Confidentiality Advisory Group

Minutes of the meeting of the Precedent Set Review Sub Committee of the Confidentiality Advisory Group held on 30th October 2026 via correspondence.

Present:

Name	Capacity
Professor Lorna Fraser	CAG Chair
Dr Martin Andrew	CAG Member (Expert)
Dr Malcolm Booth	CAG Member (Expert)
Mrs Sarah Palmer-Edwards	CAG Member (Expert)

Also in attendance:

Name	Position (or reason for attending)
Ms Katy Cassidy	HRA Confidentiality Advisor
Ms Rachel Katzenellenbogen	HRA Approvals Specialist
Mr Richard Reed	HRA Approvals Administrator

1. DECLARATIONS OF INTEREST

1a	**26/CAG/0116**	**An observational study of pre-hospital support for older people**
	Conflict:	CAG Member Sarah Palmer-Edwards declared an interest in this item having had involvement with the study at Barts Health NHS Trust. The Precedent Review Sub-Committee agreed that they should not participate in the review of this application.

2. NEW PRECEDENT SET REVIEW APPLICATIONS FOR CAG CONSIDERATION

2a	**26/CAG/0113**	**ERACC: Prospective cohort study**
	Chief Investigator:	Dr Sarah Vollam
	Sponsor:	University of Oxford
	Application type:	Research

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

Summary of application

This application from the University of Oxford is for the purpose of medical research as part of a project to develop a structured, evidence based recovery pathway to improve care for patients after ICU discharge.

Many patients and their families find leaving ICU frightening and often feel unsupported. While most hospitals have Critical Care Outreach Teams who support patients after they leave ICU, there is no standard practice. This study aims to review the types of care patients leaving ICU need, how long the needs last and how often they occur in the hopes of defining a standard recover pathway.

Confidential patient information will be accessed in order to collate the dataset and anonymise it before sharing it.

Confidential information requested

Cohort	The cohort is all people who have been discharged from ICU at three NHS trusts It is a prospective cohort of 900 people. Although it is a prospective study, by the time the data is pulled some members of the cohort may have died.
Data Sources	• Oxford University Hospitals NHS Foundation Trust • Great Western Hospitals NHS Foundation Trust • Walsall Healthcare NHS Trust
Identifiers required for access purposes	• Name • NHS number • Hospital date of birth • Postcode – unit level
Identifiers required for analysis purposes	• Postcode (converted to Indices of Multiple Deprivation) • 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 were satisfied that no other practical alternatives would be suitable for this study, given that this would be a very difficult for families at a time when loved ones were critically ill, and would also be likely to introduce bias.

The CAG noted that a public involvement group had reviewed materials over several meetings. The group consisted of 8 contributors with some demographic diversity, and the public involvement engagement was considered proportionate for the study.

The CAG request the wording on the poster stating that 'The study supports the NHS National Opt-out' to be changed so that it would be clear that if the NDOO was in place, patient data would not be included in this study [Action 2].

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 organisations: • Great Western Hospitals NHS Foundation Trust • Walsall Healthcare NHS Trust 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 that the wording on the poster is changed to be clear that if an NDOO is in place then patient data will not be used in this study.	

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 a Research Ethics Committee. **Confirmed 14th October 2026.**
2.	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 **Oxford University Hospitals NHS Foundation Trust** 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.

2b	26/CAG/0115	The CITY Study
	Chief Investigator:	Miss Christiana Dinah
	Sponsor:	London North West University Healthcare NHS Trust
	Application type:	Research

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

Summary of application

This application from London North West University Healthcare NHS Trust set out the purpose of medical research to estimate how many adults under the age of 40 in the UK experience central retinal vein occlusion each year.

Central retinal vein occlusion (CRVO) is an eye condition caused by a blood clot in the main vein of the eye. This stops blood from draining properly and reduced blood flow to the retina, causing damage and vision loss. CRVO is most common in those aged 65 years and older and is rare in those under 40, making up fewer than 1 in 10 cases. However, at least 20% of young people with CRVO suffer serious vision loss. As these individuals are often of working age, CRVO can have a major impact on their jobs and daily lives. Studies into CRVO have been undertaken with older adults, but few involving younger adults. There are no specific treatment guidelines for young people, and no information to help plan prevention or eye care services for this group. The applicants plan to carry out a prospective, observations study, using the British Ophthalmological Surveillance Unit (BOSU) surveillance system, to understand how many young people under 40 develop CRVO each year in the UK and identify risk factors. The aim is to improve patient outcomes and help doctors create better management guidelines for young people with CRVO.

