Confidentiality Advisory Group

Minutes of the meeting of the Confidentiality Advisory Group held on 07 September 2023 via video conference.

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 (Item 2.1 only)
Professor Laura Shallcross	Chief investigator (Item 2.1 only)
Dr Oliver Stirrup	Study statistician and senior post-doctoral research associate (Item 2.1 only)

1. APOLOGIES FOR ABSENCE

Apologies for absence were received from: Professor Lorna Fraser, Ms Rose Payne, Dr Harvey Marcovitch and Mr David Evans.

2. DECLARATIONS OF INTEREST

2.1	**23/CAG/0135** & **23/CAG/0131**	**VIVALDI Social Care Integrated Care Experience Survey (Phase One)**
	Conflict:	CAG Member Mr David Evans has a conflict of interest with all non-research applications, and therefore was not able to review these items, and did not attend the meeting, giving his apologies.

3. SUPPORT DECISIONS

Secretary of State for Health & Social Care Decisions

There were no applications requiring a decision by the Department of Health & Social Care senior civil servant on behalf of the Secretary of State for Health & Social Care in relation to the **13 July 2023** meeting.

Health Research Authority (HRA) Decisions

The Health Research Authority agreed with the advice provided by the CAG in relation to the **13 July 2023** meeting applications.

Minutes:

The minutes of the following meetings have been ratified and published on the website: **15 June & 13 July 2023 Full CAG**

4. CONSIDERATION ITEMS

There were no items for consideration.

5. NEW APPLICATIONS FOR CAG CONSIDERATION

5.1	23/CAG/0134	VIVALDI Social Care Database
	Chief Investigator:	Professor Laura Shallcross
	Sponsor:	University College London
	Application type:	Research Database
	Submission type:	New application

The Group reviewed the above application in line with the CAG considerations.

Applicants attended to discuss the application.

Prior to the meeting the applicants were informed that there were observers in attendance at the meeting. The applicants confirmed that they had no objection to the observers being present.

Summary of application

This application from University College London set out the purpose of medical research which aims to create a research database including data on infections, hospital attendances, vaccinations, antibiotic prescriptions, and deaths in older adults who live in care homes. Applicants will create the research 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.

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 research 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 the applicants at University College London. It will be stored in the UCL Data Safe Haven. The effectively anonymous data collected will be used to measure and prevent infections in residents and stop them spreading. There is an associated non-research surveillance study, which has been submitted to CAG separately – 23/CAG/0135.

The applicants anticipate the research database will be used for research on infectious diseases, outbreaks, and Antimicrobial Resistance (AMR), subject to

approval by the study Data Access Committee (DAC). Researchers will be required to access the data for analysis within the UCL Data safe haven. If this pilot is successful, applicants anticipate that the scope of the research database could be extended to support research on infectious and non-infectious diseases. The DAC will include representation from residents, families, care providers and policymakers.

Confidential information requested

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 (but will be for a maximum of 12 months at each care home)
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.

Main issues considered, discussed and outcomes.

The CAG noted that this activity fell within the definition of medical research and was therefore assured that the application described an appropriate medical purpose within the remit of the section 251 of the NHS Act 2006.

Having reviewed the application and considered the risks and benefits involved, the CAG was also assured that the proposed activity was in the public interest.

The CAG were content that consent was not a practicable alternative, as although the plan is for the direct care team to distribute information leaflets and posters to residents where it is possible, and relatives also, any further discussion and informed consent process would take up a large amount of staff time, especially with regards to seeking any relative opinion as this would depend on when certain relatives were visiting. This would be a substantially time consuming activity which the staff would not be able to do whilst performing their clinical/caring role, and the CAG accepted the justifications put forward by the applicant. Part of the justifications were with regards to a previous study with a similar set up where consent was actively sought by an individuals in the care home, and they were still only able to consent less than 50%. The need for complete case ascertainment is important.

