Confidentiality Advisory Group

Minutes of the meeting of the Confidentiality Advisory Group held on 01st October 2026 via video conference.

Present:

Name	Capacity
Mr Dan Roulstone	CAG Vice Chair
Professor Ben Gibbison (excluding item 4d)	CAG Alternate Vice Chair
Dr Joanne Bailey	CAG Member (Expert)
Dr Malcolm Booth	CAG Member (Expert)
Dr Rebecca Harmston	CAG Member (Lay)
Ms Kim Keltie	CAG Member (Expert)
Dr Pauline Lyseight-Jones	CAG Member (Lay)
Dr Justin Yang	CAG Member (Expert)

Also in attendance:

Name	Position (or reason for attending)
Ms Katy Cassidy	HRA Confidentiality Advisor
Rachel Katzenellenbogen	HRA Approvals Specialist
Dr Paul Mills	HRA Confidentiality Advice Service Manager
Ms Wangari Njiiri – until item 4d	HRA Approvals Administrator
Mr Richard Reed	HRA Approvals Administrator
Evan Ansell	Applicant for item 4a
Padmanabhan Ramnarayan	Applicant for item 4b
Hannah Mitchell	Applicant for item 4b

Laura Chiverton	Applicant for item 4c
Isabel Hatami	Applicant for item 4c
Catherine McKenzie	Applicant for item 4d
Emma Laing	Applicant for item 4d
Andy Eames	Applicant for item 4e
Sue Mason	Applicant for item 4e
Ric Campbell	Applicant for item 4e

1. APOLOGIES FOR ABSENCE

Apologies for absence were received from: Dr Sandra Duggan.

2. DECLARATIONS OF INTEREST

2a	**26/CAG/0102**	**DELTA-ICU**
	Conflict:	CAG Member Professor Ben Gibbison declared an interest in this item 4d, as he sits on the Trial Steering Committee and knows the applicants. The Committee agreed that Professor Ben Gibbison should leave the meeting for the review of this application.

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 the advice provided by the CAG in relation to the **03 September 2026** meeting applications.

Health Research Authority (HRA) Decisions
The Health Research Authority agreed with the advice provided by the CAG in relation to the **03 September 2026** meeting applications.

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

- 03 September 2026 Full

4. NEW APPLICATIONS FOR CAG CONSIDERATION

4a	**26/CAG/0101**	**British Cardiovascular Interventional Society Acute Myocardial Infarction associated Cardiogenic Shock Registry (BCISAMICS)**
	Chief Investigator:	King's College Hospital NHS Foundation Trust
	Sponsor:	Dr Nilesh Pareek
	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.

Summary of application

This application from King's College Hospital NHS Foundation Trust is for the purpose of medical research to create a research database in the area of cardiology, specifically cardiogenic shock.

Cardiogenic shock is a serious complication of a heart attack in which the heart is unable to pump enough blood around the body. Around half of patients with severe cardiogenic shock may die, and the way these patients are treated currently varies between hospitals. This database will gather data on cardiogenic shock cases in order to facilitate research into differences in treatment, access to specialist care and patient outcomes, with the aim of identifying areas where care can be improved.

CPI will flow from Data Collection Centres, to a database hosted by Dendrite Clinical Systems, then on to KCL and ICNARC. ICNARC will undertake date linkage then send link anonymised data to KCL.

Confidential information requested

Cohort	• The cohort is people aged 18 and over who suffered from acute myocardial infarction with cardiogenic shock. • The cohort will be prospective. • The cohort is expected to be 2,800. • A portion of this cohort will be deceased.
Data Sources	• Dendrite Clinical Systems • King's College Hospital NHS Trust • Bedfordshire Hospitals NHS Trust • Betsi Cadwaladr University Health Board • Cardiff and the Vale University Health Board • East and North Hertfordshire NHS Trust • East Lancashire Hospitals NHS Trust

	• Frimley Health NHS Foundation Trust • Hull University teaching hospitals • Liverpool Heart and Chest NHS Foundation Trust • Maidstone and Tunbridge Wells NHS Trust • Manchester University NHS Foundation Trust • Mid and South Essex NHS Foundation Trust • Oxford University Hospitals NHS Trust • Royal Papworth Hospital NHS Foundation Trust • Royal Wolverhampton NHS Trust • Sheffield Teaching Hospital NHS Foundation Trust • Swansea Bay University Health Board • University Hospital Southampton NHS Foundation Trust • University Hospitals Bristol NHS Foundation Trust • University Hospitals Coventry and Warwickshire • University Hospitals Sussex NHS Foundation Trust
Identifiers required for linkage purposes	• NHS number • Date of birth
Identifiers required for analysis purposes	• Postcode – sector level • Gender • Ethnicity • Date of death

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 asked the applicant to confirm whether Dendrite would access the cloud storage and whether it would be managed in the UK. The Applicant confirmed that all cloud storage would be generated and managed in the UK and added that Dendrite had experience of managing research databases that had received Section 251 support. The CAG requested written confirmation of Dendrite's management of the cloud storage for this study, including its location [action 2].

