NHS
Health Research Authority

2 Redman Place
Stratford
London
E20 1JQ

Tel: 020 7104 8100
Email: cag@hra.nhs.uk

20 November 2024

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

Dear Professor Shallcross,

Application title: VIVALDI Social Care
CAG reference: 23/CAG/0135

Thank you for submitting a **non-research** application under Regulation 5 of the Health Service (Control of Patient Information) Regulations 2002 ('section 251 support') to process confidential patient information without consent.

This application was considered at the Confidentiality Advisory Group (CAG) meeting held on 07 September 2023. This outcome should be read in conjunction with the provisional support outcome dated 21 September 2023, the minutes of the CAG meeting date 07 September 2023 and the sub-committee minutes of November 2023 (available within 2 weeks of month end).

Confidentiality Advisory Group advice and Secretary of State for Health and Social Care decision

The CAG agreed that the minimum criteria under the Regulations appeared to have been met, and therefore advised recommending support to the Secretary of State for Health and Social Care.

The Secretary of State for Health and Social Care, having considered the advice from the Confidentiality Advisory Group as set out in the minutes, has determined the following:

- The application is underlined conditionally supported, subject to compliance with the standard and specific conditions of support.

Please note that the legal basis to allow access to the specified confidential patient information without consent is now in effect. A summary of the scope of support is provided in Appendix A.

Support provides a lawful basis to allow the information to be processed by the relevant parties for the specified purposes without incurring a breach of the common law duty of confidence only. Applicants must ensure the activity remains fully compliant with all other relevant legislation.

Specific conditions of support

1. At annual review, provide an updated definition of 'surveillance' which describes the non-research purposes more clearly, and provide an update on all the non-research uses of the data undertaken so far, in terms of public benefit.

2. Increase the number of care home residents in further patient and public involvement undertaken over the next year and report these discussions to CAG at annual review.

3. Undertake further patient and public involvement and engagement with care home residents, around the feasibility of implementing a non-research opt out which is separate from a research opt out, and report these discussions to CAG at annual review.

4. Confirmation provided from the DSPT Team at NHS England to the CAG that the relevant Data Security and Protection Toolkit (DSPT) submission(s) has achieved the 'Standards Met' threshold. **Confirmed:**

   The NHS England **22/23** DSPT reviews for **NHS England & Arden and GEM Commissioning Support Unit** (AGEM CSU/DSCRO) were confirmed as 'Standards Met' on the NHS England DSPT Tracker (checked 20 November 2023)

   Due to the number of care providers and/or software vendor organisations involved, it is the responsibility of University College London, as controller, to ensure that processing organisations meet the minimum required standard in complying with DSPTs, and take remedial action if they become aware of any that fall below this, or where any concerns are raised about an organisation.

As the above conditions have been met, this letter provides confirmation of final support. I will arrange for the register of approved applications on the HRA website to be updated with this information.

Maintaining CAG support: Reporting requirements

Please note the following guidance on reporting requirements in order to maintain CAG support for the duration of the activity.

- **Annual review report**: It is your responsibility to submit an annual review report every 12 months for the entire duration that confidential patient information is being processed without consent. The next annual review should be provided no later than **20 November 2024** and preferably 4 weeks before this date. Further guidance and the annual review form is available on the IRAS website.
- **Notifying amendments to the scope of CAG support:** Guidance on submitting CAG amendments and the amendment form is available on the IRAS website.
- **Notifying the end of activity:** Guidance on notifying the end of activity and the end closure report form is available on the IRAS website.
- **Register of supported applications:** It is a statutory requirement to publish all supported applications to process confidential patient information without consent. Supported applications are published on the HRA website.

Approved documents

The final list of documents reviewed and approved are as follows.

Document	Version	Date
CAG application from (signed/authorised) [VIVALDI-Social-Care-non-research-CAG_2Aug2023]		
Covering letter on headed paper [cover_letter_CAG_v1_16aug2023]		
Other [PPI Appendix 1_Inventory of engagement activities v1 18072023]		
Other [VIVALDI glossary V1 180723]		
Other [Vivaldi Social Care Data Flow Diagram V1_30082023]	1	30 August 2023
Other [Vivaldi Social Care Data Flow Diagram V2_17102023]	2	17 October 2023
Patient Information Materials [CAG Poster V1 150823]	1	15 August 2023
Patient Information Materials [CAG_leaflet_relatives V1 180723]	1	18 July 2023
Patient Information Materials [CAG_leaflet_residents V1 180723]	1	18 July 2023
Patient Information Materials [VIVALDI-SOCIAL-CARE-detailed-information-sheet_V1 180723]	1	18 July 2023
Patient Information Materials [VIVALDI-SOCIAL-CARE-detailed-information-sheet_V2 220923]	2	22 September 2023
Patient Information Materials [CAG_leaflet_residents V2 220923]	2	22 September 2023
Patient Information Materials [CAG_leaflet_relatives V2 220923]	2	22 September 2023
Patient Information Materials [CAG Poster V2 220923_track_changes]	2	22 September 2023
Write recommendation from Caldicott Guardian (or equivalent) of applicant's organisation [Caldicott equivalent letter of recommendation - VIVALDI database]		

Please do not hesitate to contact me if you have any queries following this letter. I would be grateful if you could quote the above reference number in all future correspondence.

