Confidentiality Advisory Group

Minutes of the meeting of the Confidentiality Advisory Group held on 18 January 2024 via video conference.

Present:

Name	Capacity
Dr Tony Calland, MBE	CAG Chair
Dr Patrick Coyle	CAG Vice Chair
Mr Thomas Boby	CAG Member (Expert)
Dr Malcolm Booth	CAG Member (Expert)
Dr Sandra Duggan	CAG Member (Lay) (did not attend for item 4e)
Mr David Evans	CAG Member (Expert) (did not attend for items 4d, 4c, 4e)
Dr Ben Gibbison	CAG Member (Expert)
Mr Andrew Melville	CAG Member (Lay)
Mrs Sarah Palmer-Edwards	CAG Member (Expert)
Mr Umar Sabat	CAG Member (Expert)

Also in attendance:

Name	Position (or reason for attending)
Mr William Lyse	HRA Approval Administrator
Ms Emma Marshall	HRA Confidentiality Specialist
Dr Paul Mills	Confidentiality Advice Service Manager
Mr Dayheem Sedighi	HRA Approval Administrator
Ms Caroline Watchurst	HRA Confidentiality Advisor

George Ritchie	Observer - Independent Member - HRA Audit & Risk Committee
Karen Eade	Observer - HRA Research Regulation Specialist (left after item 4c)
Kat Evans	Observer - HRA Senior Public Involvement Officer
Matthew Sanderson	Observer - HRA Research Regulation Specialist (left after item 4c)
Emily Hughes	Observer - HRA Research Regulation Specialist (left after item 4c)
Claire Edgeworth	Observer - Head of Strategic Information Governance, NECS/NHS England – (present for item 4d and 4e only)
Dr Nicholas Conway	Chief Investigator (Item 4a only)
Scott Cunningham	Chief Technical Officer from MyWay Digital Health ltd (Item 4a only)
Dr Nicola Fowler	Chief Investigator (Item 4b only)
Chris Terris Taylor	CT Policing Comms lead (Item 4b only)
Caitlin Clemmow	Jill Dando Institute research lab manager and lead UCL academic in the COPPER collaborative (Item 4b only)
Professor Seena Fazel	Chief Investigator (Item 4c only)
Deborah Casey	Research assistant (Item 4c only)
Dr Philip Hyde	Chief Investigator (Item 4d only)
Professor Christopher Kipps	Chief Investigator (Item 4e only)
Jo Musgrove	Programme Manager - Wessex SDE (Item 4e only)

1. INTRUDCTION AND APOLOGIES FOR ABSENCE

Apologies for absence were received from: Ms Clare Sanderson (Alternate Vice Chair), Dr Murat Soncul (Alternate Vice Chair).

CAG Member Marc Taylor attended the meeting to wish goodbye as he was not renewing his membership of CAG.

The following observers attended the meeting:

Observers (HRA internal):

- George Ritchie - Independent Member - HRA Audit & Risk Committee
- Karen Eade - HRA Research Regulation Specialist
- Kat Evans – HRA Senior Public Involvement Officer

- Matthew Sanderson - HRA Research Regulation Specialist
- Emily Hughes - HRA Research Regulation Specialist

Observers (external):

- Claire Edgeworth - Head of Strategic Information Governance, NECS/NHS England – 4d and 4e only

2. DECLARATIONS OF INTEREST

2.1	**4c. 24/CAG/0001** **4d. 24/CAG/0011 & 24/CAG/0012** **4e. 24/CAG/0013**	**The Oxford Monitoring System for Attempted Suicide (OMSAS)** **PRANA Research** **PRANA Non-research** **Wessex SDE**
	Conflict:	CAG Member Mr David Evans declared a conflict of interest in these items. Regarding item 4c, this is a non-research application, and David works in the same team as the CAG non-research decision maker. Regarding items 4d and 4e, one of these also has a non-research element, but they are also SDE applications, which David is providing support for at a national level. The Committee agreed that Mr David Evans should leave the meeting for the review of these applications.

2.2	**4b. 24/CAG/0016**	**Collaboration on Prevent In-Place Extremism Referrals: COPPER**
	Conflict:	CAG Member Mr David Evans declared a potential conflict of interest in this item, noting that he recognised the name of the individual who had provided a letter of support from NHS England for this application, as they work in the same organisation. However he does not know the person well. The Committee agreed this did not constitute a conflict of interest and they could participate in the full study discussion.

3. SUPPORT DECISIONS

Secretary of State for Health & Social Care Decisions

The Department of Health & Social Care senior civil servant on behalf of the Secretary of State for Health & Social Care has agreed/not yet provided a response to the advice provided by the CAG in relation to the **23rd November 2023** meeting applications.

Health Research Authority (HRA) Decisions

There were no applications requiring a decision by the Health Research Authority in relation to the **23rd November 2023** meeting applications.

