Health Research Authority

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

November 2022

1. New Applications

a. 22/CAG/0131 – STandardising pAthways for diagnosing hypeRtension using routine healLthcare data: an InvestiGation of the Health and economic ouTcomes: STARLIGHT, Version 1.0

Name	
Dr Tony Calland MBE	CAG Chair
Dr Sandra Duggan	CAG member
Dr Harvey Marcovitch	CAG member
Ms Caroline Watchurst	HRA Confidentiality Advisor

Context

Purpose of application

This application from The University of Oxford set out the purpose of medical research of a retrospective cohort study, to assess the value of implementing a diagnostic prediction model for identifying previously undetected hypertension among hospital inpatients, as part of a standardised care pathway that integrates patient information

between secondary and primary care. A hypertension diagnostic prediction model will be used against a linked GP/Hospital admission dataset, to differentiate between those patients whose in-hospital data predict them to have undiagnosed hypertension and those whose data do not. The study is being undertaken as part of a PhD.

Hypertension is a leading risk factor for death globally with 12.8% of deaths annually attributed. In England, 1 in 8 adults has undiagnosed hypertension. These people are at risk of serious health problems. More needs to be done in the NHS to identify people with hypertension, on top of existing checks for hypertension. Presently, the only dedicated system for checking people for hypertension is the 'NHS Health Check', which misses a wide range of undiagnosed hypertension cases. Evidence suggests that patients with elevated blood pressure recordings in hospital frequently remain hypertensive in the community, however this likelihood is often dismissed for various reasons. Untreated hypertension is associated with a progressive increase in blood pressure that can become treatment resistant. Therefore, hospital detection and timely management of hypertension offer an important intervention opportunity to address this major cause of morbidity and mortality. This project will investigate the impact and value of implementing a standardised diagnostic pathway for identifying undiagnosed hypertension in patients, using routinely collected blood pressure data obtained during hospital admissions. The aim of this, is to reduce the prevalence of undiagnosed hypertension.

This study will use data collected from patients registered with any GP Surgery in Oxfordshire, Berkshire, Northamptonshire and Buckinghamshire which contributes to the Oxford-Royal College of General Practitioners Clinical Informatics Digital Hub (ORCHID) Database, alongside data collected routinely during an admission to Oxford University Hospitals NHS Foundation Trust for the same patients. ORCHID will use a hashing algorithm to code patient NHS numbers creating a pseudonymised dataset. ORCHID will send their dataset, along with the hashing algorithm code to Oxford University Hospitals NHS Foundation Trust, permitting patient matching between data sources and amalgamation of both ORCHID and OUHNHSFT datasets for all patients who are eligible. 's251' support is required for this linkage, as despite being transferred in pseudonymous format, both parties have access to the hashing algorithm and can re-identify. Once linkage has been undertaken, the dataset will be effectively anonymised and disclosed to the applicants at Nuffield Department of Primary Care Health Sciences, University of Oxford, in order for them to undertake analysis on this effectively anonymised dataset.

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	All adult patients registered with a GP surgery in Oxfordshire, Berkshire, Northamptonshire and Buckinghamshire which contributes to the ORCHID database, for whom there is no coded diagnosis of hypertension recorded prior to June 2016 Applicant is unsure how many individuals this will be - 19,744 is the statistical calculation for the minimum required data.
Data sources	1. The Oxford-Royal College of General Practitioners Clinical Informatics Digital Hub (ORCHID) Database, Retained at University of Oxford (Nuffield Department of Primary Care Health Sciences). 2. Oxford University Hospitals NHS Foundation Trust – medical records
Identifiers required for linkage purposes	1. NHS number (hashed for transfer between organisations)
Identifiers required for analysis purposes	1. Ethnicity 2. Indices of Multiple Deprivation for the GP surgery at which the patient is registered The data will be effectively anonymous to applicants for analysis, as they will not have the means to re-identify

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 an updated patient notification which gives a brief and plain language explanation of the project, explains why consent is not possible, and explain the legal basis under which the linkage is being undertaken, including the role of CAG, and consider changing the placement of the opt out text, and the clarity of the descriptions regarding it, as per advice in this letter.**

The applicant provided an updated poster, which the CAG were broadly content with. After requesting the applicant make a few small updates on the document, the CAG were content to recommend support.

2. **Please confirm the length of time 's251' support is required, by confirming when the data received from ORCHID will be deleted by the Trust.**

With regard the length of time that S251 support is required, the applicant confirmed that this will be for the full three years that the dataset is retained by Oxford University Hospitals. The linkage of data between Oxford University Hospitals and ORCHID is entirely novel, and whilst the initial linkage is estimated to take approximately 8 weeks, OUH will not delete the data immediately after linkage. This is because it is anticipated that at each stage of the linked dataset being reviewed, validated and later analysed, there are likely to be linkage discrepancies identified that the research team will OUH to address and correct. Therefore, OUH will need to retain the dataset shared by ORCHID until the final analysis is complete. The CAG were content that this was a reasonable justification.

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 20 September 2022**

2. 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 Oxford (Nuffield Department of Primary Care Health Sciences) - EE133863-MSD-NDPCHS (regarding ORCHID) and Oxford University Hospitals' NHS Foundation Trust** were confirmed as 'Standards Met' on the NHS Digital DSPT Tracker (checked 18 October 2022)

b. 22/CAG/0115 – Evaluation of ocular and systemic outcomes after treatment of ocular melanoma and other ocular tumours

Name	
Dr Malcolm Booth	CAG member
Dr Patrick Coyle	CAG vice-chair
Mr Umar Sabat	CAG member
Ms Caroline Watchurst	HRA Confidentiality Advisor

Context

Purpose of application

This non-research application submitted by Liverpool University Hospitals NHS Foundation Trust sets out the purpose of obtaining death notification data about patients with ocular cancers treated at the Trust, in order to audit local treatment outcomes, prognosis and mortality from the disease or other causes. The data will also be used for service evaluation such as ongoing Liverpool Uveal Melanoma

Prognosticator Online (LUMPO) refinement and validation, as well as understanding the timing and nature of metastatic disease to enable clarification of screening practices. Further collaborative projects with other ocular oncology centres as well as medical oncologists may happen in the future, but any amendments to the purposes of this study will be confirmed via amendment, or new application to CAG.

Participants records were previously 'flagged' with the ONS, under a study reference MR572, which is no longer running. ONS, and more recently, NHS Digital, notified Royal Liverpool University Hospitals NHS Foundation Trust of participants' deaths (date and cause) and cancer events when they occurred. This has been completed for patients prior to September 2018. The applicant now requires 's251' in order to progress this activity for patients post September 2018.

The most common primary intraocular malignancy is uveal melanoma, with an incidence of about 7 per million per year. The chances of dying of metastatic disease within ten years increase with large tumour size, epithelioid cell type, and old age, ranging from 5% - 70%. Liverpool Ocular Oncology Service was designated a supra-regional centre in April 1997. As a specialised service there is a need to evaluate ocular and systemic outcomes after treatment of ocular melanoma and other ocular tumours as part of this service evaluation. In addition, service evaluation reports in parallel to new revised uveal melanoma guidelines will be produced to enable improvements in patient care. Regular meetings are also held with patient support groups such as Ocumel to enable such groups to better understand treatment options and outcomes.

In this application, the applicant at Liverpool University Hospitals NHS Foundation Trust will send confidential patient information to NHS Digital for all patients with ocular cancers, who have been treated at Liverpool University Hospitals NHS Trust after September 2018. This would be for approximately 250-300 patients a year, and the applicant would sent these extracts twice a year. NHS Digital would then flag these individuals, and send back linked mortality data once a month, for any deceased patients. The applicant will delete confidential patient information received 12 months after receiving it for each individual, however 's251' support will be required in an ongoing fashion for future flagging and linkages.

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 with ocular cancers, who have been treated at Liverpool University Hospitals NHS Trust after September 2018 Approximately 250-300 patients per year would be flagged to NHS Digital who would link the data and return only deceased patient information.
Data sources	3. Clinical databases at Liverpool Trust 4. NHS Digital; ONS Mortality Dataset
Identifiers required for linkage purposes	2. NHS number 3. Date of Birth Applicant has now confirmed minimum required with NHS Digital, and this is provided in separate correspondence from NHS D.
Identifiers required for analysis purposes	1. Date of death 2. Cause of death (not directly identifiable) (confirmed as part of further queries via email)
Additional information	NHS Digital provide linked outcome data back to the applicant monthly, for only deceased patients. Applicant will provide an update of the cohort for flagging to NHS Digital twice annually, in an ongoing fashion.

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 clear justification as to why it would not be practicable to seek consent for patients who will be included prospectively.**

The applicant stated that the distress these patients feel at diagnosis is enough and that team did not wish to distress people further by asking for consent to something related to their death. The CAG accepted this justification. Although the CAG would not normally accept justifications surrounding offering consent being distressing, this example is quite specific with reasons why it could be distressing.

