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

December 2022

1. New Applications

a. 22/CAG/0149 - Diabetic Retinopathy Progression Prediction Model Validation

Name	
Dr Tony Calland (Chair) MBE	CAG Chair
Dr Martin Andrew	CAG Member
Dr Sandra Duggan	CAG Member
Dr Harvey Marcovitch	CAG Member
Ms Diana Robbins	CAG Member

Context

Purpose of application

This application from the University of Birmingham set out the purpose of medical research that seeks to determine whether a model developed in primary care to identify patients at high risk of developing diabetic retinopathy can also be used in hospitals.

Diabetic retinopathy (DR), is a complication of diabetes at the back of the eye and is the fourth leading cause of preventable vision loss in the UK. Patients with diabetes are screened regularly for signs of early DR by the Diabetic Eye Screening Programme (DESP). However, when a patient develops clinical signs of advanced retinopathy, they are referred to Hospital Eye Services (HES) or surveillance clinics for closer observation and treatment to prevent vision loss. The number of patients with diabetes is increasing each year, with a consequent rise in numbers of patients with DR. This, in combination with under-resourced NHS causes an overburdening of HES, resulting in delays in patients being seen and a higher risk of harm to patients. Data from general practice has been used to develop a model to identify patients who are at a high risk of progressing to DR which requires treatment. The applicants are now seeking to test whether the same model can be used in hospital services and surveillance clinics.

A retrospective review of patients with diabetes will be undertaken. At two of the three participating trusts, the identification of patients and data extraction will be undertaken by the direct care team. At South Tyneside and Sunderland NHS Foundation Trust the identification and data extraction will be undertaken by research staff. Support is only required for activity taking place at this Trust. An anonymised dataset will be extracted and sent to the University of Birmingham for analysis.

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 12 years and over diagnosed with Diabetic Retinopathy 800 patients from South Tyneside and Sunderland NHS Foundation Trust will be included.

Data sources	1. Patient records at South Tyneside and Sunderland NHS Foundation Trust
Identifiers required for linkage purposes	1. NHS Number 2. Date of birth 3. Date of death
Identifiers required for analysis purposes	No identifiers will be retained for analysis

Confidentiality Advisory Group advice

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

1. **Please clarify whether recruitment will stop once the target number has been reached.**

The applicant confirmed that recruitment would cease once the target had been reached.

2. **Please specify whether small number suppression will be applied.**

The applicants confirmed that small number suppression would be applied and noted that they would follow NHS Digital practice for Hospital Episode Statistics Admitted Patient Care data.

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

    a. **The patient notification materials need to be revised for simplicity and clarity.**
    b. **All acronyms should be explained or removed.**
    c. **Contact details need to be provided.**
    d. **A statement that patient care will not be affected should patients opt-out from the study needs to be included.**
    e. **Please provide the updated patient notification materials**

Revised documents were provided. These were reviewed and approved by the CAG, although members asked that a contact telephone number and postal address were included on the poster.

4. **Ongoing patient and public involvement need to be undertaken specifically about the use of patient data without consent, as per the advice in this letter.**

The applicants provided details of patient and public involvement undertaken since the CAG meeting. This was small in scale, but members noted the applicants' commitment to ongoing activity.

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. A contact telephone number and postal address need to be included on the poster.

2. Favourable opinion from a Research Ethics Committee. **Confirmed 24 November 2022.**

3. Confirmation provided from the IG Delivery Team at NHS Digital to the CAG that the relevant Data Security and Protection Toolkit (DSPT) submission(s) has achieved the 'Standards Met' threshold. See section below titled 'security assurance requirements' for further information. **Confirmed:**

   NHS Digital 2021/22 DSPT review for **South Tyneside and Sunderland NHS Foundation Trust** was confirmed as 'Standards Met' on the NHS Digital DSPT Tracker (31/10/2022).

b. 22/CAG/0127 - Turning6 - A Clinical and Neurodevelopmental follow up of EPIPEG participants at 60 months

Name	
Ms. Clare Sanderson	CAG Alternate Vice-Chair
Dr Martin Andrew	CAG member
Professor Lorna Fraser	CAG member

Mr Andrew Melville	CAG member
Ms Diana Robbins	CAG member

Context

Purpose of application

This application from UCL GOS Institute of Child Health set out the purpose of medical research that seeks to investigate the association between early onset epilepsy and poor neurodevelopmental outcome. Epilepsy in the first year of life is associated with epilepsy that is difficult to treat and with poor neurodevelopmental outcomes. These can have a severe impact on the quality of life of both children and their parents, and the child's educational outcome. Little research has been undertaken into the longer-term impact of epilepsy. The applicants seek to follow-up participants from the EpiPEG study, which recruited 119 infants who had developed epilepsy within the first year of their life. The applicants propose to follow up this unique cohort of children as they reach 6 years, and will undertake comprehensive psychological assessments with the child, their parents and teachers.

The applicants will contact still living participants to seek consent to take part in the study. The original EpiPEG study was jointly undertaken by UCL GOS Institute of Child Health and Young Epilepsy (the National Centre for Young People with Epilepsy), who are joint data controllers for the EpiPEG dataset. The applicants seek support to access mortality data, provided by NHS Digital, to establish whether patients are still alive and to obtain up to date contact details for those that are before making contact. Confidential patient information will be disclosed from the EpiPEG dataset, held at Young Epilepsy, to NHS Digital for linkage to mortality data. A linked dataset will be returned to Young Epilepsy. The parents of living patients will be contacted and invited to take part in the study, after which time their involvement will be consented.

A recommendation for class 2, 3 and 6 support were requested to cover access to the relevant unconsented activities as described in the application, which can be got from the CAT assessment form, class support requested section.

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	117 patients who were recruited into the original EpiPEG study.
Data sources	1. EpiPEG records, held at Young Epilepsy (The National Centre for Young People with Epilepsy) 2. The HES and Personal Demographics Service datasets, held at NHS Digital
Identifiers required for linkage purposes	1. NHS number 2. Date of birth 3.Date of death 4.Postcode – unit level
Identifiers required for analysis purposes	1. Date of death 2. Postcode – unit level 3. Phone number 4. Email address

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. **Clarification needs to be provided on how the information provided by patients GPs, for those that failed to respond, would remain anonymous as the applicants would be able to link the data back to information for the specific patients in the study records.**

Should patients decline to participate, they will be given two options. The first will be the option to decline from participation or further contact. In the second option, families will not be involved further but would give consent to their GP or paediatrician being contacted to complete the Clinical Extraction Form. The CAG noted this and raised no further queries.

2. **Clarify the meaning of 'high risk' as stated in the protocol.**

The applicants noted that the reference to risk did not relate to a specific high risk or an at-risk population. The reference was included as the study requires undertaking psychological screening on the parents as well as the children. The applicants had a

duty of care to notify the parents if they have a result which indicates that they are potentially at risk of any of the conditions screened for.

Should a parent or child score highly and therefore be classified as 'at-risk' of, for example, anxiety or depression, following the assessment, the applicants will contact the parent directly to explain this. It will also be explained that the research team are unable to provide support and parents will be advised to contact their GP. The CAG noted this and raised no further queries.

3. **The materials used to reconsent patients should be 'future proofed' to cover any further data linkages that might be required.**

The applicants noted this and agreed to amend the invitation pack. The CAG noted this and raised no further queries.

4. **The materials used to contact patients need to explain the role of the CAG and section 251.**

The applicants noted this and agreed to amend the invitation pack. The CAG noted this and raised no further queries.

Confidentiality Advisory Group advice conclusion

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

Specific conditions of support

The following sets out the specific conditions of support.

1. A typographical error in the Invitation Letter needs to be corrected, "…including education and *metal* health."

2. Favourable opinion from a Research Ethics Committee. **Confirmed 19 May 2022.**

3. Confirmation provided from the IG Delivery Team at NHS Digital to the CAG that the relevant Data Security and Protection Toolkit (DSPT) submission(s) has achieved the 'Standards Met' threshold. See section below titled 'security assurance requirements' for further information. **Confirmed:**

The NHS Digital **21/22** DSPT reviews for organisation 'NHS Digital' and 'Young Epilepsy (the National Centre for Young People with Epilepsy)' were **confirmed** as 'Standards Met' on the NHS Digital DSPT Tracker (checked 26/09/2022).

c. 22/CAG/0144 - Randomised Evaluation of SOdium dialysate Levels on Vascular Events

Name	
Professor William Bernal	CAG Alternate Vice Chair
Mr David Evans	CAG Member
Dr Pauline Lyseight-Jones	CAG Member
Ms Rose Payne	CAG Member
Ms Kathleen Cassidy	Confidentiality Advisor

Context

Purpose of application

This application from University College London set out the purpose of medical research that seeks to determine the optimal default dialysis sodium concentration, and the impact of higher or lower dialysate sodium concentration on cardiovascular events and death in patients with kidney failure who are receiving haemodialysis.