Minutes:

The minutes of the following meetings have been ratified and published on the website:

- 17 November PS meeting
- 01 December PS meeting
- 23 November full
- 07 December full
- October sub-committee minutes
- November sub-committee minutes

4. NEW APPLICATIONS FOR CAG CONSIDERATION

4.a	**24/CAG/0002**	**MyWay IQ (MWIQ); safety and efficacy testing of a diagnosis and precision medicine tool for diabetes management**
	Chief Investigator:	Dr Nicholas Conway
	Sponsor:	MyWay Digital Health Ltd
	Application type:	Research
	Submission type:	New application

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

Applicants attended to discuss the application.

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

Summary of application

This application from MyWay Digital Health Ltd set out the purpose of medical research that aims to generate early clinical safety/efficacy data towards the registration of MyWayIQ (MWIQ) as a medical device, to identify if the use of MWIQ is safe, usable and effective when used by primary care health care practitioners (HCPs) involved in the care of people with diabetes, in comparison to usual care. In order to answer this question, the system must be deployed within a real-world environment.

Diabetes affects ~10% of the world's population and rising, with treatment costs ~15% of NHS budget; mainly spent treating preventable complications. 80% of costs are due to diabetes-related complications. The majority are preventable

through better clinician evidence-based management and patient self-management. Despite clear evidence for pre-emptive personalised approaches, care remains suboptimal, and outcomes poor. Precision medicine approaches through clinician-focused computer decision-support could transform care.

The applicants will test MWIQ within 7 general practices within Greater Manchester. Up to 14 HCPs involved in the care of people with diabetes will be invited to use MWIQ within diabetes clinics over a period of 6-9 months. Feedback will be sought via online interviews and questionnaires. Investigators will also analyse how the computer was used by the HCP during the clinic and if there were any changes in clinical outcomes (e.g. glucose control, weight, blood pressure, change in medication) using an anonymised data set. The use of the tool does not require 's251' support, as no confidential patient information is processed.

The use of confidential patient information is limited to one specific task - the pre-screening clinic attendees by clinical experts – 'Validator Participants', who are not part of the direct care team. In order to pre-screen clinic attendees, the Validator Participants will require access to the MyWay Clinical system, including confidential patient information. Accessing identifiers will allow them to systematically review MWIQ outputs for eligible patients attending diabetes clinics, in advance of the consultation. These data will be viewed within the web-based electronic patient record (MyWay Clinical platform) and shall not be downloaded/archived/stored. Validator Participants will report any safety issues linked to each patient scheduled to be seen at the GP surgeries engaged in testing. This is to ensure that any potential risks are highlighted at an early stage, for patient safety purposes.

Confidential information requested

Cohort	Patients aged 18 years or over with a diagnosis of diabetes (any type), and attendance at an investigation site diabetes clinic during the period of study The anticipated study period is 05 February 2024 – 02 August 2024, however this will begin once CAG support is in place. Approximately 1000 patients
Data sources	1. MyWay Digital Health Ltd - MyWay Clinical (MWC) platform; Diabetes clinic lists at 7 general practices in Manchester, UK: • Northenden Group Practice • Cornbrook Medical Practice • Peel Hall Medical Practice • The Park Medical Practice • Brooklands Medical Practice • Northern Moor Medical Practice • Woodlands Medical Practice

Identifiers required for purposes of validator review	1. Name 2. NHS number 3. GP registration 4. Date of Birth 5. Address including Postcode 6. Gender
Identifiers required for analysis purposes	1. N/A – no identifiers required for analysis.

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 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 noted that the patient notifications (letter, leaflet and poster) did not make clear exactly where the breach of confidentiality occurs. It was only stated that the validators were NHS staff and did not mention that these individuals were not part of the usual direct care team, and the viewing of identifiers was not made clear. The CAG asked that the notifications were updated to make the specific breach of confidentiality clearer to the patients. The CAG noted that the poster also does not contain the opt out option, and this should be included on all patient notifications. **(Action 2a)**

The CAG asked the applicant if the patient notification materials had been reviewed by a patient and public involvement (PPI) group, and the applicant answered that the leaflet and poster had, but the letter had not been reviewed. The review consisted of one PPI representative who is on the steering group, and other members of the steering group. The CAG asked that the updated patient notification materials be reviewed by patients and the public. (**Action 2b)**

Regarding PPI input, the CAG noted that focus groups involving people with diabetes, facilitated by University of Dundee and VOCAL has been carried out, but this was not specific with regards to the use of identifiers without consent, it has been focussed on the intervention itself. The CAG also noted that the number of patient representatives involved in the PPI groups (2 and 7) was not proportionate to the scale of cohort of the application. Therefore, the CAG asked further patient and public involvement was undertaken with proportionate representative groups, particularly around the specific issue of use of confidential patient information without consent. **(Action 3)**

The CAG asked the applicant to clarify what would happen if the validators discovered issues with the data. The applicant responded that any issues discovered by the validators would be escalated to the data safety monitoring board. The information would also be discussed at a weekly steering group meeting with the developers and the members of the manufacturers. The applicant confirmed that the information would be non-identifiable at that point. The CAG was satisfied with the response.