2. **Please provide a new data flow diagram updating the data items for linkage and making it clear which organisations data is flowing between.**

The applicant provided an updated data flow diagram, that initially the CAG were not content with. On provision of v2.1, the CAG were content to accept this.

3. **Please develop a patient notification which includes an application specific opt out option (for example a clinic poster)**

The applicant provided the Trust privacy notice, commenting that Page 4 of the Privacy Notice contains the 'opt-out' option - this will be sent out to all patients attending clinic and will also be displayed in the clinic areas. The CAG were not content with this, noting it was Trust wide not application specific, and requested that patient notification specific to this project needs to be provided that describes in language accessible to a lay reader:

a. How confidential patient information is used in this project,
b. That processing of confidential patient information is undertaken without consent,
c. That the legal basis for this processing is s251 support, given by the Secretary of State for Health and Social Care following the recommendation by CAG.
d. The project specific opt-out mechanism needs to be described, including contact details for patients to use to request the removal of their data. The

CAG usually expect that telephone, email and postal contact details are given.

e. The privacy notice refers to the National Data Opt-Out allowing patients to opt-in to specific projects. This isn't correct and should be removed.

The applicant has since provided an updated one page notification document that is specific for this application and provides an opt out option. The CAG were content with this.

4. **Please confirm that the national Data Opt Out will be applied to the dataset prior to sending to NHS Digital.**

The applicant confirmed this, and the CAG were content.

5. **Please provide feedback from patients and the public regarding the use of confidential patient information without consent.**

The applicant provided a supportive letter from OcuMel UK, confirming the use of confidential patient information without consent was supported by patients. The CAG were content with this.

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. 's251' support provided for five years in the first instance. An amendment will be required at that time to extend the duration of 's251' support if required.

2. 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 Liverpool University Hospitals NHS Foundation Trust and NHS Digital were confirmed as ‘Standards Met’ on the NHS Digital DSPT Tracker (checked 31 August 2022)

c. 22/CAG/0038 – Twins’ Early Development Study (TEDS) Medical Record Linkage

Name	
Dr Tony Calland MBE	CAG Chair
Dr Martin Andrew	CAG member
Dr Malcolm Booth	CAG member
Mr Tony Kane	CAG member
Dr Harvey Marcovitch	CAG member
Mr Andrew Melville	CAG member
Professor Sara Randall	CAG member
Mr Dan Roulstone	CAG member
Ms Clare Sanderson	CAG alternative vice-chair
Dr Paul Mills	HRA Confidentiality Advice Service Manager
Ms Caroline Watchurst	HRA Confidentiality Advisor

Context

Purpose of application

This application from King’s College London (KCL) set out the purpose of medical research that seeks to create a research database, to investigate how genetic and

environmental factors influence development, with a particular focus on psychological development and mental health.

The Twins Early Developmental Study (TEDS) is a longitudinal study which recruited over 16,000 twin pairs who were born in England and Wales between 1994 and 1996. Approximately 10,000 families are still actively engaged. The twin pairs have been assessed across cognitive, emotional and behavioural domains from early infancy into adulthood. Genotyping data is available for 10,346 individuals. The applicants now intend to link the already collected data with data from patients' medical records, obtained from NHS Digital, in order to build predictive longitudinal, genetic and clinical models of mental health outcomes, such as disorder risk and response to treatment. The applicants noted that it was important to gather information at this stage in patients' lives, as new mental health conditions often peak in the mid-twenties.

The data flow is separated into three pathways; obtaining up to date contact details for participants, the secondary care linkage undertaken by NHS Digital, and linkage to primary care data undertaken by the GP practices of patients included in TEDS.

In pathway one; confidential patient information from the TEDS dataset, held in the South London and **Maudsley Clinical Data Linkage Service** (SLAM CDLS) Safe Haven, will be disclosed to NHS Digital for linkage to the Personal Demographics Service (PDS), in order to obtain patients address and GP registration information. The linked dataset will then be returned to the TEDS research team. The research team will then send information about the study and how to opt-out to patients.

In pathway two; confidential patient information from the TEDS dataset, excluding those who opted-out, will be disclosed to NHS Digital for linkage to the Hospital Episode Statistics (HES), Mental Health Services Dataset (MHSDS) and the Improving Access to Psychological Therapies (IAPT) dataset. NHS Digital will then send a linked dataset, which has been pseudonymised by removal of patients NHS number, name, address and date of birth, to the TEDS research team. The research team will use the TEDS ID to link the dataset to the existing TEDS dataset.

In pathway three; confidential patient information will be disclosed from the TEDS dataset to patients GPs, firstly to seek GPs assent to access the GP health records for

TEDS participants and then for linkage to their primary care record. The data from GPs will be pseudonymised and returned to TEDS with the TEDS ID as the identifier.

Only fully anonymised data will be made available to researchers. The policy on the application process to use the data was provided. Lay individuals would be included on the Data Access Committee.

A recommendation for class 1, 2, 3, 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	Sets of twins born between 1994 and 1996 who were enrolled into TEDS. 26000 patients will be included.
Data sources	5. TEDS database at King's College London/ SLaM CLDS Safe Haven 6. HES and MHSDS datasets held by NHS Digital 7. IAPT service data held by NHS Digital 8. Locally held information contained in the lifetime primary care electronic patient record, provided by participants' GP surgery
Identifiers required for linkage purposes	4. Name 5. NHS number 6. GP Registration 7. Date of birth 8. Postcode – unit level

Identifiers required for analysis purposes	3. Gender 4. Occupation 5. Ethnicity

Confidentiality Advisory Group advice

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

1. **Please provide the Favourable Opinion from a Research Ethics Committee once this is in place, as per standard condition of support.**

The applicant provided the Favourable opinion of the REC to the CAG on 09 November 2022. This was all that was required prior to 's251' support being in place.

Confidentiality Advisory Group advice conclusion

The CAG agreed that the minimum criteria under the Regulations appeared to have been met, and therefore advised recommending conditional 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. Support is provided for 5 years from the date of final support, to allow the applicant time to complete the exit strategy, and gain consent from participants to undertake the proposed linkages. A duration amendment will be required at this time, if an extension of support is required. Please report on the progress of consent for linkage at each annual review

2. Please reaffirm the continued holding of identifiable information within the annual newsletters to ensure all participants are aware of this, reporting on this at the first annual review.

3. Favourable opinion from a Research Ethics Committee. **Confirmed 03 November 2022**

4. 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 **South London and Maudsley NHS Foundation Trust (RV5) and NHS Digital** were confirmed as '**Standards Met'** on the NHS Digital DSPT Tracker (checked 18 November 2022)

   Regarding participating GP surgeries; due to the number of organisations involved it is the responsibility of King's College London, as controller, to ensure that participating 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 about a practice.

d. 22/CAG/0135 – UK Genetic Prostate Cancer Study

Name	
Dr Tony Calland MBE	CAG Chair
Professor Lorna Fraser	CAG member
Mr Andrew Melville	CAG member
Ms Caroline Watchurst	HRA Confidentiality Advisor

Context

Purpose of application

This application from The Institute of Cancer Research sets out the purpose of medical research that seeks to find genetic changes which are associated with prostate cancer risk. The UK Genetic Prostate Cancer Study (UKGPCS) was first established in 1993 and is the largest prostate cancer study of its kind in the UK, involving nearly 200 hospitals. Individuals are included with consent. If applicants can find alterations in

genes that increase the chances of getting prostate cancer, it may be possible to screen family members to see if they are also at a higher risk of developing prostate cancer, and to develop new prostate cancer treatments in the future.

An amendment in 2008 included the collection of survival data through the Office of National Statistics, and this was updated on consent forms from v5 onwards. From 2011, the applicant received the cause and date of death for participants consented to UKGPCS from the Health and Social Care Information Centre (HSCIC) (the predecessor to NHS Digital). Applicants have been receiving quarterly updates on date of death and cause of death for participants on the study until recently. NHS Digital has now concluded that for participants consented prior to 2008, on forms v1-v4, the consent forms are insufficient to meet the common law duty of confidentiality. Therefore, for those participants consented prior to 2008, NHS Digital has asked the study team to apply to CAG.

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	Prostate cancer patients consented into the UK GENETIC PROSTATE CANCER STUDY prior to 2008, on consent form 1-4. The number of cases flagged on Consent form V1 to V4 total 8720 (out of which 4280 have died). Therefore ‘s251’ support will be relevant to these 8720 individuals
Data sources	9. UK GENETIC PROSTATE CANCER STUDY Dataset retained at The Institute of Cancer Research

	10. NHS Digital ONS mortality dataset
Identifiers required for linkage purposes	9. Name 10. NHS Number 11. Date of birth 12. Postcode
Identifiers required for analysis purposes	6. Date of death 7. Cause of death (not directly identifiable)
Additional information	Quarterly updates of mortality outcomes are provided to the applicant from NHS Digital.