Over 24,500 people in the UK are receiving haemodialysis to treat kidney failure. Those receiving haemodialysis have a mortality rate 10 to 100 times higher than in the general population and most deaths are due to cardiovascular disease. A main contributor to this is retention of sodium and fluid, which causes thickening of the heart muscle, wide changes in weight between dialysis sessions and vascular disease. Dialysate is a saline solution exposed to blood during the dialysis session. Most units use a default dialysate sodium prescription, meaning that all patients treated at the unit receive the same concentration, unless specifically altered by the responsible physician. There is no consensus as to the optimal dialysate sodium concentration.

100 dialysis centres will participate in the study. Confidential patient information will be transferred from participating sites to the UCL Data Safe Haven. The research team at University College London will collate the data and transfer confidential patient information to NHS Digital for linkage and to the UK Renal Registry for linkage. Linked

datasets will be returned from NHS Digital and the UK Renal Registry to the UCL Data Safe Haven. Linkages to NHS Digital and the UK Renal Registry will be undertaken on an annual basis.

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

Confidential patient information requested

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

Cohort	Patients aged 18 years and over receiving haemodialysis for kidney failure. The applicants anticipate that 12,000 patients will be recruited in England.
Data sources	1. Confidential patient information from dialysis units at participating trusts 2. Hospital Episode Statistics Admitted Patient Care (HES APC), Emergency Care Data Set (ECDS), Civil Registrations (Deaths) data set, held by NHS Digital 3. The UK Renal Registry
Identifiers required for linkage purposes	1. NHS number 2. Date of birth
Identifiers required for analysis purposes	1. Date of birth 2. Gender

Confidentiality Advisory Group advice

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

1. **Please provide clarity on which international countries are involved in this study as well as the number of patients within the United Kingdom and internationally.**

The applicants explained that RESOLVE is taking place 6 countries, including Australia, China, India, Canada, Germany and Malaysia. Globally, the study is aiming to recruit approximately 50,000 patients and the UK will recruit ~25% of these, around12,000 patients. The trial design is a cluster randomisation of dialysis units. The units will be randomised, rather than individual patients. The global sample size is 414 dialysis centres, of which, approximately 100 dialysis centres (25%) will be randomised in the UK. The study is endpoint-driven and will conclude when 26910 events have occurred.

The CAG noted this information and raised no further queries.

2. **Please provide clarity on the data flows and how the data would be sent out of the country.**

All data containing confidential patient information, as well as data from NHS Digital and UK Renal Registry (UKRR), will be kept within the UCL Data Safe Haven (DSH). Remaining baseline data collected from dialysis units will be entered directly into REDCap. The dataset will be linked using date of birth and NHS Number within the DSH.

The dataset forwarded to the University of Sydney (USYD) will contain fully anonymised data only. Only key variables needed for the primary and secondary analyses will be shared.

The CAG noted this information and raised no further queries.

3. **Statistical modelling needs to be undertaken to demonstrate the impact the seeking consent would have on the study, to evidence that consent is not feasible.**

The applicants noted that the intervention will be delivered at cluster level rather than patient level. Patients at a specific unit would receive the same intervention as they would receive as routine care. In order to answer the research question, the applicants need at least 90% of patients treated at each unit to be included. Seeking consent would mean that the target number would not be achieved. The applicants also

expressed concern that the result would be biased and those who gave consent would not be fully representative of the centre.

The CAG noted this information and raised no further queries.

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

    a. **Specific details on how patients may opt-out needs to be given, including the relevant contact details.**
    b. **The potential transfer of data outside the UK should be specified.**
    c. **The possibility of making patient notification materials available in languages other than English needs to be explored.**

The applicants provided a revised poster, which included the revisions suggested by the CAG. The applicants also noted that they planned to translate the trial patient information into the 4 different languages that are most prevalent in the haemodialysis units that will be participating in the trial.

The CAG noted this information and raised no further queries.

5. **Provide feedback on from the patient and public involvement group on the use of confidential patient information without consent.**

The applicant provided feedback from two members of the Patient Advisory Group. The CAG noted that the sample consulted was small, but agreed that overall the patient and public involvement conducted was proportionate to the scale of the application.

Confidentiality Advisory Group advice conclusion

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

Specific conditions of support

The following sets out the specific conditions of support.

1. Favourable opinion from a Research Ethics Committee. **Confirmed 01 November 2022.**

2. Confirmation provided from the IG Delivery Team at NHS Digital to the CAG that the relevant Data Security and Protection Toolkit (DSPT) submission(s) has achieved the 'Standards Met' threshold. See section below titled 'security assurance requirements' for further information. **Confirmed:**

   The NHS Digital 2021/22 DSPT reviews for **University College London, NHS Digital and The Renal Association** were confirmed as 'Standards Met' on the NHS Digital DSPT Tracker (11/10/2022).

   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.

d. 22/CAG/0137 - West Yorkshire ICB S251 non-research

Name	
Dr Murat Soncul	CAG Alternate Vice Chair
Dr Malcolm Booth	CAG Member
Dr Pauline Lyseight-Jones	CAG Member
Mr Umar Sabat	CAG Member
Professor Sara Randall	CAG Member
Ms Kathleen Cassidy	Confidentiality Advisor

Context

Purpose of application

This non-research application from the West Yorkshire Integrated Care Board (ICB) set out the purpose of using patient data to enable a whole system approach to supporting the reduction of health inequalities and improvement of efficiency of the health and care offered.

The main aims of the Population Health Management (PHM) solution will be to improve the mental and physical health outcomes and wellbeing of patients, the reduction of health inequalities, reducing the re-occurrence of ill-health and use of Artificial Intelligence to risk stratify and target individual and communities at risk of deteriorating health.

The North of England Commissioning Support Unit (NECS) will extract primary care data from all GP practices in the West Yorkshire area. Once the datasets are received by NECS, a common pseudonym will be applied. Data from the Commissioning Datasets, held by NHS Digital, will be sent from NHS Digital to NECS, using the same common pseudonym to allow NECS to link the datasets. The pseudonymised dataset will then be stored at a data warehouse within West Yorkshire ICB for analysis. Pseudonymised data will also flow back to the GP practices, this data will be limited to the practice's own patients. Patient NHS numbers will be held by NECS for re-identification purposes only

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	All active patients in the West Yorkshire area. The applicants anticipate that 2.6 million patients will be included.
Data sources	1. GP practice data 2. Commissioning Datasets held by NHS Digital
Identifiers required for linkage purposes	1. NHS Number

Identifiers required for analysis purposes	1. NHS Number The applicants confirmed that the NHS Number would not be used for analysis but would be retained for re-identification purposes.

Confidentiality Advisory Group advice

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

1. **Please clarify the data sets being used from NHS Digital.**

The applicants advised that the below datasets, held by NHS Digital, would be linked to:

Child and Young People Health Service (CYPHS)

Civil Registration of Births Dataset

Civil Registration of Deaths Dataset

Community Services Dataset (CSDS)

Diagnostic Imaging Dataset (DIDS)

e-Referral System Dataset (eRSDS)

Improving Access to Psychological Therapies (IAPT)Local provider flows ie Walk in centre, SLAM, Patient level commissioning dataset

Maternity Services Dataset (MSDS)

National Cancer Waiting Times Monitoring Dataset (CWT)

Patient Demographics Service (PDS)

Secondary Uses Service Dataset (SUS) – A&E, Inpatients and Outpatients

YAS Ambulance

Adult Social Care (ASC)

The applicants noted that other NHS Digital held datasets may be used in future. The applicants will need to liaise with NHS Digital regarding whether amendments would be needed to include any additional datasets.

The CAG noted the above and raised no further queries.

2. **Please clarify how the reidentification process works.**

The applicants provided an explanation of the re-identification process. The CAG noted the explanation given and raised no further queries.

3. **Please clarify who is holding the key for pseudonymisation and how and when the key will be used.**

The applicants advised that the Yorkshire DSCRO will hold the pseudonymisation key in a segregated area. The area is restricted to a small number of DSCRO analysts. The key will be used only to pseudonymise the GP primary care data following extraction and is maintained to respond to any approved re-identification requests. The key is not used for any other purposes.

The CAG noted the above and raised no further queries.

4. **Please clarify what training was given to the GP surgeries to help equip them to deal with the high volumes of work from this study.**

The applicants advised that they did not anticipate that GP surgeries would need to take on a high volume of additional work as a result of the application. Each practice will have a Practice Manager, an Information Officer and a PCN Business Manager Lead, who will work with the ICB to support practice performance. The ICB Primary Care Commissioning Teams will also support practices in understanding and interpreting the analysis resulting from this application. In terms of surgeries managing patient opt-out requests, an information sheet detailing the process and steps required, will be provided to each GP practice. This will support the practice in managing any requests and will ensure a consistent process is used across the ICB.

The CAG noted the above and raised no further queries.

5. **Please clarify the amount of guidance and information GP surgeries will be given, regarding opt-out.**

GP practices have been engaged with regarding the process by which patients can opt-out of this programme. All patient engagement material will be shared with the practices and a copy of the patient flyer will be displayed in the practice waiting area.

To support practices with the opt-out service, the applicants have worked with primary care data quality specialists to create a unique read code (SNOMED code) that can be entered on a patient's record. NECS are informed of this code to ensure the code is removed as part of the pseudonymisation process. An information leaflet has been produced to support practices with the opt-out process.

The local opt-out process will also be communicated to GPs via local primary care bulletins.