The CAG asked the applicant to clarify whether there were other practicable alternatives to avoid accessing confidential patient information, such as providing the validators with anonymised extracts. The applicant responded that in order to test the system they did not require any identifiers however to find the patients in the system they required the identifiers and there were no other technical alternatives to achieve that. The CAG was satisfied with the response.

Confidentiality Advisory Group advice: 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.	Security assurances for 2022/23 are outstanding for the following organisations. • MyWay Digital Health Ltd – (0DS code SP378 Please contact NHS England at exeter.helpdesk@nhs.net and provide the CAG reference number, the organisational names and references that require review, and ask NHS England to review the DSPT submissions due to a CAG application.	
2.	Please update the patient notification materials as follow and provide to CAG for review: a. Clearly explain the specific breach of confidentiality and include opt out options on all notifications.	

	b. All patient notification materials should be reviewed by a patient and public involvement group.	
3.	Further patient and public involvement should be carried out with a more extensive patient group, who represent the cohort,, specifically regarding the use of confidential patient information without consent.	

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

4.b	**24/CAG/0016**	**Collaboration on Prevent In-Place Extremism Referrals**
	Chief Investigator:	Dr Nicola Fowler
	Sponsor:	Birmingham and Solihull Mental Health Foundation Trust
	Application type:	Research
	Submission type:	New application

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

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 with the observers being present.

Summary of application

This application from Birmingham and Solihull Mental Health Foundation Trust set out the medical research purpose of creating a research database for the purpose of analysing the full cohort of referrals to the West Midlands Prevent-in-Place (PiP) team. This application aims to evaluate the relationship between mental health and susceptibility to terrorism, and the PiP service. The overall purpose is to improve understanding, transparency, and delivery of these services, which is expected to inform health related benefits to patients, communities, healthcare professionals, and policy makers.

The applicants seek to develop an anonymised database to be used in a programme of research to conduct a detailed analysis of referrals to the West Midlands Prevent-in-Place (PiP) team. The anonymised database is a collaboration between Birmingham and Solihull Mental Health Foundation Trust, West Midlands Police and University College London. The database will be used to answer questions about the mental health needs experienced by those managed within Counter Terrorism (CT) policing, service gaps or barriers and outcomes for those supported by mental health services.

Eligible patients will be identified from the West Midlands PiP, held at a West Midlands Police Secure location, by a PiP administrator, and the National Data Opt Out will be applied. No 's251' support is required for this element, as the individual will be 'direct care team'. Confidential patient information will then be disclosed (still within West Midlands Police), to both the police, and to UCL research staff. The police will use the identifiers to search CT Policing - Prevent Case Management Tracker System (PCM Tracker) for relevant entries from case notes. Data from the PCM Tracker is outside the scope of 's251' support as this is not confidential patient information. Police will then email relevant extracts alongside name and other identifiers to UCL research staff (still within West Midlands Police), for them to link the PCM data to the PiP data, in an excel spreadsheet. 's251' support is required for this element, as UCL research staff are not members of the direct care team, and 's251' support is therefore required for them to link the PCM and PiP data, and the extract the relevant PiP data from medical records, at the secure police location. All identifiers will then be removed from the excel spreadsheet, before disclosing to University College London, for retention in this anonymous format.

The Study Steering Board comprising researchers from each organisation (BSMHFT, UCL, WMCTU), R&I, legal IG and other professionals will continue to be held regularly. The research will have oversight from the Prevent In-Place Governance board, which is held monthly, the WMCTU Senior leadership Team and Operation Cicero (Police Commissioners for the Prevent In-Place service). The data will be used by the three organisations engaged in the collaboration only.

This application is a resubmission of the previously deferred 22/CAG/0151.

Confidential information requested

Cohort	Individuals referred to the Prevent In-Place (PiP) Service from 2016 to the present. Active cases and individuals that have opted out of NHS research will have been removed. Approximately >3,500
Data sources	1. West Midlands Police: a. Prevent-in-Place (PiP) records: • paper files for cases referred between April 2016 – April 2019 • electronic records after April 2019 b. CT Policing - Prevent Case Management Tracker System (PCM Tracker) – out of the scope of support as this does not contain confidential patient information.

Identifiers required during data extraction and linkage at West Midlands Police	Researchers would have access to the following whilst extracting a dataset from PiP records, and during linkage 1. Name 2. Address 3. NHS number 4. GP registration 5. Date of birth 6. Postcode 7. Gender 8. Occupation 9. Ethnicity
Identifiers required for analysis purposes and retained at UCL.	1. Postcode – district level 2. Age 3. Gender 4. Occupation 5. Ethnicity No direct identifiers and is effectively anonymous.

Main issues considered, discussed and outcomes

Minutes for the previous deferred application can be found here: Full CAG minutes 10 November 2022. The CAG discussion was based around the responses to the previous deferral.

