Health Research Authority

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

August 2023

1. New Applications

a. 22/CAG/0129 - Assessment, Management and Outcomes for children and young people referred to a National Gender Identity Development Service

Name	Capacity
Dr Tony Calland MBE	CAG Chair
Dr Martin Andrew	CAG member
Dr Pauline Lyseight-Jones	CAG member
Dr Harvey Marcovitch	CAG member
Mr Andrew Melville	CAG member
Ms Clare Sanderson	CAG alternative vice-chair
Dr Murat Soncul	CAG alternative vice-chair

Context

Purpose of application

This application from University of York sets out the purpose of medical research which seeks to describe the clinical and demographic characteristics of children and young people referred to the Tavistock and Portman NHS Foundation Trust's Gender Identity Development Service (GIDS) and their clinical management, as well as assess the intermediate outcomes of this population.

Some children and young people may experience significant levels of gender-related distress, arising from a persistent mismatch between a young person's felt gender identity and the sex they were registered as/assigned at birth. The Tavistock and Portman NHS Foundation Trust's GIDS is currently the only NHS funded service for young people with gender-related distress in England and Wales, and the number referred to the service has risen markedly over the last decade. As well, the demographic of those referred has changed, for example an increase in people who were registered as female at birth, and those who have autistic traits or are autistic. The evidence base on which current and future support to this changing population can be provided is limited and generally small in scale and short in term. This application is designed to enhance the existing evidence which will inform an independent review of gender identity development services for young people (The Cass Review) that will report to NHS England

Clinical data of children, teenagers or young adults aged under 18 years old at the point of referral to GIDS, and referred between 2009-2020, will be extracted from Tavistock and Portman NHS Foundation Trust GIDS clinical notes. This clinical data will be shared with the University of York in a pseudonymised format. Due to how clinical data have been recorded at the Tavistock and Portman NHS Foundation Trust between 2009-2020 this needs to be a manual extraction. Support is requested for six research assistants to undertake this extraction as the clinical care team do not have the capacity to undertake this. This has additionally been extended to all Adult Gender Identity Clinics.

Confidential patient information of the same cohort (Date of birth, NHS Number, Postcode, Birth registered sex) will be also shared from the following organisations to NHS England:

a) Tavistock and Portman NHS Foundation Trust
b) Two paediatric endocrine clinics that provide services to GIDS
c) Seven adult gender identity clinics (GICs - additionally will send GIC serial number). This flow will be for all service users aged up to 30 years (the

maximum age of the first service users from 2009) due to not being able to extract only GIDS service users.

NHS England will link to data sources they hold and return to all the above organisations a unique study ID. Where a service user has changed their gender (and therefore obtained a new NHS number) NHS England will use a modified matching process based on postcode and date of birth to identify the two NHS numbers. All the above organisations will send clinical information, identified by the unique study ID only, to the University of York, to enable merging the datasets together. However, those seen at adult GICs, but not at the Tavistock and Portman NHS Foundation Trust GIDS, will not have any clinical information shared with University of York, and identifiers are only sent to NHS England for matching purposes.

At no time will University of York have access to identifiable data items. All data items transferred will be structured data only and at no time will free text be extracted from clinical notes from any organisation.

A recommendation for class 1 (extracting and anonymising the information), 4 (to link patient identifiable information obtained from more than one source) and 6 (to allow access to an authorised user for one or more purposes of support) 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	1.The Tavistock and Portman NHS Foundation Trust (Gender identity development service – GIDS) • All children, teenagers or young adults aged ≤ 18 years old at the point of referral to Tavistock GIDS, who have been referred to GIDS between 2009-2020 (approximately 9000). 2. Adult Gender Identity Clinics (GICs) • All service users aged up to age 30 years 3. Paediatric Endocrine Clinics • All children, teenagers or young adults aged ≤ 18 years old at the point of referral to Tavistock GIDS, who have been referred from GIDS between 2009-2020.

Data sources	1. The Tavistock and Portman NHS Foundation Trust (Gender identity development service – GIDS) 2. NHS England, with use of following datasets: a. Hospital Episodes Data – Admitted Patient Care b. Hospital Episodes Data – A and E (pre 2019) and Emergency care dataset (from 2019) c. Hospital Episodes Data – Outpatient d. Mental Health Minimum data set e. Community prescribing data f. Death Registration data 3. University College London Hospitals NHS Foundation Trust (paediatric endocrinology service) 4. Leeds Teaching Hospitals Trust (paediatric endocrinology service) 5. NHS Gender Identity Clinics for Adults in England a. The Tavistock and Portman NHS Foundation Trust (Gender Identity Clinic) b. Leeds and York Partnership NHS Foundation Trust (Leeds Gender Identity Clinic) c. Northamptonshire Healthcare NHS Foundation Trust (Northampton Gender Identity Clinic) d. Cumbria, Northumberland, Tyne and Wear NHS Foundation Trust (Northern Region Gender Dysphoria Service) e. Nottinghamshire Healthcare NHS Trust (The Nottingham Centre for Transgender Health) f. Sheffield Health and Social Care NHS Foundation Trust (Porterbrook Clinic Gender Identity Service) g. Devon Partnership NHS Trust (The Laurels Gender Identity Clinic)
Identifiers required for linkage purposes	1. The Tavistock and Portman NHS Foundation Trust a. Date of birth b. NHS Number c. Postcode d. Birth registered sex 2. NHS Gender Identity Clinics for Adults in England a. Date of birth b. Current NHS Number c. Postcode d. Birth registered sex 3. Paediatric Endocrine Clinics a. Date of birth b. Current NHS Number c. Postcode d. Birth registered sex

Identifiers required for analysis purposes	1. Month and year of birth 2. Month and year of death (where relevant) 3. Lower Super Output Area 4. Gender – both at birth and current, where relevant 5. Ethnicity
Additional information	This will be a one-off extraction from each organisation, with no further follow up extractions planned.

Confidentiality Advisory Group advice

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

1. **Clarify who the research assistants are employed by and what safeguards (contractual and otherwise) are in place to ensure complete confidentiality is maintained whilst extracting clinical data from the Tavistock and Portman NHS Foundation Trust GIDS.**

Research assistants will be employed by University of York and will receive bespoke training on the study, data protection and confidentiality. They will also be closely supervised by senior members of the research team.

Members were content with the response.

2. **Provide details of the communication routes that will be used to reach service users of the Adult GIC services, who may not have been referred to GIDS.**

CAG were provided with a comprehensive communication plan which was developed with public involvement. This details the channels that will be used to inform service users and the wider public of the research, which includes information on the Cass Review website, gender clinics, charities and other appropriate stakeholders. A range of mediums will be used including print, electronic and social media.

Members were content with the communications plan and raised no further queries.

3. **Rewrite and submit patient notification materials and suggest engaging with support organisations in this process. In preparing this CAG suggests liaising with the support organisations who will disseminate the information. Particular attention should be given to:**
    a. **Transparency on the extent of use of identifiable information within this research.**
    b. **Clear details about what data the research assistants will have access to**
    c. **Reference to the Statutory Instrument that has been implemented**

d. **More prominence to the study-specific opt out mechanism, including a date of when people need to opt out by.**
e. **Accurately represent the role of the CAG**
f. **Layered approach to patient notification, with a dedicated webpage for this research. Layered website information should also be provided to CAG.**

4. **Provide similar patient notification materials that will be used for service users of Adult GICs.**

For points 3 and 4 above the applicant provided revised patient notification materials that took account of the points above. Following review by CAG further clarifications were asked to ensure the materials were clear on who may have access to confidential patient information as part of this work.

These were further updated and CAG were content with the notification materials.

5. **Extend the study-specific opt out mechanism from 6 weeks to 3 months and provide confirmation of this.**

The applicants agreed for the study-specific opt out mechanism to run for 3 months, once all the patient notification materials had been made available to service users and members of the public.

6. **Undertake, and report back, further patient and public involvement with a range of service users that will be within the research cohort, particularly those that may have used the Adult GIC services but not previously attended GIDS. These sessions should include reference to the Statutory Instrument.**

Following CAG and REC advice, two further patient and public involvement sessions were undertaken in conjunction with support organisations. These groups were undertaken with individuals and parents/carers whose data will be accessed by the study. The applicants provided a comprehensive overview of what was presented to attendees, what questions were asked and the participant feedback.

Members noted with interest the feedback provided as part of these sessions. The CAG felt the involvement undertaken was meaningful and that the comments were predominantly positive about both the research and the use of confidential patient information without consent to undertake the research.

7. **Provide further details on:**
    a. **the role that the transgender young adult will play as part of the research team**
    b. **the make-up of the research team (number of people, roles)**
    c. **consideration whether the transgender young adult on their own will have a significant voice in the research team, whether a disproportionate burden will be placed upon them, and whether another young adult should be recruited.**

The applicants provided CVs of the research team. They noted that the transgender young adult withdrew from the research team, but that they plan to continue to engage with the patient and public involvement groups going forward to mitigate this.

