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

January 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/0098	**Loss of sight due to delay in treatment or review in UK HES**
Contact:	Ms Rashmi Mathew
Data controller:	Moorfields Eye Hospital NHS Foundation Trust
Application type:	Research

Present:

Name	Capacity
Dr Patrick Coyle	CAG Vice Chair
Ms Rose Payne	CAG Lay Member
C. Marc Taylor	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 Moorfields Eye Hospital NHS Foundation Trust set out the purpose of medical research which aims to establish a current incidence rate, diagnosis and severity for patients suffering sight loss as a result of delay in their ophthalmic care treatment or review, over a one year surveillance programme operating via the British Opthalmological Surveillance Unit (BOSU) methodology, using the monthly reporting card amongst UK ophthalmologists.

A previous surveillance project established the frequency of sight loss due to delay in review or treatment was undertaken March 2015 - February 2016. The majority of cases were in patients with chronic eye conditions requiring long-term continuous follow-up, most notably glaucoma. Delayed follow-up appointments were the cause in most cases, indicating a lack of system capacity. In addition to pre-existing service pressures, the cessation of normal clinical practice during the coronavirus pandemic and reduced capacity in the return to normal service provision and the created backlog will have influenced the number and length of delays. Re-running the previous study will help to identify the magnitude of any changes in morbidity caused by harm due to delays.

The BOSU methodology is established and has received support in principle from the CAG. Ophthalmologists will anonymously indicate that they have seen a new patient who has suffered sight loss as a result of delay in their ophthalmic care, through the BOSU reporting system via University of Dundee. The University of Dundee system will generate the initial questionnaire for the reporting ophthalmologist to fill in via the University of Dundee data safe haven online platform. The completion of this questionnaire will contain confidential patient information, and therefore requires 's251' support. Each case will be given a unique study number by the BOSU study centre. Hospital number, month and year of birth, gender, ethnicity, and postcode will be recorded alongside clinical data on the questionnaires. All identifies will be deleted once the follow-up is completed, postcode is converted to deprivation score, and duplicates identified.

Confidential information requested

Cohort	Approximately 168 – 264 (but actual incidence as yet unclear) patients suffering sight loss as a result of delay in their ophthalmic care treatment or review who report to a treating ophthalmologist across the 12

	months reporting period, expected to be between October 2023 – September 2024
Data sources	1. Clinical records at the Trusts of BOSU reporting ophthalmologists
Identifiers required for de-duplication purposes	1. Unique BOSU study number 2. Gender 3. Age 4. Diagnosis 5. Postcode
Identifiers required for analysis purposes	1. Month and Year of birth 2. Gender 3. Postcode – converted to social deprivation score 4. Ethnicity Applicant states this will be an effectively anonymised dataset for analysis.
Additional information	1 year of baseline collection - Expected start date October 2023 – September 2024

Confidentiality Advisory Group 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

Number	Action required	Response from the applicant
1.	Security assurances are outstanding for the Health Information Centre - University of Dundee – Data safe haven. An approval letter from the Public Benefit and Privacy Panel (PBPP), where processing is taking place in Scotland, is accepted as evidence of adequate security assurance for organisations in Scotland. Please provide PBPP approval to CAG.	The applicant provided the PBPP approval to the CAG inbox on 08 January 2024.

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 13 September 2023**

2. Security assurances for Health Information Centre - University of Dundee – Data safe haven. **Confirmed in the form of PBPP approval, dated 13 October 2023**

b.

23/CAG/0177	**Investigating potential health and health equality impacts of planning deregulation: The case of permitted development housing in England**
Chief Investigator:	Professor Benjamin Clifford
Sponsor:	University College London
Application type:	Research

Present:

Name	Capacity
Dr Patrick Coyle	CAG Vice Chair
Professor Lorna Fraser	CAG Expert Member
Mr Dan Roulstone	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 University College London set out the purpose of medical research that seeks to use hospital admission and death records to determine the health effects of living in housing created through Permitted Development (PD) regulations, which is a category of building activity that does not require full planning permission. This research fills a vital gap in existing work to consider the health impacts and inequalities associated with PD housing in England. Poor-quality housing is linked to numerous health problems, with significant costs to health and social care systems. The Building Research Establishment estimated that the NHS spends about £2.5 billion per annum on housing and health-related conditions. Housing quality is therefore a significant public health issue. Low-quality housing disproportionately impacts lower socioeconomic groups, widening inequalities, whilst interventions which create healthy homes can help improve both health and broader social and economic outcomes. This study will inform wider policy debate about whether reduced regulation in the planning of urban spaces is aligned with the goal of creating healthier places for people to live.

To estimate the influence of PD housing on hospital admissions and deaths it is necessary to know who is living or has historically lived at a PD address and the most comprehensive way to identify these individuals is via the Personal Demographics Service (PDS). It is not possible to determine who the participants are until the point they are identified by linking an address to an entry in the PDS, which makes obtaining prior informed consent impossible. The study requires 's251 support' to allow NHS England to link between the PD housing addresses (and comparator non-PD housing addresses) that the UCL study team will provide, (which do not constitute confidential patient information), and the PDS, to identify name, NHS number, date of birth and address. These individuals are then linked to Hospital Episode Statistics (HES), Emergency Care Data Set (ECDS), and Civil registration deaths. Once linkage is complete, NHS England will pseudonymise the data to send to the UCL research team, after which, NHS England will delete the identifiable data.

Confidential information requested

Cohort	All individuals with an NHS number who have lived at an address on the PD or non-PD (comparator group) housing lists between 2010 to 2023. Based on estimates of 100,000 PD housing units - estimate sample size of approximately 230,000 people in the PD housing group.

	's251' support is also required for approximately 230,000 people in the comparator group.
Data sources	1. Combined list of addresses for the study (with PD and non-PD indicator variable) created at University College London and does not constitute CPI. 2. NHS England: a. Personal Demographics Service b. Hospital Episode Statistics (HES) APC and A&E c. Emergency Care Data Set (ECDS) d. Civil registration - Deaths data
Identifiers required for linkage purposes	1. Name 2. NHS number 3. Date of birth 4. Address (including postcode)
Identifiers required for analysis purposes	1. Gender 2. Ethnicity This will be effectively anonymous to the applicant 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.	Support cannot be issued until a Favourable opinion from a Research Ethics Committee is in place.	This was issued 11 December 2023 and provided to CAG
2.	Provide clarification as to why this large sample size is required, and whether a smaller sample size can provide an equally valid result.	Applicants estimate that there will be 100,000 units potentially housing 230,000 people which will give the study statistical power (90%) to detect small changes (e.g. hazard ratio of 0.95) for hospital admission rates at the 5% significance level when comparing individuals living in PD homes to other properties. Applicants note that for the common health outcomes where you expect to see a difference between groups, they do not expect the difference to be large, and therefore, a large sample

		size is required to detect these. CAG were content with this response.
3.	Please clarify why HES data will not be restricted to only relevant diagnoses?	Applicants require HES data on all hospital attendances for an individual in order to determine all-cause and amenable hospitalisations. This is important in order to understand the patterns of healthcare utilisation within the PD and non-PD groups as all-cause hospital admissions drive overall hospital admissions. Hospitalisations due to amenable causes are particularly important as these represent missed opportunities to manage a condition earlier in the care pathway. Overall, this approach will also allow applicants to look at outcomes that prior to the research being conducted are less common or unknown, which buildings on a methodology that we refined in a project exploring the effect homeless hospital discharge schemes. CAG were content with this response.
4.	Please provide further justification regarding the requirement for A&E and ECDS data	Visits to accident and emergency services are important because they can represent severe and acute exacerbations of a particular condition. This is especially pertinent in the case of asthma. Both the A&E and ECDS datasets are required in order to cover the full study period. Additionally, other research shows that vulnerable groups, who may live in the lower quality PD housing, are likely to experience barriers to accessing primary care and are, therefore, more likely to use emergency care, which we should be able to capture via the use of the A&E and ECDS datasets. CAG were content with this response.
5.	Further patient and public involvement should be carried out in line with advice in this letter; a. Further patient and public involvement should be undertaken with a group representative of	a) Applicants undertook patient and public involvement with the PLANET group, an existing PPIE group established by the NIHR-funded Health Protection Research Unit (HPRU) on Environmental Change and Health at LSHTM, which comprises 32 members from across England with ages 25-65+ years and diverse ethnic backgrounds (including Chinese, Eastern European, Indian, Pakistani, White British, South American). 75% are female, 25% are primary carers and 50% have some disability or underlying health condition. The workshop took place on 12 December 2023. Out of those in attendance, all 18