The CAG requested for the applicant to provide details on the study's medical purpose, including an overview of the health outcomes and how this research would be beneficial to patients. The applicant provided context behind the PiP service, as well as specific areas in which the study would be of benefit to patients and the public. The applicant explained that this study would directly benefit the patients within the service, noting that it would help to provide guidance regarding who and how to refer to the PiP service, and provide an evidence base for the PiP team to be able to implement evidence based interventions, to support those patients within the service who have mental health needs and display vulnerabilities.

The applicant also highlighted that the PiP service was set up 7 years ago, and there are currently only anecdotal outcomes regarding both development of the service, and as an evidence base for clinical treatment provided. The PiP service therefore needs an empirical and statistical evidence base to support the clinical service, and the treatments that are given. This research would help demonstrate an evidence base which underpins the work of PiP, providing in-depth knowledge and helping develop the clinical service further. The applicant specified that this evidence base would help support and safeguard those referred to PiP and help increase transparency within the service to the public, and that nobody has undertaken research in this area before. This knowledge will then need to be shared to engender fuller participation in the PiP system.

The applicant explained that it is really important to know if there is any link between mental health needs, and a susceptibility to be drawn to terrorism. If there is a link, it is important to identify what kind of vulnerabilities, and why different types of mental heath issues are drawn to terrorism, so that the PiP service are able to help these individuals. The applicant stated that it is known that people with broad mental health needs are overrepresented in the PiP cohort, but it is not understood why, or which patients are at risk of what, or why. It is also very important to identify if there is NOT a link between mental health and being drawn to terrorism, as there is currently stigma around this, and evidence will help to reduce stigma.

The applicant concluded by confirming that there is also a wider public benefit to all people living in the UK, as evidence from this study will help understand how people are drawn into terrorism, and with more understanding about this, it will be a step towards reducing terrorism, and keeping the public safe. The CAG acknowledged that this point is not a medical purpose, but there is an overwhelming public interest in the prevention of terrorist acts, and in protecting the public from terrorism.

The Committee was satisfied with the applicants response, commenting that the medical purposes and patient benefit was now clear.

The CAG therefore 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 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 noted that the patient notification materials could be more specific, and more widespread, to help some of the cohort to be able to see it. The CAG suggested that the current signposting via a privacy notice on a website would not be easily accessible by the intended population. This also means there is no specific opt out option from this application, although the National Data Opt Out will be applied. The CAG understood the difficulties of balancing this notification, because many of the intended cohort are not aware that they have been referred. CAG asked the applicant if it would be possible to create a more detailed patient notification, and if it was possible for this to be displayed somewhere relevant for the cohort. The applicant stated that they had assessed several different possibilities regarding the content of their notification, and how to advertise this. They discussed the possibility of displaying the notification on the Trust website. However the applicant acknowledged that their Trust was small and would not potentially reach their intended audience. The applicant also re-iterated that the PiP cohort often do not know they have been referred, and therefore there is no appropriate location where a notification could be seen by these individuals. This point also meant that it is not practicable to write to participants to seek consent, because this would firstly be a significant issue with regards to counter-terrorism, and the applicant also does not retain contact details, and therefore identifying contact

details would be more disclosive than the current design.

The applicant explained that the risk of displaying a very specific patient notification on the BSMHFT website is that attention towards Prevent by campaign groups is usually associated with a decline in actual new referrals seen. A decline in referrals would lead to significant safeguarding issues, both for mental health care, via PiP, for individual patients, and there would also be national security implications reducing the ability of the counter terrorism police. In addition, this method of notification would likely be very limited in efficacy, as it would be very unlikely to be seen by the actual relevant cohort. As discussed in detail by the applicant, there is therefore no way of actually notifying the cohort appropriately, and the privacy notice currently used therefore appears to be a balance, to avoid the significant safeguarding issues explained.

The CAG was satisfied with the applicants justification.

Regarding the patient and public involvement undertaken, the CAG noted that the research team consulted with 5 members of the Counter Terrorism Advisory Network (CTAN), on 4 December 2023. CTAN is a national stakeholder engagement forum, which was formed by Counter Terrorism Policing in 2017. It is independently chaired, and its membership consists of survivors of terrorism, academics and researchers, a variety of faith leaders, and members who reach others through community organisations and groups – all of which are independent of policing. There appeared to be support for the use of identifiable data without consent. However, the CAG queried whether it was possible to engage with those who had been previously referred to the PiP programme. The applicant specified that approaching these individuals would not provide a non-biased view of the research, noting that the service does receive lots of very positive feedback from individuals, however these are people who are very happy with the service received, and they would therefore not be representative of the cohort, because they are happy to be in the service and would be supportive. The applicant does not hold contact details for individuals, and therefore does not have a way to contact other discharged patients, and therefore this group would be extremely skewed in a positive way. It is for this reason that the CTAN was approached, and the applicants thought very carefully about the make-up of the group to try to ensure this would be representative, and also provide a more critical view. The applicant described their regular communication with the CTAN, and explained that CTAN concluded that the potential benefits of this research were significant. The CAG was satisfied with the applicants response, noting that the use of confidential patient information without consent and outside the direct care team has been discussed thoroughly with the public, and there appeared to be support for this processing.

