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

September 2023

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

1. New Applications

a. 23/CAG/0076 - Using artificial intelligence (AI) to characterize the dynamic inter-relationships between MUltiple Long-term condiTIons and PoLYpharmacy and across diverse UK populations and inform health care pathways (AI-MULTIPLY)

Name	Capacity
Dr Murat Soncul	CAG Alternate Vice Chair
Dr Harvey Marcovitch	CAG Member
Mr Andrew Melville	CAG Member
Mr Dan Roulstone	CAG Member
Mr Umar Sabat	CAG Member
Ms Katy Cassidy	HRA Confidentiality Advisor

Context

Purpose of application

This application from Newcastle University set out the purpose of medical research that seeks to determine how multiple long-term conditions and polypharmacy interact and this interaction is modified by inequalities.

Multiple long-term conditions (multimorbidity)(MLTC-M) are defined as having two or more long-term conditions (LTC) and are associated with premature mortality, significant treatment burden for patients and carers, and increased healthcare use. Healthcare systems and research infrastructure are not configured to address MLTC-M. Previous work on MLTC-M have focused on older populations due to the increased prevalence in this group. However, the number of people aged under 65 and who have a diagnosis of MLTC-M is higher. Polypharmacy (the simultaneous use of five or more medications) and MLTC-M polypharmacy are associated with MLTC-M, but the relationships between polypharmacy, MLTC-M and health outcomes are poorly understood. The aim of this application is to characterise MLTC-M and polypharmacy trajectories and to define the relationships between MLTC-M clusters, polypharmacy, and healthcare outcomes. Two work packages are involved. In Work Package 1, data from several large national and local datasets will be collected. Use of AI techniques to analyse the data will be conducted in Work Package 2.

Newcastle upon Tyne Hospitals NHS Foundation Trust (NUTH), Cumbria, Northumberland, Tyne and Wear NHS Foundation Trust (CNTW) and GP practices will disclose confidential patient information to the North of England Commissioning Support Unit (NECS). NECS will apply a common pseudonym to support linkage across datasets, using the NHS number and date of birth to create a shared dataset containing all data from each of the contributing NHS trusts for each participant. This pseudonymised data will then be shared to the Axym data system, held within NECS. The research team will not receive access to the pseudonymisation key. Axym will provide an individual secure data access environment allowing designated users from Newcastle University to interrogate their data.

A recommendation for class 1, 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	Adult patients aged 18 years and over with 2 or more multiple-long term conditions confirmed. Around 4.4 million patient records will be included.
Data sources	1. Patient records at participating NHS trusts: a. Newcastle upon Tyne Hospitals NHS Foundation Trust b. Cumbria, Northumberland, Tyne and Wear NHS Foundation Trust 2. Patient records at participating GP practices: a. Roseworth Surgery b. Park Medical Group c. Walker Medical Group d. West Road Medical Centre e. Walker Road Medical Centre f. Benfield Park Medical Centre g. Heaton Road h. Westerhope Medical Centre i. Regent Medical Centre j. St Anthony's Health Centre k. Denton Turret Medical Centre l. Dilston Road Surgery
Identifiers required for linkage purposes	1. NHS number 2. Date of birth 3. Postcode – sector level
Identifiers required for analysis purposes	1. Date of birth 2. Date of death 3. Postcode – sector level 4. Gender 5. Ethnicity

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. **Clarify why support is not required for the data that is leaving the Trusts.**

The Trusts will use the NECS supplied pseudo@source tool which ensures that identifiers are removed from the data before it leaves the Trusts. The pseudo key used is held securely by the Data Services for Commissioners Regional Office (DSCRO) based within NECS which is a legally mandated segregated area and is never shared with the NECS staff who access the data. The CAG noted this information and raised no further queries.

2. **Explain at what stage the data sources listed in the application are going to be incorporated in the research.**

Integrated pseudo anonymised primary and secondary care within the Axym secure data environment will be analysed using pre-determined machine learning, AI and epidemiological methods by NU and NuTH researchers.

The fully anonymised aggregated summary data will be exported from the SDE to NU and shared with colleagues in our consortia. This data will be compared and contrasted with other bulk aggregated data from other sources e.g., CPRD, UK Biobank. Outputs will be reported to the funder, compiled into research papers, and shared with the PPIE groups. The CAG noted this information and raised no further queries.

3. **An updated data flow diagram needs to be provided, in line with the advice in this letter.**

An updated data flow diagram was provided. This was reviewed by the CAG who raised no further queries.

4. **Confirm that this application is requesting support only for phase 1 of the research which includes the initial linkage and the 11 GP practices.**

The applicants confirmed that, in this application, support is sought for Phase 1 only.

The applicants noted the intention to extend the linkage Cumbria, Northumberland, Tyne and Wear NHS Foundation Trust and to a further 25 GP practices across Newcastle and the immediately surrounding region. The CAG noted this information and that amendments would be required to extend the support.

5. **Confirm whether the research is planning to use free text data for the data collected from practices and hospitals. If yes, please explain how you will ensure that the free text data will be anonymised.**

The Informatics teams in NuTH and CNTW will use Natural Language Processing to search for specific diagnostic terms and medications. These terms would be used to confirm diagnosis, medication, prescription details, etc., within NuTH and CNTW electronic medical records, in part because out-patient diagnostic codes and medicines are not reliably coded. This will not be needed for GP records, which are well coded. The CAG noted this information and raised no further queries.

6. **Explain how the National Data Opt-Out will be applied within GP practices.**

The GP clinical system removes patients who have a Type 1 or National Data Opt-Out from leaving the clinical system. All patients who have opted out before the data is extracted will not be included in this project. If a patient applies an opt-out after the extraction of the data, their data will still be included in the study as there would be no means to remove them from the current pseudonymised database. The CAG noted this information and raised no further queries.

7. **Patient notification materials need to be created. The materials must include the following:**

   a) **In layered approach and lay language explain the AI component of the research and justify the use of data, and how the algorithm is going to work.**

   b) **An explanation on how patients can request their data the removal of their data, either via a local opt-out or the National Data Opt-Out needs to be provided. 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.

The applicants provided a Patient Notification Poster. This was reviewed by the CAG who raised no further queries.

8. **A strategy engagement needs to be provided which explains how further patient and public involvement will be undertaken as the project expands.**

The applicants provided details on the planned patient and public involvement. This was reviewed by the CAG who raised no further queries.

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

   The NHS England **21/22** DSPT review for **Newcastle University, Newcastle upon Tyne Hospitals NHS Foundation Trust, North of England Commissioning Support Unit and Cumbria, Northumberland, Tyne and Wear NHS Foundation Trust** was confirmed as 'Standards Met' on the NHS England DSPT Tracker (04 July 2023)

Due to the number of participating organisations involved it is the responsibility of Newcastle University and Newcastle upon Tyne Hospitals NHS Foundation Trust as controller, to ensure that participating GP practices 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.

b. 23/CAG/0067 - An evaluation of the clinical efficacy and risk profile of routine spinal operations performed in the National Health Service

Name	Capacity
Ms Clare Sanderson	CAG Alternate Vice Chair
Dr Sandra Duggan	CAG Member
Dr Pauline Lyseight-Jones	CAG Member
Mrs Sarah Palmer-Edwards	CAG Member
Professor James Teo	CAG Member
Miss Kathleen Cassidy	HRA Confidentiality Advisor

Context

Purpose of application

This application from Queen Mary University of London set out the purpose of medical research that seeks to assess the clinical outcomes of common spinal surgery procedures for low back pain.

Back pain is a common disorder, affecting over three quarters of people at some point. Although more common in the elderly, younger people who suffer with bulging spinal discs also often suffer. Back pain drastically affects an individual's quality of life, preventing them from performing key daily activities such as walking, using the bathroom, exercise and sleeping. Back pain also costs the economy over £12 billion per year through lost work hours, painkiller consumption and disability benefits. Around one in ten of those affected go on to develop chronic back pain, which is linked to several mental health conditions. Spinal research undertaken so far have been limited

in numbers and in follow-up, and there is little understanding in how effective spinal surgery is and the risk of complications.

Confidential patient information from the British Spine Registry (BSR) will be disclosed to NHS England for linkage to HES data. BSR will also disclose a dataset containing the study identifier, but otherwise de-identified, to Queen Mary University of London. The study identifier will be used to link the two datasets. The final dataset, anonymised other than patient date of death, will be used for analysis.