The CAG noted the above and raised no further queries.

6. **The patient notification materials need to be revised as follows:**
    a. **The materials need to be revised into lay-friendly language.**
    b. **The materials should be reviewed during patient and public involvement.**
    c. **The patient notification materials need to explain that identifiable data will be processed during the application.**
    d. **The patient notification materials need to explain the National Data Opt-Out and the project-specific opt-out.**

A revised patient flyer was provided. This had been reviewed by the West Yorkshire Cancer Alliance Patient Engagement Group. The CAG noted this and raised no further queries.

7. **The 'Communication Strategy' is noted as too instructive. Therefore, please amend the language used, in the table, on page 3, to encourage back and forth engagement between the applicant and participants.**

The applicants provided a revised communications strategy. The CAG noted this and raised no further queries.

Confidentiality Advisory Group advice conclusion

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

Specific conditions of support

The following sets out the specific conditions of support.

1. 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:**

   NHS Digital 2021/22 DSPT review for **NHS Digital** and **The North of England Commissioning Support Unit (NECS** were confirmed as 'Standards Met' on the NHS Digital DSPT Tracker (07/12/2022).

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

e. 22/CAG/0146 – Evaluating Behaviour Science Informed Messaging on Cervical Cancer Screening Catch-up

Name	
Dr Patrick Coyle	CAG Vice Chair
Dr Martin Andrew	CAG Member
Dr Rachel Knowles	CAG Member
Ms Kathleen Cassidy	Confidentiality Advisor

Context

Purpose of application

This application from Imperial College London set out the purpose of medical research that seeks to determine how the different messages used to invite women to catch-up screenings by the NHS Cervical Cancer Screening Programme affect attendance.

In the UK, women aged 25 to 64 are invited to attend cervical cancer screening. Earlier detection of cancer is estimated to save 4,500 lives each year. Despite this, the numbers of patients attending screening has fallen, with uptake as low as 49% in some areas of London. In 2021, the NHS Cervical Screening Programme in London began sending 'catch-up' SMS messages to invite women who had not attended their previous invitation to an appointment. In this study, the applicants seek to understand which of the different messages used for the catch-up messaging were most effective.

The NHS England Team at the North of England Commissioning support unit (NECS), who are not members of the direct care team, will extract the necessary screening dataset, including confidential patient information. The dataset will be pseudonymised before transfer to the research team at Imperial College London. The pseudonymisation key will be held by NECS until the data transfer has taken place and will then be deleted, as per NHS England's protocol.

A recommendation for class 1, 2 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 25 – 64 years who have received an initial invitation to screen between 01 April 2019 to 30 November 2019, are based in London, received an 18-week reminder letter and have not attended a cervical screening appointment at the time of reminder messages being sent out.

Confidentiality Advisory Group advice

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

1. **Clarify whether patient postcodes will be retained after conversion to Lower Super Output Area, and why a further geographical data point was needed.**

The applicants advised that patients' postcodes will not be retained following conversion. They will be used to determine deprivation level which is an important variable as it known to be associated with differing baseline uptake, as well as potential healthcare inequalities. No further geographical data point will be used. The CAG noted this information and raised no further queries.

2. **The website information is to be revised as follows:**

    a. **A simpler version of the website information, linking to the more detailed information, needs to be created.**

    b. **The website information needs to explain that a project-specific dissent mechanism is available, as well as the National Data Opt-Out.**

The applicants provided revised information, which had been amended following discussion with their communications team. The CAG noted the revised information and raised no further queries.

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

    a. **To explain that the researchers wished to look at whether the patient had attended for a smear test.**

    b. **It needs to be explained that the smear and HPV immunisation data is held by NHS England and not at local hospitals.**

The applicant provided a revised privacy notice. This included an explanation that the applicants are looking at whether people attended a smear test and clarification that this information will not be coming from hospitals but from NHS England. The CAG noted this information and raised no further queries.

Confidentiality Advisory Group advice conclusion

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

Specific conditions of support

The following sets out the specific conditions of support.

1. Favourable opinion from a Research Ethics Committee. **Confirmed:** 25 October 2022.

2. Confirmation provided from the IG Delivery Team at NHS Digital to the CAG that the relevant Data Security and Protection Toolkit (DSPT) submission(s) has achieved the 'Standards Met' threshold. See section below titled 'security assurance requirements' for further information. **Confirmed:**

   The NHS Digital **2021/22** DSPT review for North of England Commissioning support unit (NECS) was confirmed as 'Standards Met' on the NHS Digital DSPT Tracker (checked 14 November 2022).

f. 22/CAG/0165 – Shaping care home COVID-19 testing policy: A pragmatic cluster randomised controlled trial of an intervention to promote regular, asymptomatic testing in care home staff: VIVALDI-CT

Name	
Dr Sandra Duggan	CAG member
Mr David Evans	CAG member
Mr Tony Kane	CAG member
Dr Harvey Marcovitch	CAG member
Ms Rose Payne	CAG member
Ms Diana Robbins	CAG member
Mr Dan Roulstone	CAG member

Dr Murat Soncul	CAG alternative vice-chair
Ms Caroline Watchurst	HRA Confidentiality Advisor

Context

Purpose of application

This application from University College London set out the medical purpose of this research, namely to investigate the feasibility, effectiveness and cost-effectiveness of regularly testing care home staff for COVID-19 to protect residents from severe infection and prevent outbreaks. This is an important question for policymakers, residents, care home staff and providers because testing impacts heavily on each of these groups in different ways. There is a unique, finite opportunity to determine whether regular COVID-19 testing in staff is worthwhile. Engagement work with providers and care home staff has shown that the issue of testing in staff is of major importance to them. This application is funded by NIHR HSDR and UKHSA.

At the start of the pandemic, policymakers' priority was to reduce deaths, severe illness and hospital admissions. The strong link between rates of infection in the community and risk of outbreaks and severe outcomes in care home residents justified the use of staff testing to prevent infection from the community. However, most residents are now fully vaccinated (90% have received 4th dose booster vaccination), and many have been infected, which substantially reduces their risk of COVID-19 related severe outcomes. Providers' main concern is that regular testing increases the risk of unnecessary care home closures due to minor outbreaks, impacting on business continuity (loss of income from new admissions) and residents' wellbeing (e.g. restrictions on visits). Based on current evidence, it is unclear whether regular testing will increase or reduce the frequency of outbreaks. Two years into the pandemic, there remains a complete lack of evidence on whether the benefits of regular testing for COVID-19 outweigh its harms and under which scenarios.

280 participating care homes are randomised to 2 arms. The intervention arm will receive multi-component testing intervention (regular asymptomatic testing of staff for COVID-19 using LFTs combined with support payments for staff who test positive), and the control arm will follow national testing policy in place at the time. The applicant requires 's251' support for 2 elements of the application. Identifiable information regarding care home residents who are admitted to hospital during the testing period will be disclosed from the care homes to NHE England, who will link these data to the NHSE Foundry (COVID-19 datastore), which includes data on COVID-19 test results, vaccination status, hospital admissions and deaths. Additionally, identifiable information (name, DOB, NHS number, sex, postcode and CQC identifier) will be disclosed alongside any COVID-19 test taken by staff members or patients at participating care homes during the trial period, from care homes to NHS England COVID-19 testing portal. This flow does not require 's251' support, as this is undertaken as part of usual clinical care. Regarding patients, 's251' support is required for NHSE to link these data to the NHSE Foundry (COVID-19 datastore), which includes data on COVID-19 test results, vaccination status, hospital admissions

and deaths. Regarding staff, 's251' support is required for NHSE to link to the NHSE Foundry (COVID-19 datastore) but only to provide the applicant pseudonymised data on the result of the COVID-19 test taken by the staff member. No outcome data is required for staff. These data will then be pseudonymised before being provided to the research team at UCL for analysis.

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

Confidential patient information requested

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

Cohort	All staff and residents in participating care homes during the study testing period 01 December 2022 – 31 March 2023. However, it is possible that the testing period may be extended. Applicants estimate this will include approximately 15,400 staff (55 per home) and 9,800 residents (35 per home).
Data sources	1. 280 participating care homes records (from the following providers): • Four Seasons Healthcare(FSHC) • HC-One • Orders of St John Care Trust (OSJCT) 2. NHS England – COVID-19 datastore (containing COVID-19 test results, vaccination status, hospital admissions and deaths from residents and staff who are in care homes that are participating in the trial. These routine datasets are already held by NHSE in the COVID-19 Datastore)
Identifiers required for linkage purposes	Residents who are admitted to hospital during the testing period: 1. NHS number 2. Name 3. Date of birth 4. Sex (derived from CQC-ID) 5. Postcode (derived from CQC-ID)

	Plus all patients and staff who are tested for COVID-19 during the trial period; 1. NHS number 2. Name 3. Date of birth 4. Sex (derived from CQC-ID) 5. Postcode (derived from CQC-ID)
Identifiers required for analysis purposes	1. N/A – data will be pseudonymised (effectively anonymised) for analysis

Confidentiality Advisory Group advice

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

Number	Action Required	Response from the applicant
1.	Please improve the notification materials, to include the following points; a) Include the website text alongside the QR code on the poster b) Ensure that the use of confidential patient information without consent is clearly described c) Ensure that the use of 's251' as a legal bass under common law is mentioned d) Ensure the opt out options are clear e) Present the revised patient notification materials to patients to ensure they are acceptable to lay people	The applicant provided updated materials. The CAG were content that these had fulfilled the requests made by CAG, and were now content to recommend support.
2.	Please confirm the exit strategy from 's251' support, regarding if a study specific pseudo ID will be applied by NHSE instead of the generic COVID-19 Datastore pseudo ID	The applicant confirmed that this will be possible, and therefore the applicant will receive effectively anonymous data. The CAG were content with this response.