The CAG requested for the applicant to specify a timescale as to when the results of the study would be published. The applicant stated that they would publish one to two years after the study concludes, through academic journals and media communications. The Committee was satisfied with the response.

Confidentiality Advisory Group advice: Fully supported.

The CAG agreed that the minimum criteria under the Regulations appeared to have been met, and therefore advised recommending support to the Health Research Authority, subject to compliance with the standard conditions of support.

4.c	**24/CAG/0001**	**The Oxford Monitoring System for Attempted Suicide (OMSAS)**
	Contact:	Professor Seena Fazel
	Data controller:	University of Oxford (The Centre for Suicide Research, Department of Psychiatry)
	Application type:	Non-research
	Submission type:	Refreshed application

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

Applicants attended to discuss the application.

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

Summary of application

This non-research application from the University of Oxford sought continuing support for The Oxford Monitoring System for Attempted Suicide (OMSAS), for the purpose investigating different aspects of Deliberate Self Harm (DSH) that will inform and contribute to the evaluation of national strategies on DSH and suicide prevention, to improve patient care, outcomes, and public health, through providing information to policy makers and agencies (e.g. DHSC, NICE, MHRA).

The Department of Health and Social Care fund the University of Oxford, to undertake OMSAS. OMSAS has been collecting data since 1976, and was supported under section 60 in 2004 – reference: PIAG 2-07 (b) 2004. OMSAS has existing support to collect confidential patient information on patients who deliberately self-harmed and presented to the John Radcliffe hospital in Oxford, from 1976 onwards, and link to NHS England data to receive mortality outcomes. This refreshed application was requested by CAG, on review of the National Data Opt Out (NDOO) exemption application, so that the scope of support could be clarified; the previous application was a 'research' application, however CAG requested a non-research application, as the described purposes appeared to clearly be non-research.

The cohort are identified as people presenting to hospital in oxford (either Oxford University Hospitals NHS Foundation Trust or Oxford Health NHS Foundation Trust) following any form of self-harm. Confidential patient information alongside clinical information is collected from both Trusts, and updated as necessary using Oxford Health NHS Foundation Trust medical

records. Confidential patient information is then disclosed to Oxford University. This is then onwardly disclosed to NHS England in order for them to link to Civil registration mortality data, and provide the applicant with date of death alongside other clinical information. The data has most of the identifiers removed for analysis, however full date of death is retained in the analysis dataset, as this is an important outcome measure regarding this cohort. The applicant also retains a key between pseudo-IDs and identifiers.

Confidential information requested

Cohort	People presenting to the General Hospital in Oxford following any form of self-harm. Numbers vary annually but the number of presentations can range from 1700 to 2000 annually, involving up to 1500-1700 individuals.
Data sources	1. Oxford Health NHS Foundation Trust – medical records 2. Oxford University Hospitals NHS Foundation Trust – medical records 3. NHS England –Civil registration mortality data
Identifiers collected by OMSAS	1. Surname, Forename, Initials 2. Date of birth 3. sex 4. NHS number (where available) 5. Full Postcode 6. Date of death (from NHS E) 7. Unique episode number
Identifiers required for linkage purposes	1. Surname, Forename, Initials 2. Date of birth 3. NHS number (where available) 4. Unique episode number 5. Full Postcode
Identifiers required for analysis purposes	1. Full date of date of death
Additional information	There is a separated database, containing identifiers and two pseudo-IDs, one representing the hospital presentation and one for unique individuals (allowing applicants to link presentations to individuals over time to investigate repetition).

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.

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 noted that the application mentioned storing the data on paper forms. The CAG was concerned whether it was more difficult to maintain confidentiality by having a permanent paper record. This also appeared to be an issue for exit strategy from 's251' support (for deceased individuals), as the applicant had confirmed in responses to CAT queries that they do delete confidential patient information for those who are deceased from electronic records, however it is currently not practicable for them to effectively anonymise the corresponding paper records. The CAG asked the applicant to clarify whether they had considered changing the data collection method from a paper system, to an electronic system. The applicant responded that it was one of their main priorities to transfer the data collection method from paper to electronic. They were currently looking at different routes to securely transfer the data to electronic records. The applicant confirmed that this would be for prospective patients in the first instance, but after that was in place, they would then look into going back over all of the paper records from 1973, which would allow them to transfer all the data from paper to electronic record. The CAG noted that this would then mean that it would be possible to fully implement an exit strategy from 's251' support for deceased individuals. The CAG asked the applicant to provide an update in 6 months on the progress of implementing a new electronic data collection method, and the transferring of retrospective data from paper to electronic format. **(Condition 1)**