	the 'control'/non-PD housing group, prior to 's251' support. b. Ongoing patient and public involvement and engagement is to be undertaken throughout the study. Please confirm plans for this.	people were members of the public who were residents of non-PD housing. During the workshop, applicants took participants through our overall research questions and the proposed data linkage methodology and asked if they had any thoughts or concerns. No concerns were raised by any of the 18 members. b) Applicants plan to have one formal meeting per year with their Public and Community Advisory Group alongside ad hoc contact when necessary. The group will also be contacted for ad hoc feedback, for example they have been contacted regarding the survey for Work Package 2 and following this, they can join an optional feedback workshop in January to discuss their findings. Residents working with Groundswell have also been invited to provide feedback on the surveys with an optional workshop. Applicants will also involve patients and the public through engaging with the PLANET group. PLANET will be kept updated through emails that their coordinator will share with members and a further workshop is planned for 2025 to discuss the data and dissemination of findings. CAG were content with this response.
6.	Please update the website as follow and provide to CAG for review. a. A layered approach with an initial notification page in simpler language, which is easily accessible by the average reader. b. Include information on some of the patient support organisations relevant to the	a) This has been provided and CAG were content. b) Applicants have added the following links to their "Useful Resources" section: Support for mental, emotion, cognitive and physical health: https://www.rootstowellbeing.org/ Asthma + Lung UK: https://www.asthmaandlung.org.uk/ British Heart Foundation: https://www.bhf.org.uk/informationsupport Macmillan Cancer Support: https://www.macmillan.org.uk/ c) Applicants have made plans for the review of the website by the Public and Community Advisory group during a workshop planned for January. Applicants will then collate the feedback and make the appropriate amendments on the website. This is scheduled for early in the new year as applicants have engaged with them

	research, for example, COPD, CVD, and housing charities. c. The website should be reviewed by a PPI group for accessibility.	frequently in this current period and do not want to over burden them. CAG were content with this response.
7.	Please provide clarification as to whether 'section 251' support is required for the flow of data back to the applicant from NHS England (ie, is a pseudo ID applied and linked back to full post code, or is the flow actually anonymous? If there is a pseudo-ID in the dataset, the exit strategy should be further described, to explain if the full postcode was removed from the dataset for analysis, and when the pseudo ID is either removed, or the key between pseudo-ID and full postcode deleted. The data flow diagram should also be updated.	Applicants confirmed that 'Section 251' support is not required for the flow of data back from NHS England to our UCL team. The data linkage process will be as follows: • NHS England will identify individuals living (or having historically lived) at an address on the PD or non-PD list • They will create a variable with the date of the match between an address on the UCL list and PDS • They will use the name, date of birth, NHS number and address to link to HES and ONS mortality datasets • They will add two variables, one to indicate if the individual is in the PD or non-PD group and the second to indicate if an admission or A&E visit occurred whilst at an address on the list or not • NHS England will then pseudonymise the data (I.e. remove name, full address, full date of birth) and UCL will receive the data with their standard token person ID. They will not provide us with a pseudo-ID that would link back to postcode. To confirm, applicants will not link the analysis dataset that NHS England provide to any other dataset at UCL, nor will there be any key to enable them to do this – the only data use for the analysis will be the data sent from NHS England. The current data flow diagram reflects this, and therefore, no changes have been made.

		CAG were content with this response.
8.	Please provide plans regarding onwards data sharing/access and retention.	The dataset will only be accessed by the UCL research team who are all UCL employees. The analysis data set will not be shared outside of the UCL Data Safe Haven and only aggregated output results will be published in peer-reviewed journals and study-wide reports. Patient-level pseudonymised data will be stored within UCL's Data Safe Haven and retained until the aggregated results have been published, which we expect would be within 1 year of the analysis concluding. The aggregated analysis results will be transferred to the UCL SharePoint and will be stored for 10 years. CAG were content with this response.

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 11 December 2023**

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 **NHS England** was confirmed as 'Standards Met' on the NHS England DSPT Tracker (checked 10 January 2024)

c. 23/CAG/0162 - Database of UK recipients of pituitary-derived human growth hormone

Name	Capacity
Professor William Bernal	CAG Alternative Vice Chair
Dr Joanne Bailey	CAG Expert Member
Mr Thomas Boby	CAG Expert Member
Dr Sandra Duggan	CAG Lay member
Mr Umar Sabat	CAG Expert Member
Dr Paul Mills	HRA Confidentiality Advice Service Manager
Ms Katy Cassidy	HRA Confidentiality Advisor

Context

Purpose of application

This application from University College London set out the purpose of setting up two research databases which will be used to conduct research investigating whether people who received injections of pituitary-derived cadaveric human growth hormone (c-hGH) are at risk of developing a disease called iatrogenic cerebral amyloid angiopathy (iCAA).

Between 1959 and 1985, nearly 2000 individuals in the UK were treated with cadaveric human growth hormone (c-hGH). Some people who received this treatment went on develop a disease called iatrogenic cerebral amyloid angiopathy (iCAA). iCAA is a disease associated with strokes caused by bleeding in the brain, as well as seizures (or fits) and cognitive changes. This occurred because some batches of pituitary-derived human growth hormone were contaminated with an abnormal form of one particular protein, called the prion protein, which went on to cause their disease.

The applicants seek to investigate whether patients who received pituitary-derived human growth hormone have been affected by diseases caused by iatrogenic protein transmission by using an existing historical database of recipients of pituitary-derived human growth hormone between 1959 and 1985, held by the UK Health Security Agency (HSA), to create two databases.

The first, the “Surveillance Snapshot” Research Database, will be created by linking data from the existing dataset to HES and ONS data, held by NHS England. This will provide a “snapshot” of data relating to admissions, A&E attendances, outpatients appoints and deaths, and to determine whether patients who received c-hGH are at an increased risk of neurological illness.

The second, the “Permission to Contact” Research Database, which will be used to invite patients who received pituitary-derived human growth hormone to participate in future research studies. The database will be created by linking data from the existing dataset to Personal Demographics Service (PDS) data, provided by NHS England to the UK HSA. This database will be retained at the UCL Data Safe Haven and used to contact patients in the database via their GP to ask for explicit consent to be included in the database. Patients will be contacted a maximum of three times and their data will be deleted if they dissent or do not respond.

A recommendation for 1, 2, 3, 4 and 6 support was requested to cover access to the relevant unconsented activities as described in the application.

Confidential patient information requested

The following sets out a summary of the specified cohort, listed data sources and key identifiers. Where applicable, full datasets and data flows are provided in the application form and relevant supporting documentation as this letter represents only a summary of the full detail.