Additional Changes

During the course of this process two additional changes were made by the applicants. Both were reviewed and accepted by the CAG:

- The Chief Investigator has changed from Prof. Lorna Fraser to Prof. Tim Dorran. The sponsor remains unchanged with University of York.
- The applicants met with all adult GIC clinical teams who confirmed that they do not have the time or resources to extract any clinical information for this study. Therefore, the scope of approval is extended to include data extraction from the adult GICs by members of the University of York research team.

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. All confidential patient information, and the resultant dataset held at the University of York, should only be used within the scope of this application. It should not be used for other purposes without further CAG advice.

2. Favourable opinion from a Research Ethics Committee. **Confirmed 10 August 2023**

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

   The NHS England **21/22** DSPT review for the following organisations was confirmed as 'Standards Met' on the NHS Digital DSPT Tracker (checked 15 August 2022):

   a. The Tavistock and Portman NHS Foundation Trust
   b. NHS Digital
   c. University College London Hospitals NHS Foundation Trust
   d. Leeds Teaching Hospitals Trust
   e. Leeds and York Partnership NHS Foundation Trust

f. Northamptonshire Healthcare NHS Foundation Trust
g. Cumbria, Northumberland, Tyne and Wear NHS Foundation Trust
h. Nottinghamshire Healthcare NHS Trust
i. Sheffield Health and Social Care NHS Foundation Trust
j. Devon Partnership NHS Trust

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

Name	Capacity
Dr Patrick Coyle	CAG Vice Chair
Dr Pauline Lyseight-Jones	CAG Member
Mr Dan Roulstone	CAG Member
Dr Joanne Bailey	CAG Member
Mr David Evans	CAG Member
Ms Kathleen Cassidy	Confidentiality Advisor

Context

Purpose of application

This application from Bangor University set out the purpose of medical research that seeks to assess the effectiveness of use of the ThinkCancer! Intervention by general practice teams, compared with usual care.

Early diagnosis of cancer is key to improving patient outcomes. Over 70% of cancers present in primary care, meaning general practice is a good setting for behaviour change, quality improvement and education. The main aim of this randomised trial is to see how a behavioural and educational package can help the whole general practice team to pick up early symptoms and signs of cancer that mean the patient should receive an urgent referral. The ThinkCancer! intervention will be delivered remotely as an educational and quality improvement workshop via three distinct workshops. Each member of practice staff will take part in two workshops. Interviews will also be held with stakeholders and patients and carers. The applicants will

collect primary care interval (PCI) data by search of patient records at participating GP practices. The PCI is time from first symptom suggestive of cancer, to time to referral to secondary care. This will be undertaken by research staff who are trained in these methods working alongside general practice staff. An anonymised dataset will be extracted.

To examine other factors which may be related to delayed Urgent Suspected Cancer (USC) referral or diagnosis, the applicants also intend to conduct a review of case notes for a sample of 60 patients. Consent will not be sought for this and the applicants are seeking support under s251. Records will be screened by a researcher to identify eligible patients and extract an anonymised dataset.

A recommendation for class 1 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 aged 18 years and over with a primary care interval exceeding the 75th and 90th centile for a given cancer type. 60 patients will be included in the case note review. The applicants anticipate that 3078 will need to be reviewed in order to identify 60 patients.
Data sources	1. Patient records at participating GP practice
Identifiers required for linkage purposes	1. Name 2. NHS Number 3. Date of birth
Identifiers required for analysis purposes	1. Postcode – district level

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.

Confidentiality Advisory Group advice conclusion

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

1. **Once identified, please clarify the GP surgeries involved. Please note that CAG will not be able to issue support until these have been identified.**

The applicant provided a list of sites that had agreed to participate. General Practice sites who intend to participate to date. The CAG noted this information.

Amendments will need to be submitted to add any further participating sites.

2. **Once completed, please submit the patient notification materials for CAG review.**

A poster and PowerPoint, developed to advise patients that their GP surgery is taking part in the study, were provided. Participating surgeries would be asked to display this information on screens and displays within the surgery. If screens were not available, the surgeries would display posters. The CAG noted this information and raised no further queries.

3. **Please undertake patient and public involvement, particularly around the specific issue of use of confidential patient information without consent and provide the feedback to CAG for review.**

The applicants provided further details on the patient and public involvement they'd carried out. The CAG noted this information and raised no further queries.

Specific conditions of support

The following sets out the specific conditions of support.

1. Favourable Opinion from REC review: **Confirmed 23 August 2023**

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:**

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

2. New Amendments

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

Name	Capacity
Ms Caroline Watchurst	HRA Confidentiality Advisor

Context

Amendment request

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

SSNAP data was previously stored on a dedicated server provided by Rackspace Ltd. Data will now be stored on a like-for-like dedicated server provided by ANS Group Ltd. This amendment therefore sought support to remove Rackspace as a processor, and to include ANS Group Ltd as a new data processor.

The applicant has confirmed there are no other changes with regards to the type of data processing, type of server and data flows.

Confidentiality Advisory Group advice

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

Confidentiality Advisory Group advice conclusion

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

Specific conditions of support

The following sets out the specific conditions of support.

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

   The NHS England **21/22** DSPT reviews for **Kings College London (SSNAP team) – (EE133874-SSNAP), Net solving Ltd (8JA87)**

   and The NHS England **22/23** DSPT reviews **for ANS Group Ltd & NHS England** were confirmed as 'Standards Met' on the NHS England DSPT Tracker (checked 26 July 2023)

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

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

22/CAG/0082 – Platform Adaptive trial of NOvel antiviRals for eArly treatMent of covid-19 In the Community – PANORAMIC

Name	Capacity
Ms Caroline Watchurst	HRA Confidentiality Advisor

Context

Amendment request

The applicants initially had existing support to allow the disclosure of confidential patient information from Pillar-2 testing data held by NHS Digital (now part of NHS England) to the University of Oxford research team for the purpose of contacting potential participants to join the study. NHS England upload the identifiers to the TIBCO MFT Internet Transfer Client. The data will be accessed from this Client by the Trial Manager at the University of Oxford. The NHS England Data Processing Service filter England test data and exclude data from devolved nations by matching the Pillar-2 testing data with data held in the Personal Demographics Service, also controlled by NHS England. Patients are contacted by telephone call by members of the research team and consent sought. Their participation then proceeds on a consented basis and data for patients who do not consent is deleted.

An amendment in 2023 was supported to revise the data flow to allow the disclosure of confidential patient information from NHSE to the Business Service Authority (BSA). Once the BSA have uploaded the relevant data to their secure platform, the data will be accessed by the DHSC to send text messages to patients who report a positive COVID-19 result via the Pillar 2 testing platform. Potential participants may then be contacted prior to consent, via a text message, using a pre-approved wording to sign post them to the PANORAMIC trial. No confidential patient information would be disclosed to the University of Oxford.

This amendment sought support to revert back to the original data flow, and remove the 2023 amendment. Since gaining support for SA07, NHS England have now informed the applicant that they will not be able to send these text messages on behalf of PANORAMIC, because the government is disassembling all the digital infrastructure that was put in place for support during the pandemic. Confidential patient information will no longer be disclosed from NHSE to the Business Service Authority (BSA), for DHSC to send text messages. Applicants therefore propose that instead of NHSE, the PANORAMIC team based within the Clinical Trials Unit at University of Oxford will contact potential participants via text message to signpost them to register for the trial, as per original study support.

This amendment also sought to extend the ‘s251’ support to allow devolved nation colleagues in Wales to send text messages to potential participants as per the process in England. The potential participant information comes from Digital Health Care Wales (DHCW) national data warehouse for Covid-19 results. Public Health Wales download the covid results data each day from the DHCW national data warehouse. Public Health Wales transfer confidential patient information to Health and Care Research Wales (HCRW) via a password protected link, which a delegated colleague (from HCRW) accesses and then sends out the texts to relevant patients.

Two new data flow schematics have been submitted in support of this amendment, the first to detail England’s data flow specifically and the second the Welsh data flow.

Confidentiality Advisory Group advice

The amendment requested was considered by the Confidentiality Advice Team. The Team agreed that the changes made were in the public interest, and reverted back to that originally supported by CAG.

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.

2. Favourable opinion from a Research Ethics Committee. **Confirmed 11 July 2023.**

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

   The NHS England 22/23 DSPT reviews for **NHS England & University of Oxford - Medical Sciences Division – Nuffield Department of Primary Care Health Sciences** were confirmed as 'Standards Met' on the NHS England DSPT Tracker (checked 21 July 2023)

   The Welsh IG team have confirmed security assurances in the form of submitted Welsh IG toolkits, for Digital Health Care Wales, Public Health Wales (Submitted 3 July 2023), and Health and Care Research Wales (submitted 22 June 2023)

ECC 3-04(k)2011 - UK Surveillance of Primary Congenital Hypothyroidism in Children

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

Context

Amendment request

This application aimed to determine the incidence in the UK of confirmed diagnoses of primary Congenital Hypothyroidism (CHT) in children up to and including age 5 years, and to report the distribution by age, sex and ethnic group. It was noted that this application followed a very similar methodology to the British Paediatric Surveillance Unit (BPSU) 'orange card' reporting method. However, the difference with this application was that identifiable data would be retained for the purposes of long term monitoring of outcomes via Hospital Episodes Statistics (HES) and the Office for National Statistics (ONS). The data for this surveillance study was originally collected in 2011-2015. The applicant had support to retain NHS numbers for data linkage to follow-up outcomes. An amendment was supported in 2019 to support linkage with National Congenital Anomaly and Rare Disease Registration Service (NCARDRS) data, which included prescription (NHS Business Services data), newborn hearing screening, hospital episodes data and death registrations.