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 a website text patient notification, that includes an opt out, for CAG review.**

The applicant provided a website text which initially only contained the National Data Opt Out. After CAG feedback, this was altered, to include a study specific opt out also. The CAG were content to accept this response.

2. **Patient and Public Involvement to establish the acceptability of this application, with a representative group of patients should be undertaken, and feedback provided to CAG for review.**

The applicant confirmed that this study has a dedicated patient and public involvement representative. On 8th November, a review was carried out with three patient representatives to discuss this use of confidential patient information without consent. The outcome was that they all agreed that it would be more distressing to write to patients to reconsent, and were supportive of this use of identifiable data. The CAG were content with this response.

3. **Please provide Favourable Opinion from a Research Ethics Committee for the submitted amendment regarding CAG input - AM2204-44.**

This was provided by the applicant, 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 for amendment regarding CAG input - AM2204-44; 27 September 2022**

2. 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 **The Institute of Cancer Research, and NHS Digital** were confirmed as 'Standards Met' on the NHS Digital DSPT Tracker (checked 19 October 2022)

e. 22/CAG/0125 – Management of Patients with Chronic Liver Disease Admitted to Hospital as an Emergency: Link MAP-CLD

Name	

Dr Tony Calland MBE	CAG Chair
Professor Lorna Fraser	CAG member
Mr Andrew Melville	CAG member
Ms Caroline Watchurst	HRA Confidentiality Advisor

Context

Purpose of application

This application from King's College Hospital NHS Foundation Trust with London School of Hygiene and Tropical Medicine as joint data controller, set out the purpose of medical research of linking together data from NHS England (previously NHS Digital), Intensive Care National Audit & Research Centre (ICNARC), and NHS Blood and Transplant (NHSBT) about 100,000 patients with Chronic Liver Disease (CLD). London School of Hygiene and Tropical Medicine (LSHTM) will retain a linked dataset for analysis, which will contain full date of death and therefore require 's251' support. The research group includes researchers from the Institute of Liver Studies at King's College Hospital, LSHTM, the University of Exeter and King's College London, and is funded by the National Institute for Health Research. The overall aim is to identify which characteristics of treatments and services for acutely ill people with CLD impact on care processes and outcomes, in order to improve the national organisation and delivery of care for all people acutely ill with chronic liver disease. 's251' support is only required for the linkage element of this study, work package2.

Liver disease is a serious and increasing health problem in the UK, responsible for many preventable deaths. However, people with liver disease often do not know that they are affected until they need to be admitted to hospital as an emergency. These people are often very ill, and a quarter die within two months of coming into hospital. The care received in hospital, and post discharge, varies greatly across the country. This variation in care has major effects on survival. This study aims to understand what clinical practices have the best results and will aim to make recommendations about how the services for patients with CLD can be made safer and more effective.

NHS England (previously NHS Digital) will identify the eligible cohort using Hospital Episode Statistics and ONS Mortality Datasets. This will include patients with CLD admitted with a first emergency hospital admission between 1 April 2009 and 31 March 2022. Confidential patient information, alongside a pseudonym (HES ID) will be

disclosed to ICNARC, who will link to their Case Mix Programme data. NHSBT will send confidential patient information, alongside a pseudonym (UKT ID) on UK Transplant Registry patients with chronic liver disease who underwent transplantation, including recipient and donor characteristics and waiting list data, to NHS England (previously NHS Digital), which will be linked to the HES/ONS cohort. All 3 organisations will send clinical data linked to a pseudo ID to LSHTM, in order for LSHTM to link the 3 datasets together. 's251' support required until full date of death is deleted.

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	All patients older than 18 years with chronic liver disease (CLD) who were admitted with a first emergency hospital admission between 1 April 2009 and 31 March 2022. However NHSBT also identify patients planned for or undergoing a liver transplant in England between one year before the study period to one year after the study period. Approximately 100,000 people.
Data sources	11. NHS England (previously NHS Digital); Hospital Episodes Statistics (HES) data (inpatient, outpatient data, A&E attendances and linked ONS mortality data) 12. NHS Blood and Transplant (NHSBT) - UK Transplant Registry 13. The Intensive Care National Audit and Research Centre (ICNARC) Case Mix Programme (ICNARC-CMP) database

Identifiers required for linkage purposes	13. NHS Number 14. Date of birth 15. Sex 16. Postcodes
Identifiers required for analysis purposes	8. Date of death 9. Ethnicity 10. Sex

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 consider if it is possible to reduce the flow of identifiable data by asking ICNARC to identify those with liver disease and sending those identifiers to NHS Digital for linkage. If this is not possible please provide justification.**

Applicants confirmed that this would not be possible, as they have concerns that inconsistency of diagnostic coding would mean that cases relevant to the study would be missed if identifiers were sent from ICNARC to NHS England (previously NHS Digital) for linkage rather than from to NHS England (previously NHS Digital) to ICNARC. The CAG were content with this response.

2. **Please confirm the study specific opt out will be applied as suggested, and provide CAG with any updates to patient facing material in light of this.**

The applicant confirmed this would be possible, and has supplied the CAG with 2 patient notification documents. The Members noted that only v1.1 has the updated opt out information, and this is the document that should be used. It is not clear that v1.2 had this information, and therefore should not be used.

3. **Please provide evidence of NHS Digital review of The NHS Digital 21/22 DSPT for London School of Hygiene and Tropical Medicine to evidence to CAG that 'standards are met', as per standard condition of support, below.**

This is now confirmed, 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 23 September 2022**

2. 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 **Intensive Care National Audit & Research Centre, NHS Blood and Transplant and NHS Digital & London School of Hygiene and Tropical Medicine** were confirmed as 'Standards Met' on the NHS Digital DSPT Tracker (checked 22 November 2022)

f. 22/CAG/0101 – Nottingham and Nottinghamshire ICB S251 non-research purposes

Name	
Dr Tony Calland MBE	CAG Chair

Dr Martin Andrew	CAG member
Dr Malcolm Booth	CAG member
Dr Katie Harron	CAG member
Mr Tony Kane	CAG member
Dr Pauline Lyseight-Jones	CAG member
Dr Harvey Marcovitch	CAG member
Mr Andrew Melville	CAG member
Professor Sara Randall	CAG member
Ms Diana Robbins	CAG member
Ms Clare Sanderson	CAG alternative vice-chair
Dr Murat Soncul	CAG alternative vice-chair
Ms Kathleen Cassidy	HRA Confidentiality Advisor

Context

Purpose of application

This non-research application from Nottingham and Nottinghamshire ICB set out the purpose of using patient and population data to enable better use of a Population Health Management solution, with the aim of providing health and social care teams with analytical products and tools to support service planning.

The Integrated Care System (ICS) Population Health Management programme forms part of a larger initiative that the ICS is undertaking to transform data to intelligence. In recent years, the quality and volume of data held for individual patients has greatly increased. Regulations and guidance are in place to protect privacy and confidentiality. However, these rules can impact on the use of data to meet the national population health management agenda. Recent Planning Guidance has emphasised Population Health Intelligence and insights, with the aim of using data to inform and design models of care to deliver tailored and at scale improvements of the health and wellbeing of the population.

Confidential patient information will be extracted by the ICBs Data Management Team from the GPRCC (GP Repository for Clinical Care). The dataset will be saved to a restricted area within Nottingham and Nottinghamshire ICB. This is outside the scope of support and already occurs to create the GPRCC.

Patient NHS numbers will be pseudonymised by replacing the NHS numbers with a common pseudonym, which will be used to link the dataset to other local and national health care data. However, the dataset will also contain patients date of birth and postcode, and therefore contains confidential patient information. Support is required for the data linkage of the GPRCC data to local and national dataset, held by NHS Digital, and the retention of the identifiable dataset within Nottingham and Nottinghamshire ICB. Support is also required to share the datasets, containing confidential patient information, with Population Health Management (PHE) analysts.

Additionally, the applicants clarified that they propose to facilitate linkage between data originating from the GPRCC and data originating from NHS Digital, by sharing with the Data Services for Commissioners Regional Offices (DSCRO) a bespoke pseudonymisation key (sometimes referred to as a SALT). This would enable the DSCRO to return a simple mapping table of the PHM pseudonym of NHS numbers held in the GPRCC to the pseudonyms of NHS numbers already applied to the national commissioning data, excluding patients who have opted out.