Cohort	Patients included in a pre-existing database of recipients of cadaveric human growth hormone between 1959 and 1985, held at the UK Health Security Agency
Data sources	1. Both databases: a. Patient information in a pre-existing database of recipients of cadaveric human growth hormone between 1959 and 1985, held at the UK Health Security Agency • “Surveillance Snapshot” Research Database

	1. The MESH (National Data Opt-Out) data set, and the HES and ONS datasets at NHS England • "Permission to contact" Research Database 1. The MESH (National Data Opt-Out) data set, and the HES and ONS datasets at NHS England 2. Personal Demographics Service (PDS) data set at UK Health Security Agency
Identifiers required for linkage purposes	1. Name 2. NHS Number 3. GP Registration 4. Date of death 5. Date of birth
Identifiers required for analysis purposes	1. Gender
Additional information	The below data items will be retained in the Permission to contact" Research Database under consent. Patient name Date of birth NHS number Gender Address including postcode, email address and telephone number

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.	Continue engagement from the patient and public involvement group for the duration of the	The applicants advised that they would create a support group of people with confirmed diagnosis of iatrogenic CAA, or at

	study.	risk of the condition. Their carers and/or family members will also be invited to this group. This group will be actively involved in providing guidance on research priorities and how the database will be managed; we plan to achieve this via regular (e.g. annual) meetings. This information was accepted by the CAG.
2.	Please amend the following within the patient notification materials: a. Amend the readability to reflect the cohort of the study. b. Provide a clear overview of the study. c. State the role of CAG within the notification for primary care. d. Specify that dissenting from participating in the study would not affect standard of care.	The participant notification was amended and provided for review. This information was accepted by the CAG.
3.	Clarify when the patient notification material would be used to promote the study, and how far in advance this would be before the confidential patient information is processed.	The patients in the “Surveillance Snapshot” Research Database will not be directly contacted. The participant notification will be included on the study website. The study website (with participant notification) will be visible once the data applications to UK

		HSA and NHS England (formerly NHS Digital) are confirmed. For the “Permission to contact” Research Database, participant notification will be included in the information pack sent to patients by their GP. This information was accepted by the CAG.
4.	Clarify how the National Data Opt-Out would be applied for both databases and provide confirmation that the primary care team will review patient records to ensure patients had not previously objected to use of their data in research.	For the “Surveillance Snapshot” Research Database, the National Data Opt-Out will be applied by NHS England at time of linkage with HES-ONS data. For the “Permission to contact” Research Database, the National Data Opt-Out will be applied by UK HSA prior to their in-house NHS England data linkage This information was accepted by the CAG.
5.	Clarify how both workflows one and two are handled.	The applicants explained that Workflow 1 is a summary only. It provides introductory information and then an overview of the two separate components of this project. Workflow 2 shows the dataflows for “Surveillance Snapshot” Research Database, which includes information on Data Controllers at each stage. Workflow 3 shows the dataflows for “Permission to contact” Research Database. This includes information on Data Controllers and Data Processors for each stage, data flows which require Section 251 support (blue arrows), as well as those that do not (data flows occurring in the context of direct care, purple; data flows with direct consent, green). This information was accepted by the CAG.

Confidentiality Advisory Group advice conclusion

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 specific and standard conditions of support as set out below.

Specific conditions of support

The following sets out the specific conditions of support.

1. Favourable opinion from a Research Ethics Committee. **Confirmed 12 April 2021**

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 **2022/23** DSPT reviews for University College London, Institute of Prion Diseases, UK Health Security Agency and NHS England were confirmed as 'Standards Met' on the NHS England DSPT Tracker (checked 17 January 2024).

d. 23/CAG/0167 - National Respiratory Audit Programme (NRAP) Pulmonary Rehabilitation Audit

Name	**Capacity**
Dr Patrick Coyle	CAG Vice Chair
Dr Joanne Bailey	CAG Expert Member
Dr Malcolm Booth	CAG Expert Member
Dr Sandra Duggan	CAG Member
Dr Pauline Lyseight-Jones	CAG Member
Ms Katy Cassidy	HRA Confidentiality Advisor

Context

Purpose of application

This application from The Royal College of Physicians set out the purpose of continuing the HQIP commissioned National Respiratory Audit Programme Pulmonary Rehabilitation Audit.

The National Respiratory Audit Programme (NRAP), which launched on 1 June 2023, is a continuation of the National Asthma and COPD audit programme (NACAP). This 3-year programme covers secondary care workstreams for adult asthma (AA), children and young people asthma (CYPA), COPD, pulmonary rehabilitation (PR) in England and Wales, and primary care in Wales only. Applications have been supported for the adult asthma and chronic obstructive pulmonary disease (COPD) secondary care audit workstreams and the children and young people asthma (CYPA) secondary care audit workstream. The applicants are now seeking support for an audit into Pulmonary Rehabilitation. The overarching aims of the programme are to identify areas of variation and deficiencies in care, support improvement of the care given to patients and improvement of outcomes for patients admitted to hospital with an exacerbation in England and Wales.

Services providing Pulmonary Rehabilitation (PR) will enter confidential patient information into the NRAP audit webtool. Once a year, Crown Informatics Ltd will extract confidential patient information from the webtool. Crown Informatics will anonymise the data by replacing NHS numbers with a study ID, amending the postcode to Lower Super Output Area (LSOA) and amending date of birth to age at assessment. The anonymised dataset will be disclosed to Imperial College London for analysis. Crown Information Ltd also disclose confidential patient information to NHS England on a monthly basis for inclusion on the National Pulmonary Rehabilitation Dashboard.

A recommendation for class 1, 4, 5 and 6 support was requested to cover access to the relevant unconsented activities as described in the application.

Confidential patient information requested

The following sets out a summary of the specified cohort, listed data sources and key identifiers. Where applicable, full datasets and data flows are provided in the application form and relevant supporting documentation as this letter represents only a summary of the full detail.

Cohort	All patients referred to PR are included who: • attend an initial assessment for pulmonary rehabilitation. • are 18 years or over on the date of assessment.
Data sources	1. NHS England: a. Hospital Episode Statistics (HES) b. Admitted Patient Care (APC) dataset c. Office of National Statistics mortality data 2. Digital Health and Care Wales a. Patient Episode Database for Wales
Identifiers required for linkage purposes	1. NHS Number 2. Date of birth 3. Home postcode
Identifiers required for analysis purposes	1. None
Additional information	Data that is returned to Imperial College London for analysis by NHSE and DHCW has been anonymised, removing patient identifiers: • NHS Number is changed to audit ID number • Date of birth is changed to age • Postcode is changed to lower layer super output area (LSOA)

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.	Provide an explanation as to why NHS England requires confidential patient information from Crown Informatics Ltd each month for inclusion on the national pulmonary rehabilitation dashboards.	Provision of data to NHS England will usually involve collection of fully identifiable personal data by NHS England. In these circumstances: • NHS England has directed NHS Digital to collect and analyse data for its commissioning purposes in The Health and Social Care Information Centre (Establishment of Information Systems for NHS Services: Data Services for Commissioners) Directions 2015 (DSFC directions). • The DSFC Directions establish NHS Digital's statutory power to collect personal data from the NCAPOP clinical databases and The NCAPOP clinical databases hold Clinical Registry Data as defined for the purposes of the DSFC directions. • Transfer of data to joint data controllers will be done through NHS approved secure. This is supported by a current DSA. The CAG noted this information and raised no further queries.
2.	Provide clarification as to whether 's251' support is required for linkage to NHS England and DHCW datasets as part of this application at this time.	The CAG advised that support is not sought for linkage to NHS England and DHCW datasets. The CAG noted this information and raised no further queries.