The CAG asked the applicant to justify collecting patients' full names for the ICNARC linkage. The Applicant explained that ICNARC specifically required each patient's NHS number and full date of death to complete the linkage successfully. A name was not essential but could be used for validation. The CAG emphasised the need to minimise the collection of data items not required for the study and requested written clarification of the rationale for collecting patients' full names [action 3].

The CAG noted that the applicant sought to retain the identifier index for five years after the final external linkage, although it would not be used for statistical analysis. The stated reasons were to address linkage discrepancies, duplicate records and data-quality queries during validation, and to identify and action subsequent National Data Opt-Out (NDOO) requests while the study remained active. The CAG questioned whether this retention period was necessary and requested further information. The Applicant stated that ICNARC would delete the data once the linkage process was complete, but that an index of NHS numbers and registry IDs would be retained to apply retrospective NDOO requests where required. The CAG noted that Section 251 support was being sought to retain identifiable data for five years, whereas the expected study duration was two years, and asked whether any challenges were anticipated. The Applicant explained that the proposed funding model was based on a per-patient fee received whenever a site recruited a patient, in line with the arrangements used in most other grant-funded studies. The Applicant added that patient data would be held in a pseudonymised registry database, with the index database also held at King's College London, and that this arrangement would not incur additional costs. CAG noted that the NDOO policy was clear that the NDOO does not need to be applied retrospectively.

The CAG requested further details of the study start date and duration. The Applicant explained that funding had been awarded for two years and that data collection was expected to begin in 2027. The CAG advised that, before formal approval could be issued, the Applicant should clarify the duration of data collection and specify at which point individuals would need to make contact if they did not want their data to be used [action 4].

The CAG noted that public involvement in the study had been limited, as the initial engagement had taken place only at King's College London, but acknowledged plans to continue it throughout the project. The CAG requested information on the demographic composition of the public involvement group. The Applicant explained that the team had approached the cardiogenic prognostication steering group based at King's College London and had also engaged patients with lived experience of cardiogenic shock, receiving a positive response. Ten semi-structured conversations had been held via Microsoft Teams and telephone. The Applicant added that the team would seek to recruit a public patient ambassador to the steering group as a key liaison contact.

The CAG asked whether the patient notification materials had been presented to a Public Involvement group for feedback. The applicant confirmed that the poster had been presented to a member of the Public Involvement group, who

had provided insights and suggestions.

The CAG requested further revisions to the patient notification materials to explain clearly the use of confidential patient information without consent, provide consistent and accessible opt-out arrangements, include a link to the study website and details of HRA/Section 251 support, and specify the data-collection period and opt-out deadline [actions 5a–5g]. The CAG also requested that the revised materials be presented to a public involvement group for feedback on the accessibility of the information [action 5h].

The CAG noted the intention to disseminate patient notification materials using a layered approach to providing study information and requested further clarification on what was meant by this. The applicant explained that patient posters would initially be displayed in relevant clinical areas within the hospital where potential participants may access services and would include contact details for patients wishing to speak with a member of the study team to obtain further information about the study. The applicant further clarified that the layered approach referred to providing information through a range of accessible formats and stages, as they did not anticipate issuing a patient information leaflet to all 1,400 patients annually, but instead sought to make different levels of information available according to patients' needs and interest in the study.

<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.	Security assurances for 2025/26 are outstanding for the following organisations. • Dendrite Clinical Systems • King's College Hospital NHS Trust Due to the number of data collection centres where confidential patient information will be accessed, individual DSPT submissions are not required for the purpose of the application. Support is recommended on the basis that the applicant ensures the required security standards are in place at each site prior to any processing of confidential patient	

	information with support under the Regulations. Please contact NHS England at ssd.nationalservicedesk@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.	The CAG request written confirmation regarding the use of cloud storage for the study, including confirmation that the storage will be managed by Dendrite, details of the location of the storage.	
3.	The CAG request written justification for the collection of patients' full names for the ICNARC linkage process, including clarification on whether this identifier is required and the rationale for its retention in line with data minimisation principles.	
4.	The CAG request further written clarification regarding the proposed retention of the identifier index for up to five years following completion of external data linkage. This should include a justification for the retention period, details of the anticipated duration of study activities, clarification on the ongoing need to retain identifiable information beyond the active study period	
5.	The CAG request for the following changes to be made to the PIS document: a) Revise the wording to state clearly that routinely collected treatment details would be recorded on the registry and that confidential patient information (CPI) would be used without consent. b) Provide clear and consistent information on the study specific opt-out methods across the poster,	

	leaflet and patient information sheet c) Explain the specific project opt process prior to presenting information on the National Data Opt Out. d) Add a link to the study website to the leaflet. e) State in both the poster and leaflet that the study had received support from the Health Research Authority following CAG advice under section 251. f) Add the dates covering the data-collection period to the patient information sheet. g) Add a deadline by which individuals should make contact if they did not want their data to be used. h) Arrange for the patient notification materials to be reviewed through patient and public involvement (PPI). i) Replace the study email address with a shorter, more intuitive address, where possible.	
6.	The CAG request clarification on the proposed study timelines, including the anticipated start date for data collection, the overall duration of the study, and confirmation by which point individuals must make contact should they wish to object to the use of their data.	

