Minutes of the meeting of the Sub Committee of the Confidentiality Advisory Group

February 2024

Please note, these minutes contain varying formats, as we work through a change of process regarding CAG outcomes.

1. New Applications

a.

23/CAG/0182	**Suicide crisis and self-harm attendance at A&E in autistic children and young people**
Chief Investigator:	Dr Pooja Saini
Sponsor:	Liverpool John Moores University
Application type:	Research

Present:

Name	Capacity
Dr Tony Calland, MBE	CAG Chair
Dr Harvey Marcovitch	CAG Expert Member
Professor Sara Randall	CAG Lay Member

Also in attendance:

Name	Position (or reason for attending)
Ms Caroline Watchurst	HRA Confidentiality Advisor

A Sub-Committee of the CAG considered the applicant's response to the request for further information detailed in the provisionally supported outcome and line with the CAG considerations in correspondence.

Summary of application

This application from Liverpool John Moores University sets out the purpose of medical research that aims to look at rates of admission for children and young people (CYP) with autism who arrive in A&E for suicidal crisis, self-harm, or following a suicide attempt, to assess the prevalence of the issue and review the services accessed to determine whether the most effective pathways for CYP are accessed.

It is estimated that 1 in 100 CYP in the UK are diagnosed with autism. Suicide is the leading cause of death for young people aged between 20 and 34 years in the UK. CYP with autism are at a higher risk of suicide than non-autistic CYP, and are more than four times as likely as their typical peers to be admitted to the hospital after harming themselves. It is currently unknown why self-harm rates are higher in CYP with autism, how mental health disorders present in CYP with autism, and how services and support should be best placed to accommodate the needs of CYP with autism.

This study requires 's251' support for data extraction at A&E sites only, all other elements of the study are out of scope for 's251' support. The initial identification of potential participants medical notes, using the electronic databases at each of five A&E sites, will be undertaken by the direct care team, who will inform the researcher. The named researcher, who is not a member of the direct care team, will have on-site access to patient medical records, which include confidential patient information. Retrieving information will be a time-consuming activity, and the direct care team have indicated that they do not have the time and resources to complete this work. Therefore 's251' support is required. Potential participants will be screened by the named researcher, and if eligible, pseudonymised data will be recorded. Although a key is retained between the NHS number and the unique anonymised study ID, this is retained by the direct care team only. Therefore support is not required for this retention, and the collected dataset can be considered anonymous to the named researcher. No confidential patient information will be recorded or retained by the researcher. Data will subsequently be analysed at Liverpool John Moores University.

Confidential information requested

Cohort	Children and young people (CYP) aged 5-30, with autism who arrive in A&E for suicidal crisis, self-harm, or following a suicide attempt Between the time period January 2015 – January

	2025. Estimated 1200 per A&E site (a total of 7,200 for 5 A&E sites proposed)
Data sources	1. Electronic databases at 5 A&E departments, and associated Trust medical records: • Alder Hey NHS Foundation Trust – Alder Hey Children's Hospital • Greater Manchester Mental Health NHS Foundation Trust - Royal Manchester Children's Hospital & North Manchester General • Cheshire and Wirral Partnership NHS Foundation Trust - Arrowe Park & Countess of Chester Hospital
Identifiers required for data extraction purposes	1. Researcher will view medical notes to extract a pseudonymised dataset 2. Hospital ID 3. NHS number 4. Date of Birth 5. Post code 6. Unique anonymised study number
Identifiers required for analysis purposes	1. Age 2. Sex 3. Ethnicity 4. Partial postcode (district level) 5. Unique anonymised study number It is not possible for the researcher to re-identify a patient from this data extract.
Additional information	A key that will be held within each Trust linking NHS number to a unique anonymised study number. If researcher needs to go back to a patient file this key will allow re-identification, however only the Trust would hold this information. No identifiable data will be held by the researcher.

Confidentiality Advisory Group advice

A Sub-Committee of the CAG considered the applicant's response to the request for further information detailed in the provisionally supported outcome in correspondence.

#	Action required	Response from the applicant

1.	Support cannot be issued until a Favourable opinion from a Research Ethics Committee is in place.	This was provided 25 January 2024 as per standard CAG condition.
2.	Security assurances for 2022/23 are outstanding for the following organisations. • Mersey care NHS Foundation Trust – (Royal Liverpool University Hospital) Please contact NHS England at exeter.helpdesk@nhs.net and provide the CAG reference number, the organisational names and references that require review, and ask NHS England to review the DSPT submissions due to a CAG application.	Since Christmas Mersey Care have stated that they are are overloaded. They are open to being added as a site in the future when there is better capacity but applicants will not be moving forward with them at this time, and therefore the DSPT review is not required. CAG were content with this.
3	Please confirm whether the age range for this study was those aged between 5 – 30 years old.	Applicants confirmed age range 5 – 30 years, and the CAG were content.
4	Provide the patient notification poster to CAG. The following updates should be made: a) References to CAG approval should be changed to state that the study has been supported by the Health Research Authority on advice from the Confidentiality Advisory Group (CAG), as CAG is advisory. b) The study specific opt out should be more prominent, and the National Data Opt Out should merely be stated as respected.	The applicants initially provided V1.3 (09.01.24), which the CAG were broadly content with, but requested minor changes. The applicant further submitted V1.4 (30.01.24), which the CAG were content to support.

5	Please clarify the following regarding the Patient and Public Engagement undertaken: a) How many individuals made up the engagement group. b) Clarify the makeup of individuals within the engagement group to confirm they represent the cohort. c) Clarify the location of when and in what format these discussions took place. d) Clarify if the use of confidential patient information without consent was discussed and if so, provide CAG with feedback from these discussions.	a)The applicant explained that the group was made up of four individuals. The initial discussions took place prior to AH maternity leave. They are looking to further build the group to include CYP. b)Two individuals with autism & two parents of CYP with autism (both of who's children have self-harmed) c)In person focus group at LJMU premise (Summer 2022 – pre AH maternity leave) & online zoom meeting d)The use of confidential information without consent has been discussed with PAG. The PAG felt as though the need for the research was great and that as data will be anonymised straight away this was acceptable. Following consultation, the Public Advisory Group felt there should be an option to opt out, thus contact information will be given and disseminated via the study webpage to allow potential participants to dissent from the use of their records. The CAG were content with these clarifications

Confidentiality Advisory Group advice: Fully supported

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

Specific conditions of support

The following sets out the specific conditions of support.

1. Favourable opinion from a Research Ethics Committee. **Confirmed 25 January 2024**

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 **22/23** DSPT reviews for **Alder Hey NHS Foundation Trust** (re Alder Hey Children's Hospital), **Greater Manchester Mental Health NHS Foundation Trust** (re Royal Manchester Children's Hospital & North Manchester General) & **Cheshire and Wirral Partnership NHS Foundation Trust** (re Arrowe Park & Countess of Chester Hospital were confirmed as 'Standards Met' on the NHS England DSPT Tracker (checked 02 February 2024)

b.

23/CAG/0181	**Does living by the coast negatively impact palliative and end-of-life care outcomes? An explanatory sequential mixed methods study exploring the inequality of provision and access to palliative care in a coastal region**
Chief Investigator:	Dr Abigail Hensley
Sponsor:	Norfolk And Norwich University Hospitals NHS Foundation Trust
Application type:	Research

Members present:

Name	Capacity
Dr Tony Calland, MBE	CAG Chair
Mr. Anthony Kane	CAG Lay Member
Mr Umar Sabat	CAG Expert Member

Also in attendance:

Name	Position (or reason for attending)
Ms Caroline Watchurst	HRA Confidentiality Advisor

A Sub-Committee of the CAG considered the applicant's response to the request for further information detailed in the provisionally supported outcome and line with the CAG considerations in correspondence.

Summary of application

This application from Norfolk And Norwich University Hospitals NHS Foundation Trust set out the purpose of medical research which aims to identify if there are differences in palliative and end of life care (PEOLC), for patients who live in coastal regions compared to patients that live further in land.

Over the last few years, it has become apparent that people who live in coastal communities are more disadvantaged. This is in terms of social deprivation, job opportunities, and access to healthcare. People that live in deprived areas are more likely to have health problems, including terminal illnesses. There is no current research looking at whether coastal communities are disadvantaged when it comes to palliative and end of life care, and this study hopes to fill that gap.

's251 support' is requested to allow the disclosure of confidential patient information (name, NHS number) from James Paget University Hospital (JPUH) and East Coast Community Healthcare (ECCH) to Norfolk and Norwich University Hospitals NHS Foundation Trust (NNUH), in order for the CI to use NHS number for de-duplication. Support is further requested for the researcher (who is not considered direct care team) to access electronic health records of the deceased patients at East Coast Community Healthcare (ECCH), in order to extract an anonymous dataset for analysis, however no '251' support is required for the researcher to extract a dataset for analysis from James Paget University Hospital, as she is direct care team at that Trust.

Confidential information requested

Cohort	Approximately 800 Patients deceased between April 2023-September 2023 from the Great Yarmouth and Waveney region of the Norfolk and Waveney Integrated Care Board, who meet the inclusion criteria: • Patient over 18 • Patient died at JPUH or died in community hospital or died in their usual residence receiving care from ECCH • Electronic records available Exclusion criteria: Traumatic or unexplained death (as these will not have received PEoLC)
Data sources	1. James Paget University Hospital (JPUH) and East

	Coast Community Healthcare (ECCH) electronic health records 2. Norfolk and Norwich University Hospitals NHS Foundation Trust (NNUH) electronic health records
Identifiers required for deduplication and data extraction purposes	De-duplication: 1. Name 2. NHS number To extract anonymous dataset: 3. Postcode 4. Date of death 5. Medical records
Identifiers required for analysis purposes	1. N/A anonymous dataset for analysis
Additional information	The deceased patient records will be allocated a unique study number for pseudonymisation at time of identification, with no identifiable data recorded. A look-up table will be kept with the unique study number and the NHS number of the record, so the two data sets from the different trusts can be cross referenced to avoid duplication of records being included. The look-up table will be kept on the NNUH trust computer which is password protected, and will only be able to be accessed by the CI. Once data collection is completed this will be deleted.

Confidentiality Advice Team advice

The Confidentiality Advice Team (CAT) considered the applicant's response to the request for further information detailed in the provisionally supported outcome in correspondence.

#	**Action required**	**Response from the applicant**
1.	Support cannot be issued until a Favourable opinion from a Research Ethics Committee is in place.	This was provided on 1 February 2024, as per standard condition of CAG support.

2.	Security assurances for 2022/23 are outstanding for the following organisations. • East Coast Community Healthcare (ECCH) Please contact NHS England at exeter.helpdesk@nhs.net and provide the CAG reference number, the organisational names and references that require review, and ask NHS England to review the DSPT submissions due to a CAG application.	This was provided on 12 January 2024, as per standard condition of CAG support.

