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

October 2022

1. New Applications

a. 22/CAG/0123 - A single-centre, retrospective cohort study of CT head pathologies in infants and toddlers presenting to ED due to head injury from an accidental fall

Name	
Professor William Bernal	CAG alternative vice-chair
Mr David Evans	CAG member
Ms Rose Payne	CAG member
Ms Caroline Watchurst	HRA Confidentiality Advisor

Context

Purpose of application

This application from Oxford University Hospital NHS Foundation Trust set out the purpose of medical research which aims to identify the range of cranial and intracranial injury, and the effect of fall height and surface on levels of head injury, in CT heads of infants and toddlers after accidental head injury due to falls. Applicants will undertake

a retrospective, data-analysis only, cohort study of infants and toddlers (≤2 years) who presented to the Emergency department (ED) with head injuries due to a fall within a 10 year period at the John Radcliffe hospital, and who underwent a CT scan to examine the consequences of those injuries. Applicants will be looking at CT scans of the heads of those children who suffered falls and identifying patterns of intracranial and cranial injury. 's251' support is required, as confidential patient information will be processed in order to link scans to clinical history using local medical records, to extract an anonymised dataset for analysis, and this will be undertaken by a medical student who is not considered part of the direct care team.

Paediatric head trauma is an important cause of hospital attendance in young children. While these injuries are mainly minor, some result in intracranial and cranial injury which is observable on CT head. A significant proportion of these head injuries is due to falls. Although there is reasonable data regarding the indications for CT in such injuries, very little is understood about the effect of the characteristics of falls on the possible intracranial and cranial injuries sustained. Results from this study will aim to help clinicians to better understand the expected spectrum of particular patterns of injury on CT head caused by a fall from a given height. Applicants also aim to identify the existence of 'outlier findings' on CT head of children who have suffered accidental injuries. There is a danger that these very uncommon injuries are more likely to be labelled as the result of abuse due to their rarity. This should improve healthcare for patients as it will clarify the CT findings which may be found as a result of accidental head injury, and reciprocally will clarify the injuries which are not seen (or are extremely unlikely) due to accidental injury. The study aims to better understand the relationship between intracranial injury and nature of fall to improve patient care in the future.

Data will be collected from the CRIS imaging database and cross-referenced with patient notes (via ORBIT and EPR, electronic patient records at the Trust) to link to clinical information regarding patients admission to ED, using MRN number (hospital ID). After this linkage has been undertaken, the patient's MRN number will be removed from the dataset for analysis. A pseudo ID will be applied. A link between the MRN number and the pseudo ID will be maintained in a separate, password protected database on hospital servers, and this will be deleted at the end of the study.

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

Confidential patient information requested

The following sets out a summary of the specified cohort, listed data sources and key identifiers. Where applicable, full datasets and data flows are provided in the application

form and relevant supporting documentation as this letter represents only a summary of the full detail.

Cohort	Infants and toddlers (≤2 years) who presented to the ED with head injuries due to a fall within a 10 year period (1 January 2012-1 January 2022) at the John Radcliffe hospital, and who underwent a CT scan to examine the consequences of those injuries Applicant has estimated 100 patients will meet the inclusion criteria. However 's251' required for all those viewed by the researcher who is not considered direct care team (ie. all infants who presented to ED with head injury and had a CT head), and the applicant estimates this to be about 300
Data sources	1. Medical records at John Radcliffe Hospital (part of Oxford University Hospital NHS Foundation Trust) including CRIS, ORBIT and EPR reporting systems, and CT scans
Identifiers required for linkage purposes	1. MRN number (hospital ID) 2. Date of birth 3. Online medical records will be viewed in order to extract a dataset for analysis
Identifiers required for analysis purposes	1. Date of birth modified to age at scan. 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 the Favourable Opinion of the Research Ethics Committee when available.**

The applicant has provided the Favourable Opinion of the REC as per standard condition of support.

Confidentiality Advisory Group advice conclusion

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

Specific conditions of support

The following sets out the specific conditions of support.

1. Favourable opinion from a Research Ethics Committee. **Confirmed 05 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 **21/22** DSPT review for **Oxford University Hospital NHS Foundation Trust** was confirmed as 'Standards Met' on the NHS Digital DSPT Tracker (checked 03 October 2022)

b. 22/CAG/0122 - Radiotherapy for Oropharyngeal Cancer and impact on Neurocognition. Short title: ROC-ON

Name	
Dr Katie Harron	CAG member
Professor Sara Randall	CAG member
Dr Murat Soncul	CAG alternative vice-chair

Ms Caroline Watchurst	HRA Confidentiality Advisor

Context

Purpose of application

This application from The University of Leeds set out the purpose of medical research of conducting a questionnaire study to evaluate the long term fatigue and neurocognitive impairment in patients who have received radiotherapy for oropharyngeal cancer. This application to CAG is only for contacting and inviting eligible patients to consent to the study.

Oropharyngeal cancer (OPC) is a type of head and neck cancer that develops in the oropharynx (the region in and near the tonsil). Patients treated with radiotherapy for OPC receive a low dose of radiotherapy to the base of the brain. This could lead to late effects including fatigue and neurocognitive deficits (in e.g., memory, language, processing speed and attention). Findings can help with better information provision, management and/or mitigation of late effects of radiotherapy. This study will help determine whether the base of the brain should be avoided when treating future head and neck cancer patients with radiotherapy and will encourage inclusion of neurocognitive function as a primary or secondary endpoint in future head and neck cancer radiotherapy trials.

Eligible patients will be identified by members of the direct care team at each site, this will include a check to ensure no invite is sent to a patient who has had OPC recurrence or is deceased. The National data opt out will be applied at this stage. A database at each site will be created containing patient name, address, NHS number and an allocated study number. This will remain on the NHS site servers. ‘s251’ support is requested for members of the research team at each site, who are not members of the direct care team, to invite participants by post to consent to complete a survey consisting of several validated questionnaires. Participants will also be invited to complete the Amsterdam Cognition Scan (ACS) online as a measure of neurocognition. A sample of participants will be asked to partake in semi-structured qualitative interviews. If the survey is not completed, after four weeks, then a reminder will be sent out.