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

Number	Condition
1.	Favourable opinion from Newcastle North Tyneside 1 Research Ethics Committee. Confirmed: 10 September 2026

The Group delegated authority to confirm its final opinion on the application to

the Chair and reviewers.

4b	26/CAG/0082	LION-CUB study
	Chief Investigator:	Professor Padmanabhan Ramnarayan
	Sponsor:	Imperial College London
	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.

Summary of application

This application is from Imperial College London for the purpose of medical research to improve outcomes of children in intensive care.

Children are admitted to intensive care when they are very sick. It is well known that children who live in poorer areas, and who are from Asian or Black ethnic groups, are more likely to go to intensive care and are more likely to have a poor outcome after they are admitted. This study is part of an attempt to understand why this happens, to make changes and eradicate these differences.

Confidential Patient Information will be sent from PICANET to NHS England where it will be linked to various data sets before being pseudonymised and sent to the researchers for analysis.

Confidential information requested

Cohort	The cohort is all children born in England between 2003 and 2025. It is estimated to be around 13 million people, a proportion of whom are anticipated to be deceased at the time of analysis.
Data Sources	• PICANet • Hospital Episode Statistics • Maternity Services Dataset • Office of National Statistics mortality data
Identifiers required for linkage purposes	• NHS number • Date of birth • Full postcode • Date of death • Sex
Identifiers required for analysis purposes	• Sub-sector level postcode • Lower layer super output area • Gender • Ethnicity • Age • Date of death

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 understood that the project data would go back to 2003, but that the NHS England Maternity data set was only created in 2015. As such, clarification was sought on if linkages would be undertaken and data collected before 2015. The applicants responded that the intention would be to look for changes in the data over time (including ethnic group data), from 2003 from PICANet and HES (Hospital Episode Statistics) sources. NHS England Maternity data would be incorporated from 2015 onwards. The CAG accepted the applicants' responses.

The CAG asked if the specific date of death was required as an identifier for analysis, or if a less precise month or year of death would be sufficient instead. The applicants clarified that the date of death would not be required for analysis, and that this was an error in the application. The CAG accepted the applicants' responses.

The CAG noted that the privacy notice and the data flow diagram stated that pseudonymised data would be kept at Imperial College London for 10 years, and asked if this was accurate. The applicants responded that Imperial GDPR guidance was strict about the use of mandatory wording in this regard, and that such wording was needed in the privacy notice and other notification materials. It was explained that Imperial considered data (from a GPPR perspective) as identifiable if it was also described as pseudonymised data. For this project, only pseudonymised data would be obtained, but the wording could potentially be updated if this was advised. The CAG stated that the wording in communication with the public needs to be clearer about identifiable data and pseudonymised datain the privacy notice and other notices [action 2].

The CAG noted that 16 people had been involved in public involvement. It was asked how representative this group was considered given the size of the cohort. The applicants responded that there was some initial bias in who had been approached to participate in public involvement, as there was an initial overrepresentation of parents that had had a child in ICU. Since then, work had been undertaken with Imperial and other partners to find a wider and more representative group. As a lot of the children in the cohort would now be adults, 2 of members had been approached that were previous users of the service. With more time, a more representative group could be established, but overall, it was felt that the group was representative of the cohort with a mix of ages, genders, and socioeconomic status. The CAG requested a plan for further public involvement engagement to be developed and submitted for review [condition 1].

The CAG noted that the NDOO (National Data Opt Out) would be applied, and

that people could contact PICANet to opt out, but it was not clear if there was a specific opt out for this project, as this would be the preferred option over the NDOO. The applicants responded that a project specific opt out would be a challenge, as the project would not hold identifiable information. As such, there was no obvious practical way to find the patients to opt out their data. This had been discussed with the public involvement group. One view expressed in this public involvement group was that the data would no longer be considered their own, but it was appreciated that a specific opt out would be preferable. The applicant indicated that a patient could contact both PICANet and NHSE England to ask if their data could be removed. The CAG understood that there were some complexities, but other comparable studies had arranged communication about the study in advance of any proposed linkages, offering affected individuals an option to opt out prior to the project commencement. A similar approach was requested for this project [action 3].

The CAG asked whether accessibility of the notifications materials had been considered. As there would be a large cohort of different ages, some of which may wish to read physical documents, with others preferring digital sources, it was asked how these preferences would be accounted for. The applicants responded that a lot of feedback from patient involvement on the notification materials was that they were too long. These had been reduced to a 1 page summary, with further links to more detailed content. The plan was to provide project information on the Imperial website and PICANet website, as well as publicising the poster through other sources. As the dataset would relate to a large proportion of the population, another consideration would be to contact the relevant Integrated care system (ICS) to disseminate project information via GP practices or other channels. The CAG requested further development of these materials, with further public involvement utilised to improve the documents [action 4].