Confidentiality Advisory Group advice: Fully supported

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

Specific conditions of support

The following sets out the specific conditions of support.

1. Favourable opinion from a Research Ethics Committee. **Confirmed 01 February 2024**

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 **22/23** DSPT reviews for **James Paget University Hospitals NHS Foundation Trust, East Coast Community Healthcare (ECCH) & Norfolk And Norwich University Hospitals NHS Foundation Trust** were confirmed as 'Standards Met' on the NHS England DSPT Tracker (checked 02 February 2024)

c.

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

Application type:	Research
Submission type:	New application

Present:

Name	Capacity
Dr Tony Calland, MBE	CAG Chair
Mr Thomas Boby	CAG Member (Expert)
Mr David Evans	CAG Member (Expert)
Dr Ben Gibbison	CAG Member (Expert)

Also in attendance:

Name	Position (or reason for attending)
Ms Caroline Watchurst	HRA Confidentiality Advisor

A Sub-Committee of the CAG considered the applicant's response to the request for further information detailed in the provisionally supported outcome and line with the CAG considerations in correspondence.

Summary of application

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

Diabetes affects ~10% of the world's population and rising, with treatment costs ~15% of NHS budget; mainly spent treating preventable complications. 80% of costs are due to diabetes-related complications. The majority are preventable through better clinician evidence-based management and patient self-management. Despite clear evidence for pre-emptive personalised approaches, care remains suboptimal, and outcomes poor. Precision medicine approaches through clinician-focused computer decision-support could transform care.

The applicants will test MWIQ within 7 general practices within Greater Manchester. Up to 14 HCPs involved in the care of people with diabetes will be invited to use MWIQ within diabetes clinics over a period of 6-9 months. Feedback will be sought via online interviews and questionnaires. Investigators will also analyse how the computer was used by the HCP during the clinic and if there were any changes in

clinical outcomes (e.g. glucose control, weight, blood pressure, change in medication) using an anonymised data set. The use of the tool does not require 's251' support, as no confidential patient information is processed.

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

Confidential information requested

Cohort	Patients aged 18 years or over with a diagnosis of diabetes (any type), and attendance at an investigation site diabetes clinic during the period of study The anticipated study period is 05 February 2024 – 02 August 2024, however this will begin once CAG support is in place. Approximately 1000 patients
Data sources	1. MyWay Digital Health Ltd - MyWay Clinical (MWC) platform; Diabetes clinic lists at 7 general practices in Manchester, UK: • Northenden Group Practice • Cornbrook Medical Practice • Peel Hall Medical Practice • The Park Medical Practice • Brooklands Medical Practice • Northern Moor Medical Practice • Woodlands Medical Practice
Identifiers required for purposes of validator review	1. Name 2. NHS number 3. GP registration 4. Date of Birth 5. Address including Postcode 6. Gender

Identifiers required for analysis purposes	1. N/A – no identifiers required for analysis.

Confidentiality Advisory Group advice

A Sub-Committee of the CAG considered the applicant's response to the request for further information detailed in the provisionally supported outcome in correspondence.

#	**Action required**	**Response from the applicant**
1.	Security assurances for 2022/23 are outstanding for the following organisations. • MyWay Digital Health Ltd – (0DS code SP378 Please contact NHS England at exeter.helpdesk@nhs.net and provide the CAG reference number, the organisational names and references that require review, and ask NHS England to review the DSPT submissions due to a CAG application.	This was sent to the CAG inbox on 22 February 2024.
2.	Please update the patient notification materials as follow and provide to CAG for review: a. Clearly explain the specific breach of confidentiality and include opt out options on all notifications. b. All patient notification materials should be reviewed by a patient and public involvement group.	This was provided by the applicant, and CAG were content with the updates. The applicant confirmed the materials had been reviewed by a patient involvement group.
3.	Further patient and public involvement should be carried out with a more	The applicant confirmed that a further PPI focus group was held on 26 January 2024, consisting of 5 people

	extensive patient group, who represent the cohort, specifically regarding the use of confidential patient information without consent.	(40% male, age range 47 to 70, 80% T2D, 20% T1D)). The group are ethnically diverse (i.e. white, black, Asian). One participant uses a wheelchair. The PPI group were satisfied with the proposed methods, and felt that the risk:benefit ratio was acceptable with regards to the use of confidential patient information without consent. The applicant has also provided a report. The CAG commented that although 5 patients was not extensive, they were now prepared to recommend support for this low risk study.

Confidentiality Advisory Group advice: Fully supported

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

Specific conditions of support

The following sets out the specific conditions of support.

1. Favourable opinion from a Research Ethics Committee. **Confirmed FIFO 08 January 2024**

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 **22/23** DSPT review for **MyWay Digital Health Ltd – (0DS code SP378)** was confirmed as 'Standards Met' on the NHS England DSPT Tracker (confirmed by email 22 February 2024)

d.

24/CAG/0006	**Evaluating the effectiveness and acceptability of free door to door transport to increase the uptake of breast screening appointments in**

	Yorkshire: A cluster randomised GP pilot trial Picture
Chief Investigator:	Dr Charlotte Kelly
Sponsor:	University of Hull
Application type:	Research

Present:

Name	Capacity
Dr Murat Soncul	CAG Alternate Vice Chair
Dr Pauline Lyseight-Jones	CAG Lay Member
Mr Dan Roulstone	CAG Expert Member

Also in attendance:

Name	Position (or reason for attending)
Ms Caroline Watchurst	HRA Confidentiality Advisor

A Sub-Committee of the CAG considered the applicant's response to the request for further information detailed in the provisionally supported outcome and line with the CAG considerations in correspondence.

Summary of application

This application from University of Hull set out the medical research purpose of aiming to understand if free door to door transport can help to increase the number of women attending their breast screening appointments in Yorkshire. As a feasibility trial, the primary aim is to assess the feasibility of conducting the future definitive RCT.

Breast cancer is the most commonly diagnosed cancer in women in Yorkshire, causing more than 800 deaths per year in the region. Breast screening is one of the key tools to help diagnose breast cancer at an early stage and improve survival rates. Across Yorkshire, in the three years up to 2019/20 an average of 28.6% of invited women had not attended their appointment. Among the non-attenders, a major reason was the difficulty in travelling to the appointment. This study will assess whether offering free, bookable, door-to-door transport to and from breast cancer screening appointments could increase the number of women attending screening. Applicants will compare two groups. Women registered at GPs in group one will receive information about booking free transport alongside their breast screening invitation. Women registered at GPs in group two will receive the breast screening invitation as normal with no additional offer of transport. No 's251' support is required for sending this information as this is undertaken as part of direct care. Applicants expect that providing free transport will increase the overall screening rates, resulting

in earlier breast cancer diagnosis and improved survival rates. The findings from this study will inform a larger study.

's251' support is requested to use data collected by Humber and East Riding Breast Screening Service (retained at Hull University Teaching Hospitals NHS Trust) on women invited for a breast screening appointment, in order to disclose confidential patient information to NHS England, for linkage to Hospital Episode Statistics (HES) to identify ethnicity and deprivation index. An anonymous dataset will be disclosed to University of Hull for analysis. The applicants are also undertaking other methodologies which do not require 's251' support, such as consented interviews with patients, and travel providers.

Confidential information requested

Cohort	Approximately 8000 eligible women (between ages 50-70) at eight average sized GP practices, who are due to be invited for a routine breast screening appointment by the Humber and East Riding Breast Screening Service in 2024 and early 2025.
Data sources	1. Hull University Teaching Hospitals NHS Trust - Humberside Breast Screening Service – BSS/NHS Breast Screening Programme (NHSBSP) data 2. NHS England – Hospital Episode Statistics (HES)
Identifiers required for linkage purposes	1. NHS Number 2. GP registration 3. Date of Birth 4. Attendance data 5. postcode
Identifiers required for analysis purposes	1. Effectively anonymous for analysis

Confidentiality Advisory Group advice

#	**Action required**	**Response from the applicant**
1.	Support cannot be issued until a Favourable opinion from a Research Ethics Committee is in place.	This was provided on 19 February 2024.

2.	Please update the patient notification materials as follow and provide to CAG for review: a. Poster, section under 'who is included', needs to be simplified and written in language suitable for a lay reader. b. Amend reference to 'ethical approval' - it is more accurate to state that the application has been supported by the Health Research Authority (HRA) on advice from the Confidentiality Advisory Group (CAG). You will also have a Favourable Opinion from the REC regarding the application. c. Provide an explanation that sending information to NHS England is about collecting data on ethnicity and deprivation and then anonymising. d. Please proofread the last paragraph on the poster with regards to study specific opt out.	This was provided and CAG were content with the updated documentation.

A Sub-Committee of the CAG considered the applicant's response to the request for further information detailed in the provisionally supported outcome in correspondence.

Confidentiality Advisory Group advice: Fully supported

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

Specific conditions of support

The following sets out the specific conditions of support.

1. Favourable opinion from a Research Ethics Committee. **Confirmed 19 February 2024**

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 **22/23** DSPT reviews for **Hull University Teaching Hospitals NHS Trust (re Humber and East Riding Breast Screening Service) & NHS England** were confirmed as 'Standards Met' on the NHS England DSPT Tracker (checked 26 February 2024)

e.

24/CAG/0005	**PremPath: Improving the optimisation and stabilisation of the preterm infant**
Chief Investigator:	Professor Nicola Mackintosh
Sponsor:	University of Leicester
Application type:	Research (CAG/REC PILOT)

Present:

Name	**Capacity**
Ms Clare Sanderson	Alternate Vice Chair
Professor Sara Randall	CAG Member (Lay)
Dr Rachel Knowles	CAG Member (Expert)

Also in attendance:

Name	**Capacity**
Ms Caroline Watchurst	HRA Confidentiality Advisor

A Sub-Committee of the CAG considered the applicant's response to the request for further information detailed in the provisionally supported outcome and line with the CAG considerations in correspondence.

Summary of application

This application from University of Leicester set out the purpose of medical research that aims to understand how the care pathway for preterm infants (before 37 weeks of pregnancy) works in practice, and to make recommendations to policy makers to improve care.

When babies are born premature, they are at greater risk of needing neonatal care. The earlier in pregnancy a baby is born, the higher the chance of the baby not

surviving or having a long-term illness. There is a specific care pathway to make sure babies who are born prematurely have the best chance of survival and quality of life. This research project will look at how well this care pathway is currently working. If the pathway looks different in different hospitals, applicants will try to understand why.