The 2019 amendment submission also requested support to link the patient cohort with education outcomes at age 7-11 years within the National Pupil Database, held by the Office of National Statistics (ONS). However the applicant confirmed that the data flows to support this linkage were not known at that time. As such, the applicant confirmed that this element was removed from the amendment request pending confirmation of the linkage process.

Applicants are now in a position to request 's251' support for the transfer of confidential patient information alongside a unique ID, for each of the 633 English children within the study dataset, from NCARDRS (NHS England), to Department for Education (DfE) and for DfE to use these identifiers to link to education outcomes at age 7-11 years within the National Pupil Database (NPD). The NPD does not hold NHS numbers for children and linkage to education data therefore requires names, date of birth, sex and full postcode history. DfE will then also extract non-identifiable educational outcome data on 3 control children per study child. DfE will destroy the identifiers and will return the educational data alongside the child's unique ID to the NCARDRS secure server where applicants can access it for analysis. The flow back is pseudonymous, but 's251' support is still required for this flow, as the recipients are able to re-identify using the unique ID.

Applicants already have support to transfer a copy of the study dataset to Public Health England (PHE), to NCARDRS, part of the National Disease Registration Service [NDRS]), when the data linkage process has been confirmed as successful, for ongoing retention by PHE within the scope of support which is in place for the NCARDRS dataset. The applicants stated that this will enable them to delete the identifiers held within the University College London (UCL) - School of Life and Medical Sciences, Data Safe Haven after the analyses were complete, or after 2023, whichever is earlier, and remove the need for continuing support under the Regulations for the study. NCARDRS is now based at NHS England, and continues to have 'S254' support to retain these data.

This amendment sought support to extend the duration of 's251' support until 31 Dec 2024, to allow the applicant time to complete the requested linkages, and anonymise the dataset retained by UCL Data Safe Haven. The planned linkage to education data has been significantly delayed by the transfer of NCARDRS from PHE to NHS Digital and then to NHS England. This led to significant disruption, hence the request to extend support until 31 Dec 2024. UCL DSH still needs to maintain the original files until the linked analyses are complete/published for final reproducibility checks, however the NPD linkage process is being undertaken via NCARDRS.

Confidentiality Advisory Group advice

The amendment requested was considered by Chair's Action. The Vice-Chair was content to recommend support for the amendment, noting that linking to the NPD will provide important information regarding the long-term consequences of screening and treatment of congenital hypothyroidism, and the extension of 's251' support is necessary because of organisational changes.

Confidentiality Advisory Group advice conclusion

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

Specific conditions of support

The following sets out the specific conditions of support.

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

   The NHS England 21/22 DSPT review for **University College London, School of Life and Medical Sciences, NHS England, and Department for Education,** was confirmed as 'Standards Met' on the NHS England DSPT Tracker (checked 15 June 2023).

2. Confirmation of a favourable opinion from a Research Ethics Committee. **Confirmed 19 June 2023**

18/CAG/0002 – Trajectories of diabetes related health measures (from linked lab data) and subsequent health and educational outcomes

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

Context

Amendment request

The project originally aimed to use linked health and education records to quantify the associations between differences in levels of HbA1c (an indicator of longer-term blood glucose levels) and educational outcomes.

This amendment sought support to include 2 additional purposes of processing. Despite no confidential patient informaiton being processed by additional investigators, these represent an extension of purpose to data collected under 's251' support. It was previously stated to CAG that *"The primary statistician working on the data will be the lead researcher Rob French, other researchers within the project team may also work on the data, but this work has not yet been allocated to named individuals."* The applicants are now in a position to update on this.

Lowri Allen, a paediatric endocrinologist and PhD student at Cardiff University School of Medicine and member of the research team, proposes to use the linked database to

quantify the associations between parents' and childrens' diagnosis of diabetes and how these affect child outcomes. This will link in an additional family structure dataset (from the Welsh Demographic Service), which is already available in SAIL using the same linkage ID, so while this is no additional processing of confidential patient information (as linkage is undertaken without identifers), this represents a new purpose and a new linkage. In the first instance this research will focus solely on Welsh cases in the linked dataset in SAIL, though once applicants have clarity on the family ID in ONS-SRS, the work may be replicated for English data.

There is also a second extension of the purpose - Alisha Bhanot, a medical student at Cardiff University, supervised by the lead researcher Rob French will use the linked diabetes and education data to model the associations between school exclusions and diabetes health outcomes. Again this will focus on the linked dataset in SAIL in the first instance and replicate in the ONS-SRS data once there is greater clarity on the data quality for exclusions.

It is noted that the amendment to CAG also requested to change the purpose to become a research database but this part of the amendment has been withdrawn, and the applicant plans to submit a research database applcaiiton to both CAG and REC.

Confidentiality Advisory Group advice

The amendment requested was considered by the Chair's Action. This was considered by the Vice Chair who was content to recommend support for these 2 additional purposes, whilst the applicant prepared a full new research database application.

Confidentiality Advisory Group advice conclusion

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

Specific conditions of support

The following sets out the specific conditions of support.

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

The NHS England 21/22 DSPT review for **NHS England** was confirmed as 'Standards Met' on the NHS England DSPT Tracker (checked 20 June 2023)
The Welsh IG team confirmed security assurances for DHCW

2. Confirmation of a favourable opinion from a Research Ethics Committee. **Confirmed 08 August 2023**

CAG 2-03(PR4)/2014 - 1970 British Cohort Study

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

Context

Amendment request

The applicants have existing support for NHS England to provide current address details of the 'untraced' cohort. The Centre for Longitudinal Studies provide identifiers for those lost to follow up to NHS England and receive current address details from NHS England to facilitate contact.

The applicants also have support to receive notifications of deaths and embarkations from NHS England, so that the study can update information on the database, and also to use the data for research (as specified by 2021 amendment).

On application to NHS England to receive death notifications including fact, date and cause of death, for everyone who has ever participated in the study, including those who have withdrawn from the study, NHS England pointed out that the 's251' support for accessing mortality data doesn't specifically mention accessing this information for those who have withdrawn from the study and NHS England requested applicants inform CAG about this.

Therefore this amendment sought support for the applicant to receive mortality data from NHS England, including fact, date and cause of death, for everyone who has ever participated in the study, including those who have withdrawn from the study (except where patients have withdrawn from the study and stop usage of their data).

Participants can;

a) withdraw from a specific data collection sweep of the study (in which case they would still be invited to take part in future sweeps of the study
b) permanently withdraw from the study (in which case they will not be invited to take part in any future sweeps of the study) or
c) permanently withdraw from the study AND request that the data can no longer be used.

If a participant withdraws from a specific data collection sweep (case a) or from participating in the study as a whole (case b), CLS will continue storing their contact details and will continue to make existing de-identified data safely available for research purposes. Applicants will use the fact of death to update the contact details database and to enable access to de-identified mortality data for research. Applicants will not seek to access mortality data for those cohort members who have requested to withdraw from the study and stop usage of their data (case c). Therefore, CLS will not include these cohort members in the matching file submitted to NHS Digital.

Justifications for the need to receive mortality data for those who have asked to withdraw from the study (but have not asked for their data to no longer be used (i.e. cases a) and b):

1. Applicants use fact of death to define the target population for all/any analyses of the cohorts. If applicants don't know whether Cohort Members that have withdrawn have died, they will not be able to accurately define the target population or assess the representativeness of achieved samples. This will impact all analyses done in the cohorts.
2. Mortality itself is a core outcome in population research (demography, epidemiology, statistics). Mortality data provided for research must include those that have withdrawn from data collection in order to avoid skewed and biased research and policy advice outputs when mortality data is used.

This appears to be clear in the study notification documents.

The applicant also confirmed that all 3 data processors (Natcen, Kantar and Ipsos) would potentially be required at different timepoints for this application, and therefore all 3 DSPTs should be listed.

Confidentiality Advisory Group advice

The amendment requested was considered by the Chairs' Action. The Chair recommended support for this amendment, and accepted the justifications provided.

Confidentiality Advisory Group advice conclusion

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

Specific conditions of support

The following sets out the specific conditions of support.

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

   The NHS England **21/22** DSPT reviews for **UCL School of Life and Medical Sciences, Natcen Social Research**, and

   The NHS England **22/23** DSPT reviews for **Kantar Public, Ipsos UK,** & **NHS England** were confirmed as '**Standards Met'** on the NHS England DSPT Tracker (checked 21 July 2023)

2. Confirmation of a favourable opinion from a Research Ethics Committee. **Confirmed already covered by email 03 August 2023**

14/CAG/1006 – Millennium Cohort Study

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

Context

Amendment request

The applicants have existing support for NHS England to provide current address details of the 'untraced' cohort. The Centre for Longitudinal Studies provide identifiers for those lost to follow up to NHS England and receive current address details from NHS England to facilitate contact.