A recommendation for class 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 who underwent any of the following spinal surgical procedures; Discectomy, Fusion, Laminectomy, Cauda equina decompression surgery, Kyphoplasty, Intervertebral disc replacement, Deformity surgery (scoliosis, kyphosis). The applicants will obtain data from HES for patients who underwent spinal surgery between 01 January 2000 – 01 January 2023. As the BSR was not set up until 2012, data from BSR will be collected between 01 January 2012 – 01 January 2023. The applicants estimate that 1,000,000 patients will be included.
Data sources	1. British Spine Registry, held by British Association for Spine Surgeons 2. HES-APC, HES-PROMS and ONS data, held by NHS England

Identifiers required for linkage purposes	1. NHS Number 2. Date of birth 3. Postcode – unit level
Identifiers required for analysis purposes	1. Date of death 2. Gender 3. Ethnicity

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.

This letter summarises the outstanding elements set out in the provisional support letter, and the applicant response. The applicant response was considered by a sub-committee of the CAG.

1. **The CAG asked that patient date of death was converted to age at death. If this could not be done, justification as to why not needed to be provided.**

The applicants explained that patients' dates of death were needed to allow accurate censoring of patients for survival analyses. Using the age of death creates inaccuracy and is not an acceptable way of performing survival analyses. Only through using the date of death can patients be censored accurately, and the competing risk of death be studied and adjusted for in the analyses. The CAG noted this information and raised no further queries.

2. **Further patient and public involvement needs to be undertaken. This needs to cover the following:**

    a. **The number of people involved in the PPI group needs to be increased.**

The applicants advised that they intended to increase the size of the group to 15 members. An update on recruitment needed to be provided in the first annual review.

    b. **Provide clarification on whether the 8 patients in the face-to-face session are from the British Spine Registry (BSR).**

The applicants explained that Barts Bone Joint Health has created a patient and public advisory group database for musculoskeletal research. Members of this group have expressed an interest in being informed about this application and in offering their input into the research. Members were recruited via local organisations, such as Social Action for Health, Barts Health NHS Trust and via social media. The majority of people in the database are from the East London area and represent a mixed demographic. The CAG noted this information and raised no further queries.

c. Patient and public involvement needs to be undertaken around the issue of use of confidential patient information for data linkages despite the consent form they originally signed stating that no linkages would be undertaken.

The applicants advised that the current BSR consent form states that "I understand that my health data may be linked to other national health databases". We have supplied a copy of the most recent BSR consent form.

The applicants have also discussed the sharing of identifiable data to NHS Digital with their patient and public involvement group. The specific variables needed for linkage were mentioned and the group were happy with this. The CAG noted this information and raised no further queries.

d. A commitment to ongoing patient and public involvement needs to be given.

The applicants will run six monthly patient and public involvement meetings. The CAG noted this information and raised no further queries.

3. A patient notification strategy and dissent mechanism need to be created:

a. Patient and public involvement needs to be undertaken to discuss the best way of notifying patients. The patient notification materials and a communication plan, created following these discussions, need to be provided to the CAG for review.

The applicants discussed this with their prior patient public involvement group. The group reached a consensus that the study should be published on the Barts Bone and Joint Health website in lay terms with updates of the results of the research posted throughout the study. There was also agreement that the website should have the

contact details of the research administrator, to allow patients to opt out from being included in the study through contacting the administrator. The research group run a stall at the Festival of Communities in East London every year to inform the local community about current research. This project will be discussed at the stall. The CAG noted this information and raised no further queries.

b. A study specific opt-out needs to be created and an explanation on how patients can opt-out included in the patient notification materials.

The study website will contain information about the study and what personal data will be used for. This will also provide the contact details of the research group administrator to allow patients to opt out from the study. The CAG noted this information and raised no further queries.

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. An update on recruitment to the patient and public involvement group needs to be provided in the first annual review.
2. Favourable opinion from a Research Ethics Committee. **Confirmed 19 June 2023**
3. 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 England **21/22** DSPT reviews for **NHS England** and **Amplitude Clinical Services Ltd** were confirmed as 'Standards Met' on the NHS England DSPT Tracker (checked 12 September 2023).

c. 23/CAG/0088 - Community based continuity of midwifery care models for women living in areas of ethnic diversity and social disadvantage

Name	Capacity
Professor William Bernal	CAG alternate vice-chair
Dr Pauline Lyseight-Jones	CAG member
Mr Andrew Melville	CAG member
Ms Katy Cassidy	HRA Confidentiality Advisor

Context

Purpose of application

This application from King's College London set out the purpose of medical research to evaluate the impact of the LEAP caseload midwifery team on care of women living in areas of ethnic diversity and social disadvantage.

Recent enquiries into maternal and perinatal death in the UK have consistently found that women and babies from the poorest backgrounds and those from Black, Asian, and Minority Ethnic (BAME) groups are at the greatest risk of severe morbidity and mortality. The proportion of preterm births also varies by ethnicity, with infants of BAME parents more likely to be born preterm. Socioeconomic circumstances could also be contributing to the differences in birth outcomes across ethnic groups, with women who live with social complexity also experiencing poorer quality maternity care. The NHS Long-Term Plan aims to reduce stillbirth, maternal and neonatal mortality, and serious neonatal brain injury by 50% by 2025. It includes a commitment to implementing a targeted model of continuity of midwifery care for 75% of women from BAME communities and a similar percentage of women from the most deprived groups to help improve outcomes for the most vulnerable mothers and babies.

Women eligible to take part in the survey will be given information in the postnatal period by the midwife prior to discharge from midwifery care. At each site, a monthly report will be run by the PI or a supporting IT midwife. This report includes the relevant information of postnatal women who gave birth (alive baby) less than 3-6 months ago and live in the LEAP postcodes. Support is needed as potential participants will be identified by the IT team/midwife, who will provide the list of potential participants to a member of the clinical research team who will subsequently send the invitation for the survey. Participation will then proceed on a consented basis.

A recommendation for class 3, 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	Women aged 16 – 50 years of age, who live in LEAP postcodes and underwent a live birth.
Data sources	1. Maternity health records at: a. Guy's and St Thomas' NHS Foundation Trust b. King's College Hospital NHS Foundation Trust
Identifiers required for linkage purposes	1. Name 2. NHS Number 3. Hospital ID 4. Date of birth 5. Postcode – unit level
Identifiers required for analysis purposes	1. Date of birth 2. Postcode – unit level 3. Occupation 4. Ethnicity

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. **Provide a formal letter of response from the Chief Investigator, providing an overview of the research and study aims, as well as details of the mechanisms used for contacting potential participants, i.e., telephone, email, or both.**

The applicants advised that the NIHR ARC South London maternity program aims to reduce health inequalities by implementing community-based models of maternity care for women and their children (up to 4 years old) living in areas of social disadvantaged and ethnic diversity in South London. The CAG reviewed this information and raised no further queries.

2. **The patient notification materials need to be revised as follows:**

    a. **The materials need to be re-written for the intended audience and reviewed by the patient and public group.**

    b. **Additional methods of dissent within the poster, such as telephone, postal address, or both, need to be described in the poster.**

    c. **The methods used to contact patients, e.g. whether the first contact will be by telephone or email, need to be described.**
    d. **A clear description of the CAG role needs to be included.**

The applicants provided revised materials, which were reviewed and accepted by the CAG.

3. **Clarify whether the storage of data to those who have opted out of the study would be retained and ensure this clarified and kept consistent throughout the patient notification materials.**

The applicants advised that the clinical research team will retain only initials, hospital and NHS numbers and ethnicity for the duration of the study. When the study ends, this data will be destroyed, and the team will add a note to the medical records to confirm that they do not wish to take part in the study. This has now been clarified in all patient notification materials. The CAG reviewed this information and raised no further queries.

4. **New participants should be involved in the patient and public involvement group.**

The applicants explained that they have a well-established PPIE Network and a PPIE Strategy Group that are involved in all aspects of the research design, co-production, analysis and interpretation and dissemination. It includes service users, and representatives of charities and local organisations working with ethnic minorities and socially disadvantaged communities. The CAG reviewed this information and raised no further queries.

5. **The patient and public involvement materials need to be made available in languages other than English. A simplified English language version also needs to be created.**

The applicants advised that they have further simplified the patient notification materials, using principles of plain English, including shorter sentences and active forms of speech. The materials will also be translated into Spanish and Portuguese, as English, Spanish and Portuguese are the three most common languages in LEAP areas, with support from the research team and PPIE group. The CAG reviewed this information and raised no further queries.

6. **The patient and public involvement materials referred to on Page 15 of the Protocol need to be provided.**

The applicants advised that the patient notification materials and survey had been submitted. The CAG noted this and raised no further queries.