The CAG highlighted several revisions to be made within the participant information leaflet. Firstly, was to amend the current description surrounding CAG having ‘approved’ the study, as the role of CAG is advisory, and research is approved by the HRA on advice from CAG. [Action 1a]

The CAG requested for further reference to the research database purpose within the participant leaflet. The CAG noted that the applicant had provided some draft wording adding in more detail about the research purpose, however they note that as further changes are requested to the notification materials, they are not able to state definitively that what was provided is sufficient for the final draft. [Action1b]

Furthermore, the CAG requested for a start date of data collection to be clearly stated within the leaflet. [Action 1c]

The CAG requested to see reference to how the study would feed back the results to residents and their relatives, and not just feed back to the care home, in the leaflets. [Action 1d]

The applicant was content with all requests made by the CAG.

The CAG requested for the National Data opt Out to be applied at the point of data extraction from care homes. [Action 2]

The applicant clarified that they were following up with the care home software providers to see if this was possible and will provide CAG with the outcome.

The CAG requested to view a breakdown of membership to the data access committee (DAC) as well as the terms of reference. These should evidence how the medical purpose and public interest for applications to use the data will be assessed. [Action 3]

The applicant was content with the request made by CAG.

The CAG queried whether all participant facing documents had been reviewed by the patient and public involvement and engagement (PPIE) group as some terminology had been deemed complex for the intended population.

The applicant clarified that each document had been reviewed by several different steering groups and PPIE groups throughout the last 18 months.

The CAG commended the applicants on their use of broad PPIE, however highlighted that it was mainly focussed on individuals who were not residents of the care home. The CAG understood the difficulties experienced whilst in a care home setting, however noted that there are many care home residents who are cognitively able to make decisions. The CAG requested for the inclusion of more residents into the patient and public involvement undertaken over the next year and reported to CAG at annual review. [Condition 1]

The CAG highlighted that within a previous Vivaldi application submission that staff were approached for participation, however it was not the case within this submission, and the Committee were interested in why not.

The applicant acknowledged this gap in their research, however stressed complications managing staff consent and opt-out. As this was a pilot study, the applicant highlighted many areas for improvement as well as a need to include staff participants, and therefore hoped to do so within the full study.

The CAG was satisfied with the applicant’s response.

The Committee queried the applicant with regards to how representative of the whole population the research would be, by asking for clarity regarding the proportion of care homes included.

The applicants confirmed that there are around 11,000 care homes in the UK, and therefore this application would cover around 5-15% of homes. The applicant acknowledges that this I not yet full coverage, as this is a pilot application where the applicant plans to hone the methodology before including all homes.

The CAG was satisfied with the applicant's response.

<u>Confidentiality Advisory Group advice:</u> Provisionally supported

The CAG was unable to recommend support to the Health Research Authority for the application based on the information and documentation received so far. The CAG requested the following information before confirming its final recommendation:

Number	Action required	Response from the applicant
1.	Please revise the notification materials: a. Amend the current description surrounding CAG having 'approved' the study, as the role of CAG is advisory, and research is approved by the Health Research Authority on advice from CAG. b. Provide further detail with regards to the research database purpose. c. Clarify a start date for data collection on the notification materials. d. Please provide reference to feeding back the results to residents and relatives, as well as the care homes.	
2.	Confirm whether the National Data Opt Out can be applied at the point of data extraction from care homes.	
3.	Please provide a breakdown of membership to the data access committee (DAC) as well as the terms of reference. These should evidence how the medical purpose and public interest for applications to use the	

	data will be assessed.	
4.	Support cannot be issued until a Favourable opinion from a Research Ethics Committee is in place.	

The CAG also set out the following provisional specific conditions of support in addition to the standard conditions of support.

Number	Condition	Response from the applicant
1.	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.	

The Group delegated authority to confirm its final opinion on the application to the Chair and reviewers.

5.2	23/CAG/0135	VIVALDI Social Care
	Contact:	Professor Laura Shallcross
	Data controller:	University College London
	Application type:	Non-research
	Submission type:	New application

The Group reviewed the above application in line with the CAG considerations.