The CAG noted that the applicants had an OMSAS Patient and Public Involvement (PPI)group to advise in an ongoing manner regarding the application more generally. The most recent meeting was held on October 2023, and had only 2 PPI representatives attending the meeting. The CAG was concerned whether this was sufficient PPI representatives considering the scale of the cohort for this application. The CAG asked the applicant to explain how they were determining the representativeness and number of people in the PPI group. The applicant responded that they used to have more representatives in their PPI group but due to different circumstances some of them have since dropped out. The applicant explained that they had difficulty recruiting people back to the PPI group mainly due to sensitivity of this cohort group. It was also unclear if the specific use of identifiable data without consent had been discussed, although as this is not a new application and the PPI group do support OMSAS, it is assumed there is inherent support for this processing. The CAG requested the applicant to expand the PPIE representatives on the PPI group, noting that these do not necessarily need to be individuals who have used the service, and could be individuals with wider links to the relevant cohort, such as family members. The use of confidential patient information without consent should be specifically discussed with the PPI group, and

feedback provided to CAG It is noted that the applicant already has an ongoing communication with their PPI group, who meet twice a year, and CAG encourage this ongoing interaction. **(Condition 2)**

The CAG asked the applicant to clarify how many people had access to the identifiable data. The applicant explained at the moment there were 4 people who had access for the purpose of processing the data, and in future a person who would be involved in data flow between application and that NHS England would also have access to the data. The CAG was satisfied with the response.

The CAG noted that the notifications in general were accurate and written in lay language. However the terminology 'data processor' should not be used to describe an individual person, as the data processor is the organisation where the data is processed. This should be changed. The CAG felt it should be made clearer on the leaflets that data is processed at multiple NHS Trusts, and NHS England, alongside the University. The section on retention periods in the privacy policy is also quite confusing currently, and the CAG asked if this could be reworded for simplicity. The CAG noted that there were some discrepancies between the leaflets and the website. The CAG requested that the website pages were updated to match the information on the leaflets, as these were updated, but the websites had not yet been. **(Condition 3)**

The CAG noted that the National Data Opt Out (NDOO) exemption for PIAG 2-07 (b) 2004 was provided for a limited time period of 6 months whilst this refreshed non-research application was submitted. The CAG confirmed that this NDOO exemption now applies to 24/CAG/0001, and is no longer time limited.

Confidentiality Advisory Group advice: Conditionally supported

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, subject to compliance with the specific and standard conditions of support as set out below.

Number	Condition	Response from the applicant
1.	Provide an update to CAG in 6 months, on the progress of implementing a new electronic data collection method, and the transferring of retrospective data from paper to electronic format.	
2.	Please increase the number of representative individuals in the PPI group, and ensure the use of confidential patient information without consent, and outside the direct care team is discussed. Feedback should be provided to CAG in 6	

	months. For further guidance in respect of the Patient and Public involvement requirements, please refer to: Guidance for CAG applicants - Health Research Authority (hra.nhs.uk) and Public Involvement - Health Research Authority (hra.nhs.uk)	
3.	Update the patient leaflet and provide to CAG within 3 months with the following: a. The Leaflet should mention collecting information from the relevant multiple Trusts and NHS England. b. The terminology surrounding data processors should be corrected. c. The section on data retention periods should be clarified. d. Update the website to match the information on the leaflets.	
4.	PIAG 2-07 (b) 2004 is superseded by 24/CAG/0001 from the date of this letter.	
5.	's251' support is provided for 5 years, at which point a duration amendment is required to extend the duration of support.	
6.	The National Data Opt-Out is not to be applied to patients included in the activities specified in 24/CAG/0001.	
7.	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 **Oxford Health NHS Foundation Trust, Oxford University Hospitals NHS Foundation Trust, University of Oxford - Department of Psychiatry - The Oxford Monitoring System for Attempted Suicide & NHS England** were confirmed as 'Standards Met' on the NHS England DSPT Tracker (checked 31 January 2024)	

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

4.d	**24/CAG/0011 & 24/CAG/0012**	**Pre-hospital Research and Audit Network (PRANA)**
	Chief Investigator:	Dr Philip Hyde
	Sponsor:	University Hospital Southampton NHS Foundation Trust
	Application type:	Research & 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 is an application from University Hospital Southampton NHS Foundation Trust that proposed to create a resource on all patients who receive pre-hospital critical care at the request of NHS ambulance services, for non-research and research uses.

Ambulance services in 2022/23 nationally attended to 8 million patients. A small proportion (estimated 0.5%) of these patients were so severely ill or injured that their lives were immediately threatened (40,000 patients). These patients received high level pre-hospital critical care from a range of specialist NHS and independent sector CQC registered pre-hospital critical care services. Although these patients are proportionally a small subset of the medical and trauma

patients cared for by ambulance services, the potential benefits in terms of reducing morbidity and mortality are disproportionately significant. Whilst patient specific data is collected by the ambulance services across their pre-hospital care pathway, data regarding pre-hospital critical care treatment is not currently collated beyond provider organisations nor linked to outcome. Therefore, the potential systematic improvements created through national data collection, analysis, review and publication are currently absent within UK pre-hospital critical care.