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. Please provide feedback from the ongoing planned patient and public involvement, to ensure there is support from care home residents for this use of confidential patient information without consent. Please provide this to CAG as soon as it is available, but at the latest, six months from the date 's251' support is provided. If strong objections are noticed in ongoing patient and public involvement, please inform CAG of these immediately.

2. Favourable opinion from a Research Ethics Committee. **Confirmed: FIFO with conditions 08 December 2022, and additional conditions confirmed met on 14 December 2022.**

3. Confirmation provided from the IG Delivery Team at NHS Digital to the CAG that the relevant Data Security and Protection Toolkit (DSPT) submission(s) has achieved the 'Standards Met' threshold. See section below titled 'security assurance requirements' for further information. **Confirmed:**

   The NHS Digital **21/22** DSPT reviews **NHS England** was confirmed as **'Standards Met'** on the NHS Digital DSPT Tracker (checked 18 November 2022)

   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.

g. 22/CAG/0160 – National Prospective Cohort Study and Surveillance of Sympathetic Ophthalmia in the United Kingdom

Name	
Dr Malcolm Booth	CAG member
Dr Pauline Lyseight-Jones	CAG member
Dr Murat Soncul	CAG alternative vice-chair
Ms Caroline Watchurst	HRA Confidentiality Advisor

Context

Purpose of application

This application from Moorfields Eye Hospital NHS Foundation Trust set out the purpose of medical research which aims to describe the incidence of patients newly presenting with sympathetic ophthalmia (SO) in the UK, over a one year surveillance programme operating via the British Opthalmological Surveillance Unit (BOSU) methodology, using the monthly reporting card amongst UK ophthalmologists.

SO is a condition where the eye becomes inflamed and can result in loss of vision. It is a very rare, but potentially blinding complication of surgery and ocular trauma, with no uniform consensus regarding its optimal management. In a previous BOSU study completed in 1998, 17 cases were reported for a 59 million UK population. The SO incidence following primary and revisional vitrectomy surgery needs to re-evaluated, as the decision to proceed with complex and repeated vitreoretinal procedures can be decided by the risk of SO, and perhaps a contemporary SO risk may not be directly associated with vitrectomy interventions. Therefore it is in the public interest to re-evaluate SO incidence so that clinicians and patients can better evaluate the risks and benefits of certain procedures.

The BOSU methodology is established and has received support in principle from the CAG. Ophthalmologists will anonymously indicate that they have seen a new patient who has sympathetic ophthalmia through the BOSU reporting system via University of Dundee. The University of Dundee system will generate the initial questionnaire for the reporting ophthalmologist to fill in via the University of Dundee data safe haven online platform. This will contain confidential patient information. Follow-up will be conducted at six-months following initial reporting, and the University of Dundee system will generate this questionnaire for the reporting ophthalmologist in the same manner as the initial questionnaire.

Each case will be given a unique study number by the BOSU study centre. Hospital number, month and year of birth, gender, and postcode will be recorded alongside clinical data on the questionnaires. All identifies will be deleted once the follow-up is completed, postcode is converted to deprivation score, and duplicates identified.

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

Confidential patient information requested

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

Cohort	Approximately 20 patients who have experienced sympathetic ophthalmia All patients with new onset bilateral, non-necrotising, diffuse granulomatous panuveitis affecting the fellow, sympathising eye following ocular surgery, trauma or laser therapy to the inciting eye (This patient would have a diagnosis associated with a newly-diagnosed sympathetic ophthalmia) who report to a treating ophthalmologist across the 12 months reporting period, expected to be between 01 February 2023 and 01 February 2024.
Data sources	3. Clinical records at the Trusts of BOSU reporting ophthalmologists
Identifiers required for linkage purposes	6. Hospital number (identify duplicates and identify same patient for follow up) 7. unique study number

Identifiers required for analysis purposes	1. Month and Year of birth 2. Gender 3. Postcode – converted to social deprivation score
Additional information	1 year of baseline collection 01 February 2023 and 01 February 2024, and then additional 6 month follow up until 01 August 2024.

Confidentiality Advisory Group advice

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

1. **Please provide to CAG updated patient notification material in line with advice in this letter, which reflects the updated BOSU methodology for this study involving Dundee.**

The applicant provided an updated document and the CAG confirmed that this was an acceptable response.

2. **Please provide further details about the Patient and Public Involvement undertaken, to evidence the acceptability of the use of confidential patient information without consent in this application.**

The applicant provided further details about the patient and public involvement undertaken, and the CAG agreed this was sufficient.

Confidentiality Advisory Group advice conclusion

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

Specific conditions of support

The following sets out the specific conditions of support.

1. Favourable opinion from a Research Ethics Committee. **Confirmed (with conditions) 25 April 2019. Evidence of conditions met 15 August 2019.**

2. Security assurance requirements **Confirmed:**

   Health Information Centre - University of Dundee – Data safe haven – security is assured via NHS Scotland Public Benefit and Privacy Panel for Health and Social Care (PBPP) Approval 9th April 2020, and amendment regarding new BOSU methodology 01 November 2022.

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

h. 22/CAG/0166 – How Do Healthcare Professionals Recognise and Respond to Deconditioning? A mixed-methods synthesis and consensus

Name	
Dr Patrick Coyle	CAG Vice Chair
Ms Rose Payne	CAG member
Professor Sara Randall	CAG member
Ms Katy Cassidy	HRA Confidentiality Advisor

Context

Purpose of application

This application from the University of Nottingham set out the purpose of medical research that seeks to develop a conceptual framework of how healthcare professionals currently recognise and treat hospital acquired deconditioning, with the aim of developing better treatments.

Hospital-Acquired Deconditioning is defined as a new loss of independence in activities, such as bathing, toileting, walking or eat. It is estimated to affect nearly one in three adults aged over 65 years. It is unclear how often in happens in adults aged over 18 years. The condition is associated with longer stays in hospital, increased rehabilitation or care needs on leaving hospital, and increased risk of mortality. Many programs are used to prevent and to treat the condition, but little evidence supporting their use exists.

Several work packages will be involved. Support under s251 is sought for Work Package 3, which will involve observations in two ward settings at Nottingham University Hospitals NHS Trust. The researcher will observe, and will not aid with patient care. Up to 56 hours of non-participant observation will be undertaken in two-hour blocks with variable start times. One block will occur in the spring/summer and one in the autumn/winter to reflect seasonal variation. Each two-hour block will begin at different times during the day to reflect the 24-hour influence with the earliest block beginning before the end of the nursing night shift and the latest beginning at the start of the nursing night shift.

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

Confidential patient information requested

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

Cohort	Healthcare professionals who have experience of working with people who are or who have been affected by hospital-acquired deconditioning are the cohort involved in Work Package 3.
Data sources	1. Nottingham University Hospitals NHS Trust

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

Confidentiality Advisory Group advice

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

1. **The posters need to be revised as follows:**

    a. **Patients are to be advised to speak to a member of nursing staff should they wish to be excluded from observations.**

    b. **An explanation that the researchers may be exposed to confidential patient information while conducting the observations, but that none of this information would be recorded in the researchers notes, needs to be included.**

The applicant provided revised posters. The CAG reviewed these and requested that a poster aimed at patients only, as their confidential patient information would be accessed without consent. A patient aimed poster was provided, which was reviewed and accepted by the CAG.

2. **Details on the demographic characteristics of the patient and public involvement group are to be provided.**

The applicant provided details on the demographics of participants in the patient and public involvement group. This was reviewed by the CAG who raised no further queries.

Confidentiality Advisory Group advice conclusion

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

Specific conditions of support

The following sets out the specific conditions of support.

1. Favourable opinion from a Research Ethics Committee. **Confirmed 22 November 2022.**

2. Confirmation provided from the IG Delivery Team at NHS Digital to the CAG that the relevant Data Security and Protection Toolkit (DSPT) submission(s) has achieved the 'Standards Met' threshold. See section below titled 'security assurance requirements' for further information. **Confirmed:**

   The NHS Digital **2020/21** DSPT review for Nottingham University Hospitals NHS Trust was confirmed as 'Standards Met' on the NHS Digital DSPT Tracker (checked 14 November 2022).

2. New Amendments

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

Name	Capacity
Ms Kathleen Cassidy	Confidentiality Advisor

Context

Amendment request

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

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

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

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

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

Confidentiality Advisory Group advice

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

Confidentiality Advisory Group advice conclusion

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

Specific conditions of support

The following sets out the specific conditions of support.