3.	Update the patient notification materials as follows and provide to CAG for review. a. Produce a new patient notification which clearly describes the purpose and content of this application, distinct from any notification relating to direct care purposes. b. A layered approach is advised. c. The notifications should also state that 'section 251 support' was recommended by the Secretary of State for Health and Social Care, on advice from the Confidentiality Advisory Group (CAG). d. An explanation on how patients can request removal of their data for this application should be included. Use of an application specific opt-out should be promoted, whilst noting that the National Data Opt-Out will be respected. The CAG usually expects that telephone, email and postal contact details are provided, should patients have queries or wish to dissent to the inclusion of their data.	A revised patient information sheet was provided. The CAG noted this information and raised no further queries.

	e. All newly developed patient notification materials should be reviewed by a patient and public involvement group	
4.	Further proportionate patient and public involvement, particularly around the specific issue of use of confidential patient information without consent is to be undertaken and feedback provided to the CAG for review.	A session of the A&LUK patient and carer panel was held on the 8 December 2023. NRAP information governance processes were reviewed, including patient information taken without consent. Feedback on the patient and caregiver information sheet was sought. A summary of the patient and carer feedback was provided for CAG review. The CAG noted this information and raised no further queries.
5.	Provide justification for the collection of mental health data.	Data will also be used to allow comparisons of parity of esteem (i.e., to understand if adults with mental health problems or from different IMDs receive the same level of care). This is to support reporting on the access and equity of services for patients with respiratory conditions. The CAG noted this information and requested that the applicant provide information at annual review to demonstrate that mental health status is being used for the purposes outlined above.

Confidentiality Advisory Group advice conclusion

The CAG agreed that the minimum criteria under the Regulations appeared to have been met, and therefore advised recommending support to The Secretary of State for Health and Social Care, subject to compliance with the specific and standard conditions of support as set out below.

Specific conditions of support

The following sets out the specific conditions of support.

1. At the first annual review, provide information to evidence that mental health status data is used for the purposes described in your response to the provisional outcome.

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 **2022/23** DSPT review for **Crown Informatics and NHS England** were confirmed as 'Standards Met' on the NHS England DSPT Tracker (checked 17 January 2024).

   Digital Health and Care Wales – Caldicott Principles into Practice (CPiP) in place.

e. 23/CAG/0093 - Natural Experiment of the impact of supervised Opiate Agonist Therapy (OAT) consumption on drug related harm and treatment outcomes

Name	Capacity
Dr Harvey Marcovitch	CAG member
Professor Sara Randall	CAG member
Dr Murat Soncul	CAG alternate vice-chair
Mr William Lyse	HRA Approvals Administrator
Ms Caroline Watchurst	HRA Confidentiality Advisor

Context

Purpose of application

This application from The University of Bristol set out the purpose of medical research, to determine and compare rates of drug related harm. This includes hospital admissions, non-fatal overdoses, self-harm, drug related deaths, suicide death and all-cause mortality. These outcomes are examined during supervised and unsupervised Opioid Agonist Treatment (OAT) (methadone or buprenorphine) and periods off OAT, before, during and after the COVID-19 pandemic. Applicants will also assess duration and retention on supervised compared with unsupervised OAT, before, during and after the COVID-19 pandemic.

Daily supervised prescription and consumption (DSC) for OAT medicines used to treat opioid dependence/opioid drug use disorders was the norm before COVID-19 lockdown for a substantial number of patients managed by community drug agencies (CDA). Although implemented to reduce drug related deaths (DRDs), evidence for intended benefits of DSC of OAT is limited, imposes additional costs on OAT delivery and patients often find DSC stigmatising and restrictive. The COVID-19 pandemic led to patients being supplied with weekly or fortnightly supplies of OAT. Face to face support has also stopped. Telephone appointments offer efficiency savings but may impact on patient experience. Evidence on the impact of lockdown on management of opioid use and drug related harm is emerging. In Scotland there was some evidence that uptake of harm reduction services declined and have not yet recovered to pre-pandemic levels. In North America drug related deaths increased. In UK changes to the delivery of OAT, including dispensing for up to 14 days for self-administration, has been well-received by patients. It's no longer possible to study DSC in a controlled trial. As the COVID-19 pandemic necessitated a shift away from DSC on DHSC advice, it has created a "natural experiment" allowing applicants to study the impact of DSC on fatal and non-fatal overdose and DRDs and wider impacts of changes to drug treatment on patients.

Applicants will use data about patients prescribed either methadone or buprenorphine, identified by Change, Grow, Live (CGL), a CDA. Date of birth, postcode and NHS number, sex, and CGL pseudo ID will be disclosed to NHS England with 's251' support', and linked with hospital episode statistics (HES) and civil registration mortality data, and the pseudonymous dataset provided to the University of Bristol for analysis. Clinical data such as OAT prescription details, assessment information and health and safety information alongside a CGL pseudo-ID will be disclosed from CGL to the University of Bristol in effectively anonymous format, and applicants will link the HES and mortality data to the CGL clinical data using CGL's patient ID number. Analysis will be undertaken on the effectively anonymous dataset.

A recommendation for class 4, 5 and 6 support was requested to cover access to the relevant unconsented activities as described in the application.

Confidential patient information requested

The following sets out a summary of the specified cohort, listed data sources and key identifiers. Where applicable, full datasets and data flows are provided in the application form and relevant supporting documentation as this letter represents only a summary of the full detail.

Cohort	Patients registered with Change, Grow, Live and prescribed opioid agonist treatment between 2015 and end of 2022. Approximately 6000
Data sources	1.Change, Grow, Live a. Clinical records 2.NHS England: a. Hospital Episode Statistics (HES) b. Civil registration mortality data
Identifiers required for linkage purposes.	1.Date of birth 2.Post code 3.NHS number 4. Sex 5. CGL patient ID
Identifiers required for analysis purposes.	1.N/A analysis will be undertaken on an anonymous dataset

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.

1. **Amend the following within the patient poster:**
   a. **Review the patient notification material to ensure that it is clear and explicit.**
   b. **Clearly explain the options for raising objections, ensuring the study specific opt out is prominent, and the NDOO is merely stated as respected.**

The applicants have updated the privacy notice and have changed the wording in the patient information poster, this now includes specific instructions, ie, who to contact, for opting-out (where it is more vague and refers to a 'service provider', this is because this poster/leaflet will be displayed/distributed in CGL clinics and could refer to any staff member within the clinic, depending on who the service user is there to see. The CAG were content with this response.

2. **Clarify how, when and where the patient notification material will be made available.**

The applicant has stated that the privacy notice will be made available at CGL clinics, hard copies will be available to take away or can be requested by email. Posters will be displayed in CGL clinics and leaflets (smaller versions of the poster) will be printed and distributed to service users in CGL clinics, they will be available to take away and also handed to patients with their prescriptions. CAG were content with this response.

3. **Provide an outline of the patient and public involvement activities undertaken and feedback the discussions held in relation to the use of confidential patient information without consent.**

The applicants held a meeting with PPI contributors on the 9th Aug, and a summary of the relevant points of the discussion has been provided. This was attended by the study PPI coordinator, two researchers and three public contributors, one of whom was a service user and two were staff from local organisations for people with substance addiction issues, both were also ex-service users. Applicants asked the public contributors for their feedback on the project and specifically about the use of patient data routinely collected by a community drug agency, which there was support for. CAG were content with this response.

4. **Clarify who modifies the postcode, and at what time point, and confirm the duration the postcode will be retained in identifiable format.**

Change Grow Live will provide the post code to NHS England for linkage purposes only, they will not be sending patient post codes to us at the University and NHS England will remove post code from the data set before sending the linked HES and mortality to the University. CAG were content with this response.

5. **Please provide the NHS England 22/23 DSPT review for Change, Grow, Live, as per standard condition of support.**

This has been received on 18 January 2024.

Amendment considered alongside provisional response

The applicants have made an amendment to the data flow, which the Sub-Committee considered during the consideration of the provisional response. The applicants had originally planned for CGL to send their whole patient dataset to NHS England to be linked with HES and mortality data, but now NHS England only want to receive the key information vital for linkage (plus a patient ID number generated by CGL), this includes NHS number, date of birth, postcode and sex. The main difference in the data flow is that CGL will now send applicants their (anonymised) data set, NHS England will send applicants the HES and mortality data for the cohort and applicants will link the data using CGL's patient ID number. Applicants won't be in receipt of any more sensitive data than originally planned. The Sub-Committee were content to recommend support for this change to the data flow.