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: 10 February 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 21/22 DSPT reviews for **King's College London**, **Guy's and St Thomas' NHS Foundation Trust** and **King's College Hospital NHS Foundation Trust** were confirmed as 'Standards Met' on the NHS England DSPT Tracker (19/07/2023)

   As the above conditions have been accepted or met, this letter provides confirmation of final support. I will arrange for the register of approved applications on the HRA website to be updated with this information.

d. 23/CAG/0086 - Transforming Ovarian Cancer diagnostic pathways (TranSforming Ovarian caNcer diAgnosTic pAthways - SONATA)

Name	Capacity
Professor William Bernal	CAG alternate vice-chair
Dr Pauline Lyseight-Jones	CAG member
Mr Andrew Melville	CAG member
Ms Katy Cassidy	HRA Confidentiality Advisor

Context

Purpose of application

This application from the University of Birmingham set out the purpose of medical research that seeks to determine the accuracy of the ROMA algorithm in diagnosing ovarian cancer.

Approximately 7,500 women in the UK are diagnosed with Ovarian cancer (OC) each year. 5-year survival is around 45%, lower than comparable European countries. Improved diagnostics are critical to improving outcomes. Standard of care tests in the NHS for primary care are sequential CA125 and ultrasound. Standard care of test in the NHS for secondary care is an algorithm that combines CA125 and an ultrasound score called the Risk of Malignancy Index algorithm (RMI). The same tests are used at both primary care and secondary care, often with ultrasound repeated in secondary care. The risk of ovarian malignancy algorithm (ROMA), a newer algorithm, incorporates cancer antigen 125 (CA125), human epididymal protein 4 (HE4), ultrasound findings and menopausal status. A pilot study conducted in primary care demonstrated that ROMA had a better diagnostic performance compared to RMI. The applicants now seek to undertake a larger scale evaluation, testing the ROMA algorithm incorporating CA125, HE4 and ultrasound results against CA125 testing alone.

Confidential patient information for patients who underwent CA125 testing for ovarian cancer at the request of their GP will be disclosed from Black Country Pathology Services and South Tyne and Wear Pathology Service to Sandwell and West Birmingham Hospitals NHS Trust. Confidential patient information from Gateshead Health NHS Foundation Trust, The Royal Wolverhampton NHS Trust will be disclosed to Sandwell and West Birmingham NHS Trust, for linkage to the pathology services data. Confidential patient information for patients treated at Sandwell and West Birmingham NHS Trust will also be linked to the pathology services data. Any data not needed for analysis will be deleted. NHS numbers will be replaced with a study identifier and dates of birth amended to age group and time to cancer/non-cancer diagnosis. The anonymised data set will be encrypted for secure transfer for analysis at the University of Birmingham.

A recommendation for class 1, 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	Female patients who presented to primary with symptoms of ovarian cancer and underwent a CA125 test after the study start date, which is currently planned for 31 August 2023. The applicants estimate that 41000 patients will be included.
Data sources	1. Confidential patient information from patient records held at: a. Black Country Pathology Services b. South of Tyne and Wear Pathology Service c. Gateshead Health NHS Foundation Trust d. The Royal Wolverhampton NHS Trust e. Sandwell and West Birmingham NHS Trust
Identifiers required for linkage purposes	1. NHS number 2. Date of birth 3. Postcode – unit level
Identifiers required for analysis purposes	1. Date of birth 2. Postcode – unit level 3. Ethnicity
Additional information	Dates of birth will be amended to age group and time to cancer/non-cancer diagnosis before the dataset is transferred to the University of Birmingham 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.

1. **Provide details on how documentation in hard copy would be kept securely.**

The applicants will ensure that no hard copy documentation containing any personal or identifiable is produced, eliminating the risk of disclosure via hard copies. Other study documentation, including the study master file, will be kept in locked filing cabinets in locked offices at Sandwell and West Birmingham NHS Trust. The CAG noted this information and raised no further queries.

2. **Additional ways of promoting the study, such as advertising on the Target Ovarian Cancer website, or the websites of other charities and organisations need to be explored.**

The participating NHS trusts, Sandwell and West Birmingham Hospitals, Royal Wolverhampton NHS trust and Gateshead Health NHS trust will host information on the SONATA study on their websites. Ovacome, a national patient cancer support charity, has agreed to host information on the SONATA study on their website. The applicants will also approach Target Ovarian cancer. The CAG noted this information and raised no further queries.

3. **The Privacy Notice needs to be revised as follows:**

a. **The purpose of the study needs to be explained.**
b. **The use of confidential patient information, as proposed in the application, needs to be explained.**
c. **Information about the CAG and its role needs to be provided.**
d. **Patients should be asked to provide their NHS number, if known, but advised that other identifiers can also be used to identify and remove their data.**

A revised privacy notice was provided. This was reviewed by the CAG. Members agreed that the role of the CAG had not been accurately described and asked that the information about CAG is revised to *"The application was reviewed by the Confidentiality Advisory Group (CAG). CAG is an independent group of lay people and professionals which provides expert advice on the use of confidential patient information without consent. CAG recommended that our application should be supported and the Maker within the Health Research Authority approved this."*

4. **Ensure the National Data Opt-Out is applied.**

The applicants advised that the data processing, linkage and analysis will now be undertaken within the West Midlands Secure Data Environment. The Check for National Data Opt-outs service provided by NHS England via the secure Message Exchange for Social Care and Health (MESH) messaging service will be used to ensure that the National Data Opt-Out is applied. The CAG noted this information and raised no further queries.

5. **Clarify why it is "unlikely" that the research team would be able to "reliably identify dissenting patients."**

The applicants clarified that they will be able to reliably identify dissenting patients as carrying out data processing and analysis within the West Midlands Secure Data

Environment at University Hospitals Birmingham NHS Foundation Trust will facilitate access to information on patients who have opted out and enables them to be excluded from data linkage and analysis. The applicants have also revised the privacy notice and have explored further avenues to publicise the study. The CAG noted this information and raised no further queries.

6. **Provide detail on the demographic of the patient and public involvement group, along with any feedback and any changes made to the study as a result.**

Feedback had been sought from 3 patients as well as an organisational response from Ovacome. The three patients are diverse in age and ethnic backgrounds. All have found the study interesting and are very supportive. One patient has expressed a keenness to fully participate in the research as a patient participant and she will be part of the project oversight committee and be part of the outputs to ensure that patient voice is threaded through the project.

Members noted that the patient and public involvement activity is limited and it is unclear whether the specific issue of use of confidential patient information without consent has been discussed. The CAG asked that further activity was undertaken and feedback provided at the first annual review.

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. The Privacy Notice needs to be revised to contain the following text about the role of the CAG, *"The application was reviewed by the Confidentiality Advisory Group (CAG). CAG is an independent group of lay people and professionals which provides expert advice on the use of confidential patient information without consent. CAG recommended that our application should be supported and the Maker within the Health Research Authority approved this."*

2. Further patient and public involvement is to be carried out and feedback provided at the first annual review.

3. Favourable Opinion from a Research Ethics Committee. **Confirmed** (17 July 2023)

4. 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.

e. 22/CAG/0173 - Preservation of the Boyd Orr Cohort Database Version 1

Name	Capacity
Dr Malcolm Booth	CAG member
Dr Rachel Knowles	CAG member
Mr Andrew Melville	CAG member
Ms Rose Payne	CAG member
Dr Murat Soncul	CAG alternate vice-chair
Ms Katy Cassidy	HRA Confidentiality Advisor

Context

Purpose of application

This application from the University of Bristol set out the purpose of continued storing of confidential patient information retained for patients who participated in the “The Carnegie Survey of Family Diet and Health in Pre-war Britain”.

The Survey was originally conducted in England and Scotland between 1937 – 1939. In the early 1990s, the applicants used the information originally collected for around 85% of the cohort on the NHS Central Register and, until 2013, the applicants

received death and cancer notifications for the cohort. The applicants have agreed a data retention period for ONS cancer and mortality data to 2039 but there has been no research activity on the database since 2013, and no processing of data from NHS Digital since 2008. The applicants advised that the dataset was unique, as the detailed records of childhood diet and health for patients held is older than those collected in any other dataset. The dataset has been used to investigate childhood body size and diet in relation to adult chronic disease, and to demonstrate protective associations between childhood fruit and vegetable intake and adult cancer risk.

This application was originally supported by CAG in 2014 under reference CR19/2014. After the applicant submitted the first annual review in 2022, they were requested to re-submit a refreshed application due to the length of time that had passed without CAG oversight. This refreshed application 22/CAG/0173 will therefore supersede CR19/2014. The applicants are now seeking support to allow one final download and linkage of cancer registration and death certificate data from NHS Digital and to allow secondary analysis of the data. Once the applicants have obtained mortality outcomes on all participants, which is likely to be achieved within the next 3-5 years, they will explore the use of a pseudonymised approach. The applicants note that this process will be relatively easy with the electronic data they hold, however they also hold an archive of paper records covering a thirty-year period which will be more challenging to anonymise. The applicants therefore seek to hold the confidential patient information until this process can be completed.