The applicants noted that support under Regulation 5 of the COPI Regulations was sought for 2 years initially as there may be changes in statute law to allow Health and Care organisations to process confidential patient information. If these changes do not occur within the next 2 years, an extension to support will be sought

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	All patients who use or have used a Nottingham and Nottinghamshire Integrated Care System (ICS) based provider. This will include: 1. Patients who are registered with a GP practice in Nottingham and Nottinghamshire 2. Patients/Citizens who have used any local providers

	3. Patients/Citizen who reside from outside of Nottingham and Nottinghamshire. 4. Patients/Citizens who have been registered but subsequently left the area or died, irrespective of age or characteristics.
Data sources	1. GPRCC (GP Repository for Clinical Care), held at Nottingham and Nottinghamshire Integrated Care Board (ICB) 2. National Datasets, held by NHS Digital: a. Primary care (SystmOne, EMISWeb) – Read codes, medications, referrals b. Community data (CityCare, PICS and Nottinghamshire Healthcare Trust (CHP) c. Mental Health data (community and inpatient) d. Acute data (admissions, ED attendance) e. Adult Social Care (City and County Councils) f. Out-of-Hours Care (NEMS, DHU 111 and EMAS) g. Secondary Uses Service (SUS) · CHSDS Community Health Services h. MHD – Mental Health Datasets i. National IAPT Patient datasets j. MSDS Maternity Service Data Set
Identifiers required for linkage purposes	1. NHS Number 2. Date of birth 3. Postcode
Identifiers required for analysis purposes	1. Age 2. Date of birth 3. Postcode 4. Lower Super Output Area, 5. Ethnicity 6. Gender

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 clarification on the legal basis of the current GPRCC data set and provide clarification on whether the GPRCC is currently**

used for direct care purposes only or whether it is used for any other purpose.

The applicants advised that data from providers (secondary care, community providers, general practice, mental health providers and local authority), already flows into the GPRCC for direct care purposes. Each organisation has a data sharing agreement/processing agreement between them and the processor/ICB, which documents the legal basis for each flow of data.

As the focus of the project is to deliver direct patient care, the applicants will not seek explicit patient consent to share information from GP clinical systems. The GPRCC is not currently used for any other purpose, no secondary use on patient level data takes place.

The CAG noted this information and raised no further queries.

2. **Provide clarification on how the National Data Opt-Out will be applied.**

The National Data Opt-Out will be applied. A pseudonym list of all patients will be disclosed to NHS Digital, who will send back a list of patients who have not registered with the National Data Opt-Out. This list will be kept up to date and shared as frequently as possible from the DSCRO to ensure that the data is up to date and accurate. The CAG noted this information and raised no further queries.

3. **Provide clarification on who will undertake the data linkage and whether this is undertaken by the direct care team.**

A request defining the data required will be submitted by an SAIU member of staff or ICS analyst with appropriate permissions. This request will be sent to the Data Management Team which is hosted within the SAIU, then an extract of the requested data is retrieved from GPRCC. The data linkage is not completed by a member of staff providing direct care to patients. The linkage of data will happen by the system but facilitated by the data management team. Local objections will be removed. Database and lists are managed by the data management team, analysts can query linked datasets. The CAG noted this information and raised no further queries.

4. **Clarify why patients email addresses will be collected and where they will be obtained from.**

This data field exists within the GPRCC but will not be used for secondary use purposes. Patient email addresses will be collected from GP practices, however, they will not be included or used for the purposes of this project, that the S251 is sought for. The CAG noted this information and raised no further queries.

5. **Clarify the data that will be collected on the "sexual life" of patients and why this was needed.**

The applicants advised that "sexual life" is a category of data available via the GPRCC. This was given as an example in the applications, as the applicants would like to be able to research based on the full data set available within the GPRCC. On further questioning by the CAG, the applicants explained that the sexual life data would be used to support the PHM approach and help to ensure that specific cohorts of the population are not isolated. For example, sexuality and gender identity are not reported in most datasets, but there is evidence that demonstrates that LEGT individuals have poorer experience of health services, poorer mental health outcomes and report poorer experience of end-of-life care. The applicant assured CAG that the data would be pseudonymised and low numbers reduced. The CAG noted this additional information and raised no further queries.

6. **The following changes to the patient notification materials are needed:**

    a. **The Poster and leaflet are to be revised for simplicity and readability**

    b. **The poster needs to explain that the CAG had recommended support. Suggested wording is given above.**

    c. **The example given on the poster of a specific patient needs to be rethought.**

    d. **The dissent mechanisms, including the National Data Opt-Out and the project-specific dissent mechanism, need to be explained on the poster.**

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

7. **Explain why the patient notification materials mention schools, including whether any data will be collected from schools or other educational data sources. was a mention of 'Schools' within the patient notification materials.**

The applicants confirmed that no data has been or will be collected from schools. Mention of schools was removed from the patient communication materials. The CAG noted this information and raised no further queries.

8. **Further patient and public involvement need to be undertaken and feedback from this provided to the CAG**

The CAG reviewed the feedback provided. Members were satisfied by the activity undertaken so far and asked that patient and public involvement was ongoing, particularly review of the patient notification materials, and feedback provided at annual reviews.

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. Ongoing patient and public involvement is to be carried out and reported back on at annual reviews.
2. 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. **Confirmed**:

   The NHS Digital 2021/22 DSPT reviews for **Nottingham and Nottinghamshire Integrated Care Board (ICB) and NHS Digital** were confirmed as 'Standards Met' on the NHS Digital DSPT Tracker (checked 31 August 2022)

1. New Amendments

22/CAG/0051 – Our Future Health

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

Context

Amendment request

This application from Our Future Health Ltd aims to create a research tissue bank for use in research into early detection of disease. The aim is to speed up the discovery of new methods of early disease detection, and the evaluation of new diagnostic tools, to help identify and treat diseases early, with the hope that this will lead to better patient outcomes. The applicants have 's251' support to allow the disclosure of confidential patient information from NHS Digital to APS Group, the contracted mailing supplier, to facilitate the sending of invitation letters to selected patients. The initial CAG support provided support for approximately 3 million patients to be contacted.

This amendment sought support for approximately 12 million patients to be contacted. This amendment is sought due to the creation of pop-up clinics and mobile units to enable volunteers' measurements and blood sample to be taken, which were not available to the applicant at the time of the CAG application. This means applicants can invite individuals at a higher rate, and greater scale to support achieving recruitment targets.

Confidentiality Advisory Group advice

The amendment requested was considered by Chairs' Action. The Chair was content to support the amendment, noting there were no changes to any data flows or methodology.

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 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: **Confirmed:**

   The NHS Digital **2021/22** DSPT review for **APS Group Ltd** was confirmed as 'Standards Met' on the NHS Digital DSPT Tracker (checked 16 November 2022)

2. Confirmation of a favourable opinion from a Research Ethics Committee. **Confirmed on 1 November 2022 that this is covered as part of original REC Favourable Opinion**

PIAG 1-07(d)/2004 - British Regional Heart Study (Men)

Name	Capacity
Ms Caroline Watchurst	HRA Confidentiality Advisor

Context

Amendment request
This application from UCL Medical School set out a study which aims to determine both established and new risk factors responsible for the considerable variation in ischaemic heart disease and stroke in Great Britain. It is also concerned with the effects of risk factor changes and their impact on CVD events. The aim is to continue to collect CVD-related incident morbidity for prevention and the promotion of a disability-free life in older men aged over 65 years. The study sought to trace and contact those patients lost to the original cohort of 7735 who agreed to take part in the original study, but who have since moved.

This amendment sought support to amend the purposes of the original ‘s251’ support, by informing CAG that pseudonymised information would be disclosed from British Regional Heart Study (BRHS) Research Team at University College London (UCL) to Newcastle University. This is because a key member of the UCL research team Professor Sheena Ramsay is now based there. Sheena holds an Honorary Contract with UCL and is a Co-director of the British Regional Heart Study (BRHS). Professor Ramsay and her team will use the data for analytical and analysis purposes agreed in the Data Sharing Agreement. There will be no changes to the research purpose for use of the BRHS data, and University College London remain the data controller for the CAG application, as UCL determine the purposes and manner of processing regarding the confidential patient information processed under ‘s251’ support. No confidential patient information will be disclosed to Newcastle University. Therefore they are not a data processor with regards to the CAG application. An amendment has been completed to inform CAG of the change in arrangements.

Confidentiality Advisory Group advice

The amendment requested was considered by the Confidentiality Advice Team. The CAT discussed with the applicant regarding whether a new application was required regarding adding Newcastle University as a Joint data controller and processor. It was determined as part of discussions and confirmed by the applicant that University of Newcastle was not jointly determining the purposes of the application jointly with UCL, and UCL will remain the sole data controller for the purposes of the CAG application. It is noted that for NHS Digital purposes (regarding their Data Sharing Agreements), that Newcastle University is considered a joint data controller for their purposes, under GDPR guidelines.

Confidentiality Advisory Group advice conclusion

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

Specific conditions of support

The following sets out the specific conditions of support.

1. Confirmation provided from the 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 **Confirmed:**

The NHS Digital **21/22** DSPT reviews for **University College London& NHS Digital** were confirmed as 'Standards Met' on the NHS Digital DSPT Tracker (checked 11 November 2022)

2. Confirmation of a favourable opinion from a Research Ethics Committee. **Confirmed non substantial 27 October 2022**

21/CAG/0090 – Paediatric Intensive Care Audit Network (Non research application): PICANet

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

Context

Amendment request

This application has 's251' support to allow the disclosure of confidential patient information from participating English and Welsh PICUs and transport teams to the University of Leeds for the non-research purposes of the national clinical audit of the Paediatric Intensive Care services.