Applicants attended to discuss the application.

Prior to the meeting the applicants were informed that there were observers in attendance at the meeting. The applicants confirmed that they had no objection to the observers being present.

Summary of application

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.

Confidential information requested

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.

Main issues considered, discussed and outcomes

The CAG noted that this activity fell within the definition of the management of health and social care services and was therefore assured that the application described an appropriate medical purpose within the remit of the section 251 of the NHS Act 2006.

Having reviewed the application and considered the risks and benefits involved, the CAG was also assured that the proposed activity was in the public interest generally, however requested further clarification with regards to the non-research purposes.

With regards to the non-research scope of support, the Members commented that the surveillance purposes described were relatively general and not well defined. The CAG therefore sought clarification regarding the applicants intended use of surveillance data, with regards to the intended public interest/benefits of this non-research application. Furthermore, the CAG noted the term surveillance could make participants uncomfortable, and queried if the applicant explain the activity with any better descriptive terminology.

The applicant clarified that their objective was to be able to put a framework in place to effectively measure infection rates in care homes, with the eventual purpose of protecting individual residents, as there is currently no central record of this. It was noted that historically there has been some resistance in place from care homes with regards to giving data to a central place, in case it is used for performance management, but noted that this was absolutely not the intention of this application. For this reason, the applicant stressed that they plan to work slowly and carefully on the creation of this application. The data collected is not intended for use by the CQC. The non-research purposes of the data collection are intended to be fed back to care home providers, to policy makers and commissioners, in order to learn from care homes with positive outcomes, in order to improve care and implement best practice via improved policy.

The applicant clarified that as this is a pilot, they intend to learn along the way the best way of actioning the above described purposes, by gradually working with residents and relatives encouraging them to provide feedback and queries to help positively influence policy change, by advising the applicants on

questions that they would like to be answered, using the collected data. The applicant agreed with the CAG regarding the terminology ‘surveillance purposes’ and stated that they do try to use the word measuring instead on public facing documents.

The CAG accepted that the applicant needed some time as part of the pilot to investigate the public benefit of the non-research purposes, and therefore requested that the applicant provide an updated definition of ‘surveillance’ which describes the non-research purposes more clearly, and to provide an update on all the non-research uses of the data undertaken so far, in terms of public benefit (at the point of annual review). [Condition 1]

The CAG were content that consent was not a practicable alternative, as although the plan is for the direct care team to distribute information leaflets and posters to residents where it is possible, and relatives also, any further discussion and informed consent process would take up a large amount of staff time, especially with regards to seeking any relative opinion as this would depend on when certain relatives were visiting. This would be a substantially time consuming activity which the staff would not be able to do whilst performing their clinical/caring role, and the CAG accepted the justifications put forward by the applicant. Part of the justifications were with regards to a previous study with a similar set up where consent was actively sought by an individual in each care home, and they were still only able to consent less than 50%. The need for complete case ascertainment is important.

The CAG highlighted several revisions to be made within the participant information leaflet. The CAG requested the applicant amend the current description surrounding CAG having ‘approved’ the study, as the role of CAG is advisory and non-research is approved by the Secretary of State for Health and Social Care, on advice from CAG. As these notifications will be used for both research and non research, both the HRA and the SofS decision makers should be included on the notifications. [Action1a]

The CAG requested for further reference to the non-research purposes within the participant leaflet. [Action1b]

Furthermore, the CAG requested for a start date of data collection to be clearly stated within the leaflet. [Action 1c]

The CAG requested to see reference to how the study would feed back the results to residents and their relatives, and not just feed back to the care home, in the leaflets. [Action 1d]

The applicant was content with all requests made by the CAG.

The CAG requested for the National Data Opt Out to be applied at the point of data extraction from care homes. [Action 2]

The applicant clarified that they were following up with the care home software providers to see if this was possible and will provide CAG with the outcome.

