving-research/learning/

IRAS project ID: 330194	**Please quote this number on all correspondence**

Yours sincerely

PP

Dr Kass Gibson
Chair

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

Enclosures: (RD) Conditions of Approval

Research Database – Conditions of Approval

Copy to: Professor Mark   Emberton University College London
                      Confidentiality Advise Team