Confidentiality Advisory Group

Minutes of the meeting of the Confidentiality Advisory Group held on 05th November 2026 via video conference.

Present:

Name	Capacity
Mr Dan Roulstone	CAG Vice Chair
Professor Ben Gibbison	CAG Alternate Vice Chair
Mr Thomas Boby	CAG Member (Expert)
Dr Sandra Duggan	CAG Member (Lay)
Mr Anthony Kane	CAG Member (Lay)
Ms Kim Keltie	CAG Member (Expert)
Professor Sara Randall	CAG Member (Lay)
Ms Mary Thomas	CAG Member (Lay)

Also in attendance:

Name	Position (or reason for attending)
Ms Katy Cassidy	HRA Confidentiality Advisor
Dr Paul Mills	HRA Confidentiality Advice Service Manager
Ms Wangari Njiiri	HRA Approvals Administrator
Mr Richard Reed	HRA Approvals Administrator
Ms Caroline Watchurst	HRA Confidentiality Advisor
Professor Thomas Booth	Applicant for 4a – Chief Investigator
Ambreen Rashid	Applicant for 4a – Senior Clinical Trial Manager
Dr Jack Baldwin	Applicant for 4a – Principal Bioinformatician
Dr Andrew Wong	Applicant for 4b – Chief Investigator

Professor Nish Chaturvedi	Applicant for 4b – Director of the NSHD
Fatima El Oulidi	Internal Observer – North West Greater Manchester REC

1. APOLOGIES FOR ABSENCE

Apologies for absence were received from CAG Members Dr Martin Andrew and Dr Joanne Bailey.

2. DECLARATIONS OF INTEREST

There were no declarations of interest.

3. SUPPORT DECISIONS

Secretary of State for Health & Social Care Decisions
There were no applications requiring a decision by the Department of Health & Social Care senior civil servant on behalf of the Secretary of State for Health & Social Care in relation to the **01 October** meeting.

Health Research Authority (HRA) Decisions
The Health Research Authority agreed with the advice provided by the CAG in relation to the **01 October 2026** meeting applications.

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

- 25 September PS
- 09 October PS

4. NEW APPLICATIONS FOR CAG CONSIDERATION

4a	**26/CAG/0114**	**TRIAGE**
	Chief Investigator:	Prof Thomas C Booth
	Sponsor:	King's 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.

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

Summary of application

This application from King's College London set out the purpose of medical research to compare the effect of the Magnetic resonance Imaging abnormality Deep learning Identification (MIDI) Artificial Intelligence (AI) tool against standard NHS care on the Turnaround Time (TAT) for abnormal adult brain MRI scans in the outpatient setting.

The NHS is facing growing pressure from rising MRI demand and a shortage of radiologists, leading to increasing reporting delays that can adversely affect patient outcomes, including delayed diagnosis and treatment. If the TRIAGE trial is successful, it could help identify urgent brain conditions faster, give patients the care they need more quickly and reduce waiting times for those waiting for urgent scan results.

The TRIAGE trial is a multicentre, cluster-randomised crossover trial. Participating NHS sites will be randomised to one of two sequences, alternating between an intervention phase (MIDI ON, where abnormal scans identified by AI are prioritised for reporting) and a control phase (MIDI OFF, where MIDI operates silently without influencing clinical workflow). Following a 2-month run-in period and, at some sites, a preceding feasibility phase, sites will complete two 7-month intervention periods separated by a 5-month washout and crossover period, enabling each hospital to act as its own comparator.

's251' Support is sought to allow the viewing of confidential patient information by Newton's Tree engineers, in case of a technical fault, at participating NHS trusts using an on-premises VNP. The AI tool will contain confidential patient information embedded in the MRI scans at Leeds and Cambridge only. No confidential patient information will be disclosed outside of the Trust environment. No 's251' support is required for this at the other participating sites, as scans will be pseudonymised before being uploaded to the AI tool via cloud software.

's251' support is also required for confidential patient information to be disclosed from all participating sites to Queen Mary University of London (QMUL) at their Pragmatic Clinical Trials Unit (PCTU) for analysis, and MR images and associated reports will be transferred from the participating NHS Trusts to Leeds Teaching Hospitals NHS Trust (Leeds) and/or King's College London (KCL), which also requires 's251' support, as these also contain confidential patient information.

Confidential information requested

Cohort	100,800 Patients aged 18 years and over referred for brain MRI scans at participating hospitals. Estimated scanned Between March 2027 to January 2029.