Confidentiality Advisory Group advice conclusion

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 specific and standard conditions of support as set out below.

Specific conditions of support

The following sets out the specific conditions of support.

1. Favourable opinion from a Research Ethics Committee. **Confirmed 21 August 2023.**

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 **Change, Grow, Live and NHS England** were confirmed as 'Standards Met' on the NHS England DSPT Tracker (checked 18 January 2024)

2. New Amendments

21/CAG/0033 – Risk of Aneurysm Rupture Study: ROAR

Name	Capacity
Ms Caroline Watchurst	HRA Confidentiality Advisor

Context

Amendment request

This application from University Hospitals Southampton NHS Foundation Trust aims to explore whether the PHASES (Population, Hypertension, Age, Size, Earlier subarachnoid haemorrhage, and Site) rupture risk tool provides accurate estimates of rupture risk over 5 years for unruptured intra-cranial aneurysms in a UK population. ‘s251’ support is in place to allow the disclosure of confidential patient information from participating Trusts to the coordinating centre at University Hospitals Southampton NHS Foundation Trust, the onwards disclosure to NHS England and Department of Health & Care Wales (DHCW) for the purposes of linkage with HES, ONS and PEDW data, the return of identifiable data to University Hospitals Southampton NHS Foundation Trust, and for the retention of identifiers until the final linkage is requested (as the 25 trusts will be sending their datasets in at different timepoints).

This amendment sought support to include Personal Demographics Service (PDS) Dataset as an additional data source from NHS England. This is in order for the applicant to be able to check successful linkage of patients data, to ensure that where data is missing, the reason for that missing data is known. Without the amendment, the aneurysm rupture rates produced by this study will be unreliable as they will contain an unmeasured degree of inaccuracy. Whilst this inaccuracy is likely to only be a few percent based on pilot data it is important that data be as accurate as possible.

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. See section below titled 'security assurance requirements' for further information. **Confirmed**:

   The NHS Digital **22/23** DSPT reviews for **University Hospitals Southampton NHS Foundation Trust** and the DSPT equivalent for **NHS England** were confirmed as 'Standards Met' on the NHS England DSPT Tracker (checked 21 December 2023).

   DHCW has a valid Caldicott Principles into Practice (CPiP) outturn report

   As there are more than 5 organisations processing confidential patient information without consent, the CAT team has not individually checked the DSPTs; this is the responsibility of the applicant to ensure these are in place.

2. Confirmation of a favourable opinion from a Research Ethics Committee. **Confirmed non substantial 04 January 2023**

21/CAG/0033 – Risk of Aneurysm Rupture Study: ROAR

Name	Capacity
Ms Caroline Watchurst	HRA Confidentiality Advisor

Context

Amendment request

This application from University Hospitals Southampton NHS Foundation Trust aims to explore whether the PHASES (Population, Hypertension, Age, Size, Earlier subarachnoid haemorrhage, and Site) rupture risk tool provides accurate estimates of rupture risk over 5 years for unruptured intra-cranial aneurysms in a UK population. 's251' support is in place to allow the disclosure of confidential patient information from participating Trusts to the coordinating centre at University Hospitals Southampton NHS Foundation Trust, the onwards disclosure to NHS England and Department of Health & Care Wales (DHCW) for the purposes of linkage to outcome data, the return of identifiable data to University Hospitals Southampton NHS Foundation Trust, and for the retention of identifiers until the final linkage is requested (as the 25 trusts will be sending their datasets in at different timepoints).

This amendment sought support to include the Maternity Services Data Sets as an additional data source from NHS England. The initial application allows for the linkage of a cohort of patients to the NHS England HES-APC and Civil Registration Deaths datasets for the purpose of identifying potential aneurysm rupture events in the cohort of patients with a known unruptured aneurysm. Hospital episodes from HES-APC are limited by diagnosis or treatment codes for data minimisation. The purpose of this amendment is to allow the same cohort of patients to be linked by NHS England to the Maternity Services Data Sets as well as identify HES-APC episodes which contain any data in the fields (ANASGEST, ANASDATE, DELMETH_1, EPITYPE), regardless of the diagnosis or treatment codes.

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. See section below titled 'security assurance requirements' for further information. **Confirmed**:

   The NHS Digital **22/23** DSPT reviews for **University Hospitals Southampton NHS Foundation Trust** and the DSPT equivalent for **NHS England** were confirmed as 'Standards Met' on the NHS England DSPT Tracker (checked 21 December 2023).

   DHCW has a valid Caldicott Principles into Practice (CPiP) outturn report

   As there are more than 5 organisations processing confidential patient information without consent, the CAT team has not individually checked the DSPTs; this is the responsibility of the applicant to ensure these are in place.

2. Confirmation of a favourable opinion from a Research Ethics Committee. **Confirmed non substantial 25 July 2023**

21/CAG/0033 – Risk of Aneurysm Rupture Study: ROAR

Name	Capacity
Ms Caroline Watchurst	HRA Confidentiality Advisor

Context

Amendment request

This application from University Hospitals Southampton NHS Foundation Trust aims to explore whether the PHASES (Population, Hypertension, Age, Size, Earlier subarachnoid haemorrhage, and Site) rupture risk tool provides accurate estimates of rupture risk over 5 years for unruptured intra-cranial aneurysms in a UK population. 's251' support is in place to allow the disclosure of confidential patient information from participating Trusts to the coordinating centre at University Hospitals Southampton NHS Foundation Trust, the onwards disclosure to NHS England and Department of Health & Care Wales (DHCW) for the purposes of linkage with HES, ONS and PEDW data,

the return of identifiable data to University Hospitals Southampton NHS Foundation Trust, and for the retention of identifiers until the final linkage is requested (as the 25 trusts will be sending their datasets in at different timepoints).

This amendment sought support to confirm that 's251' support is in place until the final data linkage to NHS England data, regardless of the date this occurs, rather than the estimated end of 2022. The original CAG application states that the exit strategy for 's251' support will be when the final linkage of patients to NHS England (formerly NHS Digital) has been conducted. In the initial application this was estimated to be by the end of 2022. Email correspondence with the CAT has confirmed that 'Section 251 support' will continue until this final data linkage. The purpose of this amendment is to confirm with official HRA approval that 's251' support is in place until the final data linkage to NHS England (formerly NHS Digital), regardless of the date this occurs.

Confidentiality Advisory Group advice

The amendment requested was considered by the Confidentiality Advice Team who raised no queries regarding this amendment. CAT has previously confirmed with the applicant that support remains in place until the linkage has been completed, as there is no specific end date listed in the original support letter. This amendment is therefore to assure NHS England as data controllers that 's251' support remains in place until the final linkage is undertaken.

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. See section below titled 'security assurance requirements' for further information. **Confirmed**:

The NHS Digital **22/23** DSPT reviews for **University Hospitals Southampton NHS Foundation Trust** and the DSPT equivalent for **NHS England** were confirmed as 'Standards Met' on the NHS England DSPT Tracker (checked 21 December 2023).

DHCW has a valid Caldicott Principles into Practice (CPiP) outturn report

As there are more than 5 organisations processing confidential patient information without consent, the CAT team has not individually checked the DSPTs; this is the responsibility of the applicant to ensure these are in place.

2. Confirmation of a favourable opinion from a Research Ethics Committee.
   Confirmed non substantial 30 November 2023

22/CAG/0006 – Developing a digital handover application for paramedics to provide a personalized approach to pre-hospital stratification for OOHCA – the RAPID-MIRACLE study

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 the London Ambulance Service to King's College Hospital NHS Foundation Trust, and then to the treating hospital trust so that the investigator at this site can complete the eCRF, and the return of a pseudonymised dataset to King's College Hospital NHS Foundation Trust.