The BOSU unit, run by the Royal College of Ophthalmologists to assist with the

epidemiological study of rare ocular disorders, will be used. At the end of every month, ophthalmologists receive a report email with the case definitions of all conditions currently the subject of surveillance. Respondents either confirm that they have no new cases to report or click to login to the BOSU digital reporting system to report how many cases of each disorder they have seen. Reporting clinicians access the appropriate data collection proformas, held within study specific areas at the Health Information Centre Dundee University data safe haven. The surveillance unit receives no information at all concerning the patient, as this is transferred directly from the secure online area for questionnaire completion to the researchers area with the data safe haven. The data collection includes the patient's eligibility for inclusion in the study. Also by collecting a minimum amount of unique identifiers duplicate reports of the same case can be identified using probability matching and then excluded, for a more stable estimate of the incidence to quantify the public health problem. All pseudonymised data will be deleted once duplicates have been identified and follow-up has been completed.

Confidential information requested

Cohort	All patients aged 18 – 39 years (inclusive), diagnosed with central retinal vein occlusion (CRVO) is defined by retinal haemorrhages in four quadrants with dilated and tortuous retinal veins, based on the CVOS study case definition, in the one year period of data collection. 120 patients will be included. The applicants advised that the exact dates of the data collection period are dependent on when all required approvals and support are in place.
Data Sources	Information provided by the treating clinicians.
Identifiers required for linkage purposes	Hospital ID Number Postcode – unit level
Identifiers required for analysis purposes	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 no other practical alternatives would be available that would not risk of bias and/or loss of cases.

The CAG noted that public involvement for the study was proportionate and supportive of the study, and that findings would also be shared with the public.

The CAG requested copies of the study notification materials, as these had not been provided with the application [Action 1].

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.	The CAG request copies of patient notification materials. These should explain the study plans, confirm what data will be used, and clearly state the options for opting out. BOSU may be able to provide an example from other studies.	

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 a Research Ethics Committee. **Conditions Confirmed 28 October 2026.**
2.	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 **University of Dundee - Health Informatics Centre** 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.

2c	**26/CAG/0116**	**An observational study of pre-hospital support for older people**
	Chief Investigator:	Professor Simon Conroy
	Sponsor:	Barts Health NHS Trust
	Application type:	Research

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

Summary of application

This application from Barts Health NHS Trust set out the purpose of medical research to investigate the impact of REACH on Barts' hospitals and the local community.

The Remote Emergency Access Coordination Hub (REACH), established by Barts Health in 2020, provides senior emergency physician support to London Ambulance Service clinicians and has shown promising early results, with many older patients having their needs safely managed in the community rather than hospital. The applicants aim to assess the longer-term impact of REACH on subsequent hospital use, patient outcomes, costs, acceptability to patients and families, and effects on community services. The study aims to provide robust evidence to inform future service planning, commissioning, and funding decisions across the North East London Integrated Care System.

Linked, anonymised NHS datasets for individuals who received REACH or Silver Triage support will be compared with matched older adults from London areas without these services. The analysis will employ a quasi-experimental Difference-in-Differences (DiD) design, supplemented by propensity score matching and synthetic control methods, to assess whether the introduction of these services was associated with changes in outcomes beyond underlying trends. Outcomes will include days spent in hospital within three months of an emergency care contact (primary outcome), as well as emergency department attendance, hospital admission, length of stay, readmissions, mortality and overall emergency care costs. NHS England will undertake data linkage and pseudonymisation before the data are transferred to the NHS E secure data environment for analysis.

Confidential information requested

Cohort	Patients aged 65 years and over who had emergency care contact or REACH/Silver Triage contact between 2015 and 2025, or comparable emergency care contact in a London area in the same time period without equivalent pre-hospital frailty support. The index emergency care contact must have taken place between 01 January 2015 and 31 December 2025, with follow-up until 31 March 2026.

	As NHS England supplies HES and ECDS by financial year, data will be requested for financial years 2014/15 to 2025/26 (01 April 2014 to 31 March 2026).
Data Sources	• REACH service records for people aged 65 or over, from Barts Health NHS Trust. • Silver Triage service records for people aged 65 or over, from Central and North West London NHS Foundation Trust (CNWL). • Emergency Care Data Set (ECDS), HES Accident and Emergency for periods before full ECDS coverage, HES Admitted Patient Care; and Civil Registration (Deaths), for all patients aged 65 years and over with an emergency care contact in London during the study period, from NHS England.
Identifiers required for linkage purposes	• NHS number and date of birth for every person in the cohort • date(s) of contact, where the NHS number is missing or needs confirming (Name or any other identifiers mentioned in the original application are no longer needed)
Identifiers required for analysis purposes	• Date of death • Postcode – unit level • 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 other ways of consenting to the study would not be feasible, as a significant proportion of patients would have died since contact (as the REACH project had been running since 2020).