A researcher is undertaking research using a number of different methodologies at four NHS Trusts. One is University Hospitals of Leicester, however 3 sites are not yet confirmed, and will be added via amendment. Observation locations are likely to include preterm birth clinics, medical assessment units, antenatal clinic, antenatal ward, foetal medicine, obstetric and neonatal units. Some elements of the study, including consented interviews and viewing procedural documents do not require 's251' support. However, the researcher, who is not considered part of the direct care team, is also undertaking ethnographic observations of staff caring for babies, mums and families. The focus of the observations will be team working and work processes around the optimisation of care for preterm infants, including how parents are involved in these processes. This will include preterm birth clinics, medical assessment units, antenatal clinic, antenatal ward, foetal medicine, obstetric and neonatal units, hand-overs and multidisciplinary team (MDT) meetings. Support under Regulation 5 is required for this aspect of the study as the applicant may be exposed to confidential patient information when undertaking the observations. Observations will be recorded via handwritten field notes. Identifiable patient information will not be recorded. The researcher will aim to observe each site for approximately 3-4 days, between 1 February and 1 December 2024.

Confidential information requested

Cohort	Patients whose confidential patient information was discussed during observations of preterm birth clinics, medical assessment units, antenatal clinic, antenatal ward, foetal medicine, obstetric and neonatal units between approximately 01 February and 1 December 2024. There will be 3-4 days of observations at each site. The size of the cohort will vary by site: • University Hospitals of Leicester have 30 cots in NICU and 12 in SCBU, therefore on any day, there may be 42 preterm infants being cared for across the Trust. • Site 2 (tbc) 32 cots • Site 3 (tbc) 20 cots • Site 4 (tbc) 15 cots
Data sources	Observations of team working, clinical processes, and decision-making, recorded via written field notes, at four NHS Trusts: University Hospitals of Leicester 3 not yet confirmed, will be added via amendment.

Identifiers required for linkage purposes	No items of confidential patient information will be recorded for linkage purposes.
Identifiers required for analysis purposes	No items of confidential patient information will be recorded for linkage purposes.

Confidentiality Advisory Group advice

A Sub-Committee of the CAG considered the applicant's response to the request for further information detailed in the provisionally supported outcome in correspondence.

Number	Action required	Response from the applicant
1.	Support cannot be issued until a Favourable opinion from a Research Ethics Committee is in place.	This was provided on 26th February 2024, via the PILOT process.

A Sub-Committee of the CAG also considered the applicant's response to the provisionally applied conditions, detailed in the minutes, and the provisionally supported outcome in correspondence.

#	Condition	Response from the applicant
1.	Where the PIS states; '*What are your choices about how your information is used? You can stop being part of the study at any time, without giving a reason, but we will keep information about you that we already have.'* Please revise to state; *'if you don't want to be included in the observations, please let … know and we will make sure no information about you, or your baby is included'.*	Edited as requested, ACG were content.
2.	Explain why the research team would keep the already collected information, after a participant has opted-out. Is this due to the	This was included in error and has been removed – CAG were content with this response.

	data already being anonymised? If so, please clarify this within the PIS.	
3.	Clearly outline in all patient notification materials that the Chief Investigator will potentially overhear confidential patient information during the process of observations, however no confidential patient information will be recorded.	Added to parent observation PIS, Parent postcard, observation poster. CAG were content with this.
4.	Ensure both the poster and the postcard PIS refer to the PIS.	QR code will be added to observation poster, and CAG were content with this solution.
5.	Where the postcard states; '*if you are present during PremPath observations, we will not collect any information that could identify you or you baby.'* Please revise to state*; 'if you are present during PremPath observations the researcher may hear information that could identify you or you baby. This will not be recorded.'*	Edited as requested, ACG were content.

Confidentiality Advisory Group advice: Fully supported

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

Specific conditions of support

The following sets out the specific conditions of support.

1. Favourable opinion from a Research Ethics Committee. **Confirmed 26 February 2024**

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 **22/23** DSPT review for **University Hospitals of Leicester** was confirmed as 'Standards Met' on the NHS England DSPT Tracker (checked 29 February 2024)

2. New Amendments

18/CAG/0100 – HPS-4/TIMI 65/ORION-4: A double-blind randomized placebo-controlled trial assessing the effects of inclisiran on clinical outcomes among people with atherosclerotic cardiovascular disease

Name	Capacity
Ms Caroline Watchurst	HRA Confidentiality Advisor

Context

Amendment request

The applicants have existing support to process confidential patient information supplied by acute hospitals trusts and NHS England (previously NHS Digital) to the Clinical Trial Service Unit at the University of Oxford in order to contact patients to seek consent to include their data on a pre-screening database.

In the original application, Paragon Customer Communications were included as a data processor. Paragon received data about potentially eligible patients from the University of Oxford in order the mail invitation letters to them. Recruitment for ORION-4 is now complete and therefore data is no longer provided to Paragon under section 251 of the NHS act 2006. This current amendment is to remove Paragon as a data processor.

Confidentiality Advisory Group advice

The amendment requested was considered by the Confidentiality Advice Team. The CAT raised no queries as part of this amendment.

Confidentiality Advisory Group advice conclusion

In line with the considerations above, the CAT agreed that the minimum criteria under the Regulations appeared to have been met for this amendment, and therefore advised recommending support to the Health Research Authority.

Specific conditions of support

The following sets out the specific conditions of support.

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 2022/23 DSPT review for University of Oxford - Medical Sciences Division - Nuffield Department of Population Health was confirmed as 'Standards Met' on the NHS England DSPT Tracker (checked 12 January 2024).

2. Confirmation of a favourable opinion from a Research Ethics Committee. **Confirmed 12 December 2023**

23/CAG/0031 – Sentinel Stroke National Audit Programme (SSNAP) – (non- research application)

Name	Capacity
Ms Caroline Watchurst	HRA Confidentiality Advisor

Context

Amendment request

Sentinel Stroke National Audit Programme (SSNAP) - the national clinical audit of stroke services, collects data on all patients with a new episode of stroke or TIA (transient ischaemic attack), or those suspected of having a stroke, admitted to hospital in England and Wales. SSNAP is part of the National Clinical Audit and Patient Outcomes Programme (NCAPOP).

This amendment sought support to change the Chief Investigator from Professor Charles Wolfe to Professor Vasa Curcin.

Confidentiality Advisory Group advice

The amendment requested was considered by the Confidentiality Advice Team who raised no queries regarding this amendment.

Confidentiality Advisory Group advice conclusion

In line with the considerations above, the CAT agreed that the minimum criteria under the Regulations appeared to have been met for this amendment, and therefore advised recommending support to the Secretary of State for Health and Social Care.

Specific conditions of support

The following sets out the specific conditions of support.

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 **22/23** DSPT reviews for **Kings College London (SSNAP team) – (EE133874-SSNAP), Net solving Ltd (8JA87), ANS Group Ltd & NHS England** were confirmed as 'Standards Met' on the NHS England DSPT Tracker (checked 23 January 2024)

   The Welsh IG team have confirmed that security assurances are in place for Digital Health and Care Wales (DHCW)

   Due to the number of participating organisations involved it is the responsibility of the applicant, as controller, to ensure that all organisations processing confidential patient information meet the minimum required

standard in complying with DSPTs (or CPiPs for Wales), and take remedial action if they become aware of any that fall below this, or where any concerns are raised about a care provider. These will not be individually checked by the CAT team due to the number of organisations involved.

16/CAG/0153 – UK Renal Registry

Name	Capacity
Dr Tony Calland, MBE	CAG Chair
Ms Caroline Watchurst	HRA Confidentiality Advisor

Context

Amendment request

The UK Renal Registry (UKRR) has 's251' support for clinical teams to provide the audit team with confidential patient information regarding patients with Chronic kidney disease (CKD), including those receiving renal/Kidney replacement therapy (KRT), and Acute kidney injury (AKI). It receives data from renal units and laboratories in the UK. Support is also in place to receive linked outcome data from UKHSA (previously PHE), NHS Blood & Transplant, NHS England (Civil registration mortality data & HES), and DHCW (PEDW data).

This amendment sought 's251' support to increase the frequency of linkage to NHS England Civil registration mortality dataset to quarterly, instead of the current annual linkage.

Understanding the causes and timelines leading to a patient's death is a key metric in auditing the quality of care received by patients in kidney centres across the UK. Submitting centres are required as part of their reporting to include dates and causes of death as recorded renal IT systems. However, unlike many of the metrics measured by the UKRR which can be validated at submission, applicants rely on external data to validate cause and date of death for a patient, namely the linked mortality outcome data provided by NHS England. At the current annual frequency of linkage, this means that the UKRR is in some cases unable to validate the cause and date of death for a patient until over a year after their reported death. Not only does this slow down the validation process and subsequent analyses of the UKRR's audit, it also negatively impacts the UKRR's ability to question and challenge kidney centres and their staff as to the circumstance surrounding a patient's death as knowledge of the case(s) is lost either to the impacts of time on memory or through staff turnover.

Increasing the frequency of linkage to quarterly would allow the UKRR to spot discrepancies sooner, more accurately challenge and question kidney centres and potentially spot patterns in treatments and behaviors that are negatively impacting patient outcomes and work with kidney centres to correct these deviations.

Confidentiality Advisory Group advice

The amendment requested was considered by Chair's Action. The CAG Chair was content to recommend support for this amendment.

Confidentiality Advisory Group advice conclusion

In line with the considerations above, the CAG agreed that the minimum criteria under the Regulations appeared to have been met for this amendment, and therefore advised recommending support to the Secretary of State for Health and Social Care.

Specific conditions of support

The following sets out the specific conditions of support.

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 22/23 DSPT reviews for **UKHSA, NHS England, The Renal Association & NHS Blood & Transplant** was confirmed as 'Standards Met' on the NHS England DSPT Tracker (checked 23 January 2024)

   Digital Health and Care Wales has been confirmed to have met the standards of the Welsh IG toolkit, by the Welsh IG team.

23/CAG/0047 – A randomised controlled phase III trial of a novel behavioural intervention for primary care teams to promote the earlier diagnosis of cancer (ThinkCancer!)

Name	Capacity
Ms Caroline Watchurst	HRA Confidentiality Advisor

Context

Amendment request

This application seeks to assess the effectiveness of use of the ThinkCancer! Intervention by general practice teams, compared with usual care. ‘s251’ support is in place to allow research staff to access confidential patient information held in patient records at participating GP practices, listed in the document “General Practice sites who intend to participate to date” in order to extract an anonymised dataset.

This amendment sought support to include further additional participating GP practices to the application, as additional data processors under ‘s251’ support. These are listed below:

1. Strathmore Medical Practice (BCUHB)
2 .Beech Avenue Practice (BCUHB)
3. Plas Meddyg Surgery (BCUHB)
4. Middle Lane Surgery (BCUHB)
5. Gwrych Medical Centre (BCUHB)
6. Bronyffynnon Surgery (BCUHB)
7. Bellevue Group Practice (ABUHB)
8. Nant Dowlais Health Centre (ABUHB)
9. Willowbrook Surgery (CVUHB)
10. Court Road Surgery (CVUHB)
11. Briton Ferry Health Centre (SBUHB)
12. King’s Road Surgery (CVUHB)
14. St Isan Road Surgery (CVUHB)
15. West Quay Medical Centre (CVUHB)
16. Oak Tree Surgery (CTMUHB)
17. Four Elms Medical Centre (CVUHB)
18. St David’s Court Surgery (CVUHB)
19. Borth Surgery (HDUHB)

20. Queen Square Medical Practice (North West England)
21. Fearnhead Cross Medical Centre (North West England)
22. Eric Moore Partnership (North West England)
23. Richmond Medical Centre (North West England)
24. Whitefield Health Centre (North West England)
25. Dingle Park Practice (North West England)
25. Garswood Surgery (North West England)
26. Shifa Surgery (North West England)

Confidentiality Advisory Group advice

The amendment requested was considered by the Confidentiality Advice Team who raised no queries regarding this amendment.