The CAG queried whether all participant facing documents had been reviewed by the patient and public involvement and engagement (PPIE) group as some terminology had been deemed complex for the intended population.

The applicant clarified that each document had been reviewed by several different steering groups and PPIE groups throughout the last 18 months.

The CAG commended the applicants on their use of broad PPIE, however highlighted that it was mainly focussed on individuals who were not residents of the care home. The CAG understood the explanations provided by the applicant in the application, of difficulties experienced whilst undertaking PPIE in a care home setting, due to residents with hearing loss and cognitive impairment. However members noted that there are many care home residents who are cognitively able to make decisions. The CAG therefore requested for the inclusion of more residents into the patient and public involvement undertaken over the next year and actions taken to be reported to CAG at annual review. [Condition 2]

The CAG highlighted that within a previous Vivaldi application submission that staff were approached for participation, however it was not the case within this submission, and the Committee were interested in why not.

The applicant acknowledged this gap in their application, however stressed complications managing staff consent and opt-out. As this was a pilot study, the applicant highlighted many areas for improvement as well as a need to include staff participants, and therefore hoped to do so within the full study.

The CAG was satisfied with the applicant’s response.

The Committee queried the applicant with regards to how representative of the whole population the research would be, by asking for clarity regarding the proportion of care homes included.

The applicants confirmed that there are around 11,000 care homes in the UK, and therefore this application would cover around 5-15% of homes. The applicant acknowledges that this is not yet full coverage, as this is a pilot application where the applicant plans to hone the methodology before including all homes.

The CAG was satisfied with the applicant's response.

With regards to an application specific opt out, the CAG noted there is an opt out available which opts the individual out of both the research and the non-research activities. The CAG queried the applicant on whether they had given any thoughts to creating a specific non-research opt out, separate from the opt out for research.

The applicant stated that they were trying to keep things as simple as possible, and some of the notifications are already quite complex. They stated this would likely be hard to operationalise, but they could think of some care homes where it might be feasible. In general it would probably be quite complex to separate it out.

The CAG note the applicants responses, and therefore felt that the best way to resolve this was for the applicant to undertake further patient and public involvement around this specific point, with care home residents, and explore if it was feasible to have separated out research vs non research opt outs. It is best to explore this as part of the pilot. The CAG requested for the applicant to report their discussion at the next CAG annual review. [Condition 3]

The applicant stated that they were happy to investigate this with their PPIE group. The applicant specified that the care home population was complex to work with and by incorporating two separate opt-outs, it could cause confusion. However, the applicant was content to provide an update within the next annual review.

There are some outstanding questions from the non-research application form with regards to confirming the physical data security arrangements of the NHS England Foundry. It is noted that the CAG do not wish to know the exact physical location of this data, but rather the security controls that physically protect and control access to the data. These are standard queries and a response should be given prior to 's251' support being provided [Action 3].

<u>Confidentiality Advisory Group advice:</u> Provisionally supported

The CAG was unable to recommend support to the Secretary of State for Health and Social Care for the application based on the information and documentation received so far. The CAG requested the following information before confirming its final recommendation:

Number	Action required	Response from the

		applicant
1.	Please revise the notification materials: a. Amend the current description surrounding CAG having 'approved' the study, as the role of CAG is advisory, and research is approved by the Secretary of State for Health and Social care on advice from CAG. b. Provide further detail with regards to the non-research purposes. c. Clarify a start date for data collection on the notification materials. d. Please provide reference to feeding back the results to residents and relatives, as well as the care homes.	
2.	Confirm whether the National Data Opt Out can be applied at the point of data extraction from care homes.	
3.	Please provide updated responses to the physical data security questions in the CAG application form.	

The CAG also set out the following provisional specific conditions of support in addition to the standard conditions of support. The CAG requested for the applicant to report their conditions at the next CAG annual review.

Number	**Condition**	**Response from the applicant**
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.	

The Group delegated authority to confirm its final opinion on the application to the Chair and reviewers.