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 2025/26 are outstanding for the following organisation: • University of Leeds Please contact NHS England at ssd.nationalservicedesk@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.	The CAG noted that the privacy notice, the data flow diagram, and other notification materials state that Imperial College London will hold identifiable data for 10 years. It is understood that this duration relates to the Imperial GDPR consideration that pseudonymised data equates to identifiable data. CAG requested the information is made clear that this is pseudonymised data, and no direct identifiers are held at Imperial. Justification would need to be provided if Imperial College London were to refuse this request.	
3.	The CAG noted that no project specific opt out had been developed for this study. While it is understood that the project will not hold identifiable information, and that removing individual's data post-linkage would therefore be very challenging, communications should be developed in advance to notify the public of the project commencement and proposed linkages. This communication should offer patients the opportunity to opt-out with their data withheld before linkage occurs. 4-6 weeks before the project commencement is typically considered adequate time for this. Please confirm details on how this will be managed.	
4.	The CAG request further development of the notification materials. For instance, as some of the cohort will be in their 30's, an appropriate age range should be included (as it stated that this project applied to those under 18). Additionally, the QR is currently a placeholder in the poster – please update this and submit any new content for review if required. Further public involvement should also be utilised to improve the documents (please also see condition 1).	
5.	The CAG request that the data flow diagram is updated to make the data flows clearer, adding linkage of HES and MSD data outside PICANet.	

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

Number	Condition
1.	The CAG request further public involvement to be undertaken, especially with patients that are now adults. Please provide an ongoing report at a 3 month interval with details on further public involvement progression.
2.	Favourable opinion from a Research Ethics Committee. **Confirmed 03rd September 2026**
3.	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 **25/26** DSPT review for NHS England was confirmed as 'Standards Met' on the NHS England DSPT Tracker.

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

4c	**26/CAG/0108**	**Service Evaluation for Newborn screening for Spinal Muscular Atrophy (SENS)**
	Chief Investigator:	Professor Laurent Servais
	Sponsor:	University of Oxford
	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.

Summary of application

This application from University of Oxford is for the purpose of medical research to evaluate the effectiveness of the newborn screening program for spinal muscular atrophy (SMA).

SMA is a disease that causes progressive muscle weakness. There are many types- the most severe and most common, type 1, affects very young babies, and is life-threatening if untreated. Other types can cause significant disability. Three new treatments can slow or prevent symptoms, but they work best when given before symptoms appear. This has led to many countries introducing newborn screening (NBS) for SMA, so that affected babies can be treated as early as possible.

A UK pilot project screened nearly 33,000 babies and found the test to be accurate and practical, but this pilot was too small to show whether screening improves outcomes or is good value for money for the NHS. The UK National Screening Committee would also like to know how acceptable NBS for SMA is for different groups of people. This new study is designed to answer those questions.

's251' support is required for confidential patient information (full date of birth for all screened, and NHS number for positive cases) from screened babies to be disclosed from the newborn screening laboratories to STRONG, based at University of Oxford, to allow the full evaluation to be completed.

Confidential information requested

Cohort	All newborn babies who are born from 1 October 2026 until September 2030 and are screened for standard NHS NBS at the seven designated screening centres (positive and negative data), about 755,000 in total
Data Sources	• 7 newborn screening laboratories: o Manchester University NHS foundation Trust o Epsom and St Helier University Hospitals NHS trust o Birmingham Woman's and Children's NHS foundation trust o Sheffield Children's Hospital o Great Ormond Street Hospital o Royal Victoria Infirmary Newcastle upon Tyne o Guys and St Thomas's NHS foundation trust
Identifiers required for linkage purposes	1. All screened babies: Date of birth, ethnicity. 2. NHS number & sex in addition for positive cases
Identifiers required for analysis purposes	• Full date of birth
Additional information	University of Oxford will receive the data from the labs on a monthly basis.

Main issues considered, discussed and outcomes

The CAG identified that the terms service evaluation and research study had been used interchangeably throughout the application and queried the rationale for presenting the project as research rather than as a service evaluation. The applicant explained that newborn screening for Spinal Muscular Atrophy had initially been undertaken by NHS England as a service evaluation; however, as the programme had progressed, there had been discussions involving NHS England and the NIHR regarding the future development of the initiative. The

applicant further clarified that the purpose of the proposed study was to undertake statistical analysis of data obtained through the newborn screening pathway, with the findings intended to inform evidence generation and be submitted to the UK National Screening Committee for consideration when assessing whether Spinal Muscular Atrophy screening should be incorporated into routine newborn screening practice. The CAG accepted this response.

The CAG identified that public involvement had been limited and was considered insufficient in view of the anticipated volume of data to be processed. However, the public involvement undertaken had indicated general support for the use of Confidential Patient Information without obtaining consent. CAG requested further information on the demographic makeup of the public involvement and whether there was further provisions made to conduct ongoing public involvement. The applicants explained that two public involvement groups had contributed to the public engagement activities, noting that participants were predominantly members of the Spinal Muscular Atrophy Steering Group, comprising parents and patients with lived experience of Spinal Muscular Atrophy, who were provided with a summary of the study and invited to respond to a series of questions.