The PRANA registry intends to enable data from critically ill and injured patients' whole care pathways (from moment of recognition of illness or injury onwards) to be utilised to improve understanding of pre-hospital disease, improved diagnosis and treatments of pre-hospital disease, reduce risk for patients and clinicians, evaluate the impact of new professional roles on the UK health economy, enable future service planning and improvement, evaluate the effectiveness of health policy, identify targets for disease prevention, inform prevention of injury and illness and enable future research and innovation.

All pre-hospital services (ambulances/air-ambulances) in England and Wales will flow identifiable information to the Wessex SDE held at University Hospital Southampton NHS Foundation Trust on a quarterly basis. This data will be linked with a range of relevant national datasets and national audits to create a resource to be used for research and non-research purposes. All requests for use of data will be considered by a PRANA data access committee, which includes a lay representative, before agreement by the Wessex SDE data access committee.

Confidential information requested

Cohort	Every patient who has received pre-hospital enhanced or critical care at the request of NHS ambulance services, unless they have chosen that their data should not be used. Estimated to be approximately 40,000 per year, and will be a prospective data collection only.
Data sources	1. University Hospital Southampton NHS Foundation Trust 2. East Midlands Ambulance Service 3. East of England Ambulance Service 4. Isle of Wight Ambulance Service 5. London Ambulance Service 6. North East Ambulance Service 7. South East Ambulance service 8. South West Ambulance service 9. West Midlands Ambulance Service 10. Yorkshire Ambulance service 11. Welsh Ambulance Service 12. London's Air Ambulance 13. Great North Air Ambulance

	14. Air Ambulance Kent Surrey Sussex 15. East Anglia Air Ambulance 16. Lincolnshire, Nottinghamshire Air Ambulance 17. Thames Valley Air Ambulance 18. MAGPAS air ambulance 19. Hampshire and Isle of Wight Air Ambulance 20. North West Air Ambulance 21. Essex and Hertfordshire Air Ambulance 22. West Midlands Air Ambulance 23. Devon Air Ambulance 24. Derbyshire, Leicestershire, Rutland Air Ambulance 25. Warwickshire, Northamptonshire Air Ambulance 26. Cornwall Air Ambulance 27. Great Western Air Ambulance 28. Wiltshire Air Ambulance 29. Dorset and Somerset Air Ambulance 30. Yorkshire Air Ambulance 31. Emergency Medical Retrieval and Transport Service Wales 32. Paediatric Intensive Care Audit Network (PICANet) 33. National Major Trauma Registry (previously called Trauma Audit Research Network) 34. Intensive Care National Audit and Research Centre (ICNARC) 35. Department for Transport – STATS-19 36. Hospital Event Statistics 37. Ambulance data set (NHS England) 38. National Organ Donation Registry 39. Out of hospital Cardiac Arrest Outcomes registry (OHCAO) 40. Coroner services 41. All Coroner services in England and Wales
Identifiers required for linkage purposes	1. NHS number 2. Patient's first name 3. Patient's family name 4. Patient's date of birth 5. Patient's home postcode
Identifiers required for analysis purposes	1. Name 2. Date of birth 3. Date of death 4. Postcode 5. Gender 6. Occupation 7. Ethnicity

Main issues considered, discussed and outcomes

The CAG noted that this activity fell within the definition of medical research and health and social care services and was therefore assured that the applications described an appropriate medical purpose within the remit of 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 requested clarification around the patient notification leaflet, specifically whether the leaflet would be presented to patients during the initial treatment. The Applicant stated that the patients would be critically ill and therefore it would be inappropriate to discuss the study leaflet at this time. The Applicant clarified that the intention was for the follow-up nurse to discuss the study with the patient, once recovered, or a family member/guardian. The CAG acknowledged the Applicants response, however, requested for the patient leaflet to provide a further depth of information regarding the study. This should provide more information, or a link to the PRANA website containing more information, on how identifiable patient information is used without consent to create the final dataset. **(Action 1a)**. The leaflet should also clearly outline that it is intended for either patients once recovered or family members **(Action 1b)**

The CAG queried whether it was possible to provide further signposting of the notification on other stakeholder or Trust websites, this would help to further promote the study. The Applicant confirmed that this was possible. The CAG was satisfied with the Applicants response.