The applicants also have support to receive notifications of deaths and embarkations from NHS England, so that the study can update information on the database, and also to use the data for research (as specified by 2021 amendment).

On application to NHS England to receive death notifications including fact, date and cause of death, for everyone who has ever participated in the study, including those who have withdrawn from the study, NHS England pointed out that the 's251' support for accessing mortality data doesn't specifically mention accessing this information for those who have withdrawn from the study and NHS England requested applicants inform CAG about this.

Therefore this amendment sought support for the applicant to receive mortality data from NHS England, including fact, date and cause of death, for everyone who has ever participated in the study, including those who have withdrawn from the study (except where patients have withdrawn from the study and stop usage of their data).

Participants can;

a) withdraw from a specific data collection sweep of the study (in which case they would still be invited to take part in future sweeps of the study
b) permanently withdraw from the study (in which case they will not be invited to take part in any future sweeps of the study) or
c) permanently withdraw from the study AND request that the data can no longer be used.

If a participant withdraws from a specific data collection sweep (case a) or from participating in the study as a whole (case b), CLS will continue storing their contact details and will continue to make existing de-identified data safely available for research purposes. Applicants will use the fact of death to update the contact details database and to enable access to de-identified mortality data for research. Applicants will not seek to access mortality data for those cohort members who have requested to withdraw from the study and stop usage of their data (case c). Therefore, CLS will not include these cohort members in the matching file submitted to NHS Digital.

Justifications for the need to receive mortality data for those who have asked to withdraw from the study (but have not asked for their data to no longer be used (i.e. cases a) and b):

1. Applicants use fact of death to define the target population for all/any analyses of the cohorts. If applicants don't know whether Cohort Members that have withdrawn have died, they will not be able to accurately define the target population or assess the representativeness of achieved samples. This will impact all analyses done in the cohorts.
2. Mortality itself is a core outcome in population research (demography, epidemiology, statistics). Mortality data provided for research must include those that have withdrawn from data collection in order to avoid skewed and biased research and policy advice outputs when mortality data is used.

This appears to be clear in the study notification documents.

The applicant also confirmed that all 3 data processors (Natcen, Kantar and Ipsos) would potentially be required at different timepoints for this application, and therefore all 3 DSPTs should be listed.

Confidentiality Advisory Group advice

The amendment requested was considered by the Chairs' Action. The Chair recommended support for this amendment, and accepted the justifications provided.

Confidentiality Advisory Group advice conclusion

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

Specific conditions of support

The following sets out the specific conditions of support.

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

   The NHS England **21/22** DSPT reviews for **UCL School of Life and Medical Sciences, Natcen Social Research**, and

   The NHS England **22/23** DSPT reviews for **Kantar Public, Ipsos UK,** & **NHS England** were confirmed as '**Standards Met'** on the NHS England DSPT Tracker (checked 21 July 2023)

2. Confirmation of a favourable opinion from a Research Ethics Committee. **Confirmed already covered by email 03 August 2023**

CAG 1-03(PR2)/2014 - National Child Development Study

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

Context

Amendment request

The applicants have existing support for NHS England to provide current address details of the 'untraced' cohort. The Centre for Longitudinal Studies provide identifiers for those lost to follow up to NHS England and receive current address details from NHS England to facilitate contact.

The applicants also have support to receive notifications of deaths and embarkations from NHS England, so that the study can update information on the database, and also to use the data for research.

On application to NHS England to receive death notifications including fact, date and cause of death, for everyone who has ever participated in the study, including those who have withdrawn from the study, NHS England pointed out that the 's251' support for accessing mortality data doesn't specifically mention accessing this information for those who have withdrawn from the study and NHS England requested applicants inform CAG about this.

Therefore this amendment sought support for the applicant to receive mortality data from NHS England, including fact, date and cause of death, for everyone who has ever participated in the study, including those who have withdrawn from the study (except where patients have withdrawn from the study and stop usage of their data).

Participants can;

a) withdraw from a specific data collection sweep of the study (in which case they would still be invited to take part in future sweeps of the study
b) permanently withdraw from the study (in which case they will not be invited to take part in any future sweeps of the study) or
c) permanently withdraw from the study AND request that the data can no longer be used.

If a participant withdraws from a specific data collection sweep (case a) or from participating in the study as a whole (case b), CLS will continue storing their contact details and will continue to make existing de-identified data safely available for research purposes. Applicants will use the fact of death to update the contact details database and to enable access to de-identified mortality data for research. Applicants will not

seek to access mortality data for those cohort members who have requested to withdraw from the study and stop usage of their data (case c). Therefore, CLS will not include these cohort members in the matching file submitted to NHS Digital.

Justifications for the need to receive mortality data for those who have asked to withdraw from the study (but have not asked for their data to no longer be used (i.e. cases a) and b):

1. Applicants use fact of death to define the target population for all/any analyses of the cohorts. If applicants don't know whether Cohort Members that have withdrawn have died, they will not be able to accurately define the target population or assess the representativeness of achieved samples. This will impact all analyses done in the cohorts.
2. Mortality itself is a core outcome in population research (demography, epidemiology, statistics). Mortality data provided for research must include those that have withdrawn from data collection in order to avoid skewed and biased research and policy advice outputs when mortality data is used.

This appears to be clear in the study notification documents.

The applicant also confirmed that all 3 data processors (Natcen, Kantar and Ipsos) would potentially be required at different timepoints for this application, and therefore all 3 DSPTs should be listed.

Confidentiality Advisory Group advice

The amendment requested was considered by the Chairs' Action. The Chair recommended support for this amendment, and accepted the justifications provided.

Confidentiality Advisory Group advice conclusion

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

Specific conditions of support

The following sets out the specific conditions of support.

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

   The NHS England **21/22** DSPT reviews for **UCL School of Life and Medical Sciences, Natcen Social Research**, and

   The NHS England **22/23** DSPT reviews for **Kantar Public, Ipsos UK,** & **NHS England** were confirmed as '**Standards Met'** on the NHS England DSPT Tracker (checked 21 July 2023)

2. Confirmation of a favourable opinion from a Research Ethics Committee. **Confirmed already covered by email 03 August 2023**

CAG 1-03(PR3)/2014 - Next Steps (previously known as Longitudinal Study of Young People in England)

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

Context

Amendment request

The applicants have existing support for NHS England to provide current address details of the 'untraced' cohort. The Centre for Longitudinal Studies provide identifiers for those lost to follow up to NHS England and receive current address details from NHS England to facilitate contact.

The applicants also have support to receive notifications of deaths and embarkations from NHS England, so that the study can update information on the database, and also to use the data for research (as specified by 2021 amendment).

On application to NHS England to receive death notifications including fact, date and cause of death, for everyone who has ever participated in the study, including those who have withdrawn from the study, NHS England pointed out that the 's251' support for accessing mortality data doesn't specifically mention accessing this information for

those who have withdrawn from the study and NHS England requested applicants inform CAG about this.

Therefore this amendment sought support for the applicant to receive mortality data from NHS England, including fact, date and cause of death, for everyone who has ever participated in the study, including those who have withdrawn from the study (except where patients have withdrawn from the study and stop usage of their data).

Participants can;

a) withdraw from a specific data collection sweep of the study (in which case they would still be invited to take part in future sweeps of the study
b) permanently withdraw from the study (in which case they will not be invited to take part in any future sweeps of the study) or
c) permanently withdraw from the study AND request that the data can no longer be used.

If a participant withdraws from a specific data collection sweep (case a) or from participating in the study as a whole (case b), CLS will continue storing their contact details and will continue to make existing de-identified data safely available for research purposes. Applicants will use the fact of death to update the contact details database and to enable access to de-identified mortality data for research. Applicants will not seek to access mortality data for those cohort members who have requested to withdraw from the study and stop usage of their data (case c). Therefore, CLS will not include these cohort members in the matching file submitted to NHS Digital.

Justifications for the need to receive mortality data for those who have asked to withdraw from the study (but have not asked for their data to no longer be used (i.e. cases a) and b):

1. Applicants use fact of death to define the target population for all/any analyses of the cohorts. If applicants don't know whether Cohort Members that have withdrawn have died, they will not be able to accurately define the target population or assess the representativeness of achieved samples. This will impact all analyses done in the cohorts.
2. Mortality itself is a core outcome in population research (demography, epidemiology, statistics). Mortality data provided for research must include those that have withdrawn from data collection in order to avoid skewed and biased research and policy advice outputs when mortality data is used.

This appears to be clear in the study notification documents.

The applicant also confirmed that all 3 data processors (Natcen, Kantar and Ipsos) would potentially be required at different timepoints for this application, and therefore all 3 DSPTs should be listed.

Confidentiality Advisory Group advice

The amendment requested was considered by the Chairs' Action. The Chair recommended support for this amendment, and accepted the justifications provided.

Confidentiality Advisory Group advice conclusion

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

Specific conditions of support

The following sets out the specific conditions of support.