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

Confidential patient information requested

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

Cohort	Adult Oropharyngeal cancer (OPC) patients, irradiated over the previous 10 years, ≥ 2 years after treatment, and remain disease free An invite to take part in the study will be sent out to around 1000 potential respondents.
Data sources	Pre-existing clinical databases - 1. Leeds Cancer Centre (Leeds Teaching Hospitals NHS Trust) 2. The Christie Hospital NHS Trust
Identifiers required for inviting patients to consent	1. Names 2. addresses 3. NHS numbers
Identifiers required for analysis purposes	1. N/A all data for analysis is collected with consent

Confidentiality Advisory Group advice

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

2. **Please provide the favourable opinion from the REC, as per standard condition of support below**

The applicant provided this on 09 October 2022.

Response to condition

This applicant also responded to a provisional condition as part of the response to provisional. The applicant response was considered by a sub-committee of the CAG.

1. **Please update the PIS with the terminology surrounding CAG support, and provide for CAG review withing one month of the date support provided.**

The applicant provided an updated document, with the changes made as requested. The CAG were content with the changes made.

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 07 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 **21/22** DSPT reviews for **Leeds Cancer Centre (Leeds Teaching Hospitals NHS Trust) and The Christie Hospital NHS Trust** were confirmed as '**Standards Met'** on the NHS Digital DSPT Tracker (checked 09 September 2022)

c. 22/CAG/0062 - A Study of Cardiovascular Events iN Diabetes – PLUS

Name	
Dr Patrick Coyle	CAG vice-chair
Ms Clare Sanderson	CAG alternative vice-chair
Dr Malcolm Booth	CAG member
Dr Harvey Marcovitch	CAG member
Mr Umar Sabat	CAG member
Ms Kathleen Cassidy	Confidentiality Advisor

Context

Purpose of application

This application from the University of Oxford set out the purpose of medical research that seeks to determine whether use of Semaglutide can safely help to reduce cardiovascular problems in patients with Type 2 diabetes who have not previously had a heart attack or stroke.

People with type 2 diabetes mellitus (T2DM) are at twice the risk of suffering cardiovascular events, such as heart attacks and stroke, compared to those without diabetes. Previous large-scale randomised clinical trials conducted involving patients with T2DM who have, or are at a high risk of developing, cardiovascular disease have established that treatment with glucagon-like peptide-1 (GLP-1) receptor agonists reduced cardiovascular events. The treatments can also improve blood sugar control, reduce weight and blood pressure, and may also reduce deterioration in kidney function and the metabolic complications of T2DM. However, such treatments require regular injections and uptake of the treatments are low in the UK and globally. Oral Semaglutide

is the first oral GLP-1 receptor agonist. Its effects on blood sugar, weight and blood pressure are similar to injectable GLP-1 receptor agonists. The trials conducted so far have involved patients with T2DM and existing cardiovascular disease, or who are at a high risk of developing cardiovascular disease. The applicants seek to conduct a trial to assess whether oral Semaglutide should be used in a broad range of people with T2DM at moderate to high cardiovascular risk.

NHS Digital will identify potentially eligible patients. The National Data Opt-Out will be applied, as well as a study specific opt-out. NHS Digital will also undertake a vital status check and obtain up-to-date addresses. The data linkages undertaken at NHS Digital will be carried out under Directions, in line with the Pilot NHS DigiTrials Recruitment Support Services Direction 2021. Support is required to disclose the dataset, containing confidential patient information, will be disclosed to Paragon Customer Communications. Paragon generate the invitation letter with patients NHS numbers securely encoded into the Replay Form and then send the invitation letters and information sheets to patients. Patients wishing to take part then send the Reply Form to the study team in Oxford. The patients' participation will then proceed on a consented basis.

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

Confidential patient information requested

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

Cohort	Patients aged 55 years and over diagnosed with Type 2 diabetes.
Data sources	1. NHS Digital held datasets: a. Hospital Episode Statistics Admitted Patient Care b. NHS BSA Medicines Dataset c. Personal Demographics Service Dataset
Identifiers required for linkage purposes	1. Name 2. NHS number 3. GP registration 4. Date of birth 5. Postcode – unit level

Identifiers required for analysis purposes	1. Name 2. Date of birth 3. Postcode – unit level 4. 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. **The patient notification materials need to be revised as follows:**

    a. **The Initial Invitation Letter needs to advise patients that they can request not to be contacted again and give telephone, postal and email contacts to do so.**

    b. **The patient information leaflet needs to explain the role of DigiTrials and how confidential patient information was processed to identify and contact patients.**

    c. **The patient facing materials need to be revised to state that no additional hospital or clinic visits are required, rather than no hospital or clinic visits are required.**

Revised documents were provided. These were 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 19 May 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 **NHS Digital** and **Paragon Customer Communications** were confirmed as 'Standards Met' on the NHS Digital DSPT Tracker (checked 26 September 2022).

c. 22/CAG/0039 - An investigation into effective Antimicrobial Stewardship (AMS) Strategies during a pandemic (COVID-19) in an acute care setting

Name	
Dr Will Bernal	CAG alternative vice-chair
Dr Malcolm Booth	CAG member
Ms Sophie Brannen	CAG member
Ms Kathleen Cassidy	Confidentiality Advisor

Context

Purpose of application

This application from University of Hertfordshire sets out the purpose of medical research that seeks to investigate the effectiveness of antimicrobial stewardship (AMS) during the Covid-19 pandemic in Luton and Dunstable (L&D) University Hospital, and explore the organisational antibiotic prescribing behaviour during the pandemic. A

mixed method of quantitative research and questionnaires will be used. This CAG application is only relating to the retrospective review of medical records, as 's251' support is not required for the questionnaire element.

Antimicrobial resistance (AMR) is a global crisis that requires urgent attention. Antimicrobial stewardship (AMS) is a set of actions to promote the effective use of antimicrobial interventions. In acute-care settings, antibiotics are widely administered, leading to increased opportunities for AMR. It is estimated that around 20–50% of antibiotics are unnecessary or inappropriately used. The Covid-19 pandemic increased the threat of AMR - although Covid-19 is a viral infection, there are overlapping clinical and radiological features with bacterial respiratory tract infection, so it is inevitable that antibiotics were prescribed for many patients. It is important to identify effective AMS strategies to facilitate AMS interventions in an acute care setting, especially at time of emergency or crisis, to maintain the rational use of antibiotics and offer practical solutions to Antimicrobial Resistance (AMR).

The direct care team at L&D hospital will identify the eligible cohort from Trust medical records, by undertaking a search for patients prescribed antibiotics for bacterial respiratory tract infection or pneumonia. The data collection will be undertaken by the research student, who is not considered direct care team. Although no confidential patient information will be extracted for analysis, 's251' support is required, as the research student will view the electronic medical records, which includes confidential patient information, such as date of birth in order to extract age. Information will be collected about antibiotics that were prescribed upon patient admission and at 48-72 hours. A pseudonymous study ID will be applied, and the key between the study ID and the confidential patient information will be retained by the direct care team within the Trust, although the researcher will have access to this key. 's251' support is required until the researcher who is not considered direct care team, no longer has access to the key.