On 22nd June 2022, a CAG amendment was supported to allow PICANet to collect identifiable patient data from seven Level 2 paediatric critical care (PCC) units as part of a pilot study for a level 2 expansion, as well as continuing to collect Level 3 data from PICUs.

This amendment seeks support to extend the pilot level 2 data collection to all designated Level 2 PCC units in England. NHS England is currently working with the PCC Operational Delivery Networks (ODN) to designate regional Level 2 units, the total number of which is expected to be between 35 – 45. The PICANet Level 2 expansion will begin on 1st January 2023 with current designated Level 2 PCC units;

other Level 2 PCC units will be included in the audit as they are designated by the ODNs.

This data collection mirrors how PICANet currently works, regarding children admitted to all designated Level 2 PCC units in England, (sometimes referred to as 'High Dependency Units"), after the pilot evidenced the feasibility. PICANet currently only collects data on children admitted to PICUs, however there are children outside of PICU who receive level 1 or 2 paediatric critical care and data for these children are not nationally captured in a standardised clinical audit. Therefore NHS England has commissioned PICANet to undertake the collection of personal, organisational, and clinical data on children admitted to level 2 PCC Units.

The level 2 data collection will mirror the current PICANet methodology, collecting the same items of confidential patient information. There will be a slightly amended clinical data collection based on the differing types of treatment that are given in level 2 PCCs. The additional items are, for example, observations recorded on admission for the national Paediatric Early Warning Score and interventions that are delivered on Level 2 critical care (which is the expansion that the CAG amendment addresses).

Confidentiality Advisory Group advice

The amendment requested was considered by Chair's Action. The Vice-Chair was content to recommend support for this amendment, noting that this is a very important audit and this amendment is a logical extension of the previous pilot to include level 2 PCCs, which will include units being newly designated as PCCs.

Confidentiality Advisory Group advice conclusion

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

Specific conditions of support

The following sets out the specific conditions of support.

1. Confirmation provided from the IG Delivery Team at NHS Digital to the Confidentiality Advisory Group 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 Leeds - LASER** (8KM29) and **University of Leicester College of Life Sciences** (EE133832-CMBSP) were confirmed as ‘**Standards Met’** on the NHS Digital DSPT Tracker (checked 11 November 2022)

Due to the number of participating PICUs/transport providers involved it is the responsibility of the applicant, as controller, to ensure that all organisations processing confidential patient information meet the minimum required standard in complying with DSPTs (or CPiPs/Welsh IG toolkit for Wales), and take remedial action if they become aware of any that fall below this, or where any concerns are raised about a care provider. These will not be individually checked by the CAT team due to the number of organisations involved.

18/CAG/0038 – A randomised controlled trial to evaluate invitation to community-based low dose computed tomography (LDCT) screening for lung cancer versus usual care in a targeted population at risk.

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

Context

Amendment request

This study from the Leeds Teaching Hospitals NHS Trust aims to test targeted Low Dose Computed Tomography (LDCT) scans screening in community settings concentrating on deprived areas of Leeds. The intention is to randomise 55-80 year old smokers or ex-smokers to intervention or usual care groups prior to approach. The intervention group will be invited to an assessment for a Lung Health Check (including LDCT screening for high-risk people) framed as a pilot health service.

An amendment was supported on 4 January 2022 to allow Reed Wellbeing (on behalf of One You Leeds (OYL)) and YLST Database in Leeds Institute for Data Analytics to disclose confidential patient information to NHS Digital in order for NHS Digital (as a trusted third party) to link the cohort together and provide information back to Reed Wellbeing, to allow assessment of the rates at which study participants have accessed smoking cessation services from (OYL) during the study period, to allow assessment of the rates at which study participants (both intervention and control populations) have accessed smoking cessation services from One You Leeds (OYL) during the study period.

Reed Wellbeing (on behalf of OYL) and YLST Database in Leeds Institute for Data Analytics would disclose confidential patient information (YLST unique ID, NHS number and Date of birth from YLST and Patient name, Address, Date of birth and OYL unique ID from OYL) to NHS Digital in order for NHS Digital (as a trusted third party) to link the cohort together and provide information back to Reed Wellbeing (on behalf of OYL) - YLST unique ID and OYL unique ID only.

On discussion with NHS Digital as the trusted third party, the applicant is seeking support in this amendment to change those dataflows, as it is not possible for NHS Digital to undertake the linkage in the design initially proposed. The new data flows requiring ‘s251’ support are as follows;

1. Reed Wellbeing Ltd would disclose confidential patient information (name, address, date of birth, gender and a OYL unique ID) about the OYL cohort to NHS Digital. This is very similar to the previously supported flow, however gender is additionally supplied.

2. NHS Digital will use the supplied confidential patient information to link to the Personal Demographics Service (PDS), to identify the NHS Number. This is a newly requested process.

3. NHS Digital would disclose confidential patient information (NHS Number and OYL unique ID) to the University of Leeds, where linkage with the YLST cohort would take place in the Leeds Institute for Data Analytics Virtual Research Environment (LIDA VRE). This is a newly requested process. NHS numbers for people seen by OYL who are not in the YLST study would be permanently deleted/destroyed immediately following matching. A certificate of data destruction would be issued by the LIDA DAT team.

4. University of Leeds would disclose confidential patient information (OYL unique ID for matched participants) back to Reed Momenta, in order for them to link back to the required clinical fields, and provide the required information back to University of Leeds (also via the OYL unique ID).

Confidentiality Advisory Group advice

The amendment was considered by the CAG Chair, who was content to recommend support for this amendment, stating CAG are very supportive of the principle behind the research.

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 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: **Confirmed**

   Leeds Teaching Hospitals NHS Trust, University of Leeds – LASER, CFH Docmail LTD, and Reed Wellbeing Ltd, and NHS Digital have confirmed 'Standards Met' on DSPT 2021/22 (by check of DSPT tracker 11 November 2022)

2. Confirmation of a favourable opinion from a Research Ethics Committee; **Confirmed 16 November 2022**

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

Name	Capacity
Ms Caroline Watchurst	HRA Confidentiality Advisor

Context

Amendment request

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

The Welsh Health board named in the original CAG application was Cardiff and Vale University Health Board. This was an administrative error. Betsi Cadwaladr University Health Board is the correct Welsh health board. The applicants are therefore seeking to remove Cardiff and Vale University Health Board as a data processors, and replace with Betsi Cadwaladr University Health Board.

Confidentiality Advisory Group advice

The amendment requested was considered by the Confidentiality Advice Team, who determined that the applicants were correcting an error made in the original application.

Confidentiality Advisory Group advice conclusion

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

Specific conditions of support

The following sets out the specific conditions of support.

1. Favourable opinion from a Research Ethics Committee. **Confirmed no REC review required, as the correct site was listed in the original application to the REC, and is therefore already covered by the original REC Favourable Opinion.**

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

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

Name	Capacity
Ms Caroline Watchurst	HRA Confidentiality Advisor

Context

Amendment request

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

‘S251’ support is in place to recruit all (Approximately 1000) young people in England aged 16- 24 years, between 4-6 months of a new cancer diagnosis. Screening was planned to take place over a 10 month time period, which would start once all approvals were in place. Screening started in October 2021, and therefore the applicant has ‘s251 support to screen patients diagnosed up until July 2022. Due to delays at local R&D level opening sites to recruitment, the applicant has only screened about half of the eligible patients expected, and recruitment has not been equitable across the countries.

This amendment therefore sought support to extend the recruitment period to include young people diagnosed from August 2022 to December 2022. This will mean participating sites will be screening and uploading patient details until June 2023 rather than the anticipated final data upload in November 2022. The patient notification materials have been updated to include the new dates, and these are accepted by CAG as notifications.

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

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

Specific conditions of support

The following sets out the specific conditions of support.

1. Confirmation provided from the 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: **Confirmed:**

   Due to the number of organisations involved it is the responsibility of University College London Hospitals NHS Foundation Trust as controller, to ensure that all organisations processing confidential patient information without consent meet the minimum required standard in complying with DSPTs, and take remedial action if they become aware of any that fall below this, or where any concerns are raised about a practice. This will not be individually checked by

the Confidentiality Advice Team (CAT), as there are more than 5 organisations involved.

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

2. Confirmation of a favourable opinion from a Research Ethics Committee.
   Confirmed 10 November 2022

19/CAG/0136 – Acute Leukemia in Pregnancy Registry Study

Name	Capacity
Ms Caroline Watchurst	HRA Confidentiality Advisor

Context

Amendment request

This application from the Hull and East Yorkshire Hospitals NHS Trust aims to establish a research database focused on women who were diagnosed with acute leukaemia or high-risk myelodysplasia in pregnancy or who have later conceived after receiving previous treatment for either condition.