A recommendation for class 1, 2 and 6 support were 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 who participated in the Carnegie Survey of Family Diet and Health in Pre-war Britain 1937-1939.
Data sources	1.Data held in the Boyd-Orr dataset at the University of Bristol.

	2.Datasets held by NHS Digital, which have not been specified.
Identifiers required for linkage purposes	1. Name 2. NHS Number 3. Date of birth 4. Postcode – unit level
Identifiers required for analysis purposes	1. Date of birth 2. Postcode – unit level 3. Gender 4. Ethnicity

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. **CR19/2014 will be expired from the date of this letter and superseded by 22/CAG/0173. Please note the new annual review date.**

The applicants advised that they had noted the information.

2. **Please check whether NHS Digital still hold the identifiers from the original cohort within their database and are able to refresh the dataset without requiring the disclosure of confidential patient information form the University of Bristol to NHS Digital.**

The applicants advised that ONS closed the Boyd Orr study in 2016 and therefore no longer hold the cohort details in the system. The CAG noted this information and raised no further queries.

3. **The CAG requested that patient notification materials were created and for the following to be included:**

a. **Clearly state that the research team hold access to confidential patient information.**

b. **Clarify that section 251 and CAG support is in place for this study.**

c. **Develop a clear local opt-out process and explain this within the patient notification.**

The Boyd Orr website was updated. A local opt-out process had been created. The CAG noted this information and raised no further queries.

4. **Please undertake further patient and public involvement with a representative group of the original cohort from the hospital. This should involve a discussion on the use of confidential patient information and provide the outcomes to CAG.**

Further patient and public involvement will be undertaken. The applicants intend to recruit people into the patient and public involvement group who are of a similar socioeconomic, regional and gender distribution to the Boyd Orr cohort. The CAG noted this information and raised no further queries.

5. **Please clarify whether anonymisation would be used as the exit strategy.**

The applicants confirmed that anonymisation will be used as an exit strategy. The CAG noted this information and raised no further queries.

6. **Please provide clarification on how the dataset would be managed once the study was concluded.**

The applicants advised that, once the study was concluded, the data will be processed in line with the FAIR principles. The applicants have discussed with the University of Bristol Archives whether the database can be stored within the Archives, which the applicants have done for a previous study. The CAG advised that this would be acceptable and asked the applicant to discuss with the University of Bristol archives

data management professionals to agree a process that will ensure no confidential patient information is stored within the archives. Feedback from the discussions need to be provided at the first annual review.

7. **Please provide a time scale regarding exiting support.**

The applicants anticipate that support will be needed for 5 years to allow relinkage and analysis. The CAG noted this information and raised no further queries.

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. Explore with the University of Bristol archives data management professionals to agree a process that will ensure no confidential patient information is stored within the archives and provide feedback from these discussions at the next annual review.

2. Favourable opinion from a Research Ethics Committee. **Confirmed 23 August 2022**

3. Confirmation provided from the IG Delivery Team at NHS Digital 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 **21/22** DSPT reviews for **University of Bristol – Bristol Medical School** & **NHS England** were confirmed as 'Standards Met' on the NHS Digital DSPT Tracker (checked 20 September 2023).

f. 23/CAG/0089 - Hospitalisation decision-making in Primary Care: How do, and how should clinicians approach decisions regarding hospital admission for those living with frailty or who could be near the end of their life?

Name	Capacity
Professor William Bernal	CAG alternate vice-chair
Dr Rachel Knowles	CAG member
Dr Pauline Lyseight-Jones	CAG member
Mr Andrew Melville	CAG member
Ms Katy Cassidy	HRA Confidentiality Advisor

Context

Purpose of application

This application from University of Bristol set out the purpose of medical research that seeks to how Primary Care clinicians approach hospitalisation decisions for frail people and those near the end of life.

This project will look at care for people living with frailty and other complex, incurable medical problems who may be near the end of their lives. It will focus on admissions to hospital and the decisions that can lead to this. A literature review has been conducted to explore what is already known about hospitalisation decisions for frail people.

Observations of staff who make decisions whether patients should be admitted to hospital will be undertaken at nursing homes, care homes, residential homes where a clinician attends to visit patients within the Bristol, North Somerset and South Gloucestershire Integrated Care System. The specific sites are Severn Side Integrated Urgent Care and Weston Care Home GP group in Weston-Super-Mare. At these sites the researcher will accompany the clinician and observe interactions with, and discussions about, frail patients who they are considering admitting to hospital. The researcher will also have informal conversations directed at understanding the decision-making process. Verbal consent will be sought from patients should their care be directly observed. Support is sought to allow for disclosures of confidential patient information that occur when the researcher is observing meetings where patients won't be present, but their information may be discussed.

A recommendation for class 5 and 6 supports 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 aged 18 years and over who are potentially towards the end of their life as per the GSF-PIG: • Those with advanced, chronic, incurable disease. • General frailty and coexisting conditions meaning they may be in the final 12 months of life. • Existing conditions leading to risk of a sudden catastrophic event that may be terminal.
Data sources	Observations of staff meetings at: • University Hospitals Bristol and Weston NHS Foundation Trust • Weston Super Mare Care Home Hub, part of Pier Health • Severnside Urgent Care Service
Identifiers required for linkage purposes	No items of confidential patient information are required for linkage purposes.

Identifiers required for analysis purposes	No items of confidential patient information are required for analysis 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.

1. **The patient notification materials need to be provided. The materials need to explain that patients can dissent, how to dissent and contact details to register dissent need to be included.**

The applicants provided a Patient and Public Notification Poster that will be displayed at Nursing Homes and in waiting rooms associated with the sites. The CAG noted this information and raised no further queries.

The applicant also advised that they had taken steps to engage with community groups in the Weston- Super- Mare population in which the data collection will take place. An update will be provided at the first annual review.

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. Continue to undertake patient and public involvement. Consideration needs to be given on how the residents and family members from the two

participating homes can be involved. Feedback from the patient and public involvement needs to be provided at the first annual review.

2. Favourable opinion from a Research Ethics Committee. Confirmed:14 August 2023.

3. 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 21/22 DSPT review for **Bristol, North Somerset and South Gloucestershire Integrated Care System** was confirmed as 'Standards Met' on the NHS England DSPT Tracker (19/07/2023)

g. 23/CAG/0099 - Defining delirium and its impact in Parkinson's Disease (DELIRIUM-PD)

Name	Capacity
Professor Sara Randall	CAG member
Dr Murat Soncul	CAG alternate vice-chair
Mr Marc Taylor	CAG member
Ms Caroline Watchurst	HRA Confidentiality Advisor

Context

Purpose of application

This research application from Newcastle University set out the purpose of medical research which aims to find out how well and how accurately a new Parkinson's-specific delirium tool (developed in the DELIRIUM-PD study - 18/CAG/0207), can identify delirium in people with Parkinson's in hospital compared to a detailed examination by an expert. Applicants will also identify if the tool can improve the care of people with Parkinson's while in hospital and shorten their length of stay. The applicants aim to make this new tool freely available, as raising awareness and correctly identifying delirium in Parkinson's will lead to better care and could improve patient outcomes.

18/CAG/0207 had ‘s251’ support for access to confidential patient information for the purposes of identifying potential participants to approach for informed consent. Recruitment closed in January 2022 to the original study, and therefore ‘s251’ support expired. The applicant has since received additional funding to validate the tool that was developed as per the original study aims. The sponsor has agreed that this should be a Substantial Amendment to the original study as it is a direct continuation and will include the same participants and identical protocols, however as the ‘s251’ support expired, a new application to CAG was required.

All patients with Parkinson’s who attend movement disorder services in Newcastle upon Tyne will receive a letter and information sheet about the study which will explain that, should they be admitted to hospital, they will be approached by a researcher about the study. An electronic alert; a system already in use by the hospitals (Recurring Admission Patient Alerts or RAPA), will notify researchers of their admission. Applicant’s will visit participants who consent to participate over consecutive days whilst in hospital and will complete a delirium assessment.

A recommendation for class 3 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	Patient with a diagnosis of Parkinson's disease or Parkinson’s disease dementia according to UK Brain Bank Criteria made by a movement disorder specialist, that have attended the Newcastle Newcastle-upon-Tyne Hospital (NuTH) Foundation NHS Trust movement disorder clinics for the management of their Parkinson’s within 18 months of the start of the study. Applicant will recruit/consent 100 more patients, however - Approximately 1,100 letters will be sent, and approximately 1,600 patient records screened for eligibility.

Data sources	1.Newcastle Newcastle-upon-Tyne Hospital (NuTH) Foundation NHS Trust movement disorder clinics medical records
Identifiers required for facilitating invitation process	1.Name 2.Address including postcode 3.Hospital number
Identifiers required for analysis purposes	1.N/A analysis is undertaken with consent as the legal basis under common law

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. **Please provide the Caldicott letter of support, as per standard requirement for applications to CAG.**

This has been provided as per standard requirement.