The CAG requested further information regarding the methods used to engage the public involvement groups and how the questions had been disseminated. The applicants confirmed that the questions had been circulated by email. The applicants further highlighted that, moving forward, consideration would be given to undertaking more in-depth patient and public involvement activities, such as focus groups, to support future engagement. The applicants also stated that the study documentation had been shared with a study collaborator who had established links with a wider public involvement groups relevant to the proposed research cohort. In addition, the applicants advised that the wider public involvement group comprised approximately 20 members, including members of the public, healthcare professionals, and patients with Spinal Muscular Atrophy. The CAG asked whether study documentation including patient notification materials had been presented to a public involvement group for scrutiny and review. The applicant stated that a draft submission of the patient notification materials had been submitted for CAG review and noted that since then further feedback had been received from the wider public involvement group and subsequently additional revisions had been made.

The CAG asked whether there were any plans to undertake further patient and public involvement activities during the conduct of the study, particularly relating to the use confidential patient information without consent. The applicant stated that they had established positive working relationships with a number of public involvement and steering groups and would continue to engage with these groups throughout the conduct of the project. The applicant explained that this ongoing engagement would include discussions regarding the use of confidential patient information and the National Data Opt-Out process, with feedback being actively sought to ensure that study information is clear, accessible, and understandable to the general public, and that individuals remain appropriately informed about how their data are being used. The CAG requested that further patient and public involvement activities be undertaken

throughout the duration of the study to ensure ongoing engagement regarding the use of confidential patient information. The CAG advised that these activities should include discussions on how confidential patient information is being used, the rationale for its use, and an overview of the study's progress. [Condition 1].

The CAG were unclear on how the applicant would maintain the anonymity of research patients and asked for additional details. The applicant highlighted that data would be transferred from the Newborn Screening Laboratories to the study team through an encrypted, password-protected process and would subsequently be stored within a highly secure database environment. It was noted that the secure data environment would operate in accordance with the University's information governance and compliance requirements and would incorporate additional access restrictions and security controls. The applicant further explained that even though the numbers of children with SMA were small, only aggregated data would be published and patients would not be individually identifiable from this.

The CAG highlighted that the patient poster did not provide the necessary detail for readers to make an informed decision on whether to opt out of the study. The CAG asked whether there was scope to amend the opt-out process, noting that the current approach required individuals to contact the study team via the Oxford email address if they wished to opt out of the study. Following a review of the patient poster, the applicant stated that feedback was received regarding the potential inclusion of a QR code to enable individuals to access further information and opt-out arrangements more easily. The applicant highlighted that this was an option that was currently being explored to facilitate and improve access to the opt-out process. The CAG requested that further consideration be given to making the opt-out process more accessible to the wider population by providing multiple routes through which individuals could exercise their choice regarding the use of their data [action 1].

Following discussion with the applicant, the CAG requested that copies of the revised patient notification materials, amended in response to feedback received from the public involvement group, be submitted for CAG review with further revisions to the information text to highlight the use of confidential patient information and CAGs role in the study [action 2a-2c]. The CAG highlighted that all patient-facing materials should be written in clear, accessible language to ensure that the information is easily understood by the target patient population [action 2d].

The CAG asked for further information on the communications plan. The applicant highlighted that they intended to develop a dedicated study website that would provide comprehensive information and relevant details about the study. The applicant explained that the website would be widely promoted and shared through social media platforms, LinkedIn, and other media outlets to maximise awareness and ensure that information about the study was readily accessible to the public. The CAG requested for a copy of the communications plan noting that it should be clear within the document that all communications aim to inform people about the use of confidential patient information without

obtaining explicit consent [action 3].

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.	Provide details of multiple accessible routes that will be used in this study for patients to opt out of data being included.	
2.	Provide a copy of the revised patient notification materials. The revised materials should also include: a) Ensure that multiple routes to opt out of the specific study are described, with prominence to the study specific opt out. b) State that the national data opt out will be applied. c) State that the study has received Section 251 support from the Health Research Authority, following advice from the Confidentiality Advisory Group. d) Ensure that all information is presented in clear, accessible language that is readily understood by the target patient population, for example, by review from a public involvement group	
3.	Provide a copy of the study communication plan. It should clearly demonstrate how the study will inform patients and the wider public about the use of confidential patient information without explicit consent, including the key messages, communication methods	

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

Number	Condition
1.	Undertake further patient and public involvement throughout the duration of the study to ensure ongoing engagement regarding the use of confidential patient information. It is advised that during these activities should include discussions on the following below: a. how confidential patient information is being used, the rationale for its use, b. an overview of the study's progress, potential modifications or additional requirements
2.	Favourable opinion from a Research Ethics Committee. **Confirmed 02nd July 2026**
3.	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:** Due to the number of organisations involved it is the responsibility of University of Oxford as controller, to ensure that 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.

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

4d	26/CAG/0102	DELTA-ICU
	Chief Investigator:	Professor Cathrine McKenzie
	Sponsor:	University Hospital Southampton NHS Foundation Trust
	Application type:	Research
	Submission type:	New application

Applicants attended to discuss the application.

Summary of application

This application from the University of Southampton sets out the purpose of medical research to determine the clinical effect of giving thiamine intravenously and whether this improves patients outcomes.