Confidentiality Advisory Group advice conclusion

In line with the considerations above, the CAT agreed that the minimum criteria under the Regulations appeared to have been met for this amendment, and therefore advised recommending support to the Health Research Authority.

Specific conditions of support

The following sets out the specific conditions of support.

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.**

   Due to the number of organisations involved it is the responsibility of Bangor University, as controller, to ensure that practices hosting researchers meet the minimum required standard in complying with DSPTs (in England), or Welsh CPiP or Welsh IG toolkit (in Wales), and take remedial action if they become aware of any that fall below this, or where any concerns are raised about a practice.

2. Confirmation of a favourable opinion from a Research Ethics Committee. **Confirmed non substantial 06 February 2024**

20/CAG/0084 – PIONEER: The UK Health Data Research Hub for Acute Care

Name	Capacity
Dr Tony Calland, MBE	CAG Chair
Ms Caroline Watchurst	HRA Confidentiality Advisor

Context

Amendment request

This application has ‘s251’ support to allow transfer of confidential patient information from West Midlands Ambulance NHS Trust to University Hospitals Birmingham NHS Foundation Trust to establish the PIONEER research database. Birmingham Community Healthcare NHS Foundation Trust (BCHC) has also been included as a data source via CAG amendment supported 21 November 2023.

The PIONEER team now wish to supplement this information by adding GP patient level data from the Hall Green Health, as an additional data source, for 24 months initially. Confidential Patient Information will be shared and linked with existing information in the same manner as West Midlands Ambulance NHS Trust. Doing so will enable evaluation of the full trajectory of patient healthcare journeys.

Confidentiality Advisory Group advice

The amendment requested was considered by Chair’s Action. The Chair requested some clarifications, which the applicant answered as follows. Hall Green Health was confirmed to be one large GP practice. It was formed in 2003 following the merger of five smaller practices. The GP data will come from this one (large merged) practice. The amendment will cover approximately 28,500 patients. No free text is involved. The GPs at the practice are aware of this amendment, and have provided a letter of support. The arrangements for patient notification and communication were described, and the following were provided to CAG:

- **Attachment 1**: PIONEER GP Poster for Hall Green Health. Patient Participation Group.
- **Attachment 2**: PIONEER Your Health Could Data Saves Lives Flyer. This flyer was generated with input from patients and public, and has been translated into Arabic, Cantonese, Polish, Somali, Urdu, and large print. These flyers will be available near the poster in the GP practice.
- **Attachment 3**: Hall Green Health Patient Newsletter is provided to demonstrate the way the practice communicates with their patients. After the PPG meeting, PIONEER would like to have a space in the newsletter to update patients at the practice about the planned research projects and benefits to both them and the broader public. The text will be drafted following guidance from the PPG group.

All of these communications will be discussed with Hall Green Health Patient Participation Group**.** The applicant has also updated the PIONEER Website text and privacy notice to include Hall Green Health. Hall Green Health website and Twitter will

also be used. A short video will also be on display at the practice. The practice has a television with internal "adverts" on display, and applicants are going to work with the PPG to create a short video explaining what PIONEER is, and people's choices.

The CAG Chair was content to recommend support after these clarifications.

Confidentiality Advisory Group advice conclusion

In line with the considerations above, the CAG agreed that the minimum criteria under the Regulations appeared to have been met for this amendment, and therefore advised recommending support to the Health Research Authority.

Specific conditions of support

The following sets out the specific conditions of support.

1. Support is in place for 24 months from the date of this letter.

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 **22/23** DSPT reviews for **University Hospitals Birmingham NHS Foundation Trust**, **West Midlands Ambulance Service NHS Trust**, **Birmingham Community Healthcare NHS Foundation Trust & Hall green Health** were confirmed as '**Standards Met'** on the NHS England DSPT Tracker (confirmed by 21 December 2023)

3. Confirmation of a favourable opinion from a Research Ethics Committee. **Confirmed (REC considered no review required)**

22/CAG/0075 – Clinical and Radiographic outcomes of reverse shoulder arthroplasty performed with 36-mm CoCrMo vs 40-mmcross-linked UHMWPE glenospheres at minimum 2-years follow-up

Name	Capacity

Ms Caroline Watchurst	HRA Confidentiality Advisor

Context

Amendment request

This amendment sought ‘s251’ support to increase the number of patients enrolled to the study in order to capture all data available at Royal Berkshire Hospital. The previous ‘s251’ support covered 200 participants. The amendment seeks to widen the cohort to 217 participant.

This amendment also sought support to extend the duration of ‘s251’ support from 31 December 2023, until 31 March 2024, to allow Royal Berkshire Hospital more time for entry of data for these additional participants.

Confidentiality Advisory Group advice

The amendment requested was considered by the Confidentiality Advice Team, who raised no queries regarding this amendment.

Confidentiality Advisory Group advice conclusion

In line with the considerations above, the CAT agreed that the minimum criteria under the Regulations appeared to have been met for this amendment, and therefore advised recommending support to the Health Research Authority.

Specific conditions of support

The following sets out the specific conditions of support.

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 **22/23** DSPT reviews for **Wrightington, Wigan and Leigh NHS Foundation Trust and Royal Berkshire NHS Foundation Trust** were confirmed as 'Standards Met' on the NHS England DSPT Tracker (checked 08 February 2024)

2. Confirmation of a favourable opinion from a Research Ethics Committee. **Confirmed non substantial 30 January 2024**

19/CAG/0139 – The clinical and cost-effectiveness of testing for Group B Streptococcus: a cluster randomised trial with economic and acceptability evaluations (GBS3)

Name	Capacity
Ms Caroline Watchurst	HRA Confidentiality Advisor

Context

Amendment request

This application from the University of Nottingham aims to evaluate two testing approaches to identify Group B Streptococcus in pregnant women.

The applicants have existing support to process data from; electronic health records from participating maternity units in England and Wales, the National Neonatal Research Database, Patient Episodes Dataset Wales held by the DHCW (previously NHS Wales Informatics Service), Group Strep B Infant Sepsis reports held by Public Health England, Group Strep B Infant Sepsis reports held by Health Protection Wales, and the English Maternity Services Dataset and HES data held by NHS Digital, the Paediatric Intensive Care Audit Network (PICANet) and Badgernet (Maternity and Neonatal). Data from these sources will be processed in order to create a dataset for analysis. Data is retained by the Health Informatics Centre at the University of Dundee.

An amendment was supported 09 June 2023 to alter the data flow so that the GBS3 trial could receive the total maternity cohort from NHS England, regarding the financial years 20-24, taken from the Maternity Service Data Set (MSDS) and disclosed to the

Health Informatics Centre at the University of Dundee, as NHS England advised they could not undertake the more specific extraction of data.

's251' support was initially in place for NHS England to provide data restricted to the participating GBS3 hospital/ trust systems during a specific time period, directly to the Health Informatics Centre at the University of Dundee, and would include the NHS number, Date of Birth (DOB) & Postcode of the trial participants to enable linkage with other datasets from other databases. The trial cohort includes all women who gave birth or intended to give birth at a GBS3 participating site during the data collection window for each site. At the time of the June 2023 amendment being requested, NHS England advised that this complex query was beyond the data structure, and capability and capacity of NHS England.

This amendment sought support to reverse the 09 June 2023 amendment, and revert to the original planned flows. The applicants will now be able to receive data solely on the GBS3 cohort from NHS England. The reversion limits the amount of identifiable data disclosed to the Health Informatics Centre at the University of Dundee to data only from those NHS Trusts participating in GBS3 and limits individual level data to the hospital's period of participation. This adheres to the principles of data minimisation. It will also realign the English data flow to the same design as the data received from Welsh health boards.

This amendment also sought support regarding a change on the data anonymisation process. The Health Informatic Centre (HIC) TRE data manger will carry out the anonymisation (instead of the NCTU data manager). They offer this service as default to provide the highest standard of security and to reduce the margin of mistakes, and this provides a more robust and secure process to anonymise data.

Updated data flow diagrams have been submitted that reflect the above changes.

The applicant also provided updated patient notification materials, which are accepted by CAG as notifications. These are changed as UKSHA requested to amend the privacy notice to make it clearer, more detailed, for a lay audience and to highlight that the final retained dataset will be at patient level but pseudonymised.

Confidentiality Advisory Group advice

The amendment requested was considered by the Confidentiality Advice Team, noting that the changes mostly reverted back to a flow that was already supported by CAG initially, and was a less disclosive flow.

Confidentiality Advisory Group advice conclusion

In line with the considerations above, the CAT agreed that the minimum criteria under the Regulations appeared to have been met for this amendment, and therefore advised recommending support to the Health Research Authority.

Specific conditions of support

The following sets out the specific conditions of support.

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 **22/23** DSPT review for **the University of Nottingham and the DSPT equivalent for NHS England** were confirmed as 'Standards Met' on the NHS England DSPT Tracker (checked 23 January 2024)

   Due to the number of organisations involved it is the responsibility of University of Nottingham, as controller, to ensure that all organisations processing confidential patient information without consent 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. These will not be individually checked by CAT as there are more than 5 organisations.

   Health Informatics Centre at the University of Dundee – HSC-PBPP approval confirmed 04 November 2021

2. Confirmation of a favourable opinion from a Research Ethics Committee.
   Confirmed 13 February 2024

23/CAG/0015 – Flatiron Health UK Oncology Real-World Database v2.0

Name	Capacity
Dr Tony Calland, MBE	CAG Chair
Professor William Bernal	CAG Alternate Vice-Chair
Dr Martin Andrew	CAG Expert Member
Dr Pauline Lyseight-Jones	CAG Lay Member
Professor Sara Randall	CAG Lay Member
Dr Paul Mills	HRA Confidentiality Advice Service Manager
Ms Caroline Watchurst	HRA Confidentiality Advisor

Context

Amendment request

This application was conditionally supported 20 March 2023. Conditions were met on 3 November 2023. 's251' support is in place to allow the disclosure of confidential patient information from participating Trusts to Flatiron UK Ltd, for the purposes of creating a research database to collect real world data (RWD) for cancer patients aged 18 years and over. The database is comprised of routinely collected retrospective data for patients aged 18 years and over who received treatment for cancer. Support is currently only in place for Leeds Teaching Hospitals NHS Trust (LTH).