Data Sources	Electronic patient records held within participating NHS trusts, including MRI scans, and local SSNAP data; • Barts Health NHS Trust • Cambridge University Hospitals NHS Foundation Trust • Dartford and Gravesham NHS Trust • Hampshire and Isle of Wight Healthcare NHS Foundation Trust • Hampshire Hospitals NHS Foundation Trust • Isle of Wight NHS Trust • Leeds Teaching Hospitals NHS Trust • London North West University Healthcare NHS Trust • Portsmouth Hospitals University NHS Trust • Salisbury NHS Foundation Trust • University Hospital Southampton NHS Foundation Trust Central SSNAP data – controlled by HQIP, processors = Kings College London (SSNAP team), Net Solving Ltd & ANS group (CAG ref 23/CAG/0030). This will only be for a small subset of patients.
Identifiers required for the purpose of processing the scans during the AI tool review	This data is contained within the MRI scan, only within Leeds and Cambridge. • Name • NHS Number • Hospital ID Number • Date of birth
Identifiers required for analysis purposes, disclosed from Trusts to QMUL	• Date of birth - full format • Date of death - full format • Postcode – district level (not CPI) • Gender • Ethnicity
Identifiers required for analysis purposes, disclosed from Trusts to Leeds Teaching Hospitals NHS Trust (Leeds) and/or King's College London (KCL)	• MR images and reports, containing only full date of birth
Additional information	The applicant is also requesting 's251' support for potential linkage with SSNAP data, if the relevant

	information cannot be identified within the Trusts. This will be undertaken by each individual Trust disclosing NHS number and hospital ID to SSNAP (processors = Kings College London (SSNAP team), Net Solving Ltd & ANS group) and full date of death being returned to the Trust. This will then be disclosed on to QMUL as per usual.

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 when date of birth (DoB) and date of death (DoD) data would be deleted by QMUL. The applicants responded that the data would be deleted approximately one year after the last publication, to allow for any queries to be responded to. The CAG asserted that a slightly firmer deadline would be required rather than deletion at the point of the last publication request. The applicants responded that 3 years after the trial concluded should be adequate to ensure enough time for any extra analysis, as from previous experience academic publications can involve several clarification requests. The trial is planned to finish January 2029, and so the identifiers will be deleted approximately 3 years after that – so approximately January 2032. CAG were content with this clarification regarding exit strategy.

The CAG additionally noted that patients' DoB data would be embedded in DICOM images (Digital Imaging and Communications in Medicine) going to Leeds Teaching Hospitals NHS Trust (Leeds) and/or King's College London (KCL), and asked when this confidential patient information would be destroyed. The applicants responded that this would be the same timeframe as the rest of the identifiers (3 years after the end of the trial). The CAG accepted this response.

The CAG asked for justification why full DoD data was required, and why this could not be converted to a month and year, which would be no longer be considered confidential patient data. The applicants responded that conversion from full DoD had been challenging in previous trials when disclosing from participating sites. Although this appeared a simple request, it was a challenge for local sites and can be very problematic, to the extent where data from thousands of patients had been removed from studies due to a simple conversion issue. It was also noted that the full DoD would only be gathered for brain tumour and stroke subgroups, and not from any other subgroups. The applicant additionally clarified that it is required in full format for statistical analysis. The CAG accepted the applicants' response.

The CAG noted that several opt out mechanisms were present in the notification materials regarding various different elements of the application. However, CAG felt this was very confusing for patients and should be streamlined to one opt out only. For example, in the current poster design, a patient sat in the waiting room of the radiology department waiting to have their scan would read on the poster that the only way to opt out of not having their scan read by AI was to be referred by their GP to a different hospital. At this time point, i.e., imminently before the upcoming scan, it was felt this was not appropriate as an opt out option, because the patient would then have to cancel the scan they were about to have, and go back to their GP, to re-arrange a scan referral to a different hospital. This, although possible, appeared neither practical or advisable to introduce potentially months of delay to this person's clinical treatment. The CAG therefore advised that this specific opt out (Point 5) be removed from the poster designed for the radiology departments. It was noted that 's251' support is not required for the AI tools to process any scans at any site, because either confidential patient information is not included, or the confidential patient information embedded in the scans does not leave the Trust. Therefore, an opt out regarding 's251' support for these elements is not required. [Action 2a].