Many patients in critical care experience delirium, a state of altered confusion and awareness that comes and goes, causing problems with attention, thinking and memory. Delirium can have several causes, such as infection, certain medications and environmental factors. It has a huge impact on patients, their families and health care professionals. "Being free of delirium" has been included as one of six core patient important outcomes in a recently completed

international study undertaken in fourteen countries. There are currently no drug treatments known to work well at treating or preventing delirium. Recent research has suggested that delirium may be partly caused by brain cells not being able to use glucose properly. Thiamine, also known as vitamin B1, can help brain cells use glucose for energy. Therefore, thiamine might be able to help prevent or treat delirium. An analysis of three previous studies found that patients in the ICU who were given thiamine were much less likely to develop delirium. Since these studies were small, the authors recommended a larger scale trial to be done to study this further. The DELTA-ICU trial aims to provide high-quality evidence to help address this important evidence gap by testing thiamine against a placebo. By comparing thiamine to a placebo, the applicants hope to see if thiamine is effective at preventing or treating delirium.

A deferred consent model will be used, as eligible patients will lack capacity at enrolment and early administration of the intervention is considered important. Participants will enrolled and randomised immediately, with consent subsequently sought from the patient when capacity returns or, where appropriate, from a Legal Representative. Trial data will be entered into a secure electronic case report form managed by ICNARC, with direct identifiers stored separately and encrypted. Identifiable information (NHS number, date of birth, sex and postcode) will be used to link trial records with the Case Mix Programme (CMP) national clinical audit to obtain baseline, treatment and outcome data, which are combined into a final pseudonymised study dataset. Support under s251 is requested to permit the processing of confidential patient information where consent cannot be obtained, including patients who die before consent procedures can be completed, patients discharged or transferred without capacity before consent can be sought, and patients who are subsequently uncontactable despite follow-up attempts. Support under s251 is also sought to enable linkage of screening log CMP identifiers to pseudonymised audit data to assess representativeness and equality, diversity and inclusion, and to permit access to relevant medical records for source data verification and regulatory monitoring activities for participants from whom consent could not be obtained.

Confidential information requested

Cohort	Patients aged 18 years and over, admitted to critical care who are at high risk of delirium. The applicants anticipate that 520 patients will be included.
Data Sources	DELTA-ICU study data collected at participating hospitals. Intensive Care National Audit & Research Centre (ICNARC) Case Mix Programme national clinical audit for adult intensive care.
Identifiers required for linkage purposes	• NHS Number • Date of birth • Postcode – unit level

Identifiers required for analysis purposes	• Date of birth • Postcode – unit level • Gender • Ethnicity

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 project would use the full date of death and full postcode for analysis, and asked if these full identifiers would be needed, or if a partial data would be sufficient instead. The applicants responded that the date of death would be important, as approximately 1-5 patients admitted to an ICU (Intensive Carte Unit) die. Mortality data was therefore considered important for both the primary and secondary outcomes. It would also be needed to ensure that those that are randomised would not be discounted from the study because of death. Additionally, the data was needed for the case mix programme, the national ICU audit, and to ensure correct linkage. However, once linkage was complete, the level of information would be reduced in identifiability, and this would apply for full postcodes and date of birth as well. The CAG asked if there would be a way to pseudonymise the date of death such as with an indicator measuring the number of days that an individual has died, rather than a specific date, as this was considered a full identifier. The applicants responded that the full date of death could be replaced by a range of dates, but as the team would also hold the randomisation dates (needed for other clinical trials), the full exact date could be reconstructed from the range of days, and it could then still be identifiable data. The CAG asked for confirmation that after calculating the relevant outcome metrics, the date of death could be removed from the dataset, [action 3].

The CAG asked how the NDOO (National Data Opt out) would work when linked to the date of death, and if the NDOO would still be respected for those that had died in ICU. The applicants responded that all participating sites would be asked to check data as soon as possible after randomisation, including those that had died. If a patient that died had been enrolled, and later was found to have had requested the NDOO to be applied, only the survival status would be recorded and not the exact date of death. It was also noted that one of the exclusion criteria would be those at imminent risk of death in the ICU, so this event would be limited wherever possible. The CAG accepted the applicants' responses.

The CAG noted that data would be obtained from patients at the beginning of the study, as it would be generally not possibility to ask for consent in the ICU. It was also noted that a letter would also be sent to notify patients about the project, but the purpose of the letter was unclear, and it appeared that the letter

may seek consent. If so, it was not clear why consent could not be sought from the entire cohort. Additionally, non-response to the letter could not be assumed to act as consent; clarification on this process and the purpose of the letter was therefore requested. The applicants explained that most patients would experience delirium in the ICU (about 80%), but a number would be awake and not need deferred consent, and could be asked for verbal consent directly. These would be patients that are awake with no mechanical ventilation or cardiovascular support. However, the vast majority would not have mental capacity and would not be asked to consent. The letter would serve as a backup method where all attempts to consent in hospital had not been possible, such as if the patient was discharged before consent was obtained. The primary study method would be to speak to the family while the patient was in ICU, then speak to the patient in ICU, and only then if these methods had not been successful would the letter be sent. It was also confirmed that the letter was not intended to seek consent but for notification purposes only.. Given the applicants are making every opportunity to seek consent at hospital, and in line with similar applications, CAG considered that Section 251 support can be provided to use information from those who are discharged prior to consent. However, the wording on the letter should be changed to remove reference to consent, and instead providing information on how to opt out [action 4].