Structured and unstructured data will be extracted from Trust clinical systems by members of the direct care team at the Trust. The Trust will transfer the confidential patient information to a "Landing Zone" within an NHS Trust Firewall. Flatiron Health UK Ltd will access the dataset to remove the identifiers from the data to create a pseudonymised dataset identified by a key and will be transferred to a "Joint Research Environment", still within the Trust firewall. There, Flatiron Health UK Ltd will undertake further processing to anonymise the data before transfer to the Flatiron Health UK Ltd Environment. All data processed by Flatiron Health UK Ltd after this point will be anonymised. Their aim was always to add additional Trusts to the process.

This amendment sought 's251 support' to add a new data processor - University Hospitals of Leicester NHS Trust (UHL) to the Flatiron Health Research Database in

the United Kingdom (FHRD-UK). Exactly the same process/data flow will be followed regarding the new Trust, and this methodology has already been agreed by CAG. The addition of the site is for the same overall purpose which was already agreed by CAG.

Draft patient notifications have been submitted for the new Trust, and are in line with the initially supported application. Applicants agreed with CAG a notification methodology for the initial application which informed every eligible patient of the processing: an individual letter (supporting material "Letter template to Inactive patients") and information handout (supporting material "Information Handout") will be sent to every patient eligible for the research database. They will have 4 weeks to opt out, but they will still be able to opt out after this date if they want to. Anybody who has registered a National Data Opt Out (NDOO) will not be sent a letter, and their data will not be disclosed to Flatiron. Applicants do not plan to specifically send translated letters, but are aligning with UHL usual processes and will support accessibility and translation services as required.

The applicants undertook extensive public involvement for the initial application, and also have done further public involvement for the addition of this new site, with people who represent the University Hospitals of Leicester NHS Trust cohort. The use of identifiers without consent was discussed, and broadly supported. CAG has been provided the presentation that was used, and much further detail in their cover letter.

Confidentiality Advisory Group advice

The amendment requested was considered by a Sub-Committee of the CAG, via teleconference to ensure the same members as the initial application reviewed the application. Whilst condition 6 of the original application stated amendments should be considered at a full meeting, this approach was agreed to ensure consistency, rather than a different group of members reviewing without prior knowledge of the application.

The Sub-Committee recommended support for the addition of University Hospitals of Leicester NHS Trust, noting that CAG had already supported the principle. However, the CAG noted that amendments for continuing expansion of the model would continue to be reviewed via teleconference with at least a Sub-Committee of the CAG.

<u>Patient and Public Involvement</u>

The Members were pleased to see continued public involvement being undertaken, but commented that the evidence submitted as part of the initial amendment submission was not detailed, and was not specific to the use of confidential patient information without consent. Whilst the query responses provided clarity that there was general support for the use of data without consent, Members noted that

sensitivities around the use of data by commercial companies appeared to remain in some of the public participant responses.

Whilst the Sub-Committee did recognise that the applicant has undertaken a reasonable amount of public involvement, the CAG recommend that the applicant ensures that relevant information is presented to participants in future work and is also provided to CAG. CAG is especially interested in the demographics of the groups of people taking part in the discussion, the number of people attending any discussions, the type of meeting undertaken, information given and questions asked of the public involvement participants. The public involvement undertaken should be proportionate to the planned activity. CAG would like to see feedback, including specific responses, and number of people who were content with the described use of identifiable data without consent for this purpose for any ongoing public involvement. Further information and guidance can be found on the CAG guidance page.

Public benefit

The Sub-Committee noted that the National Data Guardian guidance on public benefit explains important principles surrounding the use of data by commercial entities, and that the CAG use these principles in their considerations;

'In some cases, a data use that delivers a benefit to NHS and social care organisations may also deliver a benefit to private or commercial organisations. In such scenarios, positive answers to the following questions will help to determine whether the purpose is for public benefit. These are suggestions that aim to capture the spectrum of public benefit identified by the public dialogue; it is not an exhaustive list:

1. *Will any private profit, or progress made by a commercial organisation, also lead to benefits for the health and care system that will ultimately benefit patients? For example, improving how the NHS operates by increasing service or administrative efficiency?*

2. *Where a commercial organisation makes private profit or progress that serves its own interest, is the agreement that underpins its partnership with the NHS based on fair terms? Does that agreement recognise and safeguard the value of the NHS data on which the organisation's profit or progress is founded?*

3. *Will research findings be openly shared with others who can use them to maximise benefits to patients, the wider public, and the health and social care system'*

Based on these principles, Members agreed there should be a continual assessment of how any private profit, or progress made by Flatiron, will also lead to benefits for the health and care system that will ultimately benefit patients. As such that CAG agreed the applicant should provide at the time of each annual review, and for any further amendments, the tangible benefits to the NHS Trusts, NHS patients, and services that can be improved though association with the programme. CAG also noted that these potential benefits, and details of the partnerships, should be available to patients and the applicant should consider including these in the patient notification documentation, potentially in the detailed FAQ document referred to on the poster.

The Sub-Committee understood and were content that the partnerships with Flatiron in each Trust were based on financial agreements that would provide income to the Trust.

Members understood that anonymous data would be available in a research database, for researchers in industry and academia to access, and that this would be fee based. As a unique data resource, which has been built using NHS data, the Sub-Committee asked for reassurance that researchers working within the NHS would not have to pay commercial rates for accessing the data, to align with National Data Guardian guidance.

CAG remains concerned that where some patients may be concerned about a particular aspect of one research activity (for example commercial activity), that they may be disproportionately likely to register for the National Data Opt Out (NDOO) that would exclude them from all future research irrespective of its nature. The CAG therefore request that in each annual review, the applicant should provide comparative opt out rates for both the Flatiron specific study opt out and the NDOO rates for the studied population at each of the research sites, as well as the NDOO rate for each Trust as a whole (or the relevant geographical areas if this data is not available).

<u>Patient notification</u>

The Sub-Committee discussed the materials and agreed some improvements were needed.

- Members highlighted there was an individualised 4-week time frame to opt out on the letters from the date they are sent. However, the poster had no opt out deadline as patients could see this at any time. Members queried whether there should be a final opt out deadline for anyone viewing the poster so they can understand if their request can be honoured. Members asked either for a final deadline to be added, or justification provided why the poster should not have an opt out deadline.
- As per above comments, the potential benefits, and details of the partnerships, should be available to patients, via the FAQ documentation.
- There are some spelling errors on the poster, and these should be corrected.

In addition, all patient notification documentation (including Leeds Teaching Hospitals NHS Trust) should be amended to include the common law legal basis for the processing of confidential patient information without consent, as this is not currently clear from any documentation. The specific wording can be something similar to the following example – however shortened appropriately for posters etc. '*Flatiron has support under Regulation 5 of the Health Service (Control of Patient Information) Regulations 2002 to process confidential patient information without consent, from The Health Research Authority, on advice from the Confidentiality Advisory Group (CAG), an advisory body which provides independent expert advice on the use of confidential patient information without consent in England and Wales'.*

Confidentiality Advisory Group advice conclusion

In line with the considerations above, the CAG agreed that the minimum criteria under the Regulations appeared to have been met for this amendment, and therefore advised recommending support to the Health Research Authority.

Specific conditions of support

The following sets out the specific conditions of support.

1. At annual review, (or any future amendment), please provide the tangible benefits to the NHS Trusts, NHS patients, and services that can be improved though association with the programme, in order for CAG to assess the patient benefit of this activity.

2. At annual review, please provide comparative opt out rates for each site, both Flatiron specific opt out rates and NDOO rates if possible.

3. In one month, please provide re-assurance that researchers working within the NHS would not have to pay commercial rates for accessing the data.

4. In one month, please amend the patient notifications in line with advice in this letter. This includes;
    a) Correct spelling errors on the poster
    b) Please add a final opt out deadline to the posters, or provide justification as to why the poster should not have an opt out deadline.
    c) Include details on potential patient benefits, and details of Trust partnerships in FAQs
    d) Include the common law legal basis for processing on the notifications using the example wording in this letter.

5. Confirmation provided from the DSPT Team at NHS England to the CAG that the relevant Data Security and Protection Toolkit (DSPT) submission(s) has achieved the 'Standards Met' threshold **Confirmed:**

   The NHS England **22/23** DSPT reviews **for Flatiron Health UK, Leeds teaching Hospital NHS Trust, University Hospitals of Leicester NHS Trust** were confirmed as 'Standards Met' on the NHS England DSPT Tracker (checked 06 February 2024)

6. Confirmation of a favourable opinion from a Research Ethics Committee. **Confirmed no REC review required 04 July 2023**

23/CAG/0047 – A randomised controlled phase III trial of a novel behavioural intervention for primary care teams to promote the earlier diagnosis of cancer (ThinkCancer!)

Name	Capacity
Ms Caroline Watchurst	HRA Confidentiality Advisor

Context

Amendment request

This application seeks to assess the effectiveness of use of the ThinkCancer! Intervention by general practice teams, compared with usual care. ‘s251’ support is in place to allow research staff to access confidential patient information held in patient records at participating GP practices, listed in the document “General Practice sites who intend to participate to date” in order to extract an anonymised dataset.

This amendment sought support to include further additional participating GP practices to the application, as additional data processors under ‘s251’ support. These are listed below:

1) Paxton Medical Group (NW England)
2) Vauxhall Health Centre (NW England)
3) Eastham Group Practice (NW England)
4) Brynteg surgery (HDUHB)

Confidentiality Advisory Group advice

The amendment requested was considered by the Confidentiality Advice Team who raised no queries regarding this amendment.

Confidentiality Advisory Group advice conclusion

In line with the considerations above, the CAT agreed that the minimum criteria under the Regulations appeared to have been met for this amendment, and therefore advised recommending support to the Health Research Authority.

Specific conditions of support

The following sets out the specific conditions of support.

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.**

Due to the number of organisations involved it is the responsibility of Bangor University, as controller, to ensure that practices hosting researchers meet the minimum required standard in complying with DSPTs (in England), or Welsh CPiP or Welsh IG toolkit (in Wales), and take remedial action if they become aware of any that fall below this, or where any concerns are raised about a practice.

2. Confirmation of a favourable opinion from a Research Ethics Committee.
   Confirmed non substantial 06 February 2024

21/CAG/0108 – What clinical outcomes are associated with the 'joint care' for teenagers and young adults with cancer?: BRIGHTLIGHT_2021

Name	Capacity
Dr Murat Soncul	CAG Alternate Vice Chair
Ms Caroline Watchurst	HRA Confidentiality Advisor

Context

Amendment request

This application from University College London Hospital NHS Foundation Trust (UCLH) aims to administer patient surveys to help determine if there are clinically significant differences in outcomes in 2021 for teenagers and young adults (TYA) with cancer receiving 'joint care' compared to all or no care in a teenagers and young adults Principal Treatment Centre (TYA-PTC), across England and Wales.