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

   The NHS England **21/22** DSPT reviews for **UCL School of Life and Medical Sciences, Natcen Social Research**, and

   The NHS England **22/23** DSPT reviews for **Kantar Public, Ipsos UK,** & **NHS England** were confirmed as '**Standards Met'** on the NHS England DSPT Tracker (checked 21 July 2023)

2. Confirmation of a favourable opinion from a Research Ethics Committee. **Confirmed already covered by email 03 August 2023**

23/CAG/0032 – Natural language processing of histopathology reports

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

Context

Amendment request

This application from University College London seeks to investigate use of natural language processing (NLP) in the analysis of histopathology reports. Support is currently in place to allow the disclosure of histopathology reports, which may include items of confidential patient information in the free text health data and demographic and clinical data, from participating NHS trusts to University College London.

This amendment sought support to include 2 new Trusts as participating sites and new data processors under ‘s251’ support. The 2 Trusts included are Great Ormond Street Hospital Trust and Barts Health NHS Trust.

The amendment also sought support for a new data item to be collected from participating Trusts – date of death. The original study protocol described capturing "the patient's current vital status (alive or dead)." If a patient is deceased, their date of death is additionally required to enable survival time from biopsy to be calculated for survival analyses.

This amendment also sought to clarify the handling methods regarding specimen accession identifiers. Each pathology specimen has a specimen accession identifier. Only individuals with access to the hospital laboratory information management system (LIMS) can identify the patient from whom the specimen has been taken based on the specimen accession identifier. The original study protocol did not specify how specimen accession identifiers will be processed. This is addressed in the updated protocol. Specimen accession identifiers will be converted into pseudonymised identifiers (as per the NHS numbers) using a unidirectional hash algorithm. The pseudonyms can only be linked to patient details via a hospital/laboratory specific database. The conversion will be done computationally by the hospital providing the data. Therefore there will be no processing of confidential patient information without consent, and outside the direct care team for this element, and this is therefore accepted by CAG as notification only.

All the above changes are included into an updated protocol.

Confidentiality Advisory Group advice

The amendment requested was considered by Chair's Action. The Alternate Vice-Chair was content to recommend support for the amendment request, noting the applicants make a reasonable justification to include date of death, and that it is proposed to pseudonymise it in due course.

Confidentiality Advisory Group advice conclusion

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

Specific conditions of support

The following sets out the specific conditions of support.

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

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

2. Confirmation of a favourable opinion from a Research Ethics Committee.
   Confirmed no review required by email 14 August 2023

20/CAG/0038 – The C3 Study - Version 1 (The short and long-term cardiovascular consequences of critical illness: The C3 Study)

Name	Capacity
Ms Caroline Watchurst	HRA Confidentiality Advisor

Context

Amendment request

This application aims to establish if it is possible to predict who is at risk of subsequent strokes and heart attacks and their likelihood of survival, and to discover if there is any association between these adverse events and the care patients have received whilst they were unwell. ‘Section 251’ support is in place to allow the disclosure of confidential patient information from participating Trusts to the Critical Care Research Group, NDCN, University of Oxford and for linkages to HES and ONS data at NHS England (previously NHS Digital), National Institute for Cardiovascular Outcomes Research (NICOR) Audit database (data processors now changed to NHS Arden and Greater East Midland Commissioning Support Unit (Arden & GEM) & Redcentric (Harrogate), and to Intensive Care audit data held within the Intensive Care National Audit and Research Centre (ICNARC) databases.

This amendment sought support to extend the duration of support until 30 June 2026.

The amendment also sought support to confirm that the data flow regarding linkage with NICOR data will be direct with NICOR rather than via NHS England. linkage requires confidential patient information to be disclosed from the participating sites directly to NHS Arden and Greater East Midland Commissioning Support Unit (Arden & GEM) & Redcentric (Harrogate) for linkage. An updated data flow diagram has been submitted.

The amendment also sought support to include first name and surname, as additional data items for linkage with NHS England datasets, to ensure that the quality of linkage was improved.

The patient notification documentation has been updated appropriately.

Confidentiality Advisory Group advice

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

Confidentiality Advisory Group advice conclusion

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

Specific conditions of support

The following sets out the specific conditions of support.

1. Confirmation provided from the DSPT Team at NHS England to the CAG that the relevant Data Security and Protection Toolkit (DSPT) submission(s) has achieved the 'Standards Met' threshold **Confirmed: Due to the number of participating organisations involved it is the responsibility of University of Oxford as controller, to ensure that participating organisations meet the minimum required standard in complying with DSPTs, and take remedial action if they become aware of any that fall below this, or where any concerns are raised**

2. Confirmation of a favourable opinion from a Research Ethics Committee. **Duration extension confirmed as non substantial 08 June 2023, and data flow Confirmed 03 August 2023**

22/CAG/0114 – NHS England (NICOR) National Cardiac Audit Programme (NCAP) – Non-Research

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

Context

Amendment request

NCAP has current ‘s251’ support which includes linkages of confidential patient information with ONS mortality and Hospital Episode Statistics (HES) data by NHS England (previously NHS Digital). The current data linkage processes require gender as an additional data item. Support is currently in place only for NHS number, postcode, date of birth, date of death, and patient's name. Gender was not previously identified as a requirement in the original CAG application, however, this will be detailed in the new refreshed CAG application for NCAP which is being prepared. This amendment therefore sought support for the addition of gender as a data item for linkage with NHS England datasets.

This amendment also sought support to enable the linked mortality and HES data to be retained in the NICOR IT platform/national database. This linked data (for individual hospitals) would be visible to designated clinicians and administrative audit leads in each participating hospital, as well as to appropriate staff in NICOR. Previously, linked mortality data were stored in the national database (Lotus Notes) and was made available to hospitals and clinicians for the same purpose as currently requested. However, since the development of NICOR’s current IT platform, NHS England (previously NHD Digital) previously indicated that NICOR could not retain the linked data within the national database, without specific CAG support.

The linked mortality and HES data need to be in the NICOR IT platform/national database for two key reasons. One of the functions of NCAP is to identify and report statistical outliers both positive and negative. This is done at hospital level and, for some of the NCAP domains, at clinical operator level. Once the outliers are identified, a report is sent to the hospital and/or to the clinicians, who need to double check and validate the patient data including mortality. For the hospitals to do this exercise manually is time consuming, which means that the clinicians are unnecessarily distracted with administrative duties rather than spending their time providing clinical care. Providing systemic efficiencies like this in the NHS is in the public interest. This change provides the evidence of mortality of patients under hospital’s/clinician’s care in one place, rather than having to interrogate various NHS systems. Due to the way the NICOR IT platform (national database) is set up, and the way user access is controlled, the hospital database managers or clinicians will only be able to view their own patient data. They would not be able to view any other clinician’s or any other hospital’s patient data. This amendment will therefore support the hospitals and

clinicians submitting data to NICOR to be able to readily utilise the linked outcome data to validate and verify their inputs, especially when either the hospital or the individual clinician has been identified as an outlier. The hospital database managers and clinicians will be able to see the 'evidence' that identifies them as an outlier immediately in one place, rather than having to manually go through different time-consuming systems.

The second justification for the linked mortality and HES data to be in the NICOR IT platform/national database, is that NHS England has requested publication of patient information (similar to NICOR's annual reported data) on-line and contemporaneously, on a quarterly basis. NICOR is able to quarterly publish the process measures. However, the calculation and reporting of outcome measures requires manual analysis of the mortality-linked data. Currently NCAP reports both process and outcome measures once a year. Applicants do not have the resources to do this four times a year. An alternative to this time-consuming, labour-intensive process is to automate it. Automation would result in hospitals providing NICOR with regular validated data through the national database which would be linked regularly with patient mortality and HES data. This linked de-identified/aggregated data pipeline would feed into apps/dashboards which would be presented visually, for example on the NHS England's Model Healthcare system, for use by key stakeholders (NHSE, ICBs, CQC etc.) for commissioning and regulatory purposes. As per the current NCAP annual reports, the on-line apps and dashboards would only present aggregated data, and it will not be possible to identify any patients from the information displayed. This amendment will therefore also support NICOR's requirement to meet NHS England's request for presenting patient data on-line contemporaneously. This means that all stakeholders including clinicians, patients, commissioners, and regulators are able to access de-personalised NICOR data online quarterly rather than annually. This has been a key request from all stakeholders, including patients and clinicians.

Confidentiality Advisory Group advice

The amendment requested was considered by Chairs' Action. The Chair was content to recommend support for this interim amendment, noting that the resubmitted NCAP application is expected before the end of this year, and all changes will be re-reviewed and confirmed at that stage also.

Confidentiality Advisory Group advice conclusion

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

Specific conditions of support

The following sets out the specific conditions of support.

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

   The NHS England 21/22 DSPT reviews for **NHS Arden and Greater East Midland Commissioning Support Unit (Arden & GEM) & Redcentric (Harrogate)** were confirmed as 'Standards Met' on the NHS England DSPT Tracker (checked 25 July 2023)

18/CAG/0018 – Pre-Hospital Emergency Medicine (PHEM) Feedback

Name	Capacity
Ms Caroline Watchurst	HRA Confidentiality Advisor

Context

Amendment request

This application from the Princess Alexandra Hospital NHS Trust aims to implement a service evaluation system for staff involved in the pre-hospital care of patients. The system provides staff involved with the pre-hospital care of patients the facility to follow-up on specific cases to facilitate learning, improve clinical judgement, allow an opportunity for reflection, debriefing in particularly difficult or sensitive cases and facilitate improvement in the standard of care provided in the future.