The CAG noted that the notification materials that had been reviewed by 1 person. It was asked if this was considered representative and if more public involvement was planned. The applicants responded that while there was only 1 patient representative was consulted for this study, there was also a link to a wider public involvement panel involving 5 other individuals. The study team attended this group meeting where some reviewed the patient facing documents, and there was also a discussion about the use of confidential patient information without consent. The CAG accepted the applicants' responses.

The CAG noted that the notification materials only included the option of talking to the team to discuss the project. It was asked if this could be expanded with a QR code, phone number or email address should there be a preference to carry out the opt-out in a different way. The applicants responded that while many vulnerable people that had experienced delirium may prefer a face-to-face conversation, some might prefer an online method, and as such this would be implemented. A video was also planned at a later time that could be accessed via the QR code, but this would be after REC approval and CAG support. The CAG asked to review the notification materials once the additional channels for opt-out were included [action 5].

The CAG noted that the application referred to identifiable data that could be decrypted for the user, and asked for clarification on what this would entail. The applicants responded that the reference to decryption related to the clinical trials database that would capture all clinical trial data. Initially identifiable data would be entered, and this would be to add a layer of protection so that only the relevant members of staff would see the identifiers, such as the statisticians. Additionally, this data would only be identifiable for a year. The CAG accepted the applicants' responses.

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.	Support cannot be issued until a Favourable opinion from a Research Ethics Committee is in place.	
2.	Security assurances for 2025/2026 are outstanding for the following organisation: • ICNARC (The Intensive Care National Audit & Research Centre) Please contact NHS England at ssd.nationalservicedesk@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.	
3.	Clarify at which point the full date of death will be removed after suitable alternative metric (e.g. survival status in a time period) have been calculated. CAG note that the date of death may still be able to be inferred from other data points.	
4.	Change the focus of the letter to discharged patients. Rather than seeking consent the letter should notify relevant individuals that their data had been collected under Section 251 support, providing options to opt out of this data use.	
5.	The CAG request further development of the notification materials, notably to include one or more additional routes to opt-out (e.g. email, QR code, telephone).. Additionally, the options for opt our should be made clearer in the communications materials, with a project specific opt out being the most prominent.	

6.	The CAG requested the data flow diagram to be reviewed, notably checking the colour of flows towards the bottom of the diagram and whether data is pseudonymised	

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

4e	**26/CAG/0106**	**Connected South Yorkshire**
	Database applicant:	Professor Suzanne Mason
	Application type:	Research Database
	Submission type:	New application

Applicants attended to discuss the application.

Summary of application

This application from University of Sheffield set out the purpose of creating a research database, linking health and social care information from multiple organisations across South Yorkshire to support research that improves health outcomes, healthcare services and population wellbeing.

By bringing together data from sources such as GP practices, hospitals, local authorities and other care providers, ConSY enables researchers to answer important questions that cannot be addressed using data from a single organisation alone. Researchers will only access de-identified information within a secure research environment, with projects subject to robust governance, public involvement and independent approval processes to ensure appropriate safeguards, public benefit and respect for patient choice, including applicable opt-outs.

Confidential information requested

Cohort	The cohort is all individuals who receive health or social care services from participating organisations within South Yorkshire.
Data Sources	The data sources include: • Participating GPs within South Yorkshire • NHS England national and regional datasets, including commissioning datasets • NHS provider organisations, including acute hospitals, community services, mental health services, ambulance services, and specialist providers.
Identifiers required for linkage purposes	• Name • NHS Number • Hospital ID Number • GP registration • Date of birth

	• Date of death • Postcode – unit level • Gender
Identifiers required for analysis purposes	• Postcode – district level • Gender • Ethnicity

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.

The CAG noted that the study would use both retrospective and prospective data; it was asked how far back the retrospective data would go back. The applicants responded that the intention would be to process data up to a maximum of 10 years in the past, but there was not an expectation to go back this far. The use of retrospective data would depend on which project wished to use the data. For example, changes in coding practice might mean that projects need data from different time periods. The CAG requested clarification on the exact year from which retrospective data would be used [issue 1].

The CAG noted there may be scenarios where individuals can be reidentified. Further clarity was asked on how this would work in practice. The applicants responded that in the past, concerns identified in research had been raised with the ICB (Integrated Care Board), and the ICB could then pick up with relevant service and treating clinicians to contact the individual. The CAG sought clarity that in practical terms, the team would identity evidence on anonymised or pseudonymised data and then engage with the ICB to reidentify (if possible). The applicants confirmed this. The CAG accepted the applicants' responses.

Members understood that University of Sheffield and South Yorkshire ICB are joint controllers of the application but no written confirmation of agreement with this arrangement has been provided by the ICB, though noting the attendance of an ICB representative. The CAG asked whether senior management at the ICB had approved this application. The ICB representative stated that discussions had predominantly been contained within the information governance team, with the IG group receiving the document. It has not been sent for ICB board approval though members of the executive team were aware. CAG requested written confirmation from an executive committee representative that this arrangement has been approved at a senior level within the ICB [issue 2].