1. Favourable opinion from a Research Ethics Committee. **Confirmed 14 November 2022.**
2. Confirmation provided from the IG Delivery Team at NHS Digital to the CAG that the relevant Data Security and Protection Toolkit (DSPT) submission(s) has achieved the ‘Standards Met’ threshold. See section below titled ‘security assurance requirements’ for further information. **Confirmed:** The NHS Digital 2020/21 DSPT reviews for **University College London** and **NHS Digital** were confirmed as ‘Standards Met’ on the NHS Digital DSPT Tracker (checked 04 July 2022).

ECC 1-03(d)/2012 – National Gastrointestinal Cancer Audit Programme (National Bowel Cancer Audit – NBOCA)

Name	Capacity

Ms Kathleen Cassidy	Confidentiality Advisor

Context

Amendment request

The NHS Digital and Clinical Effectiveness Unit (CEU) at The Royal College of Surgeons (RCS) has been commissioned to undertake work as part of the National Bowel Cancer Audit (NBOCA) programme, which is one of the Health Quality Improvement Partnership (HQIP) commissioned national clinical audits.

In this amendment, the applicants seek to include four additional datasets, the OnCoRe: The Rectal Cancer Oncological Complete Response Database, the Cancer Quality of Life Survey (CQoL), the Radiotherapy Data Set for Wales (RTDS Wales) and the Rapid Cancer Registration Dataset. Data received from these additional sources will be used to improve the completeness and ascertain the quality of the data collected for the audit. Updated patient notification materials, which had been revised to include the additional data sources and to advise that the National Data Opt-Out would not be applied to this audit (confirmed in October 2022), were provided.

Confidentiality Advisory Group advice

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

Confidentiality Advisory Group advice conclusion

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

Specific conditions of support

The following sets out the specific conditions of support.

1. Confirmation provided from the IG Delivery Team at NHS Digital to the CAG that the relevant Data Security and Protection Toolkit (DSPT) submission(s) has achieved the ‘Standards Met’ threshold:

Confirmed: The NHS Digital 2021/22 DSPT reviews for NHS Digital and Royal College of Surgeons of England – Clinical Effectiveness Unit were confirmed as 'Standards Met' on the NHS Digital DSPT Tracker (checked 28 November 2022).

ECC 1-06(d)/2011 – National Gastrointestinal Cancer Audit Programme (Oesophago-Gastric Cancer – NOGCA)

Name	Capacity
Ms Kathleen Cassidy	Confidentiality Advisor

Context

Amendment request

The NHS Digital and Clinical Effectiveness Unit (CEU) at The Royal College of Surgeons (RCS) has been commissioned to undertake work as part of the National Oeosphago-Gastric Cancer Audit (NOGCA) programme, which is one of the Health Quality Improvement Partnership (HQIP) commissioned national clinical audits.

In this amendment, the applicants seek to include the Radiotherapy Data Set for Wales (RTDS Wales) and the Rapid Cancer Registration Dataset as data sources. Information from the additional datasets will be used to improve the completeness and ascertain the quality of data captured by the audit. Updated patient notification materials, which had been revised to include the additional data sources and to advise that the National Data Opt-Out would not be applied to this audit (confirmed in October 2022), were provided.

Confidentiality Advisory Group advice

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

Confidentiality Advisory Group advice conclusion

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

Specific conditions of support

The following sets out the specific conditions of support.

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

   Confirmed: The NHS Digital 2021/22 DSPT reviews for NHS Digital and Royal College of Surgeons of England – Clinical Effectiveness Unit were confirmed as 'Standards Met' on the NHS Digital DSPT Tracker (checked 28 November 2022).

22/CAG/0040 – A Surveillance Study of Congenital and Hospitalized Neonatal Varicella in the United Kingdom & Portugal (NEOPOX)

Name	Capacity
Ms Caroline Watchurst	HRA Confidentiality Advisor

Context

Amendment request

This application from the UK Health Security Agency (UKHSA) aims to collect data on the number of cases, severity, and treatment of FVS and babies hospitalised with neonatal varicella infections, via the BPSU standard methodology. 's251' support is currently in place to allow the disclosure of confidential patient information from the treating physician (NHS number, date of birth and full postcode) to the UKHSA, in order for them to identify duplicate reports, and link questionnaire outcomes to baseline individuals.

This amendment sought support to remove UKHSA as the data processor for the application, and to replace with the University of Dundee (UofD) Health Informatics Centre (HIC). This is per new British Paediatric Surveillance Unity (BPSU) standard methodology, as discussed with CAG and described in the precedent set categories list on the CAG website.

All data, including confidential patient information, will be collected, housed and analysed in the accredited UofD HIC Safe Haven. There is no change to the purposes of the study, the data items being collected, the time frame of the study, the exit strategy or the dissemination of results.

Confidentiality Advisory Group advice

The amendment requested was considered by the Confidentiality Advice Team. The CAT discussed with the applicant regarding the security assurance requirements. As per guidance on the CAG website, UKHSA no longer require a DSPT review for this application, as UKHSA will not be processing confidential patient information without consent. For the University of Dundee, ie. processing of English and Welsh data by a Scottish organisation, the applicant can evidence security assurances via either a DSPT or PBPP approval. The applicant assured CAT that PBPP approval for the application is already in place, and an amendment to include University of Dundee has been made. The CAG amendment will be issued on the receipt of the amendment PBPP approval.

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. Security assurances regarding University of Dundee evidenced in the form of Public Benefit and Privacy Panel for Health and Social Care (HSC-PBPP) approval on 01 June 2022, alongside associated amendment approval provided 22nd November 2022.

2. Confirmation of a favourable opinion from a Research Ethics Committee. **Confirmed 04 November 2022**

23/CAG/0006 (supersedes 20/CAG/0071) – Birmingham and Lambeth Liver Evaluation Testing Strategies - 10 Year Follow Up

Name	Capacity
Ms Caroline Watchurst	HRA Confidentiality Advisor

Context

Amendment request

This submitted information represented a new application in relation to an existing activity under application reference 20/CAG/0071. As a result of the original application not providing clarity on the controllership, the main change is that of a change of data controller, from solely University Hospitals Birmingham NHS Foundation Trust to solely University of Birmingham. In addition the applicants with to update CAG in the change of the chief investigator, from Dr James Ferguson to Professor Richard Lilford. The intention is to replace 20/CAG/0071 with this new application once support is in place.

Confidentiality Advisory Group advice

It was noted that no other changes to people, purposes, data and flows were flagged to the CAG by the applicant.

Confidentiality Advisory Group advice conclusion

The Confidentiality Advice Team therefore recommended to the Health Research Authority that the activity be supported, subject to compliance with the specific and standard conditions of support as set out below.

Specific conditions of support

The following sets out the specific conditions of support.

1. Favourable opinion from REC **Confirmed 26 March 2020 initially, and change given Favourable Opinion on 03 March 2022.**

2. Confirmation provided from the IG Delivery Team at NHS Digital to the CAG that the relevant Data Security and Protection Toolkit (DSPT) submission(s) has achieved the ‘Standards Met’ threshold. See section below titled ‘security assurance requirements’ for further information. **Confirmed:**

The 2021/22 NHS Digital DSPT reviews for **University Hospitals Birmingham NHS Foundation Trust and University of Birmingham** were confirmed as 'Standards Met' on the NHS DSPT Tracker (checked 13 December 2022).

ECC 8-02(FT5)/2010 - SABRE (Southall and Brent Revisited)

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

Context

Amendment request

This project is a follow-up of a unique cohort of 4,858 people of South Asian, African Caribbean and European origin who were aged 40 to 69 and living in northwest and west London when first studied. The South Asian and African Caribbean participants are all first generation migrants to the UK. The study set out to examine the association between insulin resistance and cardiovascular risk in people of European, South Asian and African Caribbean origins who were living in West London. The 3,400 surviving participants are now aged between 65 and 98. They underwent very detailed clinic profiling at baseline, at 20 years and a third wave of follow-up is currently in progress at 25 years. Support was initially sought in order to permit access to cancer registration and mortality data in order to link to mortality data. An amendment supported in 2017 provided 's251' support for linkage with HES data, up until 2017, in order to bring the hospital admission data up to date for this study's long-standing cohort.

This amendment sought support to extend the follow up window to allow further linkage with HES, ONS mortality, and cancer registration datasets retained by NHS digital, from 2017 until 2024. This would enable ongoing detailed analyses of mid-life risk factors and function in later life. The applicant confirmed that they expect annual extracts will be supplied from NHS Digital using a retained flag that NHS Digital already hold. Applicants do not anticipate re-supplying identifiers unless requested by NHS Digital.

Confidentiality Advisory Group advice

The amendment requested was considered by Chair's Action. The Vice-Chair was supportive of this amendment, noting the only change of process was an extension to the time window that linked data was collected. During the review of the amendment, the Vice-Chair viewed the website and found that 's251' support was not mentioned in any patient notification documentation on the website. The Vice-Chair therefore suggests that it would be good practice to amend the patient information on the website to include 's251' as the legal basis for not complying with the common law on confidentiality with regards to any patients that are not consented.

Confidentiality Advisory Group advice conclusion

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

Specific conditions of support

The following sets out the specific conditions of support.