5.3	**23/CAG/0131**	Integrated Care Experience Survey (Phase One)
	Contact:	Terunnum Shakeel
	Data controller:	NHS England
	Application type:	Non-research
	Submission type:	New application

The Group reviewed the above application in line with the CAG considerations.

Summary of application

This non-research application submitted by Ipsos UK on behalf of NHS England, sets out the purpose of conducting The Integrated Care Experience Survey (ICES). The purpose of this survey is to allow ICBs to understand how well integrated care is working for people with multiple and complex needs and their informal carers. The survey data will be used to understand how well integrated care is being delivered and to help inform improvements in service delivery. This information will be used to inform the NHS Oversight Framework, Care Quality Commission assessment of ICSs, and evaluations of ICSs by both NHS England and the Department of Health and Social Care.

The survey sample will be compiled by each participating ICB (by their own data processor) from GP Practice data using a set specification. Eight ICBs are expected to participate in Phase One. A sample of up to 5,000 people per ICB will be invited to participate in the survey. The survey sample data including confidential patient information, will be transferred to Ipsos UK, which requires ‘s251’ support. Ipsos UK will generate a unique survey identification code for each potential participant and conduct the deceased service users check. Confidential patient information will also be disclosed from Ipsos UK to Formara and Text local, for the purposes of Formara sending postal questionnaires and survey invitation letters, and Text Local sending SMS. Ahead of each mail out, those who have already responded will be removed from the sample file and deceased checks will be repeated.

The survey will follow a similar mixed method approach as other surveys also carried out by Ipsos UK. The contacts will be as follows;

Contact	Type	Content of contact	Days from first mailing
1	Postal	Invitation letter inviting the patient to take part online	1
1.1	SMS	SMS reminder (if phone number available), 3 days after mailing 1	4
2	Postal	Reminder letter	14
2.1	SMS	SMS reminder (if phone number available), 3 days after mailing 2	17
3	Postal	Reminder letter, Paper questionnaire, Freepost return envelope	28
3.1	SMS	SMS reminder (if phone number available), 3 days after mailing 4	31

Confidential information requested

Cohort	Approximately 40,000 patients with clinically complex needs identified though GP records based on their electronic Frailty Index score (eFI)
Data sources	1. GP medical records from 8 participating ICBs: a. Bristol, North Somerset and South Gloucestershire ICB b. Derby and Derbyshire ICB c. North East and North Cumbria ICB d. Devon ICB e. Lancashire and South Cumbria ICB f. Norfolk and Waveney ICB g. South West London ICB h. Sussex ICB
Identifiers required for purposes of identifying the cohort and sending invitation to consent	**Identifiers for sample checking:** 1. Date of birth, 2. Gender, 3. Ethnic group, 4. NHS number, 5. Postcode, 6. GP practice code, 7. ICS code, 8. eFI score, 9. GP practice registration date **Identifiers required for conducting deceased checks:** 1. Name (full),

	2. Postcode, 3. Date of birth, 4. NHS number, 5. Gender **Identifiers required for sending invitation letters/surveys and SMS reminders:** 1. Title, 2. Name (full), 3. Full Address, 4. Postcode, 5. Mobile numbers (where recorded), 6. ICS code
Identifiers required for analysis purposes (disclosed to IPSOS UK prior to implied consent in place)	**Analysis will be undertaken with implied consent, however the following data items are disclosed to IPSOS UK prior to consent is received;** 1. Postcode, 2. Date of birth, 3. Ethnic Group, 4. GP Practice code, 5. ICS code, 6. eFI score, 7. GP practice registration date

Main issues considered, discussed and outcomes

The CAG noted that this activity fell within the definition of the management of health and social care services and was therefore assured that the application described an appropriate medical purpose within the remit of section 251 of the NHS Act 2006.