The CAG noted the project is similar to the Yorkshire and Humber NHS SDE (Secure Data Environment), which is a very similar activity that is part of the NHS SDE network. Members struggled to understand why this application was necessary given the wider SDE application included the same South Yorkshire data and could serve as a reasonable practical alternative. The applicants stated that the Yorkshire and Humber SDE is creating extracts of a particular nature within SDE network, but it does not represent the entirety of research in

the region, or nationally. Not all research can be conducted in the Yorkshire and Humber SDE, the SDE access may not be affordable, and it currently does not have all the data is needed. Working with the ICB, the applicants felt it important to provide routes for these projects to access data, for example, PhD students, small charity funded studies. Whilst there is some overlap, this will provide an alternative option sitting outside the network. Whilst CAG noted the rationale, members remain significantly concerned how this application and the Yorkshire and Humber SDE will interact. The CAG requested a detailed summary of the types of research this application will support that the SDE cannot and how a clear distinction will be made between the two in terms of submissions and governance [issue 3].

The CAG noted that public involvement evidence provided appeared to be that conducted by Yorkshire and Humber SDE, and not for this application. This involvement was from a geographically wider cohort than South Yorkshire, and views from those in South Yorkshire had not been highlighted. As such, it appeared to CAG that no public involvement had been undertaken, and it was unclear what the public views are from those in South Yorkshire. It was therefore asked if any public involvement engagement was planned for this specific project. The applicants responded that specific project public involvement had not been completed recently, and this was not noted in the application as it was completed 3 years' ago. Since then, there has been more work with the SDEs, but it was considered that there was a lot of overlap in the projects, including in primary care data and extract creation. To undertake a separate group of public involvement work might have been very confusing to public involvement groups and perhaps unethical to ask the public to comment on two very similar projects. Given this is a separate application with a different purpose to the SDE, CAG rejected the argument that it was unethical to undertake further public involvement and considered that no specific public engagement had been undertaken. The CAG stated that public involvement activity, testing the acceptability to use confidential patient information without consent for this specific application would be required [issue 4].

The CAG asked how it was planned to communicate this project alongside the Yorkshire and Humber SDE, and how this could be communicated clearly to the public. Members also noted that the example materials do not adequately communicate the use of confidential patient information for this application. Members also noted that the materials use the NHS Secure Data Environment branding, whilst this is being proposed as an alternative. CAG agreed that the notification materials need significant updates to clearly communicate this specific activity and how confidential patient information is used. Consideration should also be taken on how to communication this alongside the Yorkshire and Humber SDE to avoid confusion with the public, including on use of NHS SDE network branding [issue 5].

The CAG asked if a project specific opt out had been considered or if only the NDOO (National Data Opt Out) would be applied. The applicants responded that the NDOO would be applied, but there would also be ConSY database opt outs which could be actioned via contacting the team. Project specific opt outs could also be implemented if a patient chose not be part of a specific project.

Each project would therefore have a privacy notice, and the website and leaflet texts has been updated to account for these project specific opt outs. The CAG asked for more detail on how this would be managed [issue 6].

Due to the lack of written evidence of joint controllership agreement from the ICB, significant uncertainty on why the Yorkshire and Humber SDE does not provide a practical alternative, a lack of clarity on submission and governance arrangements between the two applications, no specific public involvement for this application as well as unclear notification materials, CAG recommended that the application is deferred.

Confidentiality Advisory Group advice: Deferred

The CAG was unable to recommend support to the Health Research Authority for the application based on the information and documentation received. The CAG noted that the following points should be taken into consideration and addressed prior to resubmitting this application in future.

Number	Issue:
1.	The CAG state that an exact year is required in relation to how far back retrospective data would be used.
2.	Provide written confirmation from an executive committee representative that the ICB joint controller arrangement has been approved at a senior level within the ICB for this application.
3.	Provide: a. a detailed summary of the types of research this application will support that the Yorkshire and Humber SDE cannot b. how a clear distinction on governance and submission pathways will be made between the two applications and evidence of engagement with the Yorkshire and Humber SDE
4.	Undertake proportionate project specific public involvement and provide a summary of the outcomes. Please note that the project specific public involvement should discuss the use of confidential patient information without consent. Guidance is provided here.
5.	Significantly rework the notification materials to clearly communicate this activity and how confidential patient information is used. The notification materials could be reviewed as part of the public involvement. CAG guidance is here. Consideration should also be taken on how to communication this alongside the Yorkshire and Humber SDE to avoid confusion with the public, including on use of the NHS SDE network branding
6.	The CAG state that more details are required on the project specific opt outs, and how these will be applied and managed.

5. CONSIDERATION ITEMS

There were no items for consideration.

6. ANY OTHER BUSINESS

There was no other business for discussion.

Mr Dan Roulstone	08th October 2026
…….	……..
Signed – Chair	*Date*
Professor Ben Gibbison	07th October 2026
…….	……..
Signed – Chair	*Date*
Mr Richard Reed	09th October 2026
…….	……..
Signed – Approvals Administrator	*Date*
Ms Wangari Njiiri	01st October 2026
…….	……..
Signed – Approvals Administrator	*Date*