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

   The NHS Digital 21/22 DSPT reviews for **University College London and NHS Digital** were confirmed as 'Standards Met' on the NHS Digital DSPT Tracker (checked 13 December 2022)

2. Confirmation of a favourable opinion from a Research Ethics Committee. **Confirmed 09 December 2022**

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

Name	Capacity

Ms Caroline Watchurst	HRA Confidentiality Advisor

Context

Amendment request

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

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

The amendment sought support for the addition of five new participating sites (Salisbury NHS Foundation Trust, Southport and Ormskirk NHS Trust , Stockport NHS Foundation Trust, The Princess Alexandra NHS Trust and Betsi Cadwaladr University Health Board) as data processors, 4 of which are in England, and 1 in Wales.

Confidentiality Advisory Group advice

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

Confidentiality Advisory Group advice conclusion

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

Specific conditions of support

The following sets out the specific conditions of support.

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

   The NHS Digital **21/22** DSPT review for **the University of Nottingham and the DSPT equivalent for NHS Digital** were confirmed as 'Standards Met' on the NHS Digital DSPT Tracker (checked 13 December 2022)

   Due to the number of organisations involved it is the responsibility of University of Nottingham, as controller, to ensure that all organisations processing confidential patient information without consent meet the minimum required standard in complying with DSPTs, and take remedial action if they become aware of any that fall below this, or where any concerns are raised. These will not be individually checked by CAT as there are more than 5 organisations.

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

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

17/CAG/0011 – Genetic mechanisms in polyposis of the bowel

Name	Capacity
Ms Caroline Watchurst	HRA Confidentiality Advisor

Context

Amendment request

The applicants had initially applied for support under Section 251 and its Regulations to include a cohort of up to 20 deceased patients, alongside a cohort of consented participants, which is outside the scope of this support.

The applicants confirm that they have closed to recruitment, and the number of deceased patients recruited was 5. The applicants are seeking support to to close to recruitment, but remain in follow up until 31 August 2025. This will allow applicants to collect any remaining data held for these patients and complete sequencing, where applicable.

The amendment also sought support to allow anonymised genetic, genomic and demographic data including age, gender and relevant medical history, to be deposited in a data repository (such as European Genome-Phenome Archive) so it can be used for future research and learning.

Confidentiality Advisory Group advice

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

Confidentiality Advisory Group advice conclusion

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

Specific conditions of support

The following sets out the specific conditions of support.

1. Confirmation provided from the IG Delivery Team at NHS Digital to the CAG that the relevant Data Security and Protection Toolkit (DSPT) submission(s) has achieved the 'Standards Met' threshold: **Confirmed: Cardiff University confirmed 'Standards Met' on DSPT 21/22 (by check of DSPT Tracker 13 December 2022)**

2. Confirmation of a favourable opinion from a Research Ethics Committee
   Confirmed 27 July 2022

19/CAG/0149 – Mammographic Predictors of Cancer Recurrence after Breast Conservation and Adjuvant Endocrine Therapy

Name	Capacity
Ms Caroline Watchurst	HRA Confidentiality Advisor

Context

Amendment request

This application from the University of Dundee aims to prove whether a reduction in breast density is a physiological sign that endocrine treatment provided to women with breast cancer is effective in keeping the cancer away. Support is in place to allow the disclosure of confidential patient information contained within mammogram images from trial sites which participated in the Mammo50 trial to the Royal Surrey County Hospital.

This amendment sought to extend the duration of support until 31 August 2024, due to delays caused by the Covid-19 pandemic.

Confidentiality Advisory Group advice

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

Confidentiality Advisory Group advice conclusion

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

Specific conditions of support

The following sets out the specific conditions of support.

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

   The NHS Digital 21/22 DSPT review for **Royal Surrey County Hospital** was confirmed as 'Standards Met' on the NHS Digital DSPT Tracker (checked 14 December 2022)

2. Confirmation of a favourable opinion from a Research Ethics Committee. **Confirmed non substantial 08 September 2022**

19/CAG/0149 – Mammographic Predictors of Cancer Recurrence after Breast Conservation and Adjuvant Endocrine Therapy

Name	Capacity
Ms Caroline Watchurst	HRA Confidentiality Advisor

Context

Amendment request

This application from the University of Dundee aims to prove whether a reduction in breast density is a physiological sign that endocrine treatment provided to women with breast cancer is effective in keeping the cancer away. Support is in place to allow the disclosure of confidential patient information contained within mammogram images from trial sites which participated in the Mammo50 trial to the Royal Surrey County Hospital.

This amendment sought 's251' support for a temporary change of Chief Investigator from Mrs E. Jane Macaskill to Dr Sarah Savaridas.

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

Confidentiality Advisory Group advice conclusion

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

Specific conditions of support

The following sets out the specific conditions of support.

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

   The NHS Digital 21/22 DSPT review for **Royal Surrey County Hospital** was confirmed as 'Standards Met' on the NHS Digital DSPT Tracker (checked 14 December 2022)

2. Confirmation of a favourable opinion from a Research Ethics Committee. **Confirmed 06 December 2022**

22/CAG/0070 – Implementation of an artificial intelligence module on the online imaging portal MYO-Share for guiding the diagnosis of muscle diseases

Name	Capacity
Ms Caroline Watchurst	HRA Confidentiality Advisor

Context

Amendment request

This application from Newcastle University aims to create an improved version of a machine-learning algorithm called MYO-Guide. ‘s251’ support is in place to allow research staff who are not part of the direct care team to access name, NHS number and date of birth to search for eligible patients in NHS medical and research records, whilst also anonymising MRI scans by removing the name, date of birth and NHS number from the images at the same time as screening records for eligibility.

This amendment sought ‘s251’ support to include St Georges University Hospital NHS Foundation Trust as an additional participating site, and data processor for the CAG application.

Confidentiality Advisory Group advice

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

Confidentiality Advisory Group advice conclusion

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

Specific conditions of support

The following sets out the specific conditions of support.

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

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

2. Confirmation of a favourable opinion from a Research Ethics Committee. **Confirmed non substantial 09 November 2022**

19/CAG/0047 – Development and validation of a risk assessment tool for self-harm in prisoners.

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

Context

Amendment request

This study has support to allow access to prisoner health records by a research assistant to extract wider clinical information necessary for analysis. 'S251' support is in place for this access in a variety of ways, including in person, accessing ACCT records via a link person, extracting data from electronic prison healthcare notes (SystmOne), and accessing Prison National Offender Management Information System (NOMIS) data. The study is comprised of three elements. Support under 's251' was only required for the stage 1 of the project, to create a risk assessment tool (RAT) to predict repeat self-harm, in a population of prisoners who had an ACCT. This is a paper record filled in by prison officers regarding self harm. The CAG supported the application on the basis that patients would be consented into stage 3 of the project.

This amendment sought 's251' support to undertake stage 3 of the study, the aim of which is to evaluate and validate the developed RAT and test the tool's predictive ability in a new cohort of prisoners. Consent will now not be sought because generalisability is very important, and if seeking consent, many prisoners would decline, and in order to properly validate the tool, it is important that a full non biased range of data is collected.

Applicants request 's251' support for access to ACCT records, SystmOne, (SystmOne only has ACCT information recorded if a person has gone to get treatment, and so

sometimes no information will be on SystmOne), and also NOMIS, which although usually wouldn't be considered confidential patient information, as it is usually used to find out why someone is in prison, the applicant is accessing NOMIS only to check if another ACCT has been submitted within 3 months of the index ACCT. It could in this case therefore be considered confidential patient information and in scope for 's251' support.

The new cohort of prisoners will be approximately 500 people, from 12 different prisons, which are listed as part of the amendment submission (although these may change from those named). The prisoners must have had an ACCT closed between 3-6 months prior to the census date. This will allow the applicant to collect baseline data and 3 months follow up data in one extract. In line with original support, a link person in each prison will identify these individuals, and disclose the paper ACCT records to the researchers, who will go into each of the 12 sites, and extract the data from ACCT records. ACCT records will not leave the prisons. The only identifier collected at that time will be prisoner ID, to link between the systems. Also in line with original support, The researcher will then use prisoner ID to link to SystmOne to extract additional clinical data about the event, if it is available, and link to NOMIS to extract information regarding if another ACCT has been filled in within 3 months of the index ACCT. The information on NOMIS about any other ACCT will appear as a date only. The applicant also wishes to identify the reason for this ACCT, to find out if it was self-harm or not. This will be done using the prison ID to link, via the study link person at each prison – the query being – is this ACCT because of self-harm? With the answer collected being either 'yes' or 'no'.

At each site, data will be inputted into a database on an encrypted laptop which will contain the prison unique identifier (prison number) and an associated study ID. Once data collection has been completed, the unique identifier (prison number) will be removed and each individual effectively anonymous dataset will be transferred to the University of Oxford. Each separate organisation involved has a data sharing agreement with the University of Oxford. A pseudo-anonymisation key which will contain the unique identifier (prison number) and study ID will be stored at each respective organisation on a secure server. This data will be disposed of after 3 years of the study endpoint, as per previous agreements.

The applicant has developed patient notification materials for stage 3.