The CAG queried the public benefit of this study, concerned that the questionnaire was too generic and broad and would not yield specific and/or meaningful information. An example was question 3 on the 'Peoples Questionnaire' which stated, 'Thinking about the last six months… Overall, how would you rate your care?' If a participant had a very good occupational therapist, but a very poor GP experience, they would probably overall rate their care somewhere in the middle, but this would not provide responses that would be able to make clear inferences about care and initiate any change to the specific services needed. A simple way to improve this without extensive questionnaire revision would be prompting the participant about the specific services their individual feedback relates to. The CAG will not request any changes to the content of the questionnaire at this time, however in the first instance, the applicant is requested to provide to CAG further information which shows how the questions used would yield data that would result in patient benefit, providing specific examples, in order to evidence the public interest in the breach of confidentiality. [Action 1]

The content of the questionnaire was discussed with 18 people living with complex health and care needs and 12 people with caring responsibilities for a person with complex health and care needs. However, from the evidence provided by the applicant, the Members were not clear if the applicant had specifically discussed the use of confidential patient information without consent with patients. The CAG therefore requested additional patient and public involvement and engagement (PPIE) focussing specifically on the use of confidential patient information without consent. [Action 2]

Members noted that CAG has previously recommended support for surveys that have utilised both postal and SMS contacts to encourage participation. They noted that a text 3 days after each mailing could be too soon, as the text could arrive before the letter. The Committee requested a justification for the volume and timing of postal and SMS contacts, and reassurance that sending 3 invitation letters and 3 SMS messages in quick succession was not too intrusive. The CAG suggested that evidence of whether there was appropriate justification might be gained through discussion with the PPIE group, feeding back their comments for CAG to review. [Action 3]

The CAG requested the applicant update the initial contact letter, reassuring participants what data additional to demographic information was going to be shared with the data processors, explaining the data items to be used and the flow more clearly. [Action 4a]

The role of CAG and the legal basis under common law which allowed the patient to be identified, and why and how an invitation letter was sent to them should be explained. [Action 4b]

Although the CAG noted that patient information regarding being contacted about future research is retained with consent, and therefore outside of CAG remit, the Members noted that it is stated that this data will be kept for 20 years, or longer; '*if you agree, we will keep your personal details for up to 20 years and then decide whether to keep them for longer.'*

The CAG queried whether it was appropriate to state '*and then decide whether to keep them for longer'* as this was uncertainty could discourage participation. The applicant is to consider whether this statement should be removed from the notification, and data deleted after 20 years (or less). [Action 5]

<u>Confidentiality Advisory Group advice:</u> Provisionally supported

The CAG was unable to recommend support to the Secretary of State for Health and Social Care for the application based on the information and documentation received so far. The CAG requested the following information before confirming its final recommendation:

Number	Action required	Response from the applicant
1.	Please provide to CAG further information which shows how the questionnaire would yield data that would result in patient benefit, providing specific examples, in order to evidence the public interest in the breach of confidentiality.	
2.	Please undertake further patient and public involvement and engagement, specifically focussing on the use of confidential patient information without consent.	
3.	Please provide justification regarding the amount of contacts, and the speed of the SMS contact, potentially discussing with patient and public involvement representatives regarding if sending 3 invitation letters and 3 SMS messages is too intrusive.	
4.	Please amend the initial contact letter; a) explaining the data items used and the flow more clearly b) clearly explain the role of CAG and the legal basis which allowed the patient to be identified, and why and how they are receiving a letter.	
5.	Please consider whether the phrase; '*and then decide whether to keep them for longer*' should be removed from the notification, and data deleted after 20 years (or less).	

The Group delegated authority to confirm its final opinion on the application to the Chair and reviewers.

6. ANY OTHER BUSINESS

Marc Taylor requested an insight and overview into the CAG pilot scheme. The CAT stated that this would be explained within the next office report.

The Chair thanked the members and closed the meeting.

Professor William Bernal and Ms Clare Sanderson, CAG alternate Vice-Chairs	*19 September 2023*
…….	……..
Signed – Chair	*Date*
Ms Caroline Watchurst, HRA Confidentiality Advisor	*12 September 2023*
…….	……..
Signed	*Date*