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	**Total of 588 patients** diagnosed with bacterial respiratory tract infection;

	294 patients before the onset of COVID-19: • 1st week of August 2019 (low risk of respiratory tract infections or pneumonia). • 1st week of October 2019 (onset of winter season and initiation of flu preventive/protective measures). • 1st week of December 2019 (winter season and high risk of respiratory tract infections or pneumonia). **294 patients during COVID-19**: • 1st week of April 2020: Wave 1 and first lockdown. • 1st week of November 2020: Wave 2 and second lockdown • 1st week of March 2021: Post wave 2 and COVID-19 vaccination
Data sources	1. Electronic patient records at Luton &Dunstable (L&D) University Hospital (Bedfordshire NHS Foundation Trust)
Identifiers required for the purposes of extracting a pseudonymous dataset	The applicant will view the patients' medical record and will therefore see the following; 1. Name 2. NHS number 3. Hospital ID 4. Date of birth – required to extract age 5. Date of death
Identifiers required for analysis purposes	1. Gender 2. Pseudonymous Study ID This dataset can be considered anonymous for analysis (if no full date of birth and death recorded). The applicant has clarified that patient age will be extracted, rather than date of birth.

	The applicant has clarified that date of death will be modified to age on admission + added days up to the age that would have been at the next birthday.
Additional information	The link between patients' identifiable data and study numbers will be maintained by the pharmacist at the hospital site and PI who is the PhD student. No confidential patient information will leave the Trust.

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. **Confirm that the National Data Opt-Out would be applied once this is possible within the Trust.**

The applicant advised that the National Data Opt-Out would be applied. The study protocol had been updated to provide details on this process. The CAG noted this information and raised no further queries.

2. **The poster requires revision as follows;**

    a. **The poster needs to inform patients that the medical notes of patients admitted in August, October and December 2019 will be accessed, as well as the notes of those admitted during the pandemic.**

    b. **The language used needs to be revised to be suitable for a lay audience.**

A revised poster was provided. This was reviewed and accepted by the CAG.

3. **Confirmation needs to be provided that the poster will be displayed in clinical areas and on the Bedfordshire Hospitals NHS Foundation Trust website.**

The applicants confirmed that the poster will be displayed in clinical areas. The CAG noted this information and raised no further queries.

4. **A letter of support from the Caldicott Guardian at Bedfordshire Hospitals NHS Foundation Trust is required.**

An email demonstrating that the Caldicott Guardian was supportive of the project was provided. This was reviewed and accepted by the CAG.

5. **Patient and public involvement needed to be undertaken. The patient and public involvement needs to include review of the study poster, to ensure the language used is suitable for a lay audience.**

The Protocol and Patient Information Sheet were reviewed by representatives of the Citizens Senate, which is a patient carer organisation with a good representation of many older people. The Senate recommended changes, which were incorporated into the patient facing documents. The CAG noted this information and raised no further queries.

6. **Confirm that the re-identification key will be held at the Trust, and not by the researcher.**

The applicants confirmed that the re-identification key will only be kept at the trust. The CAG noted this information and raised no further queries.

7. **Justification needs to be provided as to why the key needs to be retained until February 2023.**

The applicant advised that the start date of the study has now been revised to 01 September 2022 and is expected to be complete by 01 September 2023.

The re-identification key would be retained at the Trust. The reason for retaining the pseudonymisation key until September 2023 is to enable answering any queries that the PhD student/PI raises during their analysis. The CAG noted this information and raised no further queries.

Confidentiality Advisory Group advice conclusion

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

Specific conditions of support

The following sets out the specific conditions of support:

1. Favourable opinion from a Research Ethics Committee. **Confirmed 07 September 2022**

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

   The NHS Digital **2021/22** DSPT review for Bedfordshire Hospitals NHS Foundation Trust was confirmed as 'Standards Met' on the NHS Digital DSPT Tracker (checked 15 March 2022).

d. 22/CAG/0084 - Warrington Health and Wellbeing Survey 2022

Name	
Dr Murat Soncul	CAG Alternate Vice Chair
Ms Rose Payne	Confidentiality Advisor
Dr Harvey Marcovitch	Confidentiality Advisor
Ms Caroline Watchurst	Confidentiality Advisor

Context

Purpose of application

This application from Warrington Borough Council (WBC) set out the non-research service evaluation purpose of establishing a patient health and wellbeing survey in the region. The application will undertake a comprehensive, large scale survey of adult residents in Warrington to update the information currently held from previous local lifestyle surveys. The survey needs to collect information on a wide range of topics

including; perceptions of health status, emotional wellbeing, social connectedness and resilience, long-term and recent morbidity, disability, health risk behaviour, use of services, social circumstances, and neighbourhood issues. Impact of the Covid-19 pandemic will be an additional topic in this survey.

Historically the survey facilitation team had been based within the public health department of the local Trust and had been able to facilitate the survey distribution locally without the requirement to seek support under the Regulations. Due to revision of local services, the survey distribution team was now hosted by the Warrington Borough Council, which has led to the changes in the survey methodology. 's251' support is requested in order for a third party mailout company contracted by the council, who are not considered direct care team, to facilitate the invitation of individuals in the area, in order for them to consent into the survey. NHS Digital will supply the third party mail out company with confidential patient information about the cohort. The council themselves will never have access to any confidential patient information.

Outcomes of the survey will be used for the following purposes:

- Inform Warrington's Health & Wellbeing Strategy, Joint Strategic Needs Assessment and underpinning strategies for council and partner organisations.
- Assist in health needs assessment, by providing up-to-date data on morbidity and health and wellbeing status,
- Assist in the commissioning and targeting of resources by highlighting areas/groups experiencing health inequalities,
- Provide information for monitoring health change and the impact of local prevention and health programmes, by repeating salient aspects of previous surveys where possible and practical.

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	18+ adults living in Warrington and/or registered with a Warrington GP. (excluding prisons). Approximately 34,000 patients will be invited to participate, to aim to get 6,800 responses.