The applicant also has a study specific opt out regarding the identifiable data being disclosed to QMUL and the scans being disclosed to KCL/Leeds. This is the relevant opt out regarding 's251' support. This is at the very bottom of Point 6 on the poster. This opt out requires the patient to '*contact the radiology department at your hospital'*. The CAG felt this was ambiguous and difficult for patients. It is usually advised to have a single point of contact at the hospital, including an email address and phone number. Therefore, to streamline this for patients, and to reduce any confusion or ambiguity, it was asked if a single point of contact to opt out of the use of data for the study would be feasible. This could be either a contact for each Trust, or a study contact for the entire study, who could then feedback to each site (preferred). The applicants responded that at Site Initiation Visits (SIV) for site set up, opt out would be clearly communicated to all radiology staff, so that everybody in the department would know about the study and the posters would be by the receptionist. Receptionists would have access to the study poster next to them in reception, and would be informed of actions to take if a patient wished to opt out. In teams of a single point of contact to opt out for the whole study, the applicant agreed that potentially contact information for the study could be included on posters. The applicant asked if there was a concern about General Data Protection Regulation (GDPR) and whether it would be legally appropriate for the study team to act on the patients' behalf in this way. The CAG responded that a single point of contact for the study would be appropriate and not in conflict with GDPR, as the patient would be providing their details with the intention that they are used in order to opt out. CAG stated that a study wide opt out should therefore be implemented via telephone, email or postal address. This could merely be described as a study specific opt out for the TRIAGE study, rather than differentiating it as for the data element only. However, in practice this would opt people out of the disclosure of the identifiers out of the Trusts only. The CAG were content with this, as this is low risk but with a high potential patient benefit, and would be much less confusing for patients. [Action 2b].

The CAG also noted the prominence of the wording regarding the National Data Opt Out (NDOO) on the poster, in Section 6, as currently the website link is provided, a phone number is provided, and the patient is also asked to contact the GP if they want to opt out using NDOO, in order to opt them out of the study. The applicant stated that this had been discussed with the public involvement group. Whilst the NDOO was felt to be quite an abstract concept to the group, it was considered important to be present along with an explanation of what it was. More information would also be included on website materials as to the purpose of the NDOO. The CAG responded that while the public involvement discussions should be taken into account, the prominence of the NDOO explanations on the poster and website should be minimised, as this would opt patients out of the use of their data nationally. If a person merely did not want to be in TRIAGE it is not appropriate or necessary to point them to the NDOO, because there is a TRIAGE project-specific option. The CAG requested that the NDOO should merely be described as “respected”, and the prominence should be reduced. There should be clear instructions on how to opt out of TRIAGE at the start of the patient information materials, where they are easy to find. The poster should explain that TRIAGE will honour the National Data Opt-Out, so patients who have already registered one do not need to opt out of TRIAGE separately. [Action 2c]

The CAG noted that the poster did not summarise how identifiers are is used and by which processors – the applicant had argued in query responses that this is sufficient on the website, and CAG agreed this was justified, as the flows are quite confusing and would take a lot of poster space to accurately explain. CAG agreed that the website could explain in full how information that identifies patients is used and which organisations handle it. The process is complicated and would take up too much space to explain clearly on the poster. The poster should briefly explain that TRIAGE shares information that identifies patients with other organisations and direct readers to the website for more details. The current poster refers to a QR code but does not include one, and it gives an email address instead of a website address. Please add both a working QR code and a written website address so people can find the information even if they cannot scan the code. [Action 2d]

The poster does not state the project processing identifiers without consent has been supported under 's251' support' by the HRA following Confidentiality Advisory Group (CAG) advice. The website mentions s251 support but calls it approval instead of support. The CAG advise that both the poster and the website should be updated to confirm that the HRA has given Section 251 support for the activity following advice from the Confidentiality Advisory Group (CAG). [Action 2e].

The CAG also discussed the timing of the application of the NDOO. With regards to the scope of 's251' support; 's251' Support is sought to allow the viewing of confidential patient information by Newton’s Tree engineers, in case of a technical fault, at participating NHS trusts using an on-premises VNP. The AI tool will contain confidential patient information embedded in the MRI scans

at Leeds and Cambridge only. No confidential patient information is actually flowing to Newtons tree - MIDI is hosted on the Newton's Tree platform within the NHS Trust's own local network, so this is not a breach of confidentiality. Newton's Tree engineers may access identifiable scan data within the Trust's environment, via a hospital-approved connection, where necessary to investigate serious technical failures. This access does not involve downloading or copying the scans outside the Trust. This is the only element relating to the AI tool that requires 's251' support, at 2 sites only. The applicant proposes applying the NDOO after this timepoint, before transfer to QMUL and KCL/Leeds, rather than prior to the AI tool use. CAG were content with this proposal noting this is low risk, with potential benefit to patients, and applying the NDOO would not be practicable prior to the engineers fixing the AI tool. At this stage, the Newtons Tree engineers are essentially acting as part of the process to enable a clinical scan report to be accurately provided to the clinician. The NDOO need not be applied to the actual AI tool processing, as per policy, and so it would not be practicable to apply the NDOO to just the times when the engineers are required to provide a fix to the tool which is being used as standard of care in each Trust at that time.