This amendment sought support to extend the duration of support required until February 2023 to ensure that all the data can be cleaned and analysed prior to anonymising, as per the application.

Confidentiality Advisory Group advice

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

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

Specific conditions of support

The following sets out the specific conditions of support.

1. Confirmation provided from the 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:
   Confirmed: The CAT team has not undertaken a check of the security assurances at each site, as the study has support for over 5 participating organisations. This is the responsibility of the applicant to ensure that these are in place.

2. Confirmation of a favourable opinion from a Research Ethics Committee.
   Confirmed 19 October 2022 that Favourable ethical opinion for the research database continues to apply until 02 August 2024

18/CAG/0131 – Inflammatory Bowel Disease Registry

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

Context

Amendment request

The United Kingdom Inflammatory Bowel Disease Registry (IBD Registry) is a condition specific chronic disease registry established with the primary aim of supporting service delivery at point-of-care and facilitating audit and service evaluation at local and national level. The national IBD Registry has support to process confidential patient information, in relation to all patients in the UK who had been

diagnosed with inflammatory bowel disease (IBD). The application currently has ‘s251’ support for NHS Trusts to upload confidential patient information via a web portal system, which is collected by NHS Digital, and a recently supported amendment also allows a dual system to enable NHS Trusts to upload confidential patient information via a web portal system, direct to the IBD Registry data management platform, hosted at AIMES, instead of to NHS Digital. ‘s251 support’ is not required regarding consented patients.

This amendment sought support to include additional data items in the ‘s251’ supported data collection, (the 2022_L dataset). This does not include any additional items of confidential patient information, however for completeness, the additional 6 data items are listed below.

1. DISEASE: Diagnosis - Diagnosis during non-elective admission - To understand the circumstance of diagnosis, whether the diagnosis was made during or following an acute (non-elective) hospital admission
2. DISEASE: Diagnosis - First treatment during non-elective admission - To understand if the first treatment was received following a diagnosis as an impatient following an acute (non-elective) hospital admission
3. INTERVENTION: Medication - Drug start date qualifier - A qualifier for drug start date to understand whether it is an actual start date for treatment or the date of the recommendation
4. REVIEW - Steroids total number courses - To allow an in-clinic question to patients to understand how many courses of steroids the patient has been on in the last 12 months
5. REVIEW - Steroids total duration - To allow an in-clinic question to patients to understand the total duration (in weeks) that the patient has used steroids in the last 12 months
6. OUTCOME: Pretreatment screening - Lipid screening - To allow the clinician to confirm whether or not a lipid profile has been obtained (only for JAK inhibitors)

This amendment also sought to extend the duration of ‘s251’ support, indefinitely. If CAG were not content to support indefinitely, then the applicant has confirmed they wish to extend ‘s251’ support until the end of 2027 at a minimum.

Historically 18/CAG/0131 was given ‘s251’ support for a short amount of time, which has been extended over the years, currently until September 2023. This was due to it being thought possible that consent could be an appropriate exit strategy for all patients included in the registry. The applicants do have a separate research application with the REC, but not with CAG, as it is entirely consented for research.

Therefore the duration amendment would be only regarding the non-research registry activities.

The applicants justification for this amendment is that it would not be practicable to gain consent from every individual, due to burden on clinicians, thereby reducing the efficacy of the registry. Applicants are driving towards full national participation for Trusts. In order for this to be a reality, an extension is reasoned to be essential. It has become increasingly apparent that performing quality improvement (QI) analysis on a consented dataset is not possible. Feedback from clinical teams is that a sufficiently high proportion of consented patients will be unachievable and the effort required disproportional, putting an unsustainable increased pressure on IBD teams. To enable maximum participation in in this non-research registry, there must be minimal additional work for clinical teams. The applicants explained that there are serious concerns regarding the bias that relying on consented data for QI would introduce. Enabling applicants to extend 's251' support, and not aim to work towards an entirely consented model, will mean that Trusts can continue to receive accurate data and to not have it skewed by the impact of relying on purely consented records for analysis.

Confidentiality Advisory Group advice

The amendment requested was considered by Chairs Action. The Chair agreed with the justifications provided by the applicant that aiming for a 100% consented non-research Registry was not practicable, and a burden on clinical teams. The Chair was not content to recommend to extend 's251' support indefinitely, but was content to recommend 's251' support until the end of 2027. The five year extension is capped at the end of 2027, due to the many changes that are common in the Information Governance landscape, and it is important to continue to review, to ensure that the application is still working to the correct legislation at the time.

Confidentiality Advisory Group advice conclusion

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

Specific conditions of support

The following sets out the specific conditions of support.

1. 's251' support is provided until the end of 2027. A duration amendment will be required at that time to extend further.

2. 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: **Confirmed:**

   The NHS Digital **21/22** DSPT reviews for **Civica - (previously CIMS), AIMES management service, IBD Registry Limited and NHS Digital** were confirmed as 'Standards Met' on the NHS Digital DSPT Tracker (checked 14 November 2022).

   DHCW has a valid CPiP Outturn report/Welsh IG toolkit.

18/CAG/0185 – At-Risk Registers Integrated into primary care to Stop Asthma crises in the UK (ARRISA-UK): A pragmatic cluster randomised trial with nested economic and process evaluations examining the effects of integrating at-risk asthma registers into primary care with internet-based training and support

Name	Capacity
Ms Caroline Watchurst	HRA Confidentiality Advisor

Context

Amendment request

This study from the University of East Anglia aims to assess whether care provided to patients with asthma, who are at greater risk of hospital admissions and dying from their condition, can be improved via a GP-practice led intervention. Support under the Regulations is currently in place to allow the disclosure of specified confidential patient information from participating GP practices in England to Harvey Walsh prior to onward disclosure to NHS Digital for linkage with HES and ONS datasets.

This amendment sought support to extend the duration of the study in order to complete verification checks on the dataset, as per the protocol. The revised end of study date is 30 April 2023.

Confidentiality Advisory Group advice
The amendment requested was considered by the Confidentiality Advice Team. The CAT considered the duration request reasonable and in the public interest.

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

Specific conditions of support

The following sets out the specific conditions of support.

1. 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 **Confirmed - NHS Digital and Harvey Walsh Ltd. have confirmed Standards Met grade on the DSPT 2021/22** (By check of the DSPT tracker 14 November 2022)

2. Confirmation of a favourable opinion from a Research Ethics Committee. **Confirmed Non-substantial 21 September 2022**

22/CAG/0071 – CompreHensive GeriAtRician led MEdication Review (CHARMER) - Work Package 3 Feasibility Trial

Name	Capacity
Ms Caroline Watchurst	HRA Confidentiality Advisor

Context

Amendment request
The applicants have existing support to allow the disclosure of confidential patient information from NHS medical records from participating sites, to Norfolk and Norwich University Hospitals NHS Foundation Trust (NNUH), and from there to NHS Digital to link to Hospital Episode Statistics, ONS Mortality data and NHS prescription data.

The amendment sought support to remove London North West University Healthcare NHS Trust as a data processor covered by ‘s251’ support. Due to a change in available site resources, London North West University Healthcare NHS Trust will no longer be recruiting or collecting data on patients as part of the study.

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

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

Specific conditions of support

The following sets out the specific conditions of support.

1. Confirmation provided from the 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; **Confirmed:**

   The NHS Digital **21/22** DSPT reviews for **Northern Care Alliance NHS Foundation Trust, Norfolk and Norwich University Hospitals NHS Foundation Trust, Wrightington, Wigan and Leigh Teaching Hospitals NHS Foundation Trust, and NHS Digital** were confirmed as ‘Standards Met’ on the NHS Digital DSPT Tracker (checked 14 November 2022)

2. Confirmation of a favourable opinion from a Research Ethics Committee. **Confirmed non substantial 11 August 2022.**

PIAG 3-07(j)/2002– Study into the long term consequences of chronic diseases and their treatments

Name	Capacity
Ms Caroline Watchurst	HRA Confidentiality Advisor

Context

Amendment request

This study is following up several cohorts to investigate the long-term consequences of cancer and other chronic diseases and their treatments. As stated in the original application, the follow-up and study data collection will continue until the cohort have all died, because the purpose of the study is to obtain data on long-term mortality and cancer incidence risks in these patients. The applicant has resubmitted to the REC recently, and the new reference numbers covered by 's251' support are indicated in this letter header.

The inaugural Chief Investigator (Professor Swerdlow) has retired and role of Chief Investigator is transferred to Dr Michael Jones, for three studies under this single CAG application. This amendment seeks 's251' support for this change.

Confidentiality Advisory Group advice

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

Confidentiality Advisory Group advice conclusion

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

Specific conditions of support

The following sets out the specific conditions of support.