	's251' support also requested for potential boost sample, approximate numbers will not be known until survey is underway.
Data sources	1. NHS Digital a) Primary Care Registration System
Identifiers required for the purposes of sending survey invitations	1. Name – title, forename and surname 2. Address – house name/number, street, post town, postcode 3. Sex 4. GP practice code 5. Date of birth 6. Unique ID
Identifiers required for analysis purposes	1. Age 2. GP Practice code 3. Sex 4. Postcode – modified to LSOA/OA level by NHS Digital The final dataset to be retained for analysis will be in pseudonymised form only, with no way for applicants to re-identify
Additional information	3rd party to hold a look-up list which matches unique ID to patient name and address to allow for respondent opt-out after completing the questionnaire If required, (if certain groups are underrepresented) WBC to contact NHS Digital to request a boost sample of additional patients to be sent a letter inviting them to participate in the survey.

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 confirm, after discussions with NHS Digital, if the data source required to extract the sample is the PDS (Personal Demographics Service).**

The applicant confirmed that the data source is the Primary Care Registration System, and the CAG were content with this response.

2. **Confirm which organisation would be acting as the third-party contractor to distribute the survey. Appropriate security assurances checks will need to be undertaken when this organisation is confirmed, in the form of a DSPT reviewed by NHS Digital.**

The applicant confirmed the third party mailout company will be Direct Data Analysis, who have a long standing partnership with another company, Central Mailing Services, to whom they contract out survey mail outs. Both DSPTs are in place.

3. **Please provide a revised poster and website notification, which clearly explain the processing activity as per the advice in this letter, and include details of the specific third party contractor. This should also have an opt out option.**

The applicant provided the updated documents, and the CAG were content with this.

4. **Please provide details of how the opt out mechanism will work.**

The opt-out process for invitation mail out will involve the resident contacting Direct Data Analysis by email or telephone to instruct that they do not wish to participate in the survey. Direct Data Analysis will then perform a check of the sample list once received from NHS Digital and ensure that no resident who has instructed removal is included in the mail out. Direct Data Analysis will be asked to ensure that a record is kept of those not wishing to participate to which they must refer in the event of any other reminder or boost mail outs in relation to this specific project. The CAG were content with this response.

5. **Further patient and public involvement should be undertaken, and include questions around the use of confidential patient information without consent, and provide feedback to the CAG.**

As part of the patient and public engagement and involvement process, and following advice from the CAG, a consultation exercise was undertaken with residents to seek views and support for the use of confidential patient information for the Health & Wellbeing Survey 2022. This exercise was conducted with the support of colleagues in Healthwatch and Warrington Voluntary Action (WVA) and a total of 115 residents completed the consultation. The feedback has been provided for CAG review. Support

appears to be in place for this use of confidential patient information without consent. The Members were content with this response.

6. **Provide a copy of the final 2022 health and wellbeing survey for information purposes following the completion of patient and public engagement and planning.**

The CAG were content with the survey information provided.

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:**

   The NHS Digital **21/22** DSPT reviews for **NHS Digital, Direct Data Analysis, and Central Mailing Services** were confirmed as 'Standards Met' on the NHS Digital DSPT Tracker

e. 22/CAG/0128 - Stroke Patient Reported Experience Measures (PREMS) Survey 2022

Name	
Dr Murat Soncul	CAG alternate vice-chair
Ms Diana Robbins	CAG member

Dr Harvey Marcovitch	CAG member
Ms Caroline Watchurst	Confidentiality Advisor

Context

Purpose of application

This non-research application submitted by The Stroke Association, as joint data controllers with NHS England, sets out the purpose of conducting the 2022 Stroke Patient Reported Experience Measures (PREMS) Survey.

The purpose of the Stroke PREMS survey is to undertake a national survey which captures the patient experience of stroke care, and to use the survey findings to inform quality improvement activity at local, regional, and national level – in line with the NHS's statutory responsibility for quality improvement. No such patient experience tool or data exists at a national level, and yet this is part of the Stroke Long Term Plan ambitions for England. The survey will support nationally recognised aims of:

- Improving the quality and standard of stroke care and rehabilitation across England.
- Supporting a shift in focus towards measuring patient reported experience measures.
- Placing the experience of people affected by Stroke at the heart of Stroke services.
- Ensuring that Stroke patient experience measurement becomes a regular feature and key driver for improving and learning from patients to improve the services experienced by them.

There are approximately 80,000 strokes per year. Some patients will require inpatient stroke rehabilitation, but for the majority of patients, rehabilitation will take place in the community. The intention is to use the patient-reported data to better understand patients experiences across the entire stroke pathway, from emergency admissions, acute stroke unit stay, community or inpatient rehabilitation and life after stroke services. The outcome aims to enable further improvements to improve the experience, and hopefully outcomes, for stroke survivors.

's251' support is requested to allow Trusts to disclose confidential patient information to Quality Health for the purposes of undertaking a postal questionnaire survey. Quality Health will contact patients by post. Patients will be sent a survey pack initially. This will include the survey itself, cover letter and language leaflet. A first reminder will be sent 5 weeks after the survey to non-responders only. A second reminder and another copy of the survey will be sent 4 weeks later to non-responders only. If patients opt-out of the survey they will not receive further letters or communication. Questionnaires are sent

back to Quality Health, and this is taken as implied consent to take part. Quality Health undertake analyses, and provide anonymous outputs to the Stroke Association.

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	Adult stroke survivors (aged 18+) who have experienced a confirmed Stroke and were admitted to an NHS England stroke service within the last 4-8 months Maximum estimated number of patients contacted; 27,712
Data sources	1. NHS Patient Administration System (PAS) from participating Trusts
Identifiers required for patient invitation purposes	1. NHS number, 2. Name, 3. Address including postcode, 4. Sex, 5. Ethnicity, 6. Date of birth, 7. ICD10 code, 8. Date of stroke, 9. Specialty code, 10. Treating NHS Trust, 11. NHS Trust of residence or commissioning board.
Identifiers required for analysis purposes	1. Date of birth – modified to age 2. Ethnicity 3. Gender This would be effectively anonymous, and additionally analysis undertaken with consent as the legal basis

Confidentiality Advisory Group advice

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

1. **Please provide the formal letter of support from the Caldicott Guardian equivalent of the submitting organisation.**

The applicant provided this and the CAG were content with the provision.

2. **Ensure the website text is updated for accuracy as per this letter, and provide an updated version back to CAG.**

The applicant provided this and the CAG were content with the updates.

3. **Please ensure the flyer and the poster are updated regarding the inaccurate comment about having previously opted out of national surveys, when this should read national Data opt Out, and provide updated versions back to CAG.**

The applicant provided this and the CAG were content with the updates.