2. **Please identify a suitable online resource/website to make notification materials clearly available to patients and the public, and provide these details to CAG.**

Applicants have identified the Parkinson's North East and Cumbria Research Interest Group (NEC-RIG) website as a suitable website to make notification materials clearly available to patients and the public: https://parkinsonsnec-rig.org/

The NEC-RIG is a dedicated group bringing together people from across the North East and Cumbria to promote and increase access to Parkinson's research. Applicants can confirm that they are able to include details of the study on the website in a prominent position that is easily accessible to the public, including a specific dedicated page on the website.

The CAG were content with this response.

3. **Please amend the following within the invitation letter and associated materials:**

    a. **Ensure the objections process provides an email and postal address alongside a phone number.**
    b. **Extend the period in which patients can raise objections, from 7 day to 6 weeks.**
    c. **Specify within the introductory letter to participants that section 251 support facilitates identification of suitable participants, so that they can be approached for their explicit consent to be part of the study.**
    d. **Include that the HRA has approved (on advice from CAG) in the section of the PIS where the REC review is detailed.**

The notification documents have been updated as per advice, and the CAG were content with the changes made.

4. **Please provide a favourable opinion from the Research Ethics Committee regarding the amendment, as per standard condition of support.**

This has been provided as per standard condition of support.

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 regarding amendment 18/YH/0486/AM11 on 29 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. See section below titled 'security assurance requirements' for further information. **Confirmed:**

   The NHS England **22/23** DSPT review for **Newcastle upon Tyne Hospitals NHS Foundation Trust** was confirmed as Standards Met on the NHS England DSPT Tracker (checked 22 August 2023).

h.

23/CAG/0094	**INSIGHT 2**
Contact:	Professor Rachel Tribe
Data controller:	King's College London and Guy's and St Thomas' NHS Foundation Trust are joint data controllers
Application type:	Research

Present:

Name	Capacity
Dr Patrick Coyle	CAG Vice Chair (Expert)
Dr Rachel Knowles	CAG Member (Expert)
Ms Rose Payne	CAG Member (Lay)

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 King's College London and Guy's and St Thomas' NHS Foundation Trust set out the purpose of medical research that aims to understand how complications deviate from the normal trajectory of a healthy pregnancy. Applicants will investigate how maternal exposures and health (pre-pregnancy and during pregnancy) and alterations in the pregnancy environment can impact on in utero fetal wellbeing and subsequent maternal, infant and child health, with the eventual aim of developing prediction tools, preventative therapies and treatments that benefit both the mother and child. The study will be consented, and 's251' support is only required for the purposes of identifying patients to seek consent.

Women will be recruited through self-referral, which does not require 's251' support, and also from the general antenatal setting, specialist obstetric clinics, and potentially autoimmunity clinics. Potential participants will be identified by members of the research team from electronic medical records, routine clinics and clinic attendances at Guy's and St Thomas' NHS Foundation Trust. Potential participants will be contacted ahead of their scheduled appointment and sent a copy of the patient information sheet regarding the study to read prior to being approached in person. If participants do not wish to be approached in person, they will have the opportunity to inform the research team ahead of their appointment. This process requires 's251' support. Should patients consent, their participation will proceed on a consented basis.

Confidential information requested

Cohort	Approximately 2500 pregnant women. This will comprise women who have no underlying health problems and a healthy pregnancy outcome, or some form of pregnancy complication (or existing disease). The study will comprise of 3 cohorts: (A) general pregnancy cohort. Additionally, patients might be eligible for one or both of the following: (B) Preterm birth (PTB) risk sub-cohort with a high risk and a low risk arm; (C) Prenatal Drivers of Islet Autoimmunity (PISA) sub-cohort. 's251' support only required for those who have not self-referred
Data sources	1. Electronic medical records held at Guy's and St Thomas' NHS Foundation Trust and any additional sites that are added (Additional sites, including King's College Hospital, may be included at a later date)

Identifiers required for linkage purposes	1. Name 2. NHS number 3. Hospital ID 4. Date of Birth 5. Postcode 6. Ethnicity 7. Contact details (phone number, email and postal address)
Identifiers required for analysis purposes	1. N/A as any identifiers for analysis included with consent as the legal basis under common law

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 justification to why initials need to be retained in addition to hospital number, date of birth and NHS number with regards to not recontacting people who decline.	Applicants are happy to remove the initials, and the CAG were content with this response.
2.	Please confirm a time limit to be set for retention of identifiers, for those who decline to participate in the research.	For those who decline to participate but allow applicants to keep information to not contact them again, applicants will keep this information for the duration of the study. The CAG were content with this response.

3.	Please confirm how many people were involved in the described Patient and Public Involvement activities. Please give details of who they are, to indicate that they match the demographic and experience of the study cohort.	The video for PPI involvement was circulated on June 1st through email (attachment 1) to PPI-group members. Additionally, the project was presented by Prof. Tribe and discussed at the PPI meeting of August 18th (attachment 2) where 3 PPI members participated. Applicants did not collect any demographic data from the PPI group, however, they match the targeted audience and two-thirds were from an ethnic minority background. They have lived experience of pregnancy complications, the focus of the study, and all were identified from relevant local clinics. The CAG were content with this response.
4.	Provide confirmation that the use of confidential patient information without consent and outside the direct care team, was discussed as part of the Patient and Public Involvement activities.	This was discussed at the PPI meeting and the group was supportive. See attached meeting notes (attachment 2) where the specific question *"How do you feel about this use of confidential patient information (CPI) prior to consent?"* was asked and discussed. The CAG were content with this confirmation.
5.	Please update the patient notification materials as follows, in line with advice in this letter, and provide to CAG for review.	

	a. The patient notification should begin with wording that states directly this information is for pregnant women who attend the Trust, and that they may be contacted by phone/email about the study. b. Additionally provide a telephone number for opt out purposes. c. The notification should remove the link to the National Data Opt-Out, only reference that it will be respected is required.	a. Done b. Done c. Done The CAG were content with the updated notifications.

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 September 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 **Guy's and St Thomas' NHS Foundation Trust** was confirmed as 'Standards Met' on the NHS England DSPT Tracker (checked 22 September 2023)

i. 23/CAG/0080 - eLIXIR Research Tissue Bank/Database

Name	Capacity
Professor William Bernal	CAG Alternate Vice Chair
Mr Thomas Boby	CAG member
Dr Malcolm Booth	CAG member
Mr Umar Sabat	CAG member
Mr Marc Taylor	CAG member
Ms Katy Cassidy	HRA Confidentiality Advisor

Context

Purpose of application

This application from King's College London set out the purpose of seeking support under s251 for an existing research tissue bank and database, set up to investigate the temporal and demographic influences on the health of pregnant women and their children.

The eLIXIR Research Tissue Bank (RTB) was created in 2018. The aim of the Research Tissue Bank and Database is to investigate the mechanisms underlying common and less common disorders of pregnancy and neonatal health and their longer-term effects on the health of the mother and child.

Support is sought to allow researchers, who are not part of the direct care team, to pre-screen the medical records of potential donors to identify suitable participants and make contact ahead of their antenatal appointments to seek consent to participate in the Tissue Bank. The applicants also seek to retain a minimal dataset about potential participants who decline taking part, to ensure that the recruitment is representative of the general population served by Guy's and St Thomas' NHS Foundation Trust.

A recommendation for class 1, 2, 3, 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 receiving antenatal care at Guy's and St Thomas' NHS Foundation Trust
Data sources	1. Electronic maternity records at Guy's and St Thomas' NHS Foundation Trust
Identifiers required for linkage purposes	1. Name 2. NHS Number 3. Hospital ID Number 4. Date of birth 5. Postcode – sector level
Identifiers retained in the database	1. Initials 2. Full name 3. Address 4. NHS number 5. Hospital ID number 6. GP registration 7. Date of birth 8. Year of birth 9. Date of death 10. Postcode
Additional information	The identifiers held in the database will be held under consent.

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. **Clarify whether contacting the local Patient Advice and Liaison Service (PALS) to opt-out is practicable in all participating Trusts. If so, a contact telephone number and postal address need to be included in the patient notification materials.**

The applicants advised that the local PALS office was unable to assist with dissent processes. The CAG noted this information and raised no further queries.

2. **Clarify your opinion on not maintaining data on dissenters, in order to re-approach them upon their next pregnancy.**

The applicants provided an amended notification to specify that patients will not be contacted during the current pregnancy. A comment will be made on the patient contact log to advise that patients could be recontacted about future pregnancies. The applicants expressed concern that patients will be upset if they are recontacted but noted that those who strongly do not want to be contacted will opt-out of research entirely. The CAG noted this information and raised no further queries.