'S251' support is in place to recruit all (Approximately 1000) young people in England aged 16- 24 years, between 4-6 months of a new cancer diagnosis. The applicant has 's251 support to screen patients diagnosed from August 2022 to December 2022, meaning participating sites will be screening and uploading patient details until June 2023.

The original plan was for the analysis to be undertaken at National Cancer Registration and analysis Service (NCRAS) with the BRIGHTLIGHT_2021 researcher hosted on an honorary contract. Due to multiple changes over the last 3 years, NCRAS are no longer able to host a researcher and therefore the analysis needs to be undertaken at UCLH/UCL. Analysis does require access to confidential patient information, in the form of date of birth and date of death.

Quality Health hold all the survey data along with confidential patient information. UCLH currently holds the pseudonymised survey data only.

This amendment therefore sought support for Quality Health to disclose confidential patient information (date of birth and date of death) to UCLH. IMD quintile linked to the patient study number will also be provided, so applicants can link dates of birth and death to the survey data.

Date of diagnosis will also be required, however this is not confidential patient information. Confidential patient information will however need to be processed in order for UCLH to receive the date of diagnosis. The date of diagnosis is in the NCRAS dataset. Quality Health will send name, address, date of birth and NHS number to NHS England to undertake this linkage, which is already supported as part of the original application. However this amendment sought support for the flow of pseudo-ID alongside date of diagnosis from NHS England to UCLH. ‘s251’ support is required for this flow, as the applicant will be able to link this data to identifiers that they will hold.

UCLH will calculate all the time intervals and then delete the dates - they are needed only for time intervals. ‘s251’ support will therefore be required until the dates are deleted, which the applicant estimates to be June 2025. This amendment therefore sought ‘s251’ support to extend the duration of support until June 2025.

Confidentiality Advisory Group advice

The amendment requested was considered by Chairs’ Action. The Alternate Vice-Chair was content to recommend support for this amendment.

Confidentiality Advisory Group advice conclusion

In line with the considerations above, the CAG agreed that the minimum criteria under the Regulations appeared to have been met for this amendment, and therefore advised recommending support to the Health Research Authority.

Specific conditions of support

The following sets out the specific conditions of support.

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:**

   Due to the number of organisations involved it is the responsibility of University College London Hospitals NHS Foundation Trust as controller, to ensure that all organisations processing confidential patient information without consent 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. This will not be individually checked by the Confidentiality Advice Team (CAT), as there are more than 5 organisations involved.

   Regarding Welsh security assurances – Caldicott Principles into Practice Outturn reports (CPiP)s/Welsh IG toolkits are in place for both the Welsh Cancer Intelligence and Surveillance (WICSU) – covered by Public health Wales NHS Trust, and University Hospital of Wales Cardiff – covered by Cardiff and Vale

2. Confirmation of a favourable opinion from a Research Ethics Committee. **Confirmed 08 February 2024**

23/CAG/0005 – A randomised controlled trial of no routine gastric residual monitoring to guide enteral feeding in paediatric intensive care units.

Name	**Capacity**
Ms Caroline Watchurst	HRA Confidentiality Advisor

Context

Amendment request

This application seeks to determine whether or not measuring the stomach contents of critically ill children receiving invasive breathing support impacts on the length of time the child spends on breathing support and their calorie intake. ‘s251’ support is in place to allow the disclosure of confidential patient information from participating NHS trusts to ICNARC, further disclosure from ICNARC to PICANet and to NHS England (previously NHS Digital) for linkage to the Civil Registrations Dataset and HES, for English patients, and Digital Health and Care Wales for linkage to Patient Episodes Data, and the return of a linked dataset to ICNARC. ICNARC will combine the data with data from the GASTRIC-PICU trial database and pseudonymise the dataset for analysis.

This amendment sought support for the inclusion of The Royal London Hospital, Barts Health NHS Trust, as an additional participating site, and data processor for the CAG application.

This amendment also sought support to update the study protocol to include clarification on data collection in case of consent decline/withdrawal. This clarification adds an explanation as to what data will be collected if parent/legal guardian refuses consent for their child to be included in the study or withdraws consent. This clarification was added to the study protocol to make sure site staff have a full understanding of what data will be collected in such cases. The details of what data is collected in such cases (in terms of treatment and ventilation) have not changed and remained as per original application, however the wording was amended to make sure it is clear to sites what data should be recorded for these patients. Applicants will also be monitoring reasons for non-consent to understand and identify potential issues with the study based on parents’ comments. With staff having a better understanding of what data is being collected, they are able to explain this more clearly to the parents/legal guardians.

Confidentiality Advisory Group advice

The amendment requested was considered by the Confidentiality Advice Team, who raised no queries regarding this amendment.

Confidentiality Advisory Group advice conclusion

In line with the considerations above, the CAT agreed that the minimum criteria under the Regulations appeared to have been met for this amendment, and therefore advised recommending support to the Health Research Authority.

Specific conditions of support

The following sets out the specific conditions of support.

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 22/23 DSPT reviews for **PICANet (University of Leeds), NHS England and ICNARC** were confirmed as 'Standards Met' on the NHS England DSPT Tracker (checked 15 February 2024)

   Due to the number of participating organisations involved it is the responsibility of the data 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.

   Digital Health and Care Wales – Welsh IG has confirmed that the Welsh IG toolkit has been submitted.

2. Confirmation of a favourable opinion from a Research Ethics Committee. **Confirmed - NSA01 confirmed non substantial 14 June 2023 (for additional sites) & Confirmed - SA01 03 October 2023 (for clarification on the research without consent)**

PIAG 4-06(c)/2006 - Long-term sequelae of radiation exposure due to computed tomography in childhood

Name	Capacity

Dr Murat Soncul	CAG Alternate Vice Chair
Ms Caroline Watchurst	HRA Confidentiality Advisor

Context

Amendment request

This application is a registry, for long-term follow up, to identify risks from CT scan radiation in children and adolescents, and includes the extraction of a sub-cohort of patients who developed leukaemia. 'Section 251 support' was originally sought to enable flagging with the HSCIC Central Register and cancer registry, which is now fulfilled by NHS England, who link to Cancer Registration Data and Civil Registration Deaths Data. The application has 's251' support for access to confidential patient information for linkage purposes.

This amendment sought support to include a further purpose into the current **PIAG 4-06(c)/2006** application. The applicant proposes to disclose an effectively anonymous dataset for analysis from Newcastle University to the following 3 European (EU) processors, via a sub-licensing agreement, to be included in a meta-analysis:

1. International Agency for Cancer Research, France
2. European Institute for Biomedical Imaging Research, Austria
3. Barcelona Institute of Global Health, Spain

The advantage of this is that the increased study size will improve statistical power, meaning applicants will have a better ability to detect the risks at low doses.

The additional processing will not involve disclosure of any confidential patient information to the EU collaborators – the only data items shared will be pseudo-anonymised ID, vital status, date of death (modified to MM/YY), cause of death (ICD10Code) and text description (if available), date of cancer diagnosis, ICDO3 Topograhy, ICDO3 morphology, ICDO3 grading, ICCC3 coding (if available), diagnosis in text (if available), and if it is a primary cancer (if available).

However, **PIAG 4-06(c)/2006** would be sharing data that had been collected under 's251' for an additional purpose to the original application, some of which is NHS England data, hence the amendment request. NHS England have requested that it is explicitly stated that their data will be shared via a sub-licensing agreement.

Confidentiality Advisory Group advice

The amendment requested was considered by Chair's Action. The Alternate Vice Chair queried why the pseudo-ID was required to be disclosed to EU collaborators. The applicant confirmed that the data will be effectively anonymous to the EU partners as they have no way of re-identifying, however the Pseudo-IDs are required because there are multiple examinations for the same patient, so the EU collaborators need to be able to discriminate between individual patients, but without being able to identify. The Alternate Vice Chair was content with this explanation.

Confidentiality Advisory Group advice conclusion

In line with the considerations above, the CAG agreed that the minimum criteria under the Regulations appeared to have been met for this amendment, and therefore advised recommending support to the Health Research Authority.

Specific conditions of support

The following sets out the specific conditions of support.

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 22/23 DSPT reviews for **NHS England & Newcastle University** were confirmed as '**Standards Met'** on the NHS England DSPT Tracker (checked 21 February 2024)

2. Confirmation of a favourable opinion from a Research Ethics Committee. **Confirmed 06 February 2024**

ECC 7-04 (j)/2010 – Long term risks of paediatric fluoroscopic cardiology

Name	Capacity
Dr Murat Soncul	CAG Alternate Vice Chair
Ms Caroline Watchurst	HRA Confidentiality Advisor

Context

Amendment request

This application is a registry, for long-term follow up, of children and young adults who underwent fluoroscopic cardiology procedures, to assess their cancer risk in relation to the estimated radiation doses they received. 'Section 251 support' was originally sought to enable flagging with the HSCIC Central Register, which is now fulfilled by NHS England, who link to Cancer Registration Data and Civil Registration Deaths Data. The application has 's251' support for access to confidential patient information for linkage purposes. For analysis purposes, the following confidential patient information is retained: date of birth, date of death, postcode for deprivation scoring and gender.

This amendment sought support to include a further purpose into the current **ECC 7-04 (j)/2010** application. The applicant proposes to disclose an effectively anonymous dataset for analysis from Newcastle University to the following 3 European (EU) processors, via a sub-licensing agreement, to be included in a meta-analysis:

1. International Agency for Cancer Research, France
2. European Institute for Biomedical Imaging Research, Austria
3. Barcelona Institute of Global Health, Spain

The advantage of this is that the increased study size will improve statistical power, meaning applicants will have a better ability to detect the risks at low doses.

The additional processing will not involve disclosure of any confidential patient information to the EU collaborators – the only data items shared will be pseudo-anonymised ID, vital status, date of death (modified to MM/YY), cause of death (ICD10Code) and text description (if available), date of cancer diagnosis, ICDO3 Topograhy, ICDO3 morphology, ICDO3 grading, ICCC3 coding (if available), diagnosis in text (if available), and if it is a primary cancer (if available).

However, **ECC 7-04 (j)/2010** would be sharing data that had been collected under 's251' for an additional purpose to the original application, some of which is NHS England data, hence the amendment request. NHS England have requested that it is explicitly stated that their data will be shared via a sub-licensing agreement.

Confidentiality Advisory Group advice

The amendment requested was considered by Chair's Action. The Alternate Vice Chair queried why the pseudo-ID was required to be disclosed to EU collaborators. The applicant confirmed that the data will be effectively anonymous to the EU partners as they have no way of re-identifying, however the Pseudo-IDs are required because there are multiple examinations for the same patient, so the EU collaborators need to be able to discriminate between individual patients, but without being able to identify. The Alternate Vice Chair was content with this explanation.

Confidentiality Advisory Group advice conclusion

In line with the considerations above, the CAG agreed that the minimum criteria under the Regulations appeared to have been met for this amendment, and therefore advised recommending support to the Health Research Authority.

Specific conditions of support

The following sets out the specific conditions of support.