The applicants sought to revise the end date of the study. The projected end date is now 20 March 2025, instead of 07 September 2024.

Confidentiality Advisory Group advice

The amendment requested was considered by the Confidentiality Advice Team. The CAT agreed that the changes made were in the public interest.

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 15 December 2023**

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:**

   Due to the number of organisations involved it is the responsibility of King's College Hospital, as controller, to ensure that organisations meet the minimum required standard in complying with DSPTs, and take remedial action if they become aware of any that fall below this, or where any concerns are raised about an organisation.

21/CAG/0008 – Clinical Practice Research Datalink (CPRD)

Name	Capacity
Dr Tony Calland, MBE	CAG Chair
Ms Caroline Watchurst	HRA Confidentiality Advisor
Dr Paul Mills	HRA Confidentiality Advice Service Manager

Context

Amendment request

The applicants have existing support to allow the disclosure of confidential patient information from various data processors to NHS England (previously NHS Digital) as a trusted third party in order to link datasets and provide CPRD (MHRA) with effectively anonymised data.

In this amendment, the applicants seek to remove Dr Tim Williams as joint Director of CPRD, and name Dr Puja Myles as sole Director of CPRD.

The applicants also informed CAG that they wished to stipulate Puja Myles (Director) as the Data Applicant, and Nadia Azimikorf (Research Data Governance Officer) as the Data Custodian, and this is accepted as notification to CAG.

Due to the utility and ongoing availability of SUS-source data, CPRD also sought ‘s251’ support to receive ‘Uncurated Low Latency Hospital Data Sets for Admitted Patient Care, Outpatient, and Critical Care’ from NHS England. These are a cut of the SUS data, but which are not purpose -limited to COVID-19 monitoring. These un-curated datasets will be used by the MHRA for the purpose of safety and surveillance monitoring relating to the safety of medicines and healthcare products captured within hospital records, and by CPRD to support the safety and surveillance monitoring of clinical trials.

Confidentiality Advisory Group advice

The amendment requested was considered Chairs’ Action. The 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:**

   The NHS England 2022/23 DSPT review for NHS England was confirmed as 'Standards Met' on the NHS England DSPT Tracker (checked 11 January 2024

2. Confirmation of a favourable opinion from a Research Ethics Committee. **Confirmed 14 November 2023**

21/CAG/0009 – Motor Neuron Disease Register for England, Wales and Northern Ireland

Name	Capacity
Dr Patrick Coyle	CAG Vice Chair
Ms Caroline Watchurst	HRA Confidentiality Advisor

Context

Amendment request

This application aims to create a research database that will act as a central resource of information about all people with a diagnosis of Motor Neuron Disease (MND) as confirmed by a consultant neurologist in England, Wales and Northern Ireland, to enable the calculation of incidence and prevalence of MND in England, Wales and Northern Ireland. Confidential patient information will also be linked with clinical data from national datasets. 's251' support is in place to allow various collection of data, as detailed in the original outcome letter.

This amendment sought support to link data from clinical research trials to the MND Register, in the first instance this will be for the AMBROSIA and the ALS Biomarker

studies. This relates to patients with MND who have taken part in the projects. For the Ambrosia study – Data from **402** participants who have MND will be linked with the MND Register. For the ALS Biomarkers study – Data from **560** participants who have MND will be linked with the MND Register. The data linkage for the Ambrosia project will be a one-off transfer, while the data linkage for the ALS biomarkers project will occur every 6 months in the same manner used for each data collection centre who transfer their data. Some patients who are participating in the ALS biomarkers clinical trial will consent to the data linkage, as it is ongoing, and 's251' support will not be required where consent is in place. For patients who have participated in the AMBROSIA trial they will not consent, as the trial has now closed.

The AMBROSIA study involved patients at four NHS sites across England (Barts Health NHS Trust, The University of Oxford, The University of Sheffield and Queen Mary University of London, Basildon NHS Foundation). The ALS biomarkers study is at Barts Health NHS Trust.

Applicants will also link data from a separate app-based platform Telehealth in Motor Neuron Disease (TiM), where patients will consent to have their data linked with the MND Register, and therefore this is out of scope for 's251' support.

This amendment sought support to change the location of the data storage away from the secure server at KCL, as the applicants are changing to a trusted research environment (TRE), - the KCL CREATE TRE, which is also at King's College London.

The applicants have updated their patient notification documents with this information.

Confidentiality Advisory Group advice

The amendment requested was considered by Chairs' Action. The Vice Chair recommended support for this amendment, noting it will enhance the data available. The Vice Chair commented that the move of the database to a trusted research environment in the same institution is sensible.

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 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 04 January 2024**

23/CAG/0022 – Infant Feeding Survey 2023

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

Context

Amendment request

The 2023 Infant Feeding Survey has 's251' support to allow NHS England to use confidential patient information to link patients identified from the Maternity Services Dataset (MSD) to the Personal Demographics Service to identify the most up to date contact details, and to allow the disclosure of confidential patient information from NHS England to IPSOS UK (for the purposes of

sending questionnaires, and for analysis), and then onwards to Formara Ltd and Gov.UK Notify, for the purpose of sending out questionnaires for the 2023 Infant Feeding Survey.

For each questionnaire, mothers will receive an initial invitation followed by three reminders. The current approach is shown in the contact strategy table below.

Mailing	Contact type
1	Initial letter
1.1	SMS (timed to coincide with the initial letter)
2	Reminder letter
2.1	Reminder SMS (timed to coincide with the reminder letter)
3	Reminder letter with paper questionnaire
4	Reminder letter
4.1	Reminder SMS (timed to coincide with the reminder letter)

This amendment seeks to add an additional SMS to the mainstage contact strategy based on findings from the pilot. Applicants will add an additional SMS after mailing 3, for each phase.

Confidentiality Advisory Group advice

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

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 **NHS England, Ipsos UK, Formara Ltd, the Department of Health and Social Care (which covers GOV.UK Notify Service)**, **and TextLocal Ltd** were confirmed as '**Standards Met'** on the NHS England DSPT Tracker (03 January 2024)

21/CAG/0106 – TRIM: What Triage model is safest and most effective for the management of 999 callers with suspected COVID-19? A linked outcome study

Name	Capacity
Ms Caroline Watchurst	HRA Confidentiality Advisor

Context

Amendment request

This application seeks to determine which ambulance service triage model is safest and most effective for the management of 999 calls with suspected Covid-19. 's251' support is in place to allow the disclosure of confidential patient information from participating NHS trusts to their linked ambulance trusts, and from the ambulance trusts to NHS England (previously NHS Digital) for linkage to CHESS, ECDS, HES and the Civil Registration – deaths dataset.

This amendment sought to extend the duration of ‘s251’ support until 07 June 2025, in order to complete analyses.

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 participating sites where confidential patient information will be accessed, individual DSPT submissions are not required for the purpose of the application. Support is recommended on the basis that the applicant ensures the required security standards are in place at each site prior to any processing of confidential patient information with support under the Regulations.

2. Confirmation of a favourable opinion from a Research Ethics Committee. **Confirmed non substantial 29 November 2023**

20/CAG/0136 – A randomised controlled trial assessing the effectiveness and cost effectiveness of thrice weekly, extended, in-centre nocturnal haemodialysis versus standard care using a mixed methods approach: NightLife

Name	Capacity
Ms Caroline Watchurst	HRA Confidentiality Advisor

Context

Amendment request

The applicants have existing support to allow potential incidental disclosure of confidential patient information when researchers from the University of Leicester, who are not members of the direct care team, carry out consented interviews with haemodialysis unit staff, consented interviews with patients, and observations on haemodialysis units at nine named NHS trusts.