3. **Clarify what mechanism is in place for individuals who wish to re-join the study.**

If a participant declines in one pregnancy, they can be approached in a following pregnancy and that record would be updated to confirm their status as an adult participant. This status would remain even if in future pregnancies they declined again; in this case, a note would be added to the contact log on their page saying that they do not want to take part this pregnancy and they would not be contacted again but could be approached in a future pregnancy unless they register with the National Data Opt-Out. The CAG noted this information and raised no further queries.

4. **Make the following changes to the patient notification material:**

    a. **Regarding the outcome to query 3, ensure the notification clearly specifies that retention of identifiers will be kept for those individuals who have dissented from the study.**

    b. **Remove references to the National Data Opt-Out as a route to avoiding being approached for inclusion in research.**

Revised patient notification was submitted, which was reviewed by the CAG. Members raised no further queries.

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. Provide output from patient and public involvement discussions within the next annual review submission. Furthermore, ensure that there is an increase in participation and contribution from younger individuals.

2. Favourable opinion from a Research Ethics Committee. **Confirmed 29 August 2023.**

3. 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 **Guy's and St Thomas' NHS Foundation Trust** was confirmed as 'Standards Met' on the NHS England DSPT Tracker (26/09/2023)

The NHS England **22/23** DSPT review for **King's College London - Department of Women and Children's Health** was confirmed as 'Standards Met' on the NHS England DSPT Tracker (04/07/2023)

j. 23/CAG/0070 - North Central London Integrated Care System (NCL ICS) application for secondary use of data

Name	Capacity
Dr Patrick Coyle	CAG Vice Chair
Dr Sandra Duggan	CAG Member
Dr Pauline Lyseight-Jones	CAG Member
Professor James Teo	CAG Member

Dr Paul Mills	HRA Confidentiality Advice Service Manager
Ms Caroline Watchurst	HRA Confidentiality Advisor

Context

Purpose of application

This non-research application from North Central London Integrated Care Board (NCL ICB), sets out the purpose of creating a dataset using data from the NCL ICB direct care data platform (HealtheIntent), linked to NHS England national datasets. The NCL ICB shared care record does not include care delivered elsewhere in the country, and therefore this can lead to a gap in full understanding of a patient. This can be especially problematic in London where there can be a large transient population of students and workers. This dataset will be used for non-research secondary purposes, such as population health management (PHM), risk stratification, and planning and analysis, regarding the North Central London population.

Since 2020, GPs, Trusts and Local Authorities in NCL have submitted identifiable data to an integrated patient record system managed by NCL ICB for direct care purposes. Social care data is in the process of being included This activity does not require 'section 251 support' as is for the purposes of direct care.

Separately, NHS England datasets are acquired, under s261(4) of Health and Social Care Act 2012 Act, and CAG 7-07 (a-c) 2013 (regarding invoice validation), via the North of England Commissioning Support Unit Data Services for Commissioners Regional Office (NECS-DSCRO), and flow into NHS Northeast London ICB, who disclose the data to NCL ICB, hosted by Cerner. This activity does not require 'section 251 support' as is for the purposes of commissioning and invoice validation.

NHS England datasets will be linked to the direct care data within the NCL ICB. 'section 251 support' is sought to undertake this processing and enable use of the data for secondary purposes as described in the application. This data will be transferred to a separate segregated environment within the platform. Access to this environment would be strictly controlled via Role-based Access Control (RBAC), and only made available for the purposes of supporting the use cases described. Direct access to this data would only be permitted to create datasets for analysis, and would be limited to a small team

of developers and NCL ICB/ICS analysts. Anonymised and aggregated data outputs will be provided to end users who have need to understand the populations and services within NCL, for example clinical, analytical, commissioning or planning users. Patient-level identifiable data outputs will be provided to clinical users who have a direct clinical responsibility to those cohorts, with regards to risk stratification.

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 and receiving care within North Central London from health and social care organisations in the London Boroughs of Barnet, Camden, Enfield, Haringey and Islington Approximately 1.8 million individuals this will include deceased patients.
Data sources	1. NCL ICB direct care data platform (HealtheIntent), already linked together for purposes of clinical care, created from 198 organisations including Primary Care, Secondary Care, Mental Health Trusts, Local Authorities, Social Care 2. NHS England datasets, via NECS DSCRO, which are already flowed to NCL ICB. • Secondary Uses Service Dataset (SUS) • Emergency Care Dataset (ECDS) • Community Services Dataset (CSDS) • Mental Health Services Dataset (MHSDS) • Patient Demographics Service (PDS) • National Waiting List Data (Minimum Data Set) • Diagnostic Imaging Dataset (DIDS)

Identifiers required for linkage purposes	1. Full Name 2. NHS Number 3. Address and Postcode 4. Date of Birth 5. Gender
Identifiers required for analysis purposes	1. Postcode – modified to LSOA. 2. Date of Birth – modified to month and year 3. Gender 4. Ethnicity For the purposes of the CAG application, the applicant has stated that data is pseudonymised 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.

1. **Please revise the data flow diagram to align with the descriptions in this letter.**

A revised data flow diagram was submitted, and CAG were content with the update.

2. **Provide further description of the risk stratification purposes, as compared to direct care purposes, so the CAG is clear where support is required, specifically regarding the flow of confidential patient information back to the direct care team.**

The applicant confirmed that risk stratification work will be carried out on the anonymised data set by NCL ICB analysts. They will generate predictive models based solely on this anonymised data. These predictive models (and not any underlying data) will then be transferred into the direct care system where they can be used with identifiable data by clinicians for direct care purposes. Applicants are not seeking 's251 support' for this direct care system as a legal basis for its functioning already exist*s.* The CAG were content with this response.

3. **Confirm that, at the point of access, an individual is either part of the direct care team, or not.**

This was confirmed by the applicant and the CAG were content.

4. **Please confirm that telephone numbers are disclosed exclusively to enable contact with patients for the purpose of risk stratification, and therefore also confirm that phone number is not required for analysis purposes.**

The applicant confirmed that telephone numbers will not be disclosed and are not required for analysis purposes. This was an error in the wording of the original application. The CAG were content with this response.

5. **Please update the patient notification materials as follows, in line with advice in this letter, 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. **This should be separate from privacy notices, and a layered approach is advised.**
    c. **Patient notifications should be written in language suitable for a lay reader.**
    d. **Create a study specific opt-out which is clearly separated from the opt out used for the shared care record, which is easily accessible, by including a phone number, email and postal address.**

Applicants have provided new draft patient notification materials including a poster for displaying in GP surgeries and other health and care settings. This will have a QR code with a link to: A) Digital leaflet, final version will be in multiple languages and with "easy read" version; B) Web copy. These are subject to further review by stakeholders, including public and patient representatives. An opt out process has been developed.

The CAG noted that these are draft versions, and there is not an indication of when these documents would be finalised. The CAG commented they were content that 5a,5b, and 5d are now met, however there is still some work to be done to address lay language (5c). As an example in the draft poster; '*We will need to validate any opt-out request in writing*.'. The draft leaflet should potentially include a clear and straightforward top sheet with more detailed information following on. The text of the draft leaflet is dense, and in size 17 font – which might work if there was illustration, colour or better formatting, however as it is, it does not flow that easily. The draft web text appears to need similar attention. The CAG requested that these be improved, with feedback from their PPI, and have applied a condition to report back in three months.

6. **Please clarify at exactly what stage the National Data opt out will be applied.**

The National Data Opt-out will be applied in the processing area which carries out linkage (i.e. the new NCL ICS Controller's Population Health system as depicted in the revised data flow diagram). To confirm, the opt-outs will be applied to prevent opted-out individuals' data being processed and linked. The CAG were content with this.

7. **Provide an updated communication plan, including any materials that are to be used.**

A communications plan has been provided. The CAG commented that dates for action against which progress can be assessed are not included. This makes it difficult to assess it for progress or quality of implementation at a later date. The sub-Committee stated that the use of the term "noted" against a concern which seems critical to the issue of confidential patient data sharing (ref. Meetings: community partnership forum, Outcomes: 3) should be altered to denote firmer action on this point.

8. **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 more people, which is specific to the linkages and purposes described in this application.**
    b. **An ongoing patient and public involvement plan is to be provided.**
    c. **All newly developed patient notification materials should be reviewed by a patient and public involvement group.**

The applicant stated that the engagement plans regarding the patient notification material is covered in the Communications and Engagement Plan submitted as a response to Q7. Applicants are setting up a PPIE working group, including Healthwatch colleagues, which will be time-limited and focused on this project. They will also host ongoing follow-up sessions to ensure patients and the public understand how their feedback was taken on board and enable applicants to respond to any issues that may arise. They have stated that they will ensure ongoing patient and public involvement through GP Patient Reference Groups and patient representation on the Information Governance Working Group. Patient notification materials linked to this application will be reviewed by the PPIE group. Future plans to review the NCL ICB website will focus on co-design with the PPEI group and include all public facing information on patient data and its uses.