This amendment sought support to include additional data processors in the form of the new ambulance services and hospitals listed below;

Addition of ambulance services:

1) North East Ambulance Service
2) London Ambulance Service

Addition of Hospitals:

1) Sunderland (South Tyneside and Sunderland NHS Foundation Trust)
2) Homerton University Hospital
3) Royal Free London NHS Foundation Trust
4) North West Anglia NHS Foundation Trust (Peterborough and Hinchingbrooke Hospitals)
5) Imperial College Healthcare NHS Trust (St Mary's)
6) Guy's and St Thomas' NHS Foundation Trust (Harefield)

This amendment also clarified that the two steps of 1) Registering interest in a case to be followed up 2) and completion of questionnaires measuring learning gains, will still be exchanged within the ambulance service's own secure digital environment but rather than exchanged by linked trust email addresses, will be exchanged via digital forms and stored in spreadsheet data only accessible by limited and approved project affiliated staff. Rather than relying on PDF forms attached to emails, data will be disclosed via MS forms. The justification is the poor rate of questionnaire completion to evidence learning gains from the pilot due to the inconvenience of obtaining, completing, attaching and returning the PDF by email. This new methodology is equivalent in data security terms to emails with attachments passing entirely within this secure digital environment of the ambulance service, and will allow better response rates. Whilst not a direct change to 's251' support in terms of data items, data flow, or data processors, this change is noted.

Confidentiality Advisory Group advice

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

Confidentiality Advisory Group advice conclusion

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

Specific conditions of support

The following sets out the specific conditions of support.

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

    a. **Not checked due to the number of total sites to be included within the scope of support.**

    b. **Support is recommended on the basis that the applicant ensures the required security standards are in place at each site prior to any processing of confidential patient information with support under the Regulations – see section below titled 'security assurance requirements' for further information.**

    c. **Where NHS England confirms confirmed qualified assurance against the organisation's 22/23 DSPT submission on the basis that the Trust has not met the 95% standard relating to staff security awareness training: the applicant must ensure that all staff involved in processing data under this section 251 support must have successfully completed local security awareness training before processing any data.**

21/CAG/0123 – RE-BLEED: A digital platform for identifying bleeding patients – a feasibility study

Name	Capacity
Ms Caroline Watchurst	HRA Confidentiality Advisor

Context

Amendment request

This application to test whether a digital platform can efficiently identify patients who have suffered a bleeding event, has ‘s251’ support to allow members of the research team to access confidential patient information for patients identified as having met the study criteria, so that patients can be approached for consent.

The prospective cohort that applicants currently have ‘s251’ support for is; Adults aged 16-110 years of age who were admitted to, or attended the emergency department at, Oxford University Hospitals NHS Trust between 01 October 2021 and 31 August 2023.

This amendment sought support to change the dates for the prospective cohort, due to delays to the study. Therefore the prospective cohort that applicants will now have ‘s251’ support for is; Adults aged 16-110 years of age who were admitted to, or attended the emergency department at, Oxford University Hospitals NHS Trust between 01 October 2021 and 29 February 2024.

The applicant confirmed that the number of patients in the cohort is not increasing, and that only the dates of the cohort screening are changing.

Confidentiality Advisory Group advice

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

Confidentiality Advisory Group advice conclusion

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

Specific conditions of support

The following sets out the specific conditions of support.

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

   The NHS England **21/22** DSPT review for **Oxford University Hospitals NHS Foundation Trust** is confirmed (by check of the NHS England DSPT tracker on 16 August 2023)

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

22/CAG/0017 – Supervised Pulmonary Hypertension Exercise REhabilitation (SPHERe): a multi-centre randomised controlled trial

Name	Capacity
Ms Caroline Watchurst	HRA Confidentiality Advisor

Context

Amendment request

This application aims to test if supervised pulmonary hypertension exercise rehabilitation (SPHERe), a programme of online remotely supervised, home-based exercise rehabilitation, can improve walking distance and quality of life (QoL). There is 's251' support in place to allow the processing of confidential patient information by the Warwick Clinical Trials Unit SPHERe Clinical Research Fellow (CRF), who is not considered part of the direct care team, to support screening and sending invitation letters at participating PIC sites where there is no or low capacity for the clinical care team to do so.

This amendment is to extend the end of recruitment from 31 March 2023 to 31 August 2023, which will therefore extend the duration of 's251' support. This is to allow the applicant to meet their recruitment target, after unexpected delays were experienced. The website has been updated to reflect the new end of recruitment date.

Confidentiality Advisory Group advice

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

Confidentiality Advisory Group advice conclusion

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

Specific conditions of support

The following sets out the specific conditions of support.

1. Confirmation provided from the DSPT Team at NHS England to the CAG that the relevant Data Security and Protection Toolkit (DSPT) submissions have achieved the 'Standards Met' threshold: **Confirmed: As there are more than 5 organisations processing confidential patient data these will not be individually checked by the CAT team, and it is the responsibility of the applicant to ensure the DSPTs for these organisations have been assessed as 'standards met' by NHS England**

2. Confirmation of a favourable opinion from a Research Ethics Committee. **Confirmed non substantial 20 July 2023**

22/CAG/0094 – Research to Improve the Detection and Treatment of Latent Tuberculosis Infection: Diagnostics. (Short title: RID-TB:Dx)

Name	Capacity

Ms Caroline Watchurst	HRA Confidentiality Advisor

Context

Amendment request

This application has support to allow research nurses/clinical research practitioners, who are not considered part of the direct care team, to view confidential patient information at participating trusts and primary care organisations, to identify potential participants for the RID-TB:Dx trial, and telephone these patients to arrange an appointment for LTBI testing, and further discussion about the RID-TB:Dx trial, (where they will be approached for consent). It was initially stated that recruitment would end by January 2023.

This amendment sought support to extend the recruitment period, and thereby the 's251' support until June 2024, to allow the applicant to meet the recruitment target.

Confidentiality Advisory Group advice

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

Confidentiality Advisory Group advice conclusion

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

Specific conditions of support

The following sets out the specific conditions of support.

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

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

2. Confirmation of a favourable opinion from a Research Ethics Committee. **Confirmed non substantial 3 August 2023**

20/CAG/0034– Detecting clinical deterioration in respiratory hospital patients using machine learning

Name	Capacity
Ms Caroline Watchurst	HRA Confidentiality Advisor

Context

Amendment request

The applicants have existing support for researchers from the University of Nottingham to access confidential patient information held in electronic and paper records at Nottingham University Hospitals NHS Trust, in order to extract an anonymised dataset for analysis.

This amendment sought to extend the duration of 's251' support until 30 June 2024. This is to allow the applicant to complete the purposes of the application.

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

   The NHS England 21/22 DSPT reviews for the **University of Nottingham and Nottingham University Hospitals NHS Trust** were confirmed as 'Standards Met' on the NHS England DSPT Tracker (checked 16 August 2023)

2. Confirmation of a favourable opinion from a Research Ethics Committee. **Confirmed non substantial 02 August 2023**

22/CAG/0010 – The Integration and Analysis of Data Using ARtificial InTelligence to Improve Patient Outcomes with Thoracic Diseases

Name	Capacity
Professor William Bernal	CAG Alternate Vice-Chair
Ms Caroline Watchurst	HRA Confidentiality Advisor

Context

Amendment request

The applicants have existing support to allow the disclosure of confidential patient information from participating trusts to the Oxford University Hospitals NHS Foundation Trust, for the purposes of developing an Artificial Intelligence model to aid in the diagnosis of lung cancer in pulmonary nodules identified on CT scans performed as part of the NHSE Lung Cancer Screening Programme. Support is also in place to include national datasets from NHS England as additional data sources to ensure accurate outcome data.

This amendment sought support for the disclosure of confidential patient information from the Yorkshire Lung Screening Trial (YLST - 18/CAG/0038), at University of Leeds, to the Oxford University Hospitals NHS Foundation Trust, to be included as a new data source for DART. YLST is a clinical trial sponsored by Leeds University collecting similar data to that collected by the DART participating Trusts, and YLST data disclosed to DART will be the same as participating sites.

YLST will send DART all the data types they collect – clinical data, CTs images and also digitised pathology and PET and other scans if they are collected for patients. In terms of confidential patient information YLST will disclose clinical reports on spreadsheets which include date of birth, gender, ethnicity, and NHS number. This is required for linking the various types of data for each patient as clinical data comes from one part of the chain in each site, CT images from another and applicants do, naturally, find that on occasion NHS numbers have been transposed and other supporting identifiers are required to make the match. The records are deidentified and all identifiers removed as soon as the data reaches the DART server, and appropriate linkage has been undertaken.

The patient documentation (poster, information sheet, privacy notice) all already refer to lung health checks so would be inclusive of the Yorkshire lung cancer screening cohort.

Confidentiality Advisory Group advice

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

Confidentiality Advisory Group advice conclusion

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

Specific conditions of support

The following sets out the specific conditions of support.