Confidentiality Advisory Group advice
The amendment requested was considered by Chair's Action. The Vice-Chair considered that he was content to consider stage 3 an extension of stage 1, as the methodology is the same, rather than request a new application. As such, he was willing to recommend support, albeit noted that this should not be seen as a precedent.

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

Specific conditions of support

The following sets out the specific conditions of support.

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

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

2. Confirmation of a favourable opinion from a Research Ethics Committee.
   Confirmed 28 November 2022.

20/CAG/0101 – FFRCT In Stable Heart disease & CTA Helps Improve Patient care and Societal costs

Name	Capacity
Ms Caroline Watchurst	HRA Confidentiality Advisor

Context

Amendment request

This application from Liverpool Heart and Chest Hospital NHS Foundation Trust aims to determine which of two diagnostic pathways are superior in the chest pain pathway. 's251' support is in place to allow the disclosure of confidential patient information from NHS Trusts to NHS Digital and, from NHS Trusts, NHS Digital and Heartflow to Liverpool Heart and Chest Hospital NHS Foundation Trust for linkage purposes.

This amendment sought support to include NHS Business Services Authority (BSA) dataset as a data source, (retained by NHS England, previously NHS Digital). This is to enable applicants to extract information about the medications patients were on. Specifically, the type, dose and whether the medicine was processed. This is important to the study outcomes for 2 reasons:

1. To identify what medications patients are on, as this will contribute to the total NHS costs and could impact on clinical outcomes.
2. To ensure that any observed difference in outcomes between the FFRCT and standard care group were not due to differences in medications (particularly statins).

This information was not available on the admitted patient care database, and therefore NHS Digital advised that the applicant will need to link to the NHS Business Services Authority (BSA) dataset to retrieve this information. As the NHS BSA dataset was not specified in the CAG application, this amendment was required. There are no other changes to the application.

Confidentiality Advisory Group advice

The amendment requested was considered by the Confidentiality Advice Team, who raised no queries regarding this amendment. The data source has been listed as being retained by NHS England (previously NHS Digital), to avoid any issues regarding the upcoming changes to these organisations.

Confidentiality Advisory Group advice conclusion

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

Specific conditions of support

The following sets out the specific conditions of support.

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

   The NHS Digital 21/22 DSPT review for **Liverpool Heart and Chest Hospital NHS Foundation Trust** was confirmed as 'Standards Met' on the NHS Digital DSPT Tracker (checked 19 December 2022)

2. Confirmation of a favourable opinion from a Research Ethics Committee. **Confirmed no REC review required by email 30 November 2022**

18/CAG/0126– Connected Health Cities: Data linkage of urgent care data

Name	Capacity
Ms Caroline Watchurst	HRA Confidentiality Advisor

Context

Amendment request

The applicants have existing support to create a research database, in which routine NHS data from a number of providers of emergency and urgent care (EUC) in the Yorkshire and Humber region is collected and linked to provide a coherent picture of EUC demand in the region.

The original data linkage has been completed, however the applicants are now seeking support to delay the deletion of the patient identifiers until 25 June 2023,

which will allow them to undertake further data linkages, for which a separate new CAG application has been already supported (22/CAG/0019).

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

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

Specific conditions of support

The following sets out the specific conditions of support.

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

   The NHS Digital **21/22** DSPT reviews for **Sheffield Teaching Hospitals NHS Foundation Trust**, and **University of Sheffield School of Health and Related Research** were confirmed as 'Standards Met' on the NHS Digital DSPT Tracker (checked 20 December 2022)

2. Confirmation of a favourable opinion from a Research Ethics Committee.
   Confirmed non substantial 13 January 2022.

22/CAG/0070 – Implementation of an artificial intelligence module on the online imaging portal MYO-Share for guiding the diagnosis of muscle diseases

Name	Capacity

Ms Caroline Watchurst	HRA Confidentiality Advisor

Context

Amendment request

This application from Newcastle University aims to create an improved version of a machine-learning algorithm called MYO-Guide. ‘s251’ support is in place to allow research staff who are not part of the direct care team to access name, NHS number and date of birth to search for eligible patients in NHS medical and research records, whilst also anonymising MRI scans by removing the name, date of birth and NHS number from the images at the same time as screening records for eligibility.

This amendment sought ‘s251’ support to include The Leeds Teaching Hospitals NHS Trust as an additional participating site, and data processor for the CAG application.

Confidentiality Advisory Group advice

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

Confidentiality Advisory Group advice conclusion

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

Specific conditions of support

The following sets out the specific conditions of support.

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

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

2. Confirmation of a favourable opinion from a Research Ethics Committee. **Confirmed as non substantial 20 December 2022**

22/CAG/0014 – The Trauma Audit & Research Network (TARN)

Name	Capacity
Ms Caroline Watchurst	HRA Confidentiality Advisor

Context

Amendment request

Support is in place for clinical teams at Trusts and Health boards (England & Wales) to input data (including identifiers) to the Trauma Audit and Research Network (TARN), at The University of Manchester for the purposes of national clinical audit. Support is also in place for NHS Digital and Digital Health and Care Wales (DHCW) to disclose confidential patient information linked to outcome data for all English/Welsh patients with specified trauma ICD 10 codes to TARN, for the purposes of linking to TARN data, and for TARN to disclose this on to individual Trusts, for the purposes of validation.

This amendment sought support for the addition of a new third party data processor, MDSAS Limited (Medical Data Solutions and Services), for the purposes of maintaining and monitoring the current TARN data collection system. MDSAS will provide essential support and maintenance of the TARN data collection system. Without their input, TARN would not have a way of maintaining or repairing the system should something go wrong, which could significantly compromise TARN's ability to function as a National Clinical Audit.

MDSAS will have access to TARN servers for the purposes for maintenance and support, there will be no flow of data to or from MDSAS. MDSAS do not require access to identifiable information to undertake their maintenance and support, and the data is encrypted on the TARN servers. However, the key to decrypt identifiable information is contained within the database and, due to the age of the eDCR system, it is not possible to remove this key without de-stabilising eDCR, so in theory it could be possible for MDSAS to decrypt identifiable information, and therefore 's251' support is required. Mitigation has been put in place by the University of Manchester (who host the TARN server), ensuring that the contractual terms with MDSAS are as robust as possible. The risk has been reviewed and accepted by the University of Manchester, until such time as a new data collection system has been developed and rolled out to Trusts (currently in the planning stage).

The TARN website has been updated with this information.

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

   The NHS Digital **21/22** DSPT reviews for **The Trauma Audit & Research Network (J160), University of Manchester** (re data safe haven storage of HES and ONS data), **NHS Digital, Quality Health, and Medical Data**

Solutions and Services (MSDAS) were confirmed as '**Standards Met'** on the NHS Digital DSPT Tracker (checked 14 December 2022)

Department of Health and Care Wales (DHCW) has a Caldicott Principles into Practice (CPiP) Out-turn report with a score of 97.5%, and improvement plan for 20/21 provided 9th June 2021.

Due to the number of participating care providers involved it is the responsibility of TARN, as controller, to ensure that all organisations disclosing confidential patient information to TARN 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.

22/CAG/0014 – The Trauma Audit & Research Network (TARN)

Name	Capacity
Ms Caroline Watchurst	HRA Confidentiality Advisor

Context

Amendment request

Support is in place for clinical teams at Trusts and Health boards (England & Wales) to input data (including identifiers) to the Trauma Audit and Research Network (TARN), at The University of Manchester for the purposes of national clinical audit. Support is also in place for NHS Digital and Digital Health and Care Wales (DHCW) to disclose confidential patient information linked to outcome data for all English/Welsh patients with specified trauma ICD 10 codes to TARN, for the purposes of linking to TARN data, and for TARN to disclose this on to individual Trusts, for the purposes of validation.

This amendment sought support to include a further purpose into the current TARN application. TARN have been approached by the Department for Transport (DfT) to support them on a project looking at patterns of serious injuries associated with e-scooter collisions in England. There are concerns in this area at present and there has been little work looking at clinical outcomes of e-scooter use.

The project would involve linkage of STATS-19 police data with the TARN database so that a better understanding can be had and have the potential to form a basis for future policy making. The project will not involve disclosure of any confidential patient information to DfT - only partial patient postcode will be shared to enhance the linkage. However, TARN would be sharing data that had been collected under 's251' for a different purpose to the original TARN application, hence the amendment request.

Confidentiality Advisory Group advice

The amendment requested was considered by the Confidentiality Advice Team. This amendment was discussed with the applicant prior to submission, and handling route agreed. No confidential patient information is processed as part of the proposed linkage, but the purposes of the application have been amended accordingly.

Confidentiality Advisory Group advice conclusion

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

Specific conditions of support

The following sets out the specific conditions of support.

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

   The NHS Digital **21/22** DSPT reviews for **The Trauma Audit & Research Network (J160), University of Manchester** (re data safe haven storage of

HES and ONS data), **NHS Digital, Quality Health, and Medical Data Solutions and Services (MSDAS)** were confirmed as '**Standards Met'** on the NHS Digital DSPT Tracker (checked 14 December 2022)

Department of Health and Care Wales (DHCW) has a Caldicott Principles into Practice (CPiP) Out-turn report with a score of 97.5%, and improvement plan for 20/21 provided 9th June 2021.