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

The CAG was unable to recommend support to the Health Research Authority OR Secretary 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.	The CAG request the following changes to the patient notification documents: a) Remove the opt out option of going back to your GP to be re-referred to a different Trust for a scan from the radiology department posters. b) A single central point of contact for patients to opt out of the TRIAGE study should be available. This will replace all other local opt out arrangements (such as by the patients discussing opting out with a radiologist), and should be described as an opt out of the TRIAGE study.	

	This should be available by telephone, email, or postal address, and all patient-facing documents should be updated to make this clear. c) Reduce the prominence of the National Data Opt Out (NDOO); the TRIAGE specific opt out details should be more prominent and presented first above these details. The NDOO should merely be listed as respected. The link to the website, the phone number, and the advice to contact the GP should be removed. d) On the posters, ensure the QR code and a website address are included, and update them with minimal information regarding the flow of identifiers outside the Trusts. e) Both the poster and the website should be updated to confirm that the HRA has given Section 251 support for the activity following advice from the Confidentiality Advisory Group (CAG).	

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

Number	Condition
1.	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:** More than 5 participating Trusts/processor organisations - Due to the number of participating organisations involved, it is the responsibility of King's College London as controllers, to ensure that participating 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.

4b	26/CAG/0111	National Survey of Health and Development (NSHD) Research database
	Chief Investigator:	Dr Andrew Wong – Applicant
	Sponsor:	University College London
	Application type:	Research Database
	Submission type:	New application

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

Applicants attended to discuss the application.

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

Summary of application

This application from University College London set out the purpose of setting up a research database to process, store, enable discovery, and support the use and re-use of data from the National Survey of Health and Development.

The National Survey of Health and Development (NSHD), the world's longest-running birth cohort study, has followed 5,362 individuals born in 1946 for over 70 years. Data on health, cognition, social circumstances, lifestyle, and biological measures has been collected, at multiple time points through questionnaires, face to face visits, and data linkage, with consent sought where possible. While this unique resource has significant potential to address national ageing research priorities, the scale and complexity of the data present challenges for secure storage and reuse. The study was originally flagged as "MR1" in 1971, and the applicant receives ongoing cancer and mortality data updates. This is now received from NHS England. 's251' support is in place under CAG reference 15/CAG/0139, to receive linked data for those people who do not provide consent. Consent has been and will be sought from participants, where possible. Support is sought for participants who have died or are otherwise lost to follow-up. 's251' support is already in place for data sources; Hospital episode Statistics (HES), cancer registry and mortality data.

Applicants propose to transition to a period of less frequent data collection and would like to maximise the use of the existing data by sharing it more widely with external collaborators and other researchers. The proposed NSHD Research Database will provide a secure environment for processing, storing, and enabling access to these data, maximising their value for research and supporting evidence to improve healthy ageing and population health outcomes.

Data will be curated and stored within the database, with access provided only to approved researchers under strict governance procedures. The database will

provide secure access to pseudonymised information on NSHD participants and will support high-quality research into how biological and social factors shape ageing across the life course. Although this database will not address specific questions, it will support research that will inform policy development, support the identification of population level targets for intervention, and deliver public benefit by contributing to research into health ageing.

Confidential information requested

Cohort	Participants in the MRC National Survey of Health and Development British birth cohort (NSHD), all born in March 1946.
Data Sources	NHS England held datasets; • Hospital episode Statistics (HES) • cancer registry • mortality data • mental health datasets University College London; • MRC National Survey of Health and Development British birth cohort (NSHD) database
Identifiers required for linkage purposes	Name NHS Number Date of birth
Identifiers required for analysis purposes	The database will include an encrypted representation of property and postcode that cannot be mapped back to participant addresses or other real world geographical identifiers.

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 existing support under 15/CAG/0139 covered the retention of data and linkage to datasets held by NHS England (NHSE), and that the applicant now sought to transition the dataset to a research database. The CAG sought clarification on whether this would involve additional linkages to data sources that were not currently used. The applicant explained that they intended to continue with the existing linkages and also sought to include

mental health datasets through the existing data linkage arrangements. The CAG asked whether the mental health data would form part of the data supplied by NHSE and whether the same linkage approach would be followed. The applicant confirmed it would.