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

   The NHS England **2021/22** DSPT reviews for **Oxford University Hospitals NHS Foundation Trust**, **Oxford University** &

   The NHS England **2022/23** DSPT review for **NHS England** were confirmed as '**Standards Met'** on the NHS England DSPT Tracker (checked 21 July 2023).

   Due to the number of participating sites where confidential patient information will be accessed, support is recommended on the basis that the applicant ensures the required security standards are in place at each site prior to any processing of confidential patient information with support under the Regulations.

2. Confirmation of a favourable opinion from a Research Ethics Committee.
   Confirmed 26 June 2023

18/CAG/0146 – National Joint Registry (NJR)

Name	Capacity

Ms Caroline Watchurst	HRA Confidentiality Advisor

Context

Amendment request

The National Joint Registry (NJR) collects data on all hip, knee, ankle, elbow and shoulder replacement operations carried out in NHS and independent sector hospitals and treatment centres in England and Wales from 1 April 2003 onwards. There is ‘s251’ support in place for the disclosure of name, NHS number, DOB, Gender, Postcode and unique NJR identifier from within the NJR database at NECSWS to NHS England for linkage. The flow back includes date of death, and therefore requires ‘s251’ support. Only patients with a consent status of ‘yes’ or ‘unknown’ would have identifiers sent from NJR to NHS England for linkage. NJR would not receive any HES or civil registration data regarding the patients with a consent status of ‘no’. ‘s251’ support under regulation 5 is not required for those that have consented into NJR, as this data flow is undertaken with consent as the legal basis under common law. This linkage was undertaken for English patients only, and Welsh outcome data was received from PEDW.

This amendment sought support to include additional data items - LOPATID (local patient identifier) and PROCODE (identity of provider hospital) to the cohort submitted to NHS England for the purposes of linkage to HES, National PROMs and Civil Registration data. This is because ensuring a high rate of data linkage is necessary to ensure that the cohort available for analysis is as large as possible.

This amendment also sought support to extend the cohort of patients submitted to NHS England for the purposes of linkage to Civil Registration data to include patients treated in Wales, and patients receiving independently funded surgery in private hospitals in England. The applicant has also requested ‘s251’ support for the disclosure of data regarding patients from the Isle of Man, however this is out of CAG remit, and ‘s251’ support only covers England and Wales. Previous support has been limited to linkage to HES, PROMs and CivReg data for NHS patients in England. While HES and PROMs data is limited to this cohort, mortality data is also available for patients treated in Wales, Isle of Man and patients receiving independently funded surgery in private hospitals in England. By including more patients in this linkage model, applicants are able to profile the outcomes of patients

in these territories alongside those in England and so improve the quality and completeness of the NJR dataset for analysis to support safety and quality.

Confidentiality Advisory Group advice

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

Confidentiality Advisory Group advice conclusion

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

Specific conditions of support

The following sets out the specific conditions of support.

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

   The NHS England **21/22** DSPT review for **NEC Software Solutions (UK) Ltd** was confirmed as 'Standards Exceeded' on the NHS England DSPT Tracker (checked 16 August 2023), and the NHS England **22/23** DSPT review for **NHS England** was confirmed as 'Standards Met' on the NHS England DSPT Tracker (checked 16 August 2023).

19/CAG/0101 – Oxford Cerebrovascular Research Database

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

Context

Amendment request

This application aims to establish a research database of patients who suffered a stroke or mini-stroke (TIA) in the past 10 years who have an interest in being invited to participate in future research studies. Support is in place to allow access to medical records on site at Oxford University Hospitals NHS Trust to enable the research team to identify eligible patients using lists of those who had been discharged from a stroke unit or have attended a specialist stroke/TIA clinic. Support is also in place to allow the disclosure of confidential patient information from Oxford University Hospitals NHS Trust to University of Oxford to enable a consent approach to be made. Patients will be invited to provide their consent for inclusion on the registry so that they could be contacted in future if a research study begins for which they would be eligible to participate.

The cohort currently supported is '*Patients aged over 18 diagnosed as suffering a cerebrovascular event (Stroke or TIA) from 01 September 2009 to 01 September 2019 at Oxford University Hospitals NHS Trust. It is expected that 5000 patients would be invited to participate in the research database.'*

This amendment sought support to expand the cohort to allow retrospective identification of patients who have had a cerebrovascular event between the original search date (01 September 2019) and new end date of 30 December 2023, increased from 01 September 2019.

In addition, this amendment also therefore sought support for an increase in the total number of patients contacted to approximately 8500 (increased from 5000), to include participants from the past 4 years.

The justification for this amendment is that it will improve equity of access for different patients to research opportunities and will greatly support recruitment to ongoing and future research studies to enable important clinical trials to happen, will allow inclusion of patients with more recent cerebrovascular events (necessary for most studies) and

will increase the population of patients allowing use of their healthcare records for primary research analyses, reaching a critical mass for epidemiological analyses.

Confidentiality Advisory Group advice

The amendment requested was considered by Chair's Action. The Vice-Chair was content to recommend support for this amendment, which extends the period of time that the project can approach possible subjects retrospectively and increase the number of patients whose data can be processed.

Confidentiality Advisory Group advice conclusion

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

Specific conditions of support

The following sets out the specific conditions of support.

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

   The NHS England 21/22 DSPT reviews for **Oxford University Hospitals NHS Foundation Trust & University of Oxford Medical Sciences Division** were confirmed as 'Standards Met' on the NHS England DSPT Tracker (checked 25 July 2023)

2. Confirmation of a favourable opinion from a Research Ethics Committee. **Confirmed part of original REC Favourable Opinion – by email 17 August 2023**

22/CAG/0009 – Early detection of bladder cancer in Yorkshire: Feasibility assessments for implementing a targeted study in populations with high disease specific mortality risk

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 participating GP practices to iPlato Healthcare, for Cohort 2, and to the Participating NHS Trust Research Team, for Cohort 3, and to King's College London for both Cohorts, and then to Testcard Ltd, who will undertake the mailout to selected participants, and support to disclose confidential patient information to NHS England for linkage to NCRAS for follow-up data.

This amendment sought support to include an additional participating NHS Trust - South Tees Hospitals NHS Foundation Trust, participating in Cohort 3, as an additional data processor under 's251' support. South Tees Hospitals NHS Foundation Trust has been added, following failure to successfully setup the following 2 NHS Trusts due to a lack of local support - Doncaster and Bassetlaw Teaching Hospitals NHS Foundation Trust and Bradford Teaching Hospitals NHS Foundation Trust. Without the addition of another participating NHS Trust in Cohort 3, there would be a risk that the study would not be able to fully fulfil its objectives.

Confidentiality Advisory Group advice

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

Confidentiality Advisory Group advice conclusion

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

Specific conditions of support

The following sets out the specific conditions of support.

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

   The NHS England **21/22** DSPT reviews for **Testcard Ltd, iPlato, King's College London Cancer Epidemiology and Population Health (CPTU), &**

   The NHS England **22/23** DSPT review for **NHS England (NCRAS)** were confirmed as '**Standards Met'** on the NHS England DSPT Tracker (checked 17 August 2023)

   Due to the number of participating care 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, 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.

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

19/CAG/0182 – National Joint Registry – Research Database

Name	Capacity
Ms Caroline Watchurst	HRA Confidentiality Advisor

Context

Amendment request

This application has ‘s251’ support to allow the secondary use of data collected for audit purposes by the National Joint Registry (under reference 18/CAG/0146) for research purposes.

The National Joint Registry (NJR) collects data on all hip, knee, ankle, elbow and shoulder replacement operations carried out in NHS and independent sector hospitals and treatment centres in England and Wales from 1 April 2003 onwards. There is ‘s251’ support in place for the disclosure of confidential patient informaiton and unique NJR identifier from within the NJR database at NECSWS to NHS England for linkage. The flow back includes date of death, and therefore requires ‘s251’ support. Only patients with a consent status of ‘yes’ or ‘unknown’ would have identifiers sent from NJR to NHS England for linkage. NJR would not receive any HES or civil registration data regarding the patients with a consent status of ‘no’. ‘s251’ support under regulation 5 is not required for those that have consented into NJR, as this data flow is undertaken with consent as the legal basis under common law. This linkage was undertaken for English patients only, and Welsh outcome data was received from PEDW.

This amendment sought support to clarify that the data items submitted to NHS England for linkage will be surname, forename, date of birth, home address including postcode, NHS number and gender in line with the non-research application.

This amendment sought support to include additional data items - LOPATID (local patient identifier) and PROCODE (identity of provider hospital) to the cohort submitted to NHS England for the purposes of linkage to HES, National PROMs and Civil Registration data. This is because ensuring a high rate of data linkage is necessary to ensure that the cohort available for analysis is as large as possible.

This amendment also sought support to extend the cohort of patients submitted to NHS England for the purposes of linkage to Civil Registration data to include patients treated in Wales, and patients receiving independently funded surgery in private hospitals in England. The applicant has also requested ‘s251’ support for the disclosure of data regarding patients from the Isle of Man, however this is out of CAG remit, and ‘s251’ support only covers England and Wales. Previous support has been limited to linkage

to HES, PROMs and CivReg data for NHS patients in England. While HES and PROMs data is limited to this cohort, mortality data is also available for patients treated in Wales, Isle of Man and patients receiving independently funded surgery in private hospitals in England. By including more patients in this linkage model, applicants are able to profile the outcomes of patients in these territories alongside those in England and so improve the quality and completeness of the NJR dataset for analysis to support safety and quality.

