Confidentiality Advisory Group

Minutes of the meeting of the Precedent Set Review Sub Committee of the Confidentiality Advisory Group held on *09 October 2026* via correspondence

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Present:

Name	Capacity
Mr Dan Roulstone	CAG Vice Chair
Mr Anthony Kane	CAG Member (Lay)
Dr Rachel Knowles	CAG Member (Expert)
Mrs Cath Trigwell	CAG Member (Lay)

Also in attendance:

Name	Position (or reason for attending)
Ms Katy Cassidy	HRA Confidentiality Advisor
Ms Wangari Njiiri	HRA Approvals Administrator
Ms Caroline Watchurst	HRA Confidentiality Advisor

1. DECLARATIONS OF INTEREST

There were no declarations of interest.

2. NEW PRECEDENT SET REVIEW APPLICATIONS FOR CAG CONSIDERATION

2.a	**26/CAG/0094**	**Nationwide cluster-randomised trials in England of extending the NHS breast screening age range: the follow-up phase of AgeX (2025-2033)**
	Chief Investigator:	Dr Toral Gathani

	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 University of Oxford is for the purpose of medical research to evaluate the net effect of extending the age range for breast screening in the NHS Breast Screening Programme in England from 50-70 years to 47-73 years. This application already has support under ECC 1-04 (b) 2010, however as support has not been refreshed for 16 years, and the applicant was making changes to the application, a resubmission was agreed, to make sure the scope was clear, which will supersede ECC 1-04 (b) 2010.

The NHS Breast Screening Programme in England currently invites women aged 50–70 for a mammogram every three years. Breast screening can reduce the chance of dying from breast cancer by finding cancers earlier, when treatment is more likely to be successful. However, screening can also detect cancers that would never have caused problems during a woman's lifetime, leading to unnecessary treatment (known as overdiagnosis).

In 2007, the Government announced plans to extend routine breast screening to women aged 47–49 and 71–73. However, there was not enough evidence to know whether the benefits of offering one extra screening appointment at these ages would outweigh the potential harms. AgeX was established in 2009 to answer these questions. Between 2009 and 2020, ~4.5 million women were randomly allocated to either receive or not receive one additional breast screening invitation before age 50 or after age 70. Participants are still followed up via linkage with NHS England records to understand the long term effects of this extra screening (ECC 1-04 (b) 2010).

AgeX will assess whether one additional screening invitation reduces deaths from breast cancer. It will also examine how it affects the number of breast cancers diagnosed, the types of treatment women receive (including surgery, radiotherapy and chemotherapy), and whether providing the extra screening represents good value for money for the NHS. The analyses will include women who were eligible for screening and whose NHS records can be linked for long-term follow-up. Researchers will compare women who were invited for an extra screen with those who were not invited. The findings will provide robust evidence on the benefits, harms and cost-effectiveness of extending breast screening to younger and older women. This evidence will help inform future NHS breast screening policy and support informed decisions by women, healthcare professionals and policymakers in the UK and internationally.

's251' support is required for the ongoing retention of confidential patient information within the AgeX dataset at University of Oxford, for ongoing linkages with NHS England datasets, and to allow the applicant to include a new purpose of moving an effectively anonymous dataset to SAIL databank for storage (so that external researchers can access if required).

Confidential information requested

Cohort	AgeX dataset: 4,553,604 women aged between 47 and 73, who were randomly allocated to either receive or not receive one additional breast screening invitation before age 50 or after age 70, between 2009 and 2020

Data Sources	• University of Oxford, AgeX dataset (common law legal basis ECC 1-04 (b) 2010), which already includes NBSS database & The National Institute for Health Protection (RIDAC) (formerly PHE Cancer Screening data)
	
	• NHS England (linkage already supported under ECC 1-04 (b) 2010):
	  ○ Civil registrations of Deaths (referred to as ONS),
	  ○ Cancer Registrations
	  ○ Demographics
	  ○ Hospital Episode Statistics (HES) data
	  ○ National Cancer Registration and Analysis Data:
	  ▪ Cancer Registrations NDRS
	  ▪ Systemic Anti Cancer Therapy (SACT)
	  ▪ NDRS National Radiotherapy Dataset (RTDS)

Identifiers required for linkage purposes	1. Date of birth 2. Name 3. NHS number 4. Address including postcode 5. Gender
Identifiers required for analysis purposes	The full dates of birth and death (day, month, year) are used for analyses within University of Oxford. This is necessary to ensure the accurate identification and enumeration of deaths for AgeX's primary analysis. These are not however sent to SAIL. Only an anonymous dataset will be sent to SAIL for storage, once all confidential patient information has been removed.

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 identified that the study would be conducted solely in England. It was noted that the application sought continued retention of identifiable data by University of Oxford to support linkage with NHS England data, and analysis within University of Oxford, as previously supported by CAG. Further support was required for a new purpose of processing involving anonymised data to SAIL, where it could be accessed by other researchers. No 's251' support is required for this flow, as it does not contain any confidential patient informaiton, however it has been included as an additional purpose.

The CAG agreed that there were no practical alternatives.

It was noted that members of the public involvement group were supportive of the proposed data flows and ongoing linkage activities requiring section 251 support, and of depositing an anonymous dataset into SAIL. However, members queried the proportionality of the patient and public involvement activity, noting that six individuals had been involved in 2024 and four individuals in 2026 in relation to the retention and linkage of a cohort comprising approximately 4.5 million people. Further considerations on the potential issues of data potentially becoming available to commercial companies for research purposes were raised, despite this data being anonymous. The CAG therefore requested clarification on which organisations would be able to access the data held within SAIL [Action 2a]. The CAG requested further information on any public involvement activities undertaken to explore public views on the use of anonymised information by a wider range of organisations, including commercial organisations [Action 2b].