4. **Please ensure the cover letter is updated for accuracy with the points in this letter, and provide an updated version back to CAG.**

The applicant provided this and the CAG were content with the updates.

5. **Please later the front page of the survey to make it clear that NHS England do not hold contact information, and this is only referring to Quality Health, and provide an updated version back to CAG.**

The applicant provided this and the CAG were content with the updates.

6. **Please ensure consistency and clarity in the cover/invitation letter, and any reminder letters regarding the possibility that third parties such as relatives and carers may have opened this letter on the patients behalf, and may have a further role to play, and provide updated versions back to CAG.**

The applicant provided this and the CAG were content with the updates.

7. **Please provide more detail surrounding the patient and public involvement activity surrounding the use of confidential patient informaiton without consent, including who the 21 respondents were to ensure they are representative of the cohort, what was covered, and what were the views on use of confidential patient data without consent.**

The applicant provided a much more detailed description, and the CAG were content with the 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. 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 review for **Quality Health** was confirmed as 'Standards Met' on the NHS Digital DSPT Tracker (checked 08 September 2022).

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

Name	
Dr Murat Soncul	CAG Alternate Vice Chair
Mr David Evans	CAG Member
Mr Anthony Kane	CAG Member

Dr Pauline Lyseight-Jones	CAG Member
Ms Kathleen Cassidy	Confidentiality Advisor

Context

Purpose of application

This application from Newcastle University set out the purpose of medical research that seeks to investigate the changes in mental health services in response to Covid-19 and show how these changes have impacted health outcomes in deprived populations.

The Covid-19 pandemic has increased the incidence of mental health problems. Following the pandemic it is estimated that new or additional mental health support will be required for up to 10 million people in England. Evidence from previous studies has shown that the virus and lockdowns disproportionately affected the mental health of those living in deprived areas. A complete picture of use of mental health services by more deprived populations and the impact of the pandemic on patterns of mental health service utilisation is not available. The applicant seeks to explore changes in mental health services during the pandemic. The applicant will conduct a literature review to identify changes in mental health services during the pandemic and will conduct a Delphi survey with key stakeholders to agree on the features of services.

Support is required for the applicant to collect NHS data from 20 GP practices across the North East and North Cumbria before, during and after lockdown. The North of England Commissioning Support (NECS) Unit identify and will extract confidential patient information for the base cohort. Confidential patient information will be shared from NECS to NHS Digital for linkage and a linked dataset will be return to NECS. NECS will then create unique identifiers and provide a pseudonymised dataset to the applicant at Newcastle University.

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

Confidential patient information requested

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

Cohort	Patients aged 18 years and over who referred or self referred to NHS-funded secondary/community mental health services between 3rd March 2019 to 22nd March

	2020 in 20 selected Deep End GP practices within the Nort East and North Cumbria (NENC). The applicants estimate that 5390 patients will be included
Data sources	1. The local primary care electronic patient records (EPRs data 2. Mental Health Services Data Set (MHSDS), Improvin Access to Psychological Therapies (IAPT) data se Hospital Episode Statistics (HES), including Hospita admission records (APC), Outpatient records (OP Accident and Emergency records (A&E) and Communit Service Data Set (CSDS) at NHS Digital.
Identifiers required for linkage purposes	1. Name 2. NHS number 3. Date of birth
Identifiers required for analysis purposes	1. Date of birth 2. Date of death 3. Gender 4. Occupation 5. Ethnicity

Confidentiality Advisory Group advice

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

1. **The poster and other patient notification materials need to be proofread for clarity and simplicity. The revised documents need to be provided for review.**

The applicant provided a revised poster and privacy notice. The CAG agreed that the language of the poster was still too technical and required revision for clarity. Members also asked that the poster was reviewed by people who are not NHS professionals, to ensure that the language used is suitable for a lay audience and that a web address to the Privacy Notice was included on the poster. Revisions to the explanation of the CAG role were also requested.

A revised poster was provided, which was reviewed and accepted by the CAG.

2. **The process for patients to dissent to use of their data needs to be explained in the patient notification materials and contact details given. Any limits on opt-out need to be explained.**

The applicants had added information to the poster and privacy notice to provide the required information. The CAG noted this information and raised no further queries.

3. **Provide confirmation that the National Data Opt-Out will be applied.**

The applicants confirmed that the National Data Opt-Out will be applied. The CAG noted this information and raised no further queries.

4. **Clarify whether the patient notification materials would be translated into any other languages.**

The applicant agreed that providing patient notification materials in languages other than English would be best, however due to limited funding this was not possible. The patient notification materials written in the patient's preferred language will be provided only at the request of the patient. The CAG noted this information and raised no further queries.

5. **Advise whether patients date of birth and date of death can be converted to be less identifiable.**

The applicants advised that patient dates of birth and dates of death disclosed to Newcastle University will be generalised to month and year of birth and death. 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 23 June 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 **NHS Digital and the North of England Commissioning Support Unit** were confirmed as 'Standards Met' on the NHS Digital DSPT Tracker (checked 04 July 2022).

g. 22/CAG/0049 - LOCOMOTION

Name	
Dr Patrick Coyle (Vice Chair)	CAG Vice Chair
Mr. Anthony Kane	CAG Member
Mr Andrew Melville	CAG Member
Professor Sara Randall	CAG Member
Mr Umar Sabat	CAG Member
Mr Michael Pate	Confidentiality Advisor

Context

Purpose of application

This application from the University of Leeds (with the controller for the activity confirmed to be the University of Oxford) set out the purpose of medical research which aims to find out the most effective rehabilitation treatment for Long Covid (LC) currently being delivered across ten UK-wide LC clinics.

To achieve this, the study will comprise three parallel related workstreams and involves the comprehensive collection and examination of qualitative and quantitative data from potentially 5000 patients. These will involve creating a Quality Improvement Collaborative, developing services and training packages for LC patients and healthcare professionals, and using wearable devices to monitor symptoms and improve standard-of-care. Workstream 3 is the focus of the CAG application and aims to develop and evaluate new integrated care pathways to manage LC.

For Long Covid clinic patients, support is requested to allow the disclosure of confidential patient information from Trust direct care teams, who will transfer NHS number and DOB, to University of Oxford. These are transferred to a secure portal at Oxford and an automatic hashing algorithm is applied to the NHS number as soon as it

lands in the portal. Therefore, support is required for transfer from Trusts to Oxford prior to automatic hashing.