The CAG sought confirmation on whether the full date of death was required as an identifier for analysis purposes. The applicant clarified that they sought to retain the month and year of death for analysis rather than the full date of death, and CAG accepted this response

The CAG noted that identifiable data would be stored alongside a pseudo-ID, once NHSE had completed the linkage process. The CAG queried the rationale for retaining personal information if the pseudo-ID could be used for future linkages. The applicant explained that personal information had been retained so that patients could be approached for consent to participate in quantitative activities, such as questionnaires, to understand the determinants associated with improved mortality rates. The applicant stated that personal details were therefore required to contact patients about these activities. The CAG requested for a justification on whether the confidential patient information of deceased patients needed to be retained, as they could no longer be contacted for consented, and would not require any additional linkage [Action 1].

The CAG noted that patients would receive annual updates on the conduct of the study through birthday card newsletters, with information also available on the study website. The CAG sought further details on how patients who had opted out, or with whom the study team was no longer in contact, could obtain information about the conduct of the study. The applicant explained that the study website was the main source of communication and had been available for some time. The applicant stated that previous patients would have been aware of how to access the website and would still be able to do so. The CAG requested that a copy of the information text published on the study website was submitted for review, particularly designed to engage with individuals with whom contact had been lost, as these are the relevant cohort with regards to 's251' support. [Action 2].

The CAG noted that no public involvement specific to this research database application had been undertaken to obtain views on the use of confidential patient information without consent, or on the design of the proposed research database. The CAG queried whether further public involvement could be undertaken specifically for this application, given that it represented an extension of the existing work as a single study, as this was turning into a research database. The applicant stated that further public involvement would be undertaken to ensure that widening the scope in this way was supported by the cohort. [Action 3].

The CAG queried if it were possible for some public involvement representatives to be on the data access committee for the database, with regards to making any decisions about data release, as this was usual for research databases supported with 's251' support. [Action 4].

The CAG sought further clarification on the duration of support sought for the application, noting that the application did not specify an end date for access to identifiable information. The applicant confirmed that they sought access to identifiable information over an extended period, as the purpose of the original study was to identify factors associated with longevity, and the purpose of the research database was to act as an ongoing resource. The applicant also acknowledged that there were limits to the period for which CAG support could be reviewed and provided an estimated duration of ten years. The CAG stated that the standard period of support provided for ongoing research databases was 5 years, which would be in line with the REC Research database support. This can be extended by duration modification. (Condition 2).

The CAG queried whether the content of the birthday card would be revised to provide further information on the research database, and whether the use of confidential data without consent for research purposes would be highlighted. The applicant stated that information would be circulated to patients outlining the intended purpose, design and structure of the research project over the following ten years. The CAG accepted this 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.	Please explain if confidential patient information of the deceased can be deleted. If not, please provide justification as to why the confidential patient information of deceased patients is required to be retained for the purposes of the study.	
2.	Please provide an updated copy of the information text published on the study website, particularly looking to engage with individuals with whom contact had been lost, as these are the relevant cohort with regards to 's251' support.	
3.	Please undertake further public involvement with people that represent to cohort, to ensure that the cohort are supportive of the proposal to widen the	

	scope of 's251' support to a research database.	
4.	Please confirm if it is possible for some public involvement representatives to be on the data access committee for the database, with regards to making any decisions about data release.	

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

Number	Condition
1.	15/CAG/0139 will be superseded once this application is supported.
2.	's251' support is provided for 5 years initially, which can be extended with a duration modification.
3.	Favourable opinion from Haydock Research Ethics Committee. **Confirmed: 17 September 2026.**
4.	Confirmation provided from the DSPT Team at NHS England to the CAG that the relevant Data Security and Protection Toolkit (DSPT) submission(s) has achieved the 'Standards Met' threshold. **Confirmed:** The NHS England **25/26** DSPT review for the following organisations was confirmed as 'Standards Met' on the NHS England DSPT Tracker: • University College London - Trusted Research Environment • NHS England

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

5. CONSIDERATION ITEMS

There were no items for consideration

6. ANY OTHER BUSINESS

There was no other business for discussion

Mr Dan Roulstone	16th November 2026
……	……..
Signed – CAG Vice Chair	*Date*
Professor Ben Gibbison	13th November 2026
……	……..
Signed – CAG Alternate Vice Chair	*Date*
Mr Richard Reed	05th November 2026
……	……..
Signed – Approvals Administrator	*Date*
Ms Wangari Njiiri	05th November 2026
……	……..
Signed – Approvals Administrator	*Date*