The CAG requested that the patient notification materials were revised to provide additional opt out routes via email and a telephone number, to improve accessibility [Condition 2].

<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. • University of Oxford – Medical Sciences Division – Nuffield Department of Population Health 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 for the following information: a) Clarify which organisations and categories of researchers would be able to access the data held within the SAIL databank, including whether access may be granted to commercial organisations for research purposes. b) Provide details of any patient and public involvement activities undertaken to explore public views on the use of anonymised information by a wider range of organisations, including commercial organisations, if this is expected.	

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

Number	Condition
1.	ECC 1-04 (b) 2010 will be superseded by 26/CAG/0094, from the date the new application is supported.
2.	Please revise the patient notification materials to include an email address and a telephone number for opt out, and provide to CAG within one month.

3.	Favourable opinion from London – Harrow Research Ethics Committee. **Confirmed: 28 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 NHS England was confirmed as 'Standards Met' on the NHS England DSPT Tracker (additional DSPT pending as per requests for further information)

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

2.b	**26/CAG/0112**	**Understanding different types of premature baby lung disease**
	Chief Investigator:	Professor Daniel Hawcutt
	Sponsor:	University of Liverpool
	Application type:	Research

Summary of application

This application from the University of Liverpool set out the purpose of medical research to investigate whether babies born prematurely who develop lung disease fall into distinct groups based on their clinical features and background, and do babies in different groups follow different clinical courses and outcomes.

This study aims to improve understanding of bronchopulmonary dysplasia (BPD) in babies born very prematurely by determining whether BPD consists of distinct subgroups with different clinical characteristics, disease trajectories, and outcomes. Using routinely collected NHS data from five hospitals, the researchers will apply latent class analysis and trajectory-based analyses to identify patterns in early respiratory support and long-term health outcomes. The aim of the study is to expand beyond the current classifications, which are based on a single time point, and develop a more clinically meaningful understanding of BPD that could improve prediction of outcomes, support personalised care, and provide a foundation for future targeted treatments.

Confidential patient information is processed only within the participating NHS Trusts for the purposes of identifying eligible patients and deriving study variables. Prior to transfer, all records are pseudonymised at source through the replacement of identifiers with a unique study identifier and the removal or conversion of direct identifiers. The pseudonymisation key remains securely held at the originating NHS Trust and will never be shared with the research

team. Only pseudonymised data are transferred to and stored within the University of Liverpool's secure research environment for analysis. All dissemination will use aggregated and anonymised outputs only, with no confidential patient information leaving participating sites at any stage.

Confidential information requested

Cohort	Patients aged between 22 weeks and 16 years, diagnosed with Bronchopulmonary dysplasia (BPD) / Preterm lung disease. Approximately 500 infants will be included in Cohort 1. Cohort 2 will be matched 1:1 to Cohort 1. Cohort 3, 4, and 5 sizes to be determined by data availability at participating sites.
Data Sources	Electronic patient record systems and associated clinical records at participating NHS trusts.
Identifiers required for linkage purposes	• Name • NHS Number • Date of birth • Date of death • Postcode – sector level
Identifiers required for analysis purposes	• Date of birth • Date of death • Postcode – sector 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 proposed data flows was clearly described. The CAG asked for clarification of the time period from which patient records would be drawn for inclusion in the study [action 3].

The CAG stated that obtaining consent would not be feasible as the study

sought to collate retrospective and historic data. It further noted that clinical teams were unable to extract and anonymise the data themselves and that access by the PhD student was therefore required to undertake the process.

The CAG was satisfised with the level of public involvement conducted for this study, noting that eight parents and two pulmonary hypertension advisory groups participated in the review of the study design. An additional consultation was held with four participants to discuss the use of confidential patient information without consent. It was noted that public involvement feedback was supportive overall and acknowledged that plans for ongoing public involvement were arranged.

The CAG noted that the National Data Opt-Out would be applied and identified indications that a study-specific opt out would be made available for potential patients. However, no patient notification materials had been provided to explain how potential participants would be informed about the study or how they could contact the research team. The Committee agreed that clarification of the study-specific opt-out process was required [action 4a] and that appropriate patient notification materials should be provided [action 4b]. Members also requested that start and end dates for data collection be included to ensure individuals could understand whether they may be part of the cohort [action 4c].

The CAG requested for confirmation that no identifiable information would be retained by the research team and that dates of birth would be fully transformed into a non-identifiable format prior to use [action 5].

<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 organisations. • Newcastle upon Tyne Hospitals NHS Foundation Trust • Great Ormond Street Hospital for Children 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.	Clarify the timeframe for cohort identification and provide the start and end dates for the patient records to be included in the study.	
4.	The CAG requested further clarification regarding patient notification and opt-out arrangements: a) Provide a clear description of the study-specific opt-out process, including how patients and families can exercise their right to opt out. b) Submit appropriate patient notification materials for review, detailing how potential participants will be informed about the study and how they can contact the research team. c) Update the patient notification materials to include the start and end dates for data collection, enabling individuals to understand whether they may be included within the study cohort.	
5.	Confirm that no identifiable information will be received or retained by the research team. In particular, clarify that dates of birth will be transformed into a non-identifiable format prior to use	

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 the following organisations were confirmed as 'Standards Met' on the NHS England DSPT Tracker: • Lancashire Teaching Hospitals NHS Foundation Trust • Liverpool Women's NHS Foundation Trust • Alder Hey Children's NHS Foundation Trust

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

Mr Dan Roulstone 27 October 2026

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Signed – Chair *Date*

Ms Wangari Njiiri 20 October 2026

……. ……..

Signed – Insert job title *Date*