For linkage with NHSD (for patients identified in Long Covid clinics), the hashed data is transferred from Oxford to NHSD. As both sides have the hashing algorithm, the data is potentially identifiable; therefore, support will be required for Oxford to hold the hashed data and transfer to NHSD to link and send back.

Regulation 5 support is required to send confidential patient information from NHS Digital to ORCHID (university of Oxford). This is an existing flow of data which required support for the data flow specific to LOCOMOTION. To note there is no requirement for ORCHID to send identifiers to NHS Digital to enable this flow.

The Salford and NW London integrated care records involved in the study are only accessed by the direct care team. No identifiable data is shared, so support is not needed for access to these records.

The legal basis for collection of personal data for the prospective elements of the study (Workstreams 1 and 2) is consent, therefore these workstreams fall out of scope and support is not required for these.

Some sites are in Scotland and Northern Ireland and these fall outside of scope and are covered by their own approval mechanisms.
Some of the work package 3 cohort have consented to the use of their data and are also outside the scope of support.

The Research and Surveillance Centre was originally established by the RCGP for flu surveillance work 52 years ago. This has progressed to be part of ORCHID, and therefore RCGP acts as a collaborative partner of ORCHID for surveillance work. The sharing of this data is part of the data controller's UKHSA agreement for surveillance. This is a tri-partied legal agreement, thus, is not a data-source or entity that performs research activities for LOCOMOTION or any other research study that uses ORCHID. This means that for those suspected to have long covid but not seen at a long covid clinic, linkage of their data will take place solely within Oxford once the identifiers have been hashed.

Reference is made in the CAG form to GPDPR. As this is not operational, this data flow is outside of the scope of support.

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

Confidential patient information requested

The following sets out a summary of the specified cohort, listed data sources and key identifiers. Where applicable, full datasets and data flows are provided in the application

form and relevant supporting documentation as this letter represents only a summary of the full detail.

Cohort	Male or female patients aged 18 yrs and over, with Long Covid (LC) identified by: 1. Being referred to one of 10 participating LC clinics. 2. Not having been referred but identified as having attended their GP with likely LC, but deep phenotyping of GP coded data.
Data sources	<u>GP practices</u> • Medical records <u>NHS Digital</u> • HES data • SUS data • eMIS (routinely collected data under Regulation 3 to be used for research purposes)
Identifiers required for linkage purposes	1. NHS number 2. DOB
Identifiers required for analysis purposes	1. Postcode for deprivation scoring

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 number of records that will be accessed per GP practice for those who attended their GP practice and not via a Long Covid clinic**.

Within the data held by ORCHID from participating Research and surveillance Centre practices, ORCHID staff will prepare for us tables of data using linked pseudonymised HES and ONS data. The data included in ORCHID contains data from all patients registered with a practice that is part of the RCGP Research and

Surveillance Centre, but who has not had a national opt-out code placed in their GP record using the NHS Digital opt-out mechanism (see Q4). We are interested in data from practices in the Integrated Care System serviced by our participating Long Covid clinics. We will access all non opted-out records using the pseudonymisation in place and the Trusted Research Environment at ORCHID as we will be exploring predictors and potential bias in who 'might' have Long Covid (based on consultation reasons after acute infection), who has been coded by the GP as having Long Covid, who has investigated and treated outside the LC clinic and within the clinic.

The CAG understood that the number of records being accessed was not specifically stated, but that the number would be significant, and therefore found the response acceptable.

2. **Please justify why consent could not be taken from those individuals recruited via General Practice.**

We are not recruiting anyone in practices, only Long Covid clinics. We need to determine the impact of attending a Long Covid clinic on subsequent resource utilisation (GP and other NHS contacts), and the impact of inequalities, and potential under diagnosis, so we need the GP data (without consent) to both identify potential cases of Long Covid in the practice and form the control group in our observational study in WS3. We are therefore interested in all the records in the practice of patients over age 18.

The CAG accepted this response.

3. **Please remove reference to GPDfR form the transparency materials.**

We can see no reference to GPDfR in the transparency materials.

The CAG noted that GPDfR - General Practice Data for Research - appears in the application form and protocol. The applicant presumably would have used this but it has not yet come into existence. In the meeting, the CAG must have thought that it was in the privacy notice and wanted it removed but looking back at the privacy notice, in the papers used at the meeting, it was not there, so the applicant's response is correct.

4. **Please explain the method of local opt-out more clearly in the "Your Choices" section of the main notification document.**

For ORCHID data, National opt-outs apply, so LOCOMOTION relies on the national data opt out. The notice has been amended to include reference to this. https://www.nhs.uk/your-nhs-data-matters/manage-your-choice/

The CAG accepted the response; however, it would like the study to have a project-specific opt-out in addition to NDOO so the applicant was asked to include this in their privacy notice, which must include the fact that the subjects may opt-out of this project even if they have not exercised their right to NDOO and the mechanism of contacting a named individual via a telephone number or email address or conventional address must be clear.

The applicant responded to say that for clinic data, they have added a section to transparency notice for Trust's to add the details of a named contact who patients can contact to opt-out for this study. These patients will then be removed from the dataset by the individual trust before they transfer the data to the researchers. This transfer of data will be a single occurrence, and once it has been sent it will not be possible to remove a specific patient as the data will be anonymised. Therefore, we will include a deadline (date to be determined, but at least 4 weeks) on the transparency notice which patients will have to notify their long COVID clinic by in order to successfully opt-out.

Regarding ORCHID/GP data, study specific opt-out cannot be done as Oxford/RSC do not use this mechanism and cannot add it for a single study. Our PAG are aware of this are happy that the national data opt-out is sufficient.

The CAG accepted this response.

5. Please extend notification of the study to platforms other than the study website e.g. Twitter.

The applicant explained that they wished to hold 'one truth' for the transparency notice on the study website and that they would post a pinned link on Twitter to the study website.

The CAG accepts this response.

6. Please provide the additional notification materials for these other platforms so that the CAG can review.

The applicant explained that, to avoid confusion, they would point all other platforms at the study website.

The CAG accepts this response.

7. Please note that the CAG provides a recommendation to the Health Research Authority as to whether to provide section 251 support. It does not "approve" a study. Please amend the wording of the notification to refer to support rather than approval.

The original response did not state that section 251 support is given by the HRA on the recommendation of CAG. The transparency notice was subsequently updated and now contains wording that the CAG supports.

8. Please consider creating a summary notification document that clearly explains the aims of the study and how confidential patient information will be used without consent. This should lead to the main notification document.

A summary notification has been added as a paragraph to the transparency notice so that it 'stands alone' if needed. The CAG is content with this.