Yours sincerely

Caroline Watchurst
Confidentiality Advisor

On behalf of the Secretary of State for Health and Social Care

Email: cag@hra.nhs.uk

Included: List of members who considered the application
                                   Summary of scope of support

Confidentiality Advisory Group meeting attendance
07 September 2023

Members present:

Name	Capacity
Professor William Bernal	CAG Alternate Vice Chair
Ms Clare Sanderson	CAG Alternate Vice Chair
Dr Sandra Duggan	CAG Lay Member
Dr Ben Gibbison	CAG Expert Member
Mr Andrew Melville	CAG Lay Member
C. Marc Taylor	CAG Expert Member
Professor James Teo	CAG Expert Member

Also in attendance:

Name	Position (or reason for attending)
Mr William Lyse	HRA Approval Administrator
Ms Emma Marshall	HRA Confidentiality Specialist
Ms Caroline Watchurst	HRA Confidentiality Advisor
Dr Angelika Kristek	External Observer (Clinical Research Facilitator at Royal Berkshire NHS Foundation Trust, and a member of Dulwich REC)
Jane Oakley	Internal Observer (Head of Public Involvement at the HRA)
Zoë Fry OBE	Engagement lead for VIVALDI Social Care, & the *Executive Director for* The Outstanding Society CIC
Professor Laura Shallcross	Chief investigator
Dr Oliver Stirrup	Study statistician and senior post-doctoral research associate

Appendix A – Summary of Scope of Support

<u>Summary of application</u>

This application from University College London (with the Outstanding Society and Care England confirmed to be joint controllers), set out the non research purpose which aims to create a database including data on infections, hospital attendances, vaccinations, antibiotic prescriptions, and deaths in older adults who live in care homes. Applicants will create the database by collecting and linking data on residents in these homes. The aim is to collect data from at least 500 homes and up to 30,000 residents in England. This is a pilot project – if it is a success, the goal is to establish a long-term programme of research and surveillance for infection in care homes, informed by learning from this application. This non-research application will aid policymakers to prevent and reduce outbreaks, and to protect people who live and work in care homes from infections.

Every year care home residents experience infections and outbreaks, which reduce their physical and mental health and well-being and cause avoidable hospital admissions and deaths. Many of these infections could be avoided with better evidence on 'what works in care homes' and systems to keep track of and therefore stop infection.

The database will require confidential patient information to be collected from care homes and disclosed to Arden & GEM CSU, in order for NHS England to link to NHS and public health datasets, including records of vaccination, hospitalisation, and death. The database will then be effectively anonymised before it is shared with UKHSA. The effectively anonymous data collected will be used to measure and prevent infections in residents and stop them spreading. There is an associated research database study, which has been submitted to CAG separately – 23/CAG/0134.

A recommendation for class 4, 5 and 6 support was requested to cover access to the relevant unconsented activities as described in the application.

<u>Confidential patient information requested</u>

The following sets out a summary of the specified cohort, listed data sources and key identifiers. Where applicable, full datasets and data flows are provided in the application form and relevant supporting documentation as this letter represents only a summary of the full detail.

Cohort	The cohort will include approximately 15,000-30,000 residents from 500-1500 care homes for adults older than 65 years in England. The data will be collected prospectively between 01 October 2023 and 31 March 2025
Data sources	1. Participating care homes records 2. NHS England – Linked routine datasets: -COVID-19 / Influenza tests -NIMS vaccination data -APC / ECDS hospital attendances data -ONS mortality data -SGSS microbiology and virology results

	-Antimicrobial prescriptions -HPZone, care home level data on outbreaks
Identifiers required for linkage purposes	1. NHS number 2. Care home post code based on care home CQC-ID (only the first 3 characters) 3. National Commissioning Data Repository (NCDR) pseudo-identifier
Identifiers required for analysis purposes	1. Applicants are linking to mortality data but are only receiving date of death in MM/YY format. 2. Gender 3. Ethnicity 4. Age 5. Care home post code based on care home CQC-ID (only the first 3 characters). Therefore data will be pseudonymised (effectively anonymised) for analysis
Additional information	The pseudonymisation key will be held by NHS England. Data will be linked daily.