Confidentiality Advisory Group advice

The amendment requested was considered by the Confidentiality Advice Team, who raised no queries regarding this amendment, and noted it is in line with a non-research amendment submitted.

Confidentiality Advisory Group advice conclusion

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

Specific conditions of support

The following sets out the specific conditions of support.

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

   The NHS England **21/22** DSPT review for **NEC Software Solutions (UK) Ltd** was confirmed as 'Standards Exceeded' on the NHS England DSPT Tracker (checked 16 August 2023), and the NHS England **22/23** DSPT review for **NHS England** was confirmed as 'Standards Met' on the NHS England DSPT Tracker (checked 16 August 2023).

2. Confirmation of a favourable opinion from a Research Ethics Committee. **Confirmed non substantial 18 August 2023**

23/CAG/0034 – Precision Treatment Strategies in Multiple Sclerosis Using Next-generation MachineLearning

Name	Capacity
Ms Caroline Watchurst	HRA Confidentiality Advisor

Context

Amendment request

This application seeks to explore how multiple sclerosis types that will predict treatment effects and the risk of worsening disability can be redefined. ‘s251’ support is in place to allow members of research staff, who are not part of the direct care team, to access confidential patient information at participating NHS trusts to identify eligible patients and extract the required data.

This amendment sought support to include Nottingham University Hospitals NHS Trust as an additional participating site, and new data processor under ‘s251’ support. This amendment also sought support to corrected the names of the following two organisations which were incorrectly submitted as part of the initial application.

Public Health Wales is removed as a data processor, as this was meant to be University Hospital of Wales (which his part of Cardiff and Vale University Health Board).

Bedfordshire Integrated Health Board is removed as a data processor, as this was meant to be Bedfordshire Hospitals NHS Foundation Trust.

Confidentiality Advisory Group advice

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

Confidentiality Advisory Group advice conclusion

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

Specific conditions of support

The following sets out the specific conditions of support.

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

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

2. Confirmation of a favourable opinion from a Research Ethics Committee. **Confirmed non substantial 18 July 2023**

3. Annual Review Approvals

CAG reference	Application Title
CAG 7-06(a)2013	Investigating the accuracy of current estimates of self-harm
16/CAG/0006	UK National Flap Registry (UKNFR)
20/CAG/0038	The short and long-term cardiovascular consequences of critical illness: The C3 Study
18/CAG/0072	NHSE Improvement Getting It Right First Time (NHSE GIRFT) Programme – Litigation Claims data

16/CAG/0053	Prolonged Effects of Assisted reproductive technologies on the health of women and their children: a Record Linkage study for England (PEARL)
CAG 3-02(a)/2014	Long-term follow-up of ARTISTIC cervical screening trial cohort
20/CAG/0157	The Oxford Risk Factors And Non-invasive imaging Study: ORFAN
21/CAG/0009	The MND Register for England, Wales, and Northern Ireland.
21/CAG/0028	The MND Register for England, Wales, and Northern Ireland.
21/CAG/0155	Using patient records to identify potential participants for Natsal-4
22/CAG/0082	PANORAMIC: Platform Adaptive trial of NOvel antiviRals for eArly treatMent of covid-19 In the Community
ECC 7-05(h)/2011	CRANE Database – Epidemiology Register
22/CAG/0094	RID-TB:Dx
16/CAG/0079	National Clinical Audit of Breast Cancer in Older Patients (NABCOP)
22/CAG/0078	EXTEND study – Needs Assessed Care for Early Psychosis
18/CAG/0018	Pre-Hospital Emergency Medicine (PHEM) Feedback
ECC 8-05(d)/2011	Do specialist cancer services for teenagers and young adults (TYA) add value?
17/CAG/0082	Do specialist cancer services for teenagers and young adults (TYA) add value?
15/CAG/0123	aTTom: Adjuvant Tamoxifen Treatment – Offer More? (aTTom) trial
20/CAG/0046	An evaluation of a water fluoridation scheme in Cumbria: population based comparative cohort studies of topical fluoride exposure alone

20/CAG/0045	An evaluation of a water fluoridation scheme in Cumbria: A population based comparative cohort study of systemic and topical fluoride exposure
16/CAG/0058	National Maternity and Perinatal Audit
18/CAG/0015	Improving diagnosis and management in dementia with Lewy bodies using the CPFT Research Database (CRATE).
19/CAG/0059	National Early Inflammatory Arthritis Audit Research Database
20/CAG/0029	Incidence of Chronic Recurrent Multifocal Osteomyelitis (CRMO) in the United Kingdom (UK) and Republic of Ireland (ROI)
17/CAG/0186	REACH Pregnancy Circles Trial
22/CAG/0068	Childhood outcomes after perinatal population-based linkage study
19/CAG/0035	Updating cancer survival index trends for England and Wales to 2018
20/CAG/0034	Detecting clinical deterioration in respiratory hospital patients using machine learning
17/CAG/0125	All-cause mortality within 12 months following Hip Fracture
22/CAG/0055	Near Fatal Asthma in Children and Young People
14/CAG/1018	CEMARC Long-term Outcome Study
19/CAG/0060	Lancashire ANCA Vasculitis and Glomerulonephritis Study
18/CAG/0091	Connected Bradford - Linked Education and Health Research Database
17/CAG/0011	Genetic mechanisms in polyposis of the bowel
22/CAG/0086	Norfolk Arthritis Register
19/CAG/0209	Optimising diagnostic efficiency in the Emergency Department by using advanced machine learning methods to update and personalise a contemporary clinical prediction model for early identification and exclusion of acute coronary syndromes and long term cardiovascular outcomes

15/CAG/0148	Improving Care in the NHS
ECC 3-06(m)/2009	Prognostic Factors in Prostate Cancer for Patients treated by Watchful Waiting
19/CAG/0079	IBIS – International Breast Cancer Intervention Study Epidemiological Cohort Study (IBIS-I)
17/CAG/0189	Surveillance of Incidence of first-time diagnosis of Early Onset Depression in children aged 3-13 years the United Kingdom and Republic of Ireland (EOD-UK & ROI)
20/CAG/0078	Accuracy of using crown rump length measurements in dating pregnancies
16/CAG/0048	LATTE: Long term Anastrozole vs Tamoxifen Effects
16/CAG/0118	A Study of the Natural History of Renal Disease in TSC2/PKD1 Contiguous Gene Deletion Syndrome.(REC:10MRE092) - section 251 application to access medical information of deceased patients
19/CAG/0173	Critical illness related cardiac arrest (CIRCA): an investigation of the incidence and outcome of cardiac arrest within Intensive Care Units in the United Kingdom
20/CAG/0120	Incidence of Avoidant/Restrictive Food Intake Disorder (ARFID) in children and young people presenting to secondary care in the UK and Ireland
20/CAG/0102	National Haemophilia Database (NHD) (non-research)
20/CAG/0103	National Haemophilia Database (NHD)
21/CAG/0149	Legacies and Futures: Gestational Parents' Experiences with Vulnerability and Resilience as it Influences Parent and Neonatal Health
19/CAG/0077	Enhanced surveillance of neonatal herpes simplex disease in UK and Irish infants less than 90 days of age.
22/CAG/0040	A Surveillance Study of Congenital and Hospitalized Neonatal Varicella in the United Kingdom & Portugal (NEOPOX)

21/CAG/0102	Barts Myocardial Infarction with Non-Obstructed Coronary Arteries Registry
19/CAG/0191	Glucocorticoid induced adrenal suppression in the UK and Ireland
19/CAG/0182	National Joint Registry – Research Database
21/CAG/0153	NHS Cancer Screening Programmes: National Coordination and Quality Assurance
21/CAG/0062	Barts Haemato-Oncology Research Tissue Bank (HOTB)
CR28/2014	Study of a Birth Cohort from Hertfordshire
18/CAG/0054	SUMMIT Study: Cancer screening study with or without low dose lung CT to validate a multi-cancer early detection test
21/CAG/0090	Paediatric Intensive Care Audit Network (Non research application)
21/CAG/0098	Paediatric Intensive Care Audit Network (research application)
CR38/2014	ADDITION_Cambridge
22/CAG/0006	Developing a digital handover application for paramedics to provide a personalized approach to pre-hospital stratification for OOHCA – the RAPID-MIRACLE study
22/CAG/0016	2022 NHS Maternity Survey – Mixed Methods
21/CAG/0064	Recovery, Renewal and Reset of Services to Disabled Children
20/CAG/0130	Yorkshire and Humber Care Record (YHCR) Population Health Management (PHM) for non-research purposes

Signed – Chair	Date
Dr Tony Calland, MBE, CAG Chair, Dr Patrick Coyle, CAG Vice-Chair, Professor William Bernal, Ms Clare Sanderson & Dr Murat Soncul, CAG Alternate Vice-Chairs	*12 September 2023*

Signed – Confidentiality Advice Team	Date
Ms Caroline Watchurst, HRA Confidentiality Advisor	*04 September 2023*