1. Confirmation provided from the 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 **Confirmed:**

The NHS Digital **21/22** DSPT reviews for **The Institute of Cancer Research** & **NHS Digital** were confirmed as 'Standards Met' on the NHS Digital DSPT Tracker (checked 14 November 2022)

2. Confirmation of a favourable opinion from a Research Ethics Committee. **Confirmed; 06 April 2022 for 22/LO/0237 and 22/LO/0238 & 01 June 2022 for 22/LO/0239**

ECC 8-05(d)/2011 - BRIGHT LIGHT: Do specialist services for teenagers and young adults (TYA) with cancer add value?

Name	Capacity
Ms Caroline Watchurst	HRA Confidentiality Advisor

Context

Amendment request

This amendment requests to extend the duration of support until 31st December 2024. This applies to the analysis of the BRIGHLIGHT study data at UCL/UCLH, and is requested to ensure complete analysis is able to be undertaken. This 's251' support aligns with the Data Sharing Agreement in place with NHS Digital.

Confidentiality Advisory Group advice

The amendment requested was considered by the CAT, who raised no queries regarding the request.

Confidentiality Advisory Group advice conclusion

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

Specific conditions of support

The following sets out the specific conditions of support.

1. Confirmation provided from the 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: **Confirmed**

   University College London Hospitals NHS Foundation Trust and University College London – SLMS have confirmed **'Standards Met' on DSPT 21/22 (by check of DSPT Tracker 14 November 2022).**

2. Confirmation of a favourable opinion from a Research Ethics Committee **Confirmed 21 November 2022**

19/CAG/0162 – Accuracy, impact and cost-effectiveness of prehospital clinical early warning scores for adults with suspected sepsis

Name	Capacity
Ms Kathleen Cassidy	HRA Confidentiality Advisor

Context

Amendment request

The applicants have existing support to allow research paramedics access to confidential patient information on site at participating ambulance Trusts to enable the eligible patient cohort to be identified, the onward disclosure to NHS Digital and access to confidential patient information at participating Trusts by research nurses.

The applicants are seeking to include an additional data flow between the Northern General Hospital and the study team at Sheffield Clinical Trials Research Unit (CTRU) at Sheffield University. NHS numbers will be disclosed from the Northern General Hospital to Sheffield CTRU for patients who could not be matched to an attendance record at the Northern General Hospital or did not have a diagnostic code for the

matched attendance. The patients would then be removed from the dataset used for analysis.

The data for the patients excluded from the analysis will be retained so that their characteristics can be compared with those included in the analysis. The data will be deleted at the same time as the data for those included in the analysis.

Confidentiality Advisory Group advice
The amendment requested was considered by the Confidentiality Advice Team. The Team agreed that the amendment was in the public interest.

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

Specific conditions of support

The following sets out the specific conditions of support.

1. 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 **Confirmed: DSPTs are required for all sites processing confidential patient information without consent, however as there are more than 5, these will not be checked individually by the CAT, and is the responsibility of University of Sheffield as data controller to ensure that standards are met, and sites compliant with DSPTs.**

2. Confirmation of a favourable opinion from a Research Ethics Committee.
Confirmed 25 October 2022.

16/CAG/0118 – A Study of the Natural History of Renal Disease in TSC2/PKD1 Contiguous Gene Deletion Syndrome.

Name	Capacity

Ms Kathleen Cassidy	HRA Confidentiality Advisor

Context

Amendment request

The applicants have existing support to include deceased patients only, and allows processing of name, date of birth, date of death and NHS number, in order to identify and access medical notes at the respective health boards where the patient was registered.

The applicants are seeking to extend the study until 31 August 2023. This extension is sought in order to meet the target recruitment of 300 patients. 280 patients have been recruited so far.

Confidentiality Advisory Group advice

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

Confidentiality Advisory Group advice conclusion

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

Specific conditions of support

The following sets out the specific conditions of support.

1. 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:
   Confirmed: The NHS Digital 2021/22 DSPT review for Cardiff University was confirmed as 'Standards Met' on the NHS Digital DSPT Tracker (checked 26 October 2022).

2. Confirmation of a favourable opinion from a Research Ethics Committee. **REC confirmed that this was a Non-Substantial Amendment on 03 August 2022.**

20/CAG/0130 – Yorkshire and Humber Care Record (YHCR) Population Health Management (PHM) for non-research purposes.

Name	Capacity
Ms Kathleen Cassidy	HRA Confidentiality Advisor

Context

Amendment request

The applicants have existing support to allow the disclosure of confidential patient information from participating organisations to Humber Teaching Hospitals NHS Foundation Trust, and for Humber Teaching Hospitals NHS Foundation Trust to supply NHS Digital with NHS numbers for the purpose of pseudonymisation.

The applicants seek to remove the NHS Digital De-identify/Re-identify service, as NHS Digital have not been able to deliver this service. Instead, the Interweave Analytics deidentification tool will be used.

The Interweave Exchange is hosted by Humber Teaching Hospitals NHS Foundation Trust. Confidential patient information is retrieved by Interweave Exchange on demand from analysts working on an initiative from participating organisations in the Yorkshire and Humber region.

The data is processed by the Interweave Analytics deidentification tool. The deidentified data is given a unique identifier in order to link the datasets, however this the unique code remains with the deidentification tool rendering the data anonymous for the analytic analysis.

Confidentiality Advisory Group advice

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

Confidentiality Advisory Group advice conclusion

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

Specific conditions of support

The following sets out the specific conditions of support.

1. Confirmation provided from the 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:
   Confirmed: The NHS Digital 2021/22 DSPT review for Humber Teaching NHS Foundation Trust was confirmed as 'Standards Met' on the NHS Digital DSPT Tracker (checked 24 October 2022).

22/CAG/0059 – The Whitehall II Study

Name	Capacity
Ms Kathleen Cassidy	HRA Confidentiality Advisor

Context

Amendment request

The Stress and Health Study (Whitehall II) was originally started in 1985 to advance knowledge of the effects of social circumstances on health and the biological pathways by which they operate, with a particular focus on cardiovascular disease.

The application was originally supported in 2014, under reference CR2/2014. This study had previously accessed data under the NHS Central Register (ECC 2-04(c)/2010) application. When the applicants submitted their 2021 annual review, they were asked to submit a refreshed application. The application was given support to allow the disclosure of confidential patient information from University College London SLMS Data Safe Haven to NHS Digital and SAIL for linkage to datasets they hold and the return of pseudonymised data to University College London.

In this amendment, the applicants are seeking to correct an error made in the application reviewed in 2022. In the application, the data sources were listed with the dates of the existing linked data held by the study. Additional, updated data would also be sought from NHS Digital and SAIL, but this had not been made clear. The applicants also sought to add the Covid Vaccination Dataset and to revise the name of the "HES A&E" dataset to "Emergency Care dataset."

The applicants confirmed that data linkage would be carried out to the below datasets on an ongoing basis:

a. HES APC

b. HES Outpatients

c. HES A&E

d. Mental Health Minimum Data Set

e. Mental Health and Learning Disabilities Data Set

f. Mental Health Services Data Set

g. Diagnostic Imaging Dataset with Bridge file

h. MRIS - Members and Postings Reports

i. MRIS - Cohort Event Notification Report

j. MRIS - Cause of Death Report

k. Demographics

l. Civil Registrations - Deaths

m. Cancer Registration Date

n. COVID-19 data sets CHESS(SARI-WATCH) and SGSS and vaccination status

o. Emergency Care Dataset

Confidentiality Advisory Group advice
The amendment requested was considered by the Confidentiality Advice Team. The Team noted that the amendment had been submitted at the request of NHS Digital, as further data linkages could not be made without the amendment being given support. The CAT agreed that the amendment was in the public interest.

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

Specific conditions of support

The following sets out the specific conditions of support.

1. 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:

   Confirmed: The NHS Digital 2020/21 DSPT reviews for **University College London – School of Life and Medical Sciences**, **SAIL Databank within Swansea University** and **Natcen Social Research** were confirmed as 'Standards Met' on the NHS Digital DSPT Tracker (checked 03 October 2022).

2. Confirmation of a favourable opinion from a Research Ethics Committee. **Confirmed 24 October 2022.**

21/CAG/0149 – Legacies and Futures: Gestational Parents' Experiences with Vulnerability and Resilience as it Influences Parent and Neonatal Health

Name	Capacity
Ms Kathleen Cassidy	HRA Confidentiality Advisor

Context

Amendment request

This application aims to research what roles resilience and vulnerability play in the health and wellbeing of LGBTQ+ gestational parents, as compared to their cis-heterosexual peers, during their antenatal care and their neonates. ‘s251’ support is in place to allow the disclosure of confidential patient information from 4 participating hospital trusts to the Data Safe Haven at University College London, where the researcher will access the information in order to email information about the study to patients.

The applicants are now seeking to include two additional sites, Epsom and St Helier University Hospitals NHS Trust and Lewisham and Greenwich NHS Trust, and to make changes to the materials sent to patients.