Due to the number of participating care providers involved it is the responsibility of TARN, as controller, to ensure that all organisations disclosing confidential patient information to TARN 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.

18/CAG/0166 – National Clinical Audit for Specialist Rehabilitation following major Injury (NCASRI) – Transfer of Controllership Arrangements

Name	Capacity
Ms Caroline Watchurst	HRA Confidentiality Advisor

Context

Amendment request

In 2018, the applicants were given support to change the data controller for the National Clinical Audit of Specialist Rehabilitation following Major Injury (NCASRI) from HQIP to TARN. This support was given only for the continued holding of the dataset and not for other processing of the dataset.

In an amendment supported in 2021, the applicants have 's251' support to allow the NCASRI dataset to be used for further data linkages with UK

Specialist Rehabilitation Outcomes Collaborative (UKROC). The applicants anticipated that this linkage process would be completed by April 2022.

This amendment sought support to extend the duration of support for the previous amendment, until November 2023, in order to complete the requested linkages, which were delayed due to the Covid-19 pandemic.

Confidentiality Advisory Group advice

The amendment request was considered by the Confidentiality Advice Team, who raised no queries with this amendment, and noted that the applicants overall support, (conveyed via an annual review supported on 09 December 2022), to retain the confidential patient information in the NCARSI database, was supported until the next annual review only, and this ongoing retention will be considered on an annual basis. The due date for the next annual review is 16 November 2023.

Confidentiality Advisory Group advice conclusion

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

Specific conditions of support

The following sets out the specific conditions of support.

1. Confirmation provided from the IG Delivery Team at NHS Digital to the CAG that the relevant Data Security and Protection Toolkit (DSPT) submission(s) has achieved the 'Standards Met' threshold: **Confirmed:** The NHS Digital 2021/22 DSPT review for Trauma Audit and Research Network, was confirmed as 'Standards Met' on the NHS Digital DSPT Tracker (checked 14 December 2022)

CAG 8-03(PR11)/2013 - Hip Fracture Audit

Name	Capacity
Ms Caroline Watchurst	HRA Confidentiality Advisor

Context

Amendment request

In December 2018, the applicants were given support, via submission of an amendment, to include the National Audit of Inpatient Falls (NAIF) under the existing 's251 support' for the Hip Fracture Audit. The first phase of this new audit began in January 2019, and included a small dataset, completed by the falls team at participating trusts by retrospective case note review. The main aim of the first phase was to pilot the new audit process, which involved identifying the trust or heath board in which an inpatient fall occurred and ensuring that the falls team provided the relevant patient data. The second phase began in January 2020, and utilised a fuller dataset, collecting data on management prior to the facture-causing fall. Amendments to the dataset, in line with amendments submitted and given support for the National Hip Fracture Database (NHFD), were also made. Two amendments, making these changes, were submitted and given support in November 2019.

Updated data collection began in January 2021, after an amendment was supported on 27 November 2020 to reduce the dataset for NAIF, and to include an audit of both falls prevention activity prior to the hip or femoral fracture and the immediate post-fall care. The dataset collection questions were to be reviewed at the end of 2021 by the multidisciplinary advisory group for NAIF and a further amendment was to be submitted, if needed. A further amendment was supported to include 5 new questions into the dataset from January 2022.

This amendment sought 's251' support to include further data collected from January 2023. In January 2023 the dataset will mostly remain the same to encourage data accuracy. There will be one new question with four subset questions in the dataset, which have been added to gather more detailed data on patient safety measures followed for patients before a fall occurred. The phase 5 dataset will include 55 questions in total.

No additional items of confidential patient information will be collected as part of this amendment, and all data flows remain the same.

Confidentiality Advisory Group advice

The amendment requested was considered by the Confidentiality Advice team (CAT). CAT reviewed the information provided, and as the amendment was not making any changes to the confidential patient information being processed without consent, no queries were raised regarding this amendment. This amendment is being sent in advance of a new stand-alone NAIF application, as CAG have requested that NAIF be split out from the main Hip fracture audit, which itself requires a refreshed application to split out its functions into research and non-research.

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. The applicant is to split out the NAIF application from the hip fracture audit via new separate application to CAG.

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

   The NHS Digital **21/22** DSPT reviews for **Royal College of Physicians, Crown Informatics University of Bristol - Bristol Medical School** were confirmed as 'Standards Met' on the NHS Digital DSPT Tracker (checked 14 December 2022)

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

Name	Capacity

Ms Katy Cassidy	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.

In this amendment, the applicants provided updated patient notification materials and protocol, which had been revised following review by a Patient and Public Involvement Group.

Confidentiality Advisory Group advice

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

Confidentiality Advisory Group advice conclusion

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

Specific conditions of support

The following sets out the specific conditions of support.

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

   The NHS Digital **2020/21** DSPT reviews for **Oxford University Hospitals NHS Foundation Trust**, and **Oxford University** were confirmed as '**Standards Met'** on the NHS Digital DSPT Tracker (checked 21 December 2022).

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 08 December 2022 that REC review is not required.

3. Annual Review Approvals

18/CAG/0166	National Clinical Audit for Specialist Rehabilitation following major Injury (NCASRI)
CAG 8-06 (b)/2013	National Asthma and Chronic Obstructive Pulmonary Disease (COPD) Audit Programme (NACAP)
21/CAG/0147	2021 NHS Adult Inpatient Main Stage Survey – Mixed Methods
20/CAG/0064	Health, education and social outcomes of children with visual impairment and blindness (VI/SVIBL)
19/CAG/0101	Oxfordshire Cerebrovascular Research Database
18/CAG/0038	Yorkshire Lung Screening Trial
CAG 1-07(c)/2014	Long-term effects of whole blood and platelet donation
18/CAG/0177	Evaluation of the medium to long term impact of commercial open-group behavioural weight loss programmes on body weight and diabetes risk in adults with overweight and obesity.
17/CAG/0176	A Risk-adjusted and Anatomically Stratified Cohort Comparison Study on Open Surgery, Endovascular Techniques and Medical Management for Juxtarenal Aortic Aneurysms: (UK-COMPASS)
21/CAG/0182	PriDem: Best Practice in Primary Care Led Dementia Support
CAG 9-08(d)/2014	BioResource in Adult Infectious Disease (BioAID) 2019-2024
21/CAG/0133	Mortality and morbidity outcomes after aortovascular surgery in patients with Marfan Syndrome: A UK experience

16/CAG/0087	Epidemiology of Critical Care provision after surgery (EpiCCs)
20/CAG/0149	Yorkshire & Humberside Haematology Network Register
19/CAG/0164	Investigation of gender mortality differences in children admitted to UK Paediatric Intensive Care Units
19/CAG/0166	HPS2-THRIVE trial legacy study: long-term follow-up of participants using electronic health records
19/CAG/0167	SEARCH trial legacy study: long-term follow-up of participants using electronic health records
15/CAG/0166	UK Shunt Registry (UKSR)
18/CAG/0156	Is the current threshold for diagnosis of 'abnormality', including non ST elevation myocardial infarction, using raised highly sensitive tropin appropriate fora hosptial population? The CHARIOT study
19/CAG/0044	Evaluating the two-week wait referral system for bowel cancer
19/CAG/0018	Understanding the health needs of mothers involved in family court case: A research study exploring linkage between family court and health data
19/CAG/0150	Long-term vascular complications in young people with childhood-onset type 1 diabetes
20/CAG/0127	Admissions far away from home or to adult wards - understanding the impact of current practices for accessing inpatient care for adolescents with mental health difficulties: a surveillance study
PIAG 4-07(j)/2002	Multicentre randomised controlled trial of ‘once only’ flexible sigmoidoscopy in prevention of colorectal cancer morbidity and mortality
PIAG 3-04(FT3)/2006	Multicentre randomised controlled trial of ‘once only’ flexible sigmoidoscopy in prevention of colorectal cancer morbidity and mortality
17/CAG/0180	Whitehall Study-1
PIAG 4-08 (d)/2003	National Confidential Inquiry into Suicide and Homicide by People with Mental Illness

20/CAG/0105	National Clinical Audit of Psychosis
CAG 6-06(b)/2014	Congenital Anomaly Register and Information Service for Wales (CARIS) including Rare Disease Registration
20/CAG/0068	South London and Maudsley NHS Foundation Trust CRIS data linkage with the National Pupil Database
CAG 2-07(c)/2013	The Pesticide Users' Health Study
20/CAG/0106	The SUFFICE CoV-Study
20/CAG/0113	Heart Protection Study Long-term Follow-up: A randomised study of the effects on mortality and morbidity of HMG CoA reductase inhibitors and of antioxidant vitamins in a wide range of people at high risk of coronary heart disease

Signed – Chair	Date
Dr Tony Calland, MBE, CAG Chair, Dr Patrick Coyle, CAG Vice-Chair, Dr Murat Soncul & Professor William Bernal, & Ms Clare Sanderson, CAG Alternate Vice-Chairs	*12 January 2022*

Signed – Confidentiality Advice Team	Date
Ms Caroline Watchurst, HRA Confidentiality Advisor	*09 January 2023*