This amendment sought support to include Barts Health NHS Trust, Manchester University NHS Foundation Trust and University of Coventry & Warwickshire NHS Trust as new data processors for the application, as sites participating in Process Evaluation, workstream 2.

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. Favourable opinion from a Research Ethics Committee. **Confirmed non substantial 19 December 2023**

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**: **Security assurances are required for the sites where the observations take place. Support will be based on confirmation that the DSPT (or CPiP/Welsh IG toolkit for Wales) at the site will be complied with and that no identifiable information will be kept onsite or removed from the site. However, as this is more than 5 organisations, these will not be individually checked by the Confidentiality Advice Team, and it is the responsibility of the applicant to ensure that appropriate security assurances are in place.**

17/CAG/0145 – Outcomes of Drug Coated Balloon Angioplasty, A UK Real Life Experience from 2009 to 2015

Name	Capacity
Ms Caroline Watchurst	HRA Confidentiality Advisor

Context

Amendment request

The amendment seeks support to change the Chief Investigator from Dr Upul Wickramarachchi to Dr Simon Eccleshall, (who was previously listed as a as co-investigator). Dr Upul Wickramarachchi is no longer in post.

Confidentiality Advisory Group advice

The amendment requested was considered by the Confidentiality Advice Team (CAT), 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 **NHS Arden and Greater East Midland Commissioning Support Unit, & Redcentric (Harrogate) (regarding NICOR), NHS England, & Norfolk and Norwich University Hospitals NHS Foundation Trust** were confirmed as 'Standards Met' on the NHS England DSPT Tracker (checked 16 January 2024)

2. Confirmation of a favourable opinion from a Research Ethics Committee. **Confirmed 14 October 2019**

ECC 3-04(f)/2011– SLaM Information Governance Clinical Dataset Linking Service

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

Context

Amendment request

This application has support to link confidential patient information between South London and Maudsley NHS Foundation Trust (SLaM) and NHS Digital to provide a dataset with the purpose of investigating the associations between specific mental disorders in secondary mental health care and physical illness. This support was

provided for use in adults only. Further support in previous amendments extended the support to research in children for specific projects only, with data linked from the National Pupil Database.

This current amendment request is to include 2 additional purposes to this application, for the applicants to use the already linked data held by SLaM CRIS to undertake 2 specific research projects, regarding those who are under 18.

Project 1 - The effects of extreme heat events on mental health in vulnerable urban communities: towards evidence-based policy and practice. This project will use the HES data already linked to CRIS to investigate young people's presentations to hospital on or following days of extreme heat. The overall aim of the project is to investigate the association between ambient temperature (and related environmental factors such as air pollution) with mental health, specifically in people with a pre-existing diagnosis of mental illness.

Project 2- An investigation into the educational and health outcomes of young people following an out of area psychiatric admission in child and adolescent mental health services (CAMHS). This project will use the HES data already linked to CRIS to investigate the hospital service use of children who have experienced an inpatient psychiatric admission, comparing between those who are admitted far away from where they live, with those who are admitted close to where they live.

No further data linkages are required for purposes of this project.

Confidentiality Advisory Group advice

The amendment requested was considered by Chair's Action. The Chair was content to recommend support for this amendment, noting that these are two interesting projects, one to look into the adverse effects of children requiring in patient care but having to have that treatment at distance from home, friends and family, and the other about the changes in mental health behaviours in periods of unusual and extreme heat. The data is already processed so no further processing is required.

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 **South London and Maudsley NHS Foundation Trust** & **NHS England** were confirmed as 'Standards Met' on the NHS England DSPT Tracker (checked 16 January 2024)

2. Confirmation of a favourable opinion from a Research Ethics Committee. **Confirmed within scope of original REC Favourable opinion via email 13 July 2020.**

22/CAG/0093 – Emerging eviDence on the impact of COVID-19 on mental hEalth sErvices and health inequalities in highly dePrived communities (DEEP)

Name	Capacity
Ms Caroline Watchurst	HRA Confidentiality Advisor

Context

Amendment request

This application seeks to investigate the changes in mental health services in response to Covid-19 and show how these changes have impacted health outcomes in deprived populations. ‘s251’ support is in place to allow the disclosure of confidential patient information from the North of England Commissioning Support (NECS) Unit to NHS England, (previously NHS Digital), and the return of a linked dataset to NECS.

The application has ‘s251’ support for NECS and NHS England to retain confidential patient information after linkage, and delete the confidential patient information provided to facilitate linkage, at a timepoint of 35 months after the project completion. An extension to allow linkage to be undertaken is requested until 30 September 2024, and therefore the applicant seeks to extend to extend ‘s251’ support to 31 August 2027 (35 months after the planned linkage).

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 **North of England Commissioning Support Unit** & **NHS England** were confirmed as ‘Standards Met’ on the NHS England DSPT Tracker (checked 16 January 2024)

2. Confirmation of a favourable opinion from a Research Ethics Committee.
   Confirmed non sub-substantial 12 January 2024

22/CAG/0002 – Assembling the Data Jigsaw in Greater Manchester: improving MSK research to advance patient care and inform patient policy using linked primary and secondary care data

Name	Capacity
Dr Murat Soncul	CAG alternate vice-chair
Ms Caroline Watchurst	HRA Confidentiality Advisor

Context

Amendment request

The applicants have support to allow the Business Intelligence Team at the Northern Care Alliance to access the Salford Integrated Record (SIR) dataset and link the dataset to an extract from hospital data sources to create a de-identified dataset for research purposes, and to retain access to the hashing algorithm, used to de-identify the dataset, until the study ends.

Due to delays, this amendment sought to extend the duration of support until March 2025.

The amendment also sought support to include an additional step to the dataflow. Manual annotation will be carried out in order to accurately identify the diagnosis for Research Question 1, including the data fields listed below. The manual annotation will be carried out by clinicians working as part of the research team, to avoid further burdening the NHS site, and therefore 's251' support is required for this process, as these individuals are not direct care team, and they will view identifiers during the extraction process. This process will involve access to the structured dataset (the diagnosis line of text from the outpatient letter) by the research team within a dedicated

project space in the Datalake. Where the machine has not recognised the qualifier (ie 'suspected' diagnosis or 'family history' of condition) this will be added by the clinicians. To support the software required for annotation, a virtual machine will be mounted within the Datalake, for which additional access controls will be in place. The virtual machine remains compliant with NHS security requirements.

The amendment also notified CAG of the collection of additional data fields, as it has come to light that the model misses certain information. Certainty of the diagnosis, Family history, and 'Mentioned date'. This field is to be used if there is a date mentioned in the text that does not match the date the text was created (which is already in the dataset). These fields are required to properly identify the set of patients who actually have a diagnosis falling under one of the diseases listed. The mentioned date is useful in identifying incidence rates of the diseases of interest. These fields are not confidential patient information, and the addition of these items is accepted as notification, however the process of collection of these fields requires 's251' support as described above.

Confidentiality Advisory Group advice

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

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:

The NHS England **22/23** DSPT review for the **Northern Care Alliance** was confirmed as 'Standards Met' on the NHS England DSPT Tracker (checked 16 January 2024).

2. Confirmation of a favourable opinion from a Research Ethics Committee. **Confirmed 21 December 2023**

22/CAG/0092 – Establishing evidence to inform culturally competent mental health services (EVOLVE)

Name	Capacity
Dr Murat Soncul	CAG alternate vice-chair
Ms Caroline Watchurst	HRA Confidentiality Advisor

Context

Amendment request

This application seeks to identify and quantify changes to mental health services, and their impacts on health outcomes during the COVID-19 pandemic, in ethnic minorities. 's251' support is in place to allow the disclosure of confidential patient information from 6 participating GP practices to North of England Commissioning Support Unit (NECS), and to allow the disclosure of confidential patient information from NECS to NHS England for linkage with MHSDS, IAPT, HES (including APC, OP, A&E), and CSDS, and for the flow back to NECS, to allow NECS to link the datasets together. The outcome letter specifies the cohort as 1,328 non white patients, from six GP practices across three local authority areas (Newcastle upon Tyne, Middlesbrough and Stockton-on-Tees), who are adults over 18 years having been referred or self-referred to NHS-funded secondary mental health services or Improving Access to Psychological Therapies (IAPT) services between 23 March 2019 and 22 March 2020.