The CAG noted that public involvement engagement was quite extensive, and it was noted that the public involvement group was supportive of accessing confidential patient information without consent for the purposes of the study.

The CAG requested an updated data flow diagram to show that data was being analysed within the NHS England SDE (Secure Data Environment) [Action 3].

The CAG request a copy of the single page poster/web text that was referenced in the application but not submitted [Action 4].

The CAG request confirmation that the NDOO (National Data Opt Out) would be applied Barts Health NHS Trust before sharing with NHS England [Condition 1].

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 2025/26 are outstanding for the following organisation: • Central and North West London NHS Foundation Trust 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.	The CAG request an updated data flow diagram to show that data is being analysed within the NHS England SDE.	
4.	The CAG request a copy of the single page poster/web text that is referenced in the application but not submitted.	

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 confirmation that the NDOO will be applied at Barts Health NHS Trust before sharing with NHS England.

2.	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 reviews for **Barts Health NHS Trust and NHS England** were 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.

2d	**26/CAG/0117**	**Ultrasound features of subchorionic haemorrhage - V1**
	Chief Investigator:	Dr Heather Venables
	Sponsor:	University of Derby)
	Application type:	Research

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

Summary of application

This application, from University of Derby is for the purpose of medical research to investigate whether ultrasound can be used as a reliable predictor of adverse perinatal outcomes.

Sonographers and clinicians currently have no standardised guideline for reporting and managing Subchorionic Haemorrhage. This leads to inconsistencies in treatments that this study hopes to go some way to resolving.

The applicant will access CPI in order to collage data before anonymising it. Only anonymised data will be shared outside of the NHS.

Confidential information requested

Cohort	The cohort consists of women who had scans within their first trimester and the scans showed the presence of subchorionic haemorrhage. It is a retrospective cohort consisting a minimum of 384 cases. The study will pull data from the previous 12 month period.
Data Sources	• North West Anglia NHS Foundation Trust • Nottingham University Hospitals NHS Trust

Identifiers required for extraction purposes	Hospital ID no – used to ensure all the data for a person is linked and not connected to anyone else.
Identifiers required for analysis purposes	No identifiers will be used for analysis.

Main issues considered, discussed and outcomes

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

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

The CAG noted that requesting consent to the study would have practical difficulties and may lead to bias. Additionally, this process may be upsetting as many pregnancies would have ended in miscarriage or other complications. As such, no other practical alternatives to the study were considered appropriate.

The CAG noted that public involvement for this study was appropriate.

The CAG noted that no patient notification had been provided with the application. The National Data Opt Out (NDOO) is being honoured, however without patient notification materials there is no project specific opt out available. Given that many women may have another pregnancy and return to the same Trust, there should be a poster to describe the study, that includes a study specific opt out option. The CAG therefore requested a poster to notify patients [Condition 4]. Additionally, the CAG state that the notification materials must be displayed for 4 weeks prior to data extraction to allow opt out via a project specific opt out [Condition 2].

The CAG noted that the applicant has stated that the PACS system allows identifiers to be removed from the image for export. Therefore only anonymous images should be extracted from PACS [Condition 3].

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

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

Number	Action required	Response from the applicant
1.	Support cannot be issued until a Favourable opinion from a Research Ethics Committee is in place.	

2.	Security assurances for 2025/26 are outstanding for the following organisation: • Nottingham University Hospitals NHS Trust 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.	

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:** The NHS England **25/26** DSPT review for was **NORTH WEST ANGLIA NHS FOUNDATION TRUST** confirmed as 'Standards Met' on the NHS England DSPT Tracker
2.	The poster should be displayed for 4 weeks prior to data extraction to allow opt out via a project specific opt out. Please also see related condition 4.
3.	Only anonymised images may be removed from PACS.
4.	A poster should be developed, providing information about the study, whose data may be included, what data may be included, and how to opt out of the project. The CAG advise that the public involvement group may also be helpful to review these materials before it is sent for CAG review. Please also see related condition 2.

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

Professor Lorna Fraser	16th November 2026
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Signed – Chair	*Date*
Mr Richard Reed	09th November 2026
……	……..
Signed – Approvals Administrator	*Date*