The CAG noted the patient and public involvement undertaken to date but queried whether the use of confidential patient information without consent was discussed within these sessions, as it was not clear from the application. The Applicant noted this stated that they would conduct additional sessions, explicitly around the use of confidential patient information without consent. CAG agreed with this and requested information from these sessions to be provided to CAG. This should include a summary of the number and demographics of participants, a summary of how the use of identifiable patient information was described to participants, and a summary of the responses provided. **(Action 2)**

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

The CAG was unable to recommend support to the Health Research Authority and Secretary of State for Health and Social Care for the applications 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.	Amend the patient leaflet to: a. provide further information, or a link to the PRANA website containing more	

	information, on how identifiable patient information is used without consent to create the final dataset. b. leaflet should also clearly detail whether it is intended for either patients once recovered or family members	
2.	Conduct further patient and public engagement sessions, specifically around the use of confidential patient information without consent. Outputs from the sessions should be provided to CAG that includes a summary of: a. the number and demographics of participants b. how the use of identifiable patient information was described to participants. c. the responses and discussions on the use of confidential patient information without consent.	

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

4.e	**24/CAG/0013**	**Wessex Subnational Secure Data Environment (SNSDE) Programme**
	Chief Investigator:	Prof Christopher Kipps
	Sponsor:	University Hospital Southampton NHS Foundation Trust
	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 Hospital Southampton NHS Foundation Trust, sets out the medical purpose to create a research database.

University Hospital Southampton NHS Foundation Trust are developing the Wessex sub-national Secure Data Environment (SNSDE). This is part of a national initiative to move towards access of NHS data by default, rather than data sharing and is part of the Data Saves Lives strategy.

The Wessex SNSDE will consist of two separate parts: the data processing environment (DPE) and the trusted research environment (TRE). Patient data will flow from each of the contributing organisations to the data processing environment, where it is checked, linked, de-identified, filtered, and transformed to produce a research database that can be used to produce extracts for research purposes. Data from each individual processing environment is only linked with data from other environments once an approved programme of research has been identified. A core dataset will be transferred to the SNSDE for use. Any data that sits outside the core dataset will only be transferred for research specific purposes once the research has been approved.

Support is requested for the flow of Confidential Patient Information from individual organisations within the Wessex SDE area to University Hospital Southampton NHS Foundation Trust, and retention within the SDE. Whilst the flow itself will be pseudonymised, University Hospital Southampton NHS Foundation Trust will have access to the keys to enable reidentification for specific purposes. Linkage to HES and SUS data is also requested, but this will only be undertaken on a per project basis only.

The SNSDE will be used for data-driven translational research in any field of health or social care. Research projects will be approved by a single, dedicated Data Access Committee (DAC). This committee will comprise lay members, alongside representatives from the participating healthcare organisations. The University Hospital Southampton's existing DAC will be used whilst the Wessex SNSDE is set up. There is wider work ongoing at a national level to standardise and streamline the data access approach.

The SDE will be set up in stages, with specific datasets initially used to test the success of the linkage processes before moving to wider primary and secondar care organisations within the SDE footprint once success confirmed.

Confidential information requested

Cohort	All normally resident patients plus any patient accessing services in the Wessex area (Hampshire, Dorset and Isle of Wight ICBs) unless registered an opt out (approximately 2.7 million people).
Data sources	1. All primary and secondary care organisations within the Wessex SDE footprint

	2. Specific datasets held by University Hospital Southampton NHS Foundation Trust: a. data from NIHR Health Informatics Collaborative (HIC), (Viral Hep: IRAS ID 289900, Myeloma: IRAS ID 310036, Cardio/COVID: IRAS ID 174052) b. data from ECRIN and IDX2 lung projects (IRAS ID 186109 and 283721 respectively) c. data for clinical trial feasibility assessments d. data from PRANA (IRAS ID 338740)
Identifiers required for linkage purposes	1. NHS number 2. Hospital ID 3. Name 4. Address 5. Gender 6. Date of birth 7. Postcode 8. Date of death
Identifiers required for analysis purposes	1. Postcode (sector level) 2. Gender 3. Occupation 4. Ethnicity
Additional information	Whilst the flows of CPI will be pseudonymised to minimise risk during the transfer, University Hospital Southampton NHS Foundation Trust, will be able to identify the CPI. Whilst the applicants state that data source 4b is consented, the consent does not extend to use within the Wessex SDE.

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 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.

Members discussed whether the proposal for the project specific opt out to be administered centrally by the Wessex SDE team, and applied following the receipt of confidential patient information into the SDE was appropriate. Members considered the options and agreed that the proposal was a pragmatic and reasonable option to apply a project specific opt out.

The CAG wished to congratulate the Applicant on the quality of standard met within this application. The CAG did not raise any questions for the Applicant.

<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.	Support cannot be issued until a Favourable opinion from a Research Ethics Committee is in place. **Pending**	

6. ANY OTHER BUSINESS

Paul Mills wished to thank and urge CAG members to continue using the application review forms, prior to the meeting dates.

No further business was discussed, the Chair thanked everyone for their attendance and closed the meeting.

Dr Tony Calland MBE - CAG Chair — 25 January 2024
Dr Patrick Coyle - CAG Vice-Chair — 30 January 2024

……. ……..
Signed – Chair *Date*

William Lyse - HRA Approvals Administaror — 31 January 2024
……. ……..
Signed – Insert job title *Date*