Confidentiality Advisory Group advice

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

Confidentiality Advisory Group advice conclusion

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

Specific conditions of support

The following sets out the specific conditions of support.

1. 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. **Confirmed:**

   NHS Digital 2021/22 DSPT review for **Lewisham and Greenwich NHS Trust**

   was confirmed as 'Standards Met' on the NHS Digital DSPT Tracker (11/11/2022).

   Due to the number of organisations involved it is the responsibility of University College London, as controller, to ensure that participating sites where confidential patient information will be accessed meet the minimum required standard in complying with DSPTs, and take remedial action if they become aware of any that fall below this, or where any concerns are raised about an organisation.

2. Confirmation of a favourable opinion from a Research Ethics Committee. **Confirmed as Non-Substantial Amendment on 08 September 2022.**

20/CAG/0127 – Admissions far away from home or to adult wards - understanding the impact of current practices for accessing inpatient care for adolescents with mental health difficulties: a surveillance study

Name	Capacity
Ms Kathleen Cassidy	HRA Confidentiality Advisor

Context

Amendment request

The applicants have existing support to allow the disclosure of confidential patient information from reporting consultant psychiatrists to the research team at the University of Nottingham.

In this amendment the applicants seek to extend the duration of support to 31 December 2022.

The extension is required as IT issues at participating trusts Several NHS trusts/consultant psychiatrists have been unable to access electronic medical records due to ongoing IT issues. This has left several participating consultants in the study unable to provide data – particularly for the follow up questionnaires. We wish to extend the study end date to allow the collection of these data when NHS IT issues have been resolved.

Confidentiality Advisory Group advice
The amendment requested was considered by the Confidentiality Advice Team. The Team agreed that the extension to the duration of the project was in the public interest.

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

Specific conditions of support

The following sets out the specific conditions of support.

1. Favourable opinion from a Research Ethics Committee. Confirmed as a non-substantial amendment to the REC on 10 October 2022.

2. 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.

   The **NHS Digital** DSPT review for **University of Nottingham** was confirmed as 'Standards Met' on the NHS DSPT Tracker (checked 19 October 2022).

22/CAG/0095 – UK Early Life Cohort Feasibility Study

Name	Capacity
Ms Kathleen Cassidy	HRA Confidentiality Advisor

Context

Amendment request

The applicants have support to allow the disclosure of confidential patient information from NHS Digital to Ipsos Mori. Ipsos Mori who will send information about the study to selected patients.

In the original application, the applicants specified that the cohort involved would be children born across the UK in the year 2021. The applicants are now seeking to extend the cohort to babies born in the year 2022 and to extend the duration of the study until 31 December 2023. Instead of three consecutive birth months there will be two consecutive birth months in 2022 (or 2023 if further delays).

The inclusion criteria, “Be living in the UK and have a child of around six months of age” has been revised to “Be living in the UK and have a child of around nine months of age.”

The study pilot phase has been removed and the Baby Steps app and direct non-invasive assessments will no longer be included.

The applicants also noted changes to the interview methods and duration, and to the incentives offered to participants, however these changes are outside the scope of the s251 support.

Confidentiality Advisory Group advice

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

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

Specific conditions of support

The following sets out the specific conditions of support.

1. Favourable opinion from a Research Ethics Committee. **Confirmed 14 November 2022.**

2. 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 **2020/21** DSPT reviews for **University College London and NHS Digital** were confirmed as 'Standards Met' on the NHS Digital DSPT Tracker (checked 04 July 2022).

2. Annual Review Approvals

17/CAG/0186	REACH Pregnancy Circles: An individual-level randomised controlled trial of group antenatal care
CAG 3-02(a)2014	'Long-term follow-up of ARTISTIC cervical screening trial cohort
20/CAG/0069	C&I CRIS Linkage with HES and Mortality
16/CAG/0153	UK Renal Registry
20/CAG/0138	Avon Community Acquired Pneumonia Study (Avon CAP): A Pan-Pandemic Acute Lower Respiratory Tract Disease Surveillance Study
21/CAG/0153	NHS Cancer Screening Programmes: National Coordination and Quality Assurance
19/CAG/0117	IMS Health and HES Data Linkage
18/CAG/0146	National Joint Registry (NJR)
CR4/2014	'Asbestos Workers Survey
17/CAG/0094	The assessment of risk and safety in mental health services
21/CAG/0097	PARADISE: Predicting AF after Cardiac Surgery - A Clinical Prediction Rule for Post-operative Atrial Fibrillation in Patients Undergoing Cardiac Surgery
20/CAG/0136	A randomised controlled trial assessing the effectiveness and cost effectiveness of thrice weekly, extended, in-centre nocturnal haemodialysis versus standard care using a mixed methods approach: NightLife
20/CAG/0111	Under 16 Cancer Patient Experience Survey 2020-2023
CAG 5-07(d)/2013	National Emergency Laparotomy Audit
15/CAG/0134	The risk of major bleeding with novel anti-platelets: A comparison of ticagrelor with clopidogrel in a real-world population of patients treated for acute coronary syndrome
CAG 8-03(PR9)/2013	National Prostate Cancer Audit

PIAG 4-08(b)/2003	National Confidential Enquiry into Patient Outcome and Death (NCEPOD)
20/CAG/0087	Research database for Cambridgeshire & Peterborough NHS FT (CPFT)
18/CAG/0187	Project to Enhance ALSPAC through Record Linkage (PEARL): Phenotypic enrichment of the ALSPAC original parent/carer (G0) cohort through linkage to primary care electronic patient records and other databases.
18/CAG/0185	At-Risk Registers Integrated into primary care to Stop Asthma crises in the UK (ARRISA-UK): A pragmatic cluster randomised trial with nested economic and process evaluations examining the effects of integrating at-risk asthma registers into primary care with internet-based training and support.
19/CAG/0146	The TIGHT-K STUDY. Dysrhythmias on the cardiac intensive care unit - does maintenance of high-normal serum potassium levels matter?
19/CAG/0111	Cambridge Blood and Stem Cell Biobank
18/CAG/0126	Connected Health Cities: Data linkage of urgent care data
19/CAG/0176	All Wales Perinatal Survey (Historic data - 1993 to 2012)
19/CAG/0177	The Child Death Review Programme
20/CAG/0096	Royal Free Cohort Study (RFHCS)
21/CAG/0071	Congenital Hypothyroidism with Gland in Situ: establishing risk factors and outcomes using population-based data linkage methods
19/CAG/0198	Evaluation of an aid to diagnosis for congenital dysplasia of the hip in general practice: controlled trial randomised by practice
21/CAG/0123	RE-BLEED: A digital platform for identifying bleeding patients – a feasibility study
ECC 2-03(c)/2012	National Paediatric Diabetes Audit (NPDA)
21/CAG/0003	Transforming research with routinely collected linked clinical data using an umbrella ethics and governance approach at Newcastle Hospitals

17/CAG/0096	SEARCH: A population based study of genetic predisposition to breast cancer
20/CAG/0125	A POPULATION BASED STUDY OF GENETIC PREDISPOSITION AND GENE-ENVIRONMENT INTERACTIONS IN COLORECTAL CANCER
17/CAG/0098	SEARCH: A population based study of genetic predisposition to endometrial cancer
20/CAG/0126	A POPULATION BASED STUDY OF GENETIC PREDISPOSITION AND GENE-ENVIRONMENT INTERACTIONS IN (MULTI) CANCER
17/CAG/0097	SEARCH: A population based study of genetic predisposition to ovarian cancer
19/CAG/0188	A POPULATION BASED STUDY OF GENETIC PREDISPOSITION AND GENE-ENVIRONMENT INTERACTIONS IN PROSTATE CANCER
21/CAG/0181	Community Mental Health 2022 Survey
CR38/2014	ADDITION_Cambridge
22/CAG/0116	NHS England (NICOR) UK Transcatheter Aortic Valve Implantation (TAVI) Registry
21/CAG/0114	Trends in the Prevalence and Complexity of Children with a Life-limiting or Life-threatening condition in Wales
14/CAG/1012	NIHR Critical Care Health Informatics Collaborative
CAG 5-07(f)/2013	National Vascular Registry
19/CAG/0149	Mammographic Predictors of Cancer Recurrence after Breast Conservation and Adjuvant Endocrine Therapy
20/CAG/0099	Promoting vision-related quality of life (QoL): first stage development of a model for intervention from the evidence of what matters most to visually impaired children and their families

21/CAG/0020	The effect of age at first invitation for breast screening in the NHS Breast Screening Programme in England and Wales (AFBSS)

Signed – Chair	Date
Dr Tony Calland, MBE, CAG Chair, Dr Patrick Coyle, CAG Vice-Chair, Dr Murat Soncul & Professor William Bernal, CAG Alternate Vice-Chairs	*16 December 2022*

Signed – Confidentiality Advice Team	Date
Ms Caroline Watchurst, HRA Confidentiality Advisor	*15 December 2022*