This amendment sought support to increase the number of people in the cohort to 11,652 patients, and to clarify that the cohort will be white and non-white. The study is to compare service provision between white and non white, so applicants will need

data regardless of their ethnicity to enable the comparisons. Applicants initially estimated the number of white and non white individuals based on published studies, but NHS North Commissioning Support Unit identified more eligible patients than estimated for primary care data.

In the initial outcome letter, the applicant has support to allow NECS to link the datasets together, and retain the link between the pseudo ID and confidential patient information for 35 months after the study has completed, (to allow for any requests to check data analysis following publication). An extension to allow linkage to be undertaken is requested until 31 August 2024, and therefore the applicant seeks to extend to extend 's251' support to 31 July 2027 (35 months after the planned linkage).

Confidentiality Advisory Group advice

The amendment requested was considered by Chair's Action. The Alternate Vice Chair was content to recommend support.

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 North of England Commissioning Support Unit** (0AR) & NHS England was confirmed as 'Standards Met' on the NHS England DSPT Tracker (checked 16 January 2024)

2. Confirmation of a favourable opinion from a Research Ethics Committee.
   Confirmed non substantial 21 December 2023

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

Name	Capacity
Ms Caroline Watchurst	HRA Confidentiality Advisor

Context

Amendment request

This application from The Intensive Care National Audit & Research Centre (ICNARC) set out the purpose of medical research which aims to evaluate the clinical effectiveness of conservative versus usual oxygen therapy on 90-day all-cause mortality.

This amendment sought support to extend the duration of ‘s251’ support until 28 February 2025, to allow the applicants to reach the recruitment target.

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 **The Intensive Care National Audit & Research Centre (ICNARC) and NHS England** were confirmed as 'Standards Met' on the NHS England DSPT Tracker (checked 17 January 2024)

   Digital Health and Care Wales (DHCW) has a valid CpiP/Welsh IG toolkit in place as confirmed by the Welsh Information Governance team.

   Due to the number of participating ICU's involved it is the responsibility of ICNARC, as controller, to ensure that these participating organisations meet the minimum required standard in complying with DSPTs, and take remedial action if they become aware of any that fall below this, or where any concerns are raised.

2. Confirmation of a favourable opinion from a Research Ethics Committee. **Confirmed non substantial 10 November 2023**

22/CAG/0090 – ISIS 2 Second International Study of Infarct Survival: Legacy Database

Name	Capacity
Dr Tony Calland, MBE	CAG Chair
Ms Katy Cassidy	HRA Confidentiality Advisor

Context

Amendment request

The applicants have existing support to allow the University of Oxford to continue to hold confidential patient information collected for the ISIS-2 study. When the CAG recommended support, a condition was placed that the dataset could be retained in an identifiable format for 12 months following issue of the outcome letter. After 12 months, the dataset was to be anonymised and all items of confidential patient information deleted. In July 2023, the applicants were given an extension of support for a further 6 months, in expectation that linkages to the GP Data for Planning and Research (GPDPR) would be undertaken. The CAG noted that it was not known when GPDPR would be launched and that CAG did not want the identifiable dataset to be held for an extended period at the University of Oxford. The additional time was granted to allow the applicants to pseudonymise the datasets held at the University of Oxford and use a Trusted Third Party to hold the trial linkage identifiers until the linkage to the GPDPR data can be done. An amendment would have been submitted to seek support for the transfer of confidential patient information to the Trusted Third Party at a later date.

The applicants had approached NHS England and Digital Health and Care Wales, but neither organisation was able to act as the Trusted Third Party. The applicants proposed that the Nuffield Department of Population Health (NDPH) Information Governance Team act as the Trusted Third Party. This has been informally agreed by CAG and the applicants now seek to formalise the arrangement.

Confidentiality Advisory Group advice

The amendment requested was considered by the Confidentiality Advisory Group Chair. The Chair agreed that the request was reasonable and that support should be recommended.

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:

   The NHS Digital **2022/23** DSPT review for **University of Oxford (Nuffield Department of Population Health)** was confirmed as 'Standards Met' on the NHS Digital DSPT Tracker (checked 21 December 2023).

2. Confirmation of a favourable opinion from a Research Ethics Committee. **Confirmed that amendment does not impact REC opinion**

3. Annual Review Approvals

CAG reference	Application Title
17/CAG/0145	Outcomes of Drug Coated Balloon Angioplasty, A UK Real Life Experience from 2009 to 2015
22/CAG/0101	Nottingham and Nottinghamshire ICB S251 Non-Research Purposes
20/CAG/0105	National Clinical Audit of Psychosis
19/CAG/0054	An evaluation of knee arthroplasty fixation in an evolving challenging population
22/CAG/0099	Automated brain image analysis for timely and equitable dementia diagnosis (ABATED)
19/CAG/0150	Long-term vascular complications in young people with childhood-onset type 1 diabetes
16/CAG/0024	ADDITION – 10 Year Follow up

PIAG 4-08(b)/2003	National Confidential Enquiry into Patient Outcome and Death (NCEPOD)
20/CAG/0080	Investigating whether elevated C-reactive protein is associated with probable depression in paediatric Chronic Fatigue Syndrome/Myalgic Encephalomyelitis (CFS/ME)
22/CAG/0144	Randomised Evaluation of Sodium dialysate Levels on Vascular Events (RESOLVE)
22/CAG/0124	Feasibility of an artificial intelligence system to improve the quality and efficiency of breast cancer screening
20/CAG/0039	Phenotyping individuals with elevated mean pulmonary arterial pressure and elevated pulmonary vascular resistance in the United Kingdom
20/CAG/0137	Best Care for Abdominal Emergencies - The BCAE Study. A retrospective single, centre cohort study of patients with intestinal emergencies
20/CAG/0143	CTSU clinical trial follow-up service with NHS Digital to provide de-identified follow-up data for use in the EBCTCG breast cancer meta-analyses
19/CAG/0190	A prospective surveillance study of conservatively managed children with end-stage kidney disease in the United Kingdom and Republic of Ireland.
20/CAG/0009	The Cambridge Cohort - Mammography East-Anglia Digital Imaging Archive (CC-MEDIA)
19/CAG/0210	Discovery and Analysis Of Novel Biomarkers In Urological Diseases (DIAMOND STUDY)
20/CAG/0057	Incidence of psychosis and measures of psychotic experiences within the ALSPAC
20/CAG/0123	REadmission And Cardiovascular ouTcomes following Acute Myocardial Infarction in England and Wales (REACT-AMI)
16/CAG/0121	Epidemiology of Cancer after solid Organ Transplantation (EpCOT)
20/CAG/0133	Yorkshire Specialist Register of Cancer in Children and Young People

22/CAG/0093	Emerging eviDence on the impact of COVID-19 on mental hEalth sErvices and health inequalities in highly deprived communities (DEEP)
17/CAG/0025	Liver transplantation as treatment for patients with hepatocellular carcinoma; a study using existing electronic data
22/CAG/0135	UK Genetic Prostate Cancer Study

Signed – Chair	Date
Dr Tony Calland, MBE, CAG Chair, Dr Patrick Coyle, CAG Vice-Chair, Dr Murat Soncul & Professor William Bernal, CAG Alternate Vice-Chairs	*05 February 2024*

Signed – Confidentiality Advice Team	Date
Ms Caroline Watchurst *HRA Confidentiality Advisor*	*02 February 2024*