9. Please provide further details of the PPI conducted specifically relating to WP3. What have participants been asked? What were the views of these participants?

As in all LOCOMOTION Work Streams (WS), WS 3 has two Patient Advisory Group (PAG) members who attend all the WS management meetings. The WS has also been presented at the wider PAG. Participants were asked for their views on the potential public benefit of the research to be undertaken, the feasibility or not of asking consent and the potential risks to patents of accessing their data in the way proposed. The views are presented in the letter provided to support this application.

Examples of PAG discussions include:

Use of identifiable data without consent:
Using confidential patient information without consent only concerns retrospective data from patients already seen in clinics/hospitals and by GPs in surrounding practices that are part of the Research and Surveillance network. Due to the large number of patients about whom data needs to be collected, to help ensure strong inclusion of information across all communities and that as robust results as possible are achieved, the PAG for LOCOMOTION agrees that it is not feasible or desirable to contact every patient retrospectively to seek their consent. The PAG also agrees that the approach to linking data from general practice, hospitals and Long Covid clinics is appropriate and protects patient privacy. Following that linkage, the data will be anonymised totally for analysis.

Review of transparency notice.
The Transparency Notice has been re-written and re-laid out for clarity by CAG and is enclosed as an attachment. The revised document has paid particular attention to the need of patients with cognitive/fatigue issues.

To improve clarity, there are two versions of the Transparency Notice. One with University of Leeds details as sponsor, to go on the study website – which will be linked via ORCHID (hence ORCHID practice websites), and Twitter. Another, that can be

individualised with relevant NHS trust details to go on the clinic website and to be provided to patients in clinics.

The CAG was happy with the level of PPI conducted.

10. Please clarify the level of the postcode required for analysis. If the full postcode is to be analysed for deprivation scoring, please justify this.

The study team confirmed that they would be using the Lower Super Output Area for calculating deprivation scores. The CAG accepted this.

Confidentiality Advisory Group advice conclusion

The CAG agreed that the minimum criteria under the Regulations appeared to have been met, and therefore advised recommending support to the 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 07 December 2021**

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

The NHS Digital **21/22** DSPT review for **the University of Oxford** was confirmed as 'Standards Met' on the NHS Digital DSPT Tracker (12 September 2022)

The NHS Digital **21/22** DSPT review for **Birmingham Community Healthcare NHS Foundation Trust** was confirmed as 'Standards Met' on the NHS Digital DSPT Tracker (7 October 2022)

The NHS Digital **21/22** DSPT review for **The Newcastle Upon Tyne Hospitals NHS Foundation Trust** was confirmed as 'Standards Met' on the NHS Digital DSPT Tracker (12 September 2022)

The NHS Digital **21/22** DSPT review for **Leeds Community Healthcare NHS Trust** was confirmed as 'Standards Met' on the NHS Digital DSPT Tracker (7 October 2022)

The NHS Digital **21/22** DSPT review for **Oxford University Hospitals NHS Foundation Trust** was confirmed as 'Standards Met' on the NHS Digital DSPT Tracker (7 October 2022)

The NHS Digital **21/22** DSPT review for **Oxford Health NHS Foundation Trust** was confirmed as 'Standards Met' on the NHS Digital DSPT Tracker (12 September 2022)

The DHCW **21/22** DSPT review for **Cardiff and Vale University Health Board** was confirmed as 'Standards Met' via email (12 October 2022)

h. 22/CAG/0106 - The BCIS Out of Hospital Cardiac Arrest Pilot Registry

Name	
Ms. Clare Sanderson (AVC)	CAG Alternate Vice Chair
Dr Katie Harron	CAG Member
Mr. Anthony Kane	CAG Member
Dr Pauline Lyseight-jones	CAG Member
Professor Sara Randall	CAG Member
Ms Kathleen Cassidy	Confidentiality Advisor

Context

Purpose of application

This application from Mid and South Essex NHS Foundation Trust set out the purpose of setting up a research database to collect data on patients who have experienced an Out of Hospital Cardiac Arrest within the network of NHS hospitals covered by regional Cardiac Arrest Centres.

Out of Hospital Cardiac Arrest (OHCA) carries a high mortality, with just 8% of patients admitted to Hospital surviving to discharge. The purpose of this registry is to capture data on patients who experience Out of Hospital Cardiac Arrest (OHCA) to inform registry research projects to ultimately improve patient outcomes.

There are two data flows, one for patients treated within Essex and one for patients treated in participating trusts outside of Essex.

For patients treated within Essex, a research fellow will use local systems at The East of England Ambulance Service NHS Trust (EEAST) and The Essex and Herts Air Ambulance Trust (EHAAT) to identify patients who experienced an OHCA. Confidential patient information will be collected onto the registry. For patients treated at Essex Cardiothoracic Centre at Mid and South Essex NHS Foundation Trust, a member of the research team, working with a member of the direct care team, will input hospital-based data into the registry. For patients treated at other hospitals within Essex, a member of the direct care team at the site will input the data into the registry. If patients die before they can be consented, their data is anonymised, and all confidential patient information deleted. For patients who survive, they will be approached 3 months after discharge and consent to take part in the e-PROMS sought. Their participation will then proceed on a consented basis.

For patients treated outside of Essex, members of the local research team, which may also include members of the direct care team, will identify patients, and collect their data. Anonymised data only will be entered into the registry.

A recommendation for class 1,2,3,4,5 and 6 support were requested to cover access to the relevant unconsented activities as described in the application.

Confidential patient information requested

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

Cohort	Patients who experience an out of hospital cardiac arrest and are treated at one of the participating sites.
Data sources	1. Patient records held at: a. Mid and South Essex NHS Foundation Trust b. The East of England Ambulance Service NHS Trust c. The Essex and Herts Air Ambulance Trust d. East Anglian Air Ambulance e. Princess Alexandra Hospital NHS Trust f. The East Suffolk and North Essex NHS Foundation Trust g. King's College Hospital NHS Foundation Trust

	h. Barts Heart Centre, London i. The Bristol Heart Institute, University Hospitals Bristol NHS Foundation Trust j. University Hospital Southampton NHS Foundation Trust
Identifiers required for linkage purposes	1. NHS Number 2. Date of birth 3. Date of death 4. Postcode – sector level
Identifiers required for analysis purposes	1. Postcode – sector level 2. Gender 3. Occupation 4. Ethnicity 5. Date of death

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 scope of support required needs to be clarified, as follows:**

    a. **Clarify whether support under s251 will only extend to patients who died before consent could be sought, and all other processing of confidential patient information is undertaken either by the direct care team or by research staff under the Mental Capacity Act.**