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 22/23 DSPT reviews for **NHS England & Newcastle University** were confirmed as '**Standards Met'** on the NHS England DSPT Tracker (checked 21 February 2024)

2. Confirmation of a favourable opinion from a Research Ethics Committee. **Confirmed 06 February 2024**

22/CAG/0042 – A long-term prospective cohort study on the effects of smoking and prophylactic aspirin on all-cause mortality in male British doctors

Name	Capacity
Ms Caroline Watchurst	HRA Confidentiality Advisor

Context

Amendment request

This application has 's251' support to obtain a legal basis under common law for the ongoing retention of British Doctors Study database by the University of Oxford, the disclosure of confidential patient information from the database at the University of Oxford to NHS Digital for data linkage and the return of a linked dataset.

This amendment seeks to extend the duration of 's251' support until 31 December 2025, to allow the applicant time to receive the linked data.

Confidentiality Advisory Group advice

The amendment requested was considered by the Confidentiality Advice Team who raised no queries regarding this amendment.

Confidentiality Advisory Group advice conclusion

In line with the considerations above, the CAT agreed that the minimum criteria under the Regulations appeared to have been met for this amendment, and therefore advised recommending support to the Health Research Authority.

Specific conditions of support

The following sets out the specific conditions of support.

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 22/23 DSPT reviews for **University of Oxford-Medical Sciences Division-Nuffield Department of Population Health and NHS England** were confirmed as 'Standards Met' on the NHS England DSPT Tracker (checked 23 February 2024)

2. Confirmation of a favourable opinion from a Research Ethics Committee. **Confirmed non substantial 08 February 2024**

22/CAG/0072 – Epidemiology and Outcome from Out of Hospital Cardiac Arrest (Research application)

Name	Capacity
Ms Caroline Watchurst	HRA Confidentiality Advisor

Context

Amendment request

This application aims to collect and summarise data to be used to improve outcomes of Out of Hospital Cardiac Arrests. 's251 support' is in place to allow the disclosure of

confidential patient information from participating NHS ambulance trusts to the University of Warwick for inclusion in the OHCAO database, and the disclosure of confidential patient information to NHS England for linkage to outcome data, and the return of the linked dataset to the University of Warwick.

The exit strategy for the retention of confidential patient information is one or more of the following three scenarios, either that funding for the registry is discontinued, the registry is no longer needed and replaced by data flows directly to NHS England, or after 11 years have passed.

The information provided in the original application with regards to the potential discontinuation of the registry funding was that the contract would end in autumn 2023, although the funders have agreed in principle to extend funding in the longer term. Funding (and duration of 's251' support) was extended to 31 March 2024 via CAG amendment.

This amendment sought support to extend the duration of 's251' support for a further 5 years in total, to 31 October 2028. Therefore this amendment sought support to confirm this duration extension, and update the exit strategy accordingly.

Confidentiality Advisory Group advice

The amendment requested was considered by the Confidentiality Advice Team, who raised no queries regarding this amendment.

Confidentiality Advisory Group advice conclusion

In line with the considerations above, the CAT agreed that the minimum criteria under the Regulations appeared to have been met for this amendment, and therefore advised recommending support to the Health Research Authority.

Specific conditions of support

The following sets out the specific conditions of support.

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:**

   University of Warwick Clinical Trials Unit and NHS England were confirmed as 'Standards Met' on the NHS England DSPT Tracker (checked 23 February 2024).

   Due to the number of organisations involved it is the responsibility of the applicant, as controller, to ensure that all organisations processing confidential patient information 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. These will not be individually checked by the CAT team due to the number of organisations involved.

2. Confirmation of a favourable opinion from a Research Ethics Committee. **Confirmed 06 February 2024**

22/CAG/0087 – Epidemiology and Outcome from Out of Hospital Cardiac Arrest (Non-research application)

Name	Capacity
Ms Caroline Watchurst	HRA Confidentiality Advisor

Context

Amendment request

This application aims to collect and summarise data about people who experienced Out of Hospital Cardiac Arrests to be used to produce summary data for quality improvement work with ambulance services, charities and NHS England. 's251' support is in place to allow the disclosure of confidential patient information from participating NHS ambulance trusts to the University of Warwick for inclusion in the OHCAO database, and the disclosure of confidential patient information to NHS

England for linkage to outcome data and the return of the linked dataset to the University of Warwick.

The exit strategy for the retention of confidential patient information is one or more of the following three scenarios, either that funding for the registry is discontinued, the registry is no longer needed and replaced by data flows directly to NHS England, or after 11 years have passed.

The information provided in the original application with regards to the potential discontinuation of the registry funding was that the contract would end in autumn 2023, although the funders have agreed in principle to extend funding in the longer term. Funding (and duration of ‘s251’ support) was extended to 31 March 2024 via CAG amendment.

This amendment sought support to extend the duration of ‘s251’ support for a further 5 years in total, to 31 October 2028. Therefore this amendment sought support to confirm this duration extension, and update the exit strategy accordingly.

Confidentiality Advisory Group advice

The amendment requested was considered by the Confidentiality Advice Team, who raised no queries regarding this amendment.

Confidentiality Advisory Group advice conclusion

In line with the considerations above, the CAT agreed that the minimum criteria under the Regulations appeared to have been met for this amendment, and therefore advised recommending support to the Secretary of State for Health and Social Care.

Specific conditions of support

The following sets out the specific conditions of support.

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:**

   University of Warwick Clinical Trials Unit and NHS England were confirmed as 'Standards Met' on the NHS England DSPT Tracker (checked 23 February 2024).

   Due to the number of organisations involved it is the responsibility of the applicant, as controller, to ensure that all organisations processing confidential patient information 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. These will not be individually checked by the CAT team due to the number of organisations involved.

19/CAG/0196 – Evaluating prescribing safety indicators embedded in computerised clinical decision support software OptimiseRx

Name	Capacity
Ms Caroline Watchurst	HRA Confidentiality Advisor

Context

Amendment request

The applicants have existing support to allow ResearchOne and NHS England (previously NHS Digital) to generate a SALT link key to facilitate linkage between primary care data from GP practices and HES, ONS and IMD datasets at NHS England (previously NHS Digital). The aim of the application is to evaluate the effectiveness of the computerised clinical decision support system OptimiseRx on improving prescribing safety in general practices and the associated costs to the NHS.

This amendment sought support to extend the duration of the study from 31 December 2023, to 31 January 2025 to allow the applicant to receive the requested linked data, in order to complete the analyses.

Confidentiality Advisory Group advice

The amendment requested was considered by the Confidentiality Advice Team. No queries were raised regarding this amendment.

Confidentiality Advisory Group advice conclusion

In line with the considerations above, the CAT agreed that the minimum criteria under the Regulations appeared to have been met for this amendment, and therefore advised recommending support to the Health Research Authority.

Specific conditions of support

The following sets out the specific conditions of support.

1. Favourable opinion from a Research Ethics Committee. **Confirmed non substantial 01 February 2024**

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 **22/23** DSPT reviews for **NHS England & The Phoenix Partnership (TPP)** were confirmed as 'Standards Met' on the NHS England DSPT Tracker (checked 23 February 2024)

16/CAG/0058 – National Maternity and Perinatal Audit (NMPA)

Name	Capacity

Ms Caroline Watchurst	HRA Confidentiality Advisor

Context

Amendment request

The applicants have existing support to allow the disclosure of confidential patient information from English & Welsh NHS Trusts to the Royal College of Obstetricians and Gynaecologists, in order to link this data with data contained in other national databases for the purpose of conducting a national, prospective, clinical audit of maternity services in England and Wales, in order to improve the quality of services and the outcomes achieved for mothers and new-borns.

This amendment sought support to extend the duration of 's251' support until 31 December 2025.

This amendment also seeks support to change data processor arrangements, and to move data currently stored on a server provided by 'RedCentric' to a Microsoft Azure server managed in-house by the Royal College of Obstetricians and Gynaecologists (RCOG). The security arrangements will now be entirely controlled by the RCOG. The virtual server will reside in Microsoft Azure. The data would be moved ideally before the end of March 2024, and remain on the new server for the remainder of the project.

Confidentiality Advisory Group advice

The amendment requested was considered by the Confidentiality Advice Team, who raised no queries with this amendment.

Confidentiality Advisory Group advice conclusion

In line with the considerations above, the CAT agreed that the minimum criteria under the Regulations appeared to have been met for this amendment, and therefore advised recommending support to the Secretary of State for Health and Social Care.

Specific conditions of support

The following sets out the specific conditions of support.

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 **22/23** DSPT reviews for **The Royal College of Obstetricians and Gynaecologists** & **Microsoft UK** were confirmed as 'Standards Met' (by check of the DSPT tracker 23/02/2024)

3. Annual Review Approvals

CAG reference	Application Title
19/CAG/0146	The TIGHT-K STUDY. Dysrhythmias on the cardiac intensive care unit - does maintenance of high-normal serum potassium levels matter?
19/CAG/0084	Developing Diagnostic and Prognostic Algorithms Using Digital Pathology and Artificial Intelligence
18/CAG/0156	the distribtion of highly sensitive troponin in the critically unwell and associated morality
19/CAG/0101	Oxfordshire Cerebrovascular Research Database
21/CAG/0043	Barts Cancer Institute Breast Biobank
20/CAG/0149	Yorkshire & Humberside Haematology Network Register
22/CAG/0112	Randomised trial of the clinical and cost effectiveness of a supraglottic airway device versus intubation during in-hospital cardiac arrest (AIRWAYS-3)
20/CAG/0138	Avon CAP: A Pan-Pandemic Respiratory Infection Surveillance Study [COVID-19]
22/CAG/0131	Standardising pathways for diagnosing hypertension using routine healthcare data: an investigation of the health and economic outcomes: STARLIGHT

18/CAG/0141	CLASSIFYING STRUCTURE AND JOINT FEATURES IN EXTREMITIES USING STATISTICAL LEARNING METHODS TO ASSIST DIAGNOSIS
17/CAG/0156	Rectal Cancer Oncological Complete Response Database (OnCoRe)
18/CAG/0126	Connected Health Cities: Data linkage of urgent care data
19/CAG/0047	RAPSS (Risk Assessment for Prisoners at risk of Self-harm and Suicide)
18/CAG/0205	International Surgical Outcomes Study: Long-term survival
18/CAG/0153	The POOL study: Establishing the safety of waterbirth for mothers and babies: A cohort study with nested qualitative component.
CR12/2014	Oxford Vegetarian Study also known as Study of Cancer in Vegetarians
CAG 1-07(c)/2014	Long-term effects of whole blood and platelet donation
CAG 6-06(b)/2014	Congenital Anomaly Register and Information Service for Wales (CARIS) including rare disease registration for children.
CAG 6-06(c)/2014	Wales Abdominal Aortic Aneurysm Screening Programme (WAAASP) Evaluation
18/CAG/0180	LAUNCHES QI: Linking AUdit and National datasets in Congenital HEart Services for Quality Improvement.
ECC 1-03(FT2)/2010	Prospective Study of Outcomes in Sporadic versus Hereditary breast cancer (POSH)
20/CAG/0068	South London and Maudsley NHS Foundation Trust CRIS data linkage with the National Pupil Database
19/CAG/0149	Mammographic Predictors of Cancer Recurrence after Breast Conservation and Adjuvant Endocrine Therapy
19/CAG/0167	SEARCH trial legacy study: long-term follow-up of participants using electronic health records
19/CAG/0166	HPS2-THRIVE trial legacy study: long-term follow-up of participants using electronic health records