The CAG commented that these are good developments, but as this does not appear to have been completed, this is included as a condition of support.

9. **Please provide detailed feedback on the outcomes of the recommendations that were discussed by representatives from marginalised and vulnerable communities, as this was not described as part of the document provided.**

The applicant stated that the outputs of the One London workshop with marginalised and vulnerable communities are detailed in **the final report** (page 40). The wider recommendations from the report are being integrated into the communications plans.

The CAG commented that their query had not been satisfactorily responded to, as the CAG had already reviewed the document provided as a response. From the provisional outcome letter – 'CAG requested clarity on the outcomes of the recommendations that were discussed by representatives from marginalised and vulnerable communities, as this was not described as part of the document provided. The CAG noted references to appendix E, but this was not provided as a separate document'. Appendix E is mentioned on pg 18 of the One London document; – *'Further information relating to the marginalised and vulnerable communities workshop, including the discussion guide, is included in Appendix E'.*

The applicant is to provide Appendix E as a separate document to CAG, and any further more detailed information regarding the discussions with representatives from marginalised and vulnerable communities. The applicant is also to ensure that representatives from marginalised and vulnerable communities are included in their plans for future PPI.

10. **Please provide a clear account of your plans for reviewing data access requests and for lay involvement in the process.**

The NCL Population Health Management Group and NCL ICS Information Governance Working Group are in the process of being reviewed and will have strengthened cross-representation, to ensure that there is an effective connection between new use cases developed through the PHM Group and access considerations overseen by the IG Working Group. Lay membership will be enhanced on both groups. Terms of

Reference, membership and formal relationships are being revised. Reporting lines into the NCL ICS Digital Board are under review as part of a wider NCL governance review.

Applicants will establish a Data Access Group to review proposals to access to the new data environment in line with the CAG submission. Options for this group are being developed as part of the governance review. (Applicants will share the Terms of Reference once this process is completed).

The CAG commented that the actions indicated are acceptable, however the absence of any time frame is not helpful. The applicant is to provide a time frame for these developments.

11. **The CAG noted that the exit strategy for individual patients is unclear. Please clarify whether confidential patient information will be retained after 5 years, or if you plan to delete it at any point.**

Applicant has confirmed that they will retain and not delete any individual patient data (per patient) during the course of the three year period covered by this application.

Cag noted the response. The CAG commented that the applicant should inform CAG of a timeframe when applicants do plan on deleting any confidential patient information which is retained for the purposes of this CAG application.

12. **Please provide evidence of the NHS England DSPT review for North Central London Integrated Care Board, as per standard condition of support.**

This was received by email to the CAG inbox on 14 July 2023, as per standard condition of support.

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. Please update the patient notification materials as follows, in line with advice from PPI, ensuring they are written in language suitable for a lay reader, and provide to CAG for review in 3 months.

2. Develop the communication plan document to include target dates so that progress can be monitored. For 'outcome' 3, rather than 'noted' please use a word denoting firmer action on this point. Please provide an updated version to CAG for review in 3 months.

3. Further patient and public involvement should be carried out in line with advice in the provisional outcome letter, and an update provided to CAG for review in 3 months.
    a. Further patient and public involvement should be undertaken, with more people, which is specific to the linkages and purposes described in this application.
    b. An ongoing updated patient and public involvement plan is to be provided.
    c. All newly developed patient notification materials should be reviewed by a patient and public involvement group.
    d. Ensure that representatives from marginalised and vulnerable communities are included in plans for future PPI.

4. Please provide Appendix E as a separate document to CAG, and any further more detailed information regarding the discussions with representatives from marginalised and vulnerable communities, in 3 months.

5. Please provide a timeframe for the plans for reviewing data access requests and for lay involvement in the process to be completed. This should be within 3 months.

6. Please inform CAG of a timeframe when applicants do plan on deleting any confidential patient information which is retained for the purposes of this CAG application, in 3 months.

7. ’Section 251 support’ is provided for three years from the date of this letter. An amendment will be required at that time to extend the duration of ’section 251 support’.

8. If any additional items of confidential patient information are planned for linkage or analysis in future, this should be specified via amendment to CAG.

9. 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 England **22/23** DSPT reviews for **ORACLE CORPORATION UK LTD, Amazon Web Services, and North Central London Integrated Care Board** were confirmed as 'Standards Met' on the NHS England DSPT Tracker (checked 29 September 2023).

2. New Amendments

21/CAG/0044 – UK Longitudinal Linkage Collaboration (Study to NHS identifier flow v1)

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

Context

Amendment request

This application has 'section 251 support' to create a pseudonymised research database - The UK Longitudinal Linkage Collaboration (UK LLC) - which will bring together data from UK longitudinal population studies (LPS), linked to data from national central datasets, into one secure 'Trusted Research Environment' (TRE), initially with a focus on COVID-19 research. Support is only required regarding participating studies which have current support under Regulation 5. Studies using a consented model do not require support. The LLC research database is UK wide but Regulation 5 support does not extend to Scotland or Northern Ireland.

The current 'section 251' support for LLC allows;

- the disclosure of confidential patient information from UK Longitudinal Population Studies (LPS) which currently operate under Regulation 5 support (named as NSHD, Sabre, TWINSUK, ALSPAC, with any additional studies requiring an amendment to LLC application) to NHS Digital Health & Care Wales (DHCW) (previously NHS Wales Informatics service (NWIS) as a trusted third party.
- for DHCW to onwardly disclose identifiers to NHS England (previously NHS Digital) for the purposes of flagging patients as LLC participants and linking with relevant English covid-19 related datasets, in order to supply the LLC database with pseudonymised linked data.
- and for DHCW to retain the identifiers relating to the LPS study cohorts to ensure de-duplication, and also to retain the key between the link ID and the key ID.

This amendment sought support to remove SABRE (Southall and Brent Revisited) as a supported study.

This amendment also sought support to include TEDS (Twins' Early Development Study) data into the UK Longitudinal Linkage Collaboration (LLC), as a participating LPS. TEDS is a research database which investigates how genetic and environmental factors influence development, with a particular focus on psychological development and mental health, and is maintained by South London and Maudsley NHS Foundation Trust, who will now be an additional processor under 'section 251' support for the LLC application.

Confidentiality Advisory Group advice

The amendment requested was considered by Chair's 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 applicant must ensure that NHS England confirmation of 'standards met' for organisations processing confidential patient information is in place. As there are more than 5 organisations, the DSPTs will not been individually checked by the Confidentiality Advice Team (CAT). This will be the responsibility of the applicant.

2. Confirmation of a favourable opinion from a Research Ethics Committee. **Confirmed 31 August 2023**

CAG 7-07(a)/2013 - Application for transfer of data from the HSCIC to commissioning organisation accredited safe heavens: inclusion of invoice validation as a purpose within CAG 2-03 (a)/2013

Name	Capacity
Dr Tony Calland, MBE	CAG Chair
Dr Paul Mills	Confidentiality Advice Service Manager

Context

Amendment request

In this amendment, the applicants requested an extension to the duration of support to continue the legal basis permitting Integrated Care Boards (ICBs) and Commissioning Support Units (CSUs) to process confidential patient information under Regulation 5 of the Health Service (Control of Patient Information) Regulations 2002 for invoice validation purposes. Support is currently in place until 30 September 2023 and the applicants sought to extend this by a further 12 months until 30 September 2024.

Confidentiality Advisory Group advice
The amendment requested was considered by Chair's Action. The amendment set out that the extension would allow a continuation in ensuring that organisations receive the correct funding for the NHS services they provide which is essential to maintain the NHS. The request stated that extending support would maintain essential business continuity and healthcare services to patients.

Given the importance of this activity to ensure correct funding to providers, the Chair agreed to extend the support for a further year until 30 September 2024.

The Chair noted that the applicants are expecting legislative change over the coming year which will result in this application no longer requiring to rely from Regulation 5 support as the legal basis. There is a risk however, with any legislative change, that these timelines may extend and support may be required for a longer period. If such a case arises, the applicants should notify CAG as soon as possible to discuss handling of any future extension requests.

It is the policy position of the Department of Health and Social Care (DHSC) in England that all approved activities seeking support to process confidential patient information without consent must evidence satisfactory security assurances through completion and satisfactory review by NHS Digital of the relevant Data Security and Protection Toolkit (DSPT). In England, security is considered satisfactory once NHS Digital confirm (via internal tracker or direct email) that the relevant entity has achieved 'standards met' or 'standards met – improvement plan in place'. This process applies to all supported activities.