The applicants confirmed that support under s251 was only required for patients who died before consent could be sought.

    b. **Clarify whether all extraction of confidential patient information from patient records and inputting into the registry will be undertaken by the direct care team only at all sites.**

Data input into the registry will be undertaken by the direct care team.

    c. **Clarify the cohort size and time period of data collection, including any retrospective data collection.**

The goal of this registry is to capture cases from the community and understand where patients are conveyed to within Essex and their outcomes. In 2020, the East of England Ambulance service treated 3,570 Out of Hospital Cardiac Arrests, with just under a quarter of these patients admitted to hospital with return of spontaneous circulation. Typically, a Cardiac Arrest Centre will care for approximately 90 to 120 out of Hospital Cardiac Arrests per year. The period of prospective data collection will begin once full CAG approval is received, following a triage pathway change across Essex. Retrospective data will be collected for comparison.

d. **For data collection for patients from 2019 onwards, clarify whether these patients would be consented, if still alive, or whether support was required for both surviving and deceased patients from 2019 onwards.**

The applicants also seek to collect yearly data from 2019 to the present day to understand how changes in the service have impacted outcomes. If a patient within Essex, from 2019 to the present day has survived a cardiac arrest, they will be approached for consent in the registry. If they do not consent their data will not be used. If they died their data will be input into the registry anonymously and no linkage data/identifiable information will be held. All retrospective NHS numbers will be checked against NHS opt out and if this is in place, data will not be used.

e. **Clarify whether any linkages to datasets held by NHS Digital will be undertaken and, if so, whether support is needed for these linkages.**

The applicants confirmed that no linkages to HES or NHS Digital held datasets will be undertaken.

f. **Clarify whether support is needed for the collection of patient telephone numbers or whether the Mental Capacity Act was the legal basis for this.**

The Mental Capacity Act will be used as legal basis for obtaining a patient's phone number prior to contacting them. This will be done for survivors of Cardiac Arrest within Essex for the e-PROMs pilot.

The CAG noted the answers given to the above queries and raised no further concerns.

2. **Clarify how the local dissent mechanism will work. Any limits on patient dissent, i.e. explaining that individual patient data could not be removed once the dataset was anonymised, would need to be included in the patient notification materials.**

Patients who survived a cardiac arrest within Essex will be approached for consent for ongoing inclusion in the registry and to partake in e-PROMs. If a patient is approached and declines the linkage file will be used to identify their record in the registry and all data will be deleted. Patients who have registered with the National Data Opt-Out will not be included. Patients who have died or were treated outside Essex will not be consented, but their records will be checked against the National Data Opt-Out.

The online materials have been amended to provide an explanation on patient dissent and to clarify that data cannot be removed once full anonymisation has taken place.

3. **Advise if there are any plans to expand the membership of the Steering Committee and whether the Steering Committee had reviewed the data**

sharing criteria. If they had not, members asked that it was reviewed by the Steering Committee.

The chair of the Steering Committee has reviewed the application. The Steering Committee has 14 members, comprised of 12 health care professionals and 2 cardiac arrest survivors. Meetings will be recorded on a proforma submitted with this application. The Steering Committee will undertake a review of the data sharing criteria. The CAG noted this information and raised no further queries.

In their response to the CAG Provisional Outcome, the applicant asked for support to include patients' full dates of death in the Registry dataset. The applicant noted the importance of using this data item to meet the aims of the Registry and that similar applications had support to retain patients' date of death. The CAG noted the applicants request and agreed that patients' date of death could be retained. The list of identifiers retained for analysis, given above, has been amended to reflect this.

Confidentiality Advisory Group advice conclusion

The CAG agreed that the minimum criteria under the Regulations appeared to have been met, and therefore advised recommending support to the 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 28 July 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: As there are more than 5 organisations processing confidential patient information, these will not be individually checked by the CAT team, and it is the responsibility of the applicant to ensure the DSPTs for these organisations have been assessed as 'standards met' by NHS Digital**

i. 22/CAG/0112 - Randomised trial of the clinical and cost effectiveness of a supraglottic airway device versus intubation during in-hospital cardiac arrest

Name	
Dr Murat Soncul (AVC)	CAG Alternate Vice Chair
Dr Rachel Knowles	CAG Member
Ms Rose Payne	CAG Member
Mr Dan Roulstone	CAG Member
Mr Umar Sabat	CAG Member
Ms Kathleen Cassidy	Confidentiality Advisor

Context

Purpose of application

This application from the University of the West of England set out the purpose of medical research that seeks to determine the clinical and cost effectiveness of a supraglottic airway device versus tracheal intubation during in-hospital cardiac arrest. In hospital cardiac arrest (IHCA) occurs in approximately 1 in 1000 hospital inpatients. It is a sudden, unpredictable and life-threatening event and has significant mortality and morbidity. Survival to hospital discharge following resuscitation for IHCA is around 24% in the UK. However, additional data collected for patients who require advanced airway management, such as the insertion of a tracheal tube or a supraglottic airway device, suggests that survival for this patient group is closer to 10%.

Effective cardiopulmonary resuscitation (CPR) is central to achieving good patient outcomes, however chest compressions alone do not provide adequate lung ventilation and effective airway management is essential. A previous trial, AIRWAYS-2, explored use of tracheal intubation versus the i-gel supraglottic airway device in OHCA. This did not detect a significant difference in functional outcome (including mortality) between the two advanced airway management techniques. Since then, updated international resuscitation guidelines support the use of supraglottic airways (SGAs) in settings where intubation success rates are lower. Changes have been made in management of airways when paramedics treat Out of Hospital Cardiac Arrest (OHCA), but not where doctors manage the airways. The applicants seek to determine whether SGAs are superior to tracheal intubation in situations where intubation success rates are assumed to be high. The applicants will conduct a multi-centre, open-label, pragmatic, individually randomised, parallel group, superiority trial and economic evaluation. Patients will be recruited by NHS clinicians, usually the member of the in-hospital cardiac arrest team who is designated to manage the patient's airway. The clinician will assess patient eligibility.

Patients will be randomly allocated, at a ratio of 1:1, to receive either a supraglottic airway device (intervention arm) or tracheal intubation (control arm). The randomisation will be conducted using a phone progressive web application (PWA) which will inform the Warwick CTU that the randomisation has occurred. Patients will initially be recruited under the Mental Capacity Act, as patients will be unconscious when entered into the trial. Consent will be sought from patients who