22/CAG/0015	REDCap registry for the UK highly specialised national service for Bardet-Biedl syndrome
22/CAG/0166	How Do Health Care Professionals Recognise and Respond to Hospital-Acquired Deconditioning? A mixed-methods synthesis and consensus
19/CAG/0207	Survival of people with screen-detected heart failure (ECHOES-Survive) study
23/CAG/0082	The Prognostic Performance of the Enhanced Liver Fibrosis Test in UK Patients with Chronic Liver Disease Assessed 20 Years After Recruitment to the EUROGOLF study (EVenti)
22/CAG/0049	LOng COvid Multidisciplinary consortium: Optimising Treatments and servIces across the NHS (LOCOMOTION)
22/CAG/0106	The BCIS Out of Hospital Cardiac Arrest Pilot Registry
17/CAG/0151	A randomised trial of expedited transfer to a cardiac arrest centre for non-ST elevation out-of hospital cardiac arrest (ARREST)
20/CAG/0056	Maternal smoking during pregnancy and intellectual disability
22/CAG/0123	A single-centre, retrospective cohort study of CT head pathologies in infants and toddlers presenting to ED due to head injury from an accidental fall
PIAG 1-07(d)/2004	British Regional Heart Study (men)
PIAG 4-07(h)/2002	British Regional Heart Study (men)
20/CAG/0120	Incidence of Avoidant/Restrictive Food Intake Disorder (ARFID) in children and young people presenting to secondary care in the UK and Ireland
20/CAG/0113	Heart Protection Study Long-term Follow-up: A randomised study of the effects on mortality and morbidity of HMG CoA reductase inhibitors and of antioxidant vitamins in a wide range of people at high risk of coronary heart disease
21/CAG/0106	TRIM: What Triage model is safest and most effective for the management of 999 callers with suspected COVID19? A linked outcome study
17/CAG/0176	A Risk-adjusted and Anatomically Stratified Cohort Comparison

	Study on Open Surgery, Endovascular Techniques and Medical Management for Juxtarenal Aortic Aneurysms: (UK-COMPASS)
21/CAG/0133	Mortality and morbidity outcomes after aortovascular surgery in patients with Marfan Syndrome: A UK experience
21/CAG/0123	RE-BLEED: A digital platform for identifying bleeding patients – a feasibility study
19/CAG/0111	Cambridge Blood and Stem Cell Biobank
19/CAG/0012	Long term outcomes in Hirschsprung's and anorectal malformations
19/CAG/0002	Outcome of resuscitated term infants with no detectable heart rate at 10 minutes
19/CAG/0135	Derby Monitoring Study of Self-harm
22/CAG/0068	Childhood outcomes after perinatal brain injury: a population-based linkage study
22/CAG/0042	A long-term prospective cohort study on the effects of smoking and prophylactic aspirin on all-cause mortality in male British doctors.
23/CAG/0003	PRemature Infant Outcome Risk Study – PRIOR
21/CAG/0017	Outcomes of Patients who survived Treatment on an Intensive Care unit for COVID-19 in England and Wales: a comparative retrospective cohort study
16/CAG/0050	ECG Diabetic Foot Ulcer (DFU) Pilot
20/CAG/0003	Study of cancer risks in ataxia telangiectasia heterozygotes
23/CAG/0014	2023 NHS Maternity Survey – Mixed Methods
20/CAG/0097	Breast Cancer Metastasis
21/CAG/0008	Clinical Practice Research Datalink (CPRD)
22/CAG/0137	West Yorkshire ICB
CAG 5-07(f)/2013	National Vascular Registry

CAG 8-02(a)/2014	Assuring Transformation: Data collection by Clinical Commissioning Groups to populate patient registers and reporting
CAG 8-02(b)/2014	Data collection by NHS England Area Teams responsible for commissioning secure mental health and child and adolescent mental health services to populate patient register and reporting.
CAG 8-02(c)/2014	Assuring Transformation: Enhanced Quality Assurance Process Data flow (Disclosure by HSCIC to NHS England)
21/CAG/0155	Using patient records to identify potential participants for Natsal-4
17/CAG/0081	UK Women's Cohort Study - HES
ECC 1-04(b)/2010	Evaluating the age extension of the NHS Breast Screening Programme (AgeX Trial)
22/CAG/0130	ELUCIDate: ELUcidate long-term consequences of Childhood Infections using administrative and research Data
22/CAG/0160	National Prospective Cohort Study and Surveillance of Sympathetic Ophthalmia in the United Kingdom
23/CAG/0031	Sentinel Stroke National Audit Programme (SSNAP)
22/CAG/0010	The Integration and Analysis of Data Using ARtificial InTelligence to Improve Patient Outcomes with Thoracic Diseases
21/CAG/0149	Legacies and Futures: Gestational Parents' Experiences with Vulnerability and Resilience as it Influences Parent and Neonatal Health
22/CAG/0141	Do patients with autoimmune hepatitis (AIH) have an excessive incidence of cardio- and cerebrovascular disease and is this related to corticosteroid treatment?
18/CAG/0024	Pregnancy Outcome Prediction Study: Transgenerational and Adult Review (POPStar)
22/CAG/0149	Progression of Diabetic Retinopathy from referral to treatment or vision loss: External Validation, update and net clinical benefit of a Multivariable Prediction Model
15/CAG/0177	An investigation of the association between substance use in adolescence and mental health using linked health data
CAG 2-07(c)/2013	The Pesticide Users’ Health Study
PIAG 4-07(j)/2002	Multicentre randomised controlled trial of ‘once only’ flexible sigmoidoscopy in prevention of colorectal cancer morbidity and mortality
PIAG 3-04(FT3)/2006	Multicentre randomised controlled trial of ‘once only’ flexible sigmoidoscopy in prevention of colorectal cancer morbidity and mortality

22/CAG/0147	A Randomised Phase III Trial to Determine the Role of FDG_PET Imaging in Clinical Stages IA/IIA Hodgkin's Disease (FDG_PET Study): RAPID
21/CAG/0173	Establishing the burden of vaccine preventable acute lower respiratory tract infections in primary care, UK: Avon-CAP GP2
CAG 8-03(PR2)/2013	UK register of Fatal Anaphylactic Reactions
19/CAG/0164	UK PICU gender mortality
19/CAG/0198	Evaluation of an aid to diagnosis for congenital dysplasia of the hip in general practice: controlled trial randomised by practice
22/CAG/0076	Suicide by patients in contact with drug and alcohol services in the year prior to death
20/CAG/0081	Predicting vascular complications in diabetes
20/CAG/0002	Investigating the incidence of radiation-related cancer following endovascular aortic aneurysm repair compared to open aneurysm repair
21/CAG/0114	Trends in the Prevalence and Complexity of Children with a Life-limiting or Life-threatening condition in Wales
19/CAG/0040	Translational Research in Pulmonary Hypertension at Imperial College
17/CAG/0180	Whitehall-1 Study
22/CAG/0125	Management of Patients with Chronic Liver Disease Admitted to Hospital as an Emergency
21/CAG/0054	A cluster randomised controlled trial to assess the effectiveness and cost-effectiveness of the 'Your Care Needs You' intervention to improve safety and experience of care transitions. Short title: Using routine data to assess the impact of the YCNY intervention.
20/CAG/0111	Under 16 Cancer Patient Experience Survey 2020-2023
22/CAG/0021	The South London Stroke Register: Improving the lives of stroke survivors with data. (SLSR)

21/CAG/0177	Randomised trial of clinical and cost effectiveness of Administration of Prehospital fascia Iliaca compartment block for emergency hip fracture care Delivery
19/CAG/0173	Critical illness related cardiac arrest (CIRCA): an investigation of the incidence and outcome of cardiac arrest within Intensive Care Units in the United Kingdom
18/CAG/0171	Epidemiological studies of the Porton Down veterans
15/CAG/0127	Cellular immunity to herpesvirus infection: Studies with EBV and CMV
14/CAG/1018	CEMARC Long-term Outcome Study
CAG 9-08(d)/2014	BioResource in Adult Infectious Disease (BioAID) 2019-2024
18/CAG/0159	Housing, family and environmental risk factors for hospital admissions in children
PIAG 4-05(e)/2008	NHS Blood and Transplant (NHSBT) – Retrospective Potential Donor Audit (PDA)
22/CAG/0115	Evaluation of ocular and systemic outcomes after treatment of ocular melanoma and other ocular tumours
22/CAG/0088	Evaluating ICON: A mixed methods study to assess the impact of the ICON programme on coping strategies for carers if crying babies, and rates of abusive head trauma in infants aged under 1 year
18/CAG/0177	Evaluation of the medium to long term impact of commercial open-group behavioural weight loss programmes on body weight and diabetes risk in adults with overweight and obesity.
22/CAG/0154	Evaluating the clinical and cost-effectiveness of a conservative approach to oxygen therapy for invasively ventilated adults in intensive care: UK-ROX
17/CAG/0011	Genetic mechanisms in polyposis of the bowel
16/CAG/0064	The Renal Association: UK Renal Registry a research database
15/CAG/0138	Familial Hypercholesterolemia Register

20/CAG/0044	Revision Hip and Knee Replacement: Evaluation of Clinical, Psychological and Surgical Outcomes
22/CAG/0038	TEDS Medical Record Linkage
19/CAG/0118	The Robert Lane Tissue Bank - Collection of Genitourinary tissue
21/CAG/0159	UK Research into Ethnicity and COVID Outcomes for Healthcare workers (UK-REACH) Work Package 1.
19/CAG/0145	Transfusion Medicine Epidemiology Review
19/CAG/0115	Suspected Stroke Clinical and radiological data base (SSCRaD)
17/CAG/0184	UK collaborative clinical audit of health care for children and young people with suspected epileptic seizures (Epilepsy12)
PIAG 4-06(c)/2006	Long-term sequelae of radiation exposure from computed tomography in children and adolescents
16/CAG/0029	The Empress Study – Cancer diagnosis via emergency presentation: A case-control study

Signed – Chair

Dr Tony Calland, MBE, CAG Chair, Professor William Bernal, Ms Clare Sanderson & Dr Murat Soncul, CAG Alternate Vice-Chairs

Date

05 March 2024

Signed – Confidentiality Advice Team	Date
Ms Caroline Watchurst, HRA Confidentiality Advisor	*01 March 2024*