Following review of the information submitted in the amendment, at time of submission, and following recent review of NHS Digital's internal tracker, there are two entities that have not achieved the appropriate level of security assurances necessary to process confidential patient information under support. These are:

1. Greater Manchester Shared Services

It is important to recognise that those entities that do not meet the standard security assurance level are not covered by the legal support as the conditions of support are not being met.

The CAG understands the importance of the activity proceeding, however noted that it is important for public confidence that those operating under support maintain an appropriate level of security assurance in line with all other supported application activities.

CAG advised that, on an exceptional basis, a clear update should be provided within one month of date of this letter. In the first instance please follow steps 1-4 as outlined here to provide CAG confirmation of NHS Digital assurances of the satisfactory DSPT review of the above organisation.

Confidentiality Advisory Group advice conclusion
In line with the considerations above, the Chair 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 to extend the duration for a further 12 months.

Specific conditions of support

The following sets out the specific conditions of support.

1. Provide confirmation of NHS Digital DSPT assurances for Greater Manchester Shared Services within one month

2. Contact the Confidentiality Advice Team as soon as possible after it is clear that the legislative change will not be in place by 30 September 2024, to discuss future handling of invoice validation.

CAG 7-07(b)/2013 - Invoice validation within Clinical Commissioning Groups (CCGs) Controlled Environment for Finance (CEfF).

Name	Capacity
Dr Tony Calland, MBE	CAG Chair
Dr Paul Mills	Confidentiality Advice Service Manager

Context

Amendment request

In this amendment, the applicants requested an extension to the duration of support to continue the legal basis permitting Integrated Care Boards (ICBs) and Commissioning Support Units (CSUs) to process confidential patient information under Regulation 5 of the Health Service (Control of Patient Information) Regulations 2002 for invoice validation purposes. Support is currently in place until 30 September 2023 and the applicants sought to extend this by a further 12 months until 30 September 2024.

Confidentiality Advisory Group advice
The amendment requested was considered by Chair's Action. The amendment set out that the extension would allow a continuation in ensuring that organisations receive the correct funding for the NHS services they provide which is essential to maintain the NHS. The request stated that extending support would maintain essential business continuity and healthcare services to patients.

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Confidentiality Advisory Group advice conclusion
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The following sets out the specific conditions of support.

1. Provide confirmation of NHS Digital DSPT assurances for Greater Manchester Shared Services within one month

2. Contact the Confidentiality Advice Team as soon as possible after it is clear that the legislative change will not be in place by 30 September 2024, to discuss future handling of invoice validation.

CAG 7-07(c)/2013 - Invoice validation within NHS England within the Commissioning Support Units Controlled Environment (for Finance) (CEfF) on behalf of Clinical Commissioning Groups

Name	Capacity
Dr Tony Calland, MBE	CAG Chair
Dr Paul Mills	Confidentiality Advice Service Manager

Context

Amendment request

In this amendment, the applicants requested an extension to the duration of support to continue the legal basis permitting Integrated Care Boards (ICBs) and Commissioning Support Units (CSUs) to process confidential patient information under Regulation 5 of the Health Service (Control of Patient Information) Regulations 2002 for invoice validation purposes. Support is currently in place until 30 September 2023 and the applicants sought to extend this by a further 12 months until 30 September 2024.

Confidentiality Advisory Group advice
The amendment requested was considered by Chair's Action. The amendment set out that the extension would allow a continuation in ensuring that organisations receive the correct funding for the NHS services they provide which is essential to maintain the NHS. The request stated that extending support would maintain essential business continuity and healthcare services to patients.

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It is the policy position of the Department of Health and Social Care (DHSC) in England that all approved activities seeking support to process confidential patient information without consent must evidence satisfactory security assurances through completion and satisfactory review by NHS Digital of the relevant Data Security and Protection Toolkit (DSPT). In England, security is considered satisfactory once NHS Digital confirm (via internal tracker or direct email) that the relevant entity has achieved 'standards met' or 'standards met – improvement plan in place'. This process applies to all supported activities.

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CAG advised that, on an exceptional basis, a clear update should be provided within one month of date of this letter. In the first instance please follow steps 1-4 as outlined here to provide CAG confirmation of NHS Digital assurances of the satisfactory DSPT review of the above organisation.

Confidentiality Advisory Group advice conclusion
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Specific conditions of support

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2. Contact the Confidentiality Advice Team as soon as possible after it is clear that the legislative change will not be in place by 30 September 2024, to discuss future handling of invoice validation.

3. Annual Review Approvals

CAG reference	Application Title
21/CAG/0092	Pre-hospitAl RAndomised trial of MEDICation route in out-of-hospital cardiac arrest (PARAMEDIC3)
22/CAG/0066	A pragmatic trial of an Artificial intelligence DRiven appOInTment maNagEment SyStem
21/CAG/0060	Supporting the NHS Long Term Plan: An evaluation of the implementation and impact of NHS-funded tobacco dependence services
22/CAG/0103	National Haemophilia Database (NHD)
18/CAG/0124	Automated Cancer Diagnosis and Prognosis Using Digital Images
21/CAG/0004	Neonatal Complications of Coronavirus Disease (COVID-19) Study
21/CAG/0116	United Kingdom COVID and Gynaecological Cancers Study (UKCOGS)

21/CAG/0180	National COVID-19 Chest Imaging Database (NCCID)
22/CAG/0095	UK Early Life Cohort Feasibility Study
22/CAG/0064	Building an understanding of Ethnic minority people's Service Use Relating to Emergency care for injuries (BE SURE)
20/CAG/0013	Correlates of cognitive changes in epilepsy
19/CAG/0135	Derby Monitoring Study of Self-harm
17/CAG/0020	Clinical and Biological factors associated with relapse and length of survival following relapse in UK neuroblastomas
21/CAG/0111	Barts Cancer Research Tissue Bank (CTB)
17/CAG/0048	Long-term follow-up of the East London Sickle Cell Disease Neonatal Cohort
20/CAG/0096	Royal Free Cohort Study (RFHCS)
15/CAG/0158	Fracture Liaison Service Database (FLS-DB)
17/CAG/0107	WMUK Rory Morrison Registry
19/CAG/0139	The clinical and cost-effectiveness of testing for Group B Streptococcus: a cluster randomised trial with economic and acceptability evaluations (GBS3)
19/CAG/0144	Infections in Oxfordshire: a Research Database (IORD)
18/CAG/0044	Long Term follow up of the ASCOT Trial into Electronic Records (LATER)
22/CAG/0090	ISIS 2 Second International Study of Infarct Survival: Legacy Database
20/CAG/0084	PIONEER: The UK Health Data Research Hub for Acute Care
19/CAG/0189	Barts Gynae Tissue Bank
22/CAG/0089	Outcomes of Early Psoriatic Arthritis in a UK nation-wide cohort
15/CAG/0139	Life course pathways to ageing in the MRC National Survey of Health and Development

16/CAG/0087	Epidemiology of Critical Care provision after surgery (EpiCCs)
17/CAG/0150	National Perinatal Mortality Review Tool (PMRT)
17/CAG/0050	Educational outcomes in children born after assisted reproductive technology; a population based linkage study
20/CAG/0069	C&I CRIS Linkage with HES and Mortality
22/CAG/0104	Peripheral arterial disease, High blood pressure and Aneurysm Screening Trial (PHAST) - a cluster randomised trial of screening men for peripheral arterial disease, high blood pressure and abdominal aortic aneurysm vs screening men for abdominal aortic aneurysm
22/CAG/0036	Cardiovascular morbidity and mortality in Liothyronine-treated patients: a linked record cohort study
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
19/CAG/0192	IgG4-related Orbital Disease (IgG4-ROD): A Surveillance Study
CAG 7-07 (a)/2013	Invoice validation within the NHS England Commissioning Support Units and or the Integrated Care Boards (ICBs) controlled environment (for Finance) on behalf of Integrated Care Boards.
CAG 7-07 (b)/2013	Invoice validation within the NHS England Commissioning Support Units and or the Integrated Care Boards (ICBs) controlled environment (for Finance) on behalf of Integrated Care Boards.
CAG 7-07 (c)/2013	Invoice validation within the NHS England Commissioning Support Units and or the Integrated Care Boards (ICBs) controlled environment (for Finance) on behalf of Integrated Care Boards.

Signed – Chair	Date
Dr Tony Calland, MBE, CAG Chair, Dr Patrick Coyle, CAG Vice-Chair, Professor William Bernal, Ms Clare Sanderson & Dr Murat Soncul, CAG Alternate Vice-Chairs	*19 October 2023*

Signed – Confidentiality Advice Team	Date
Ms Caroline Watchurst, HRA Confidentiality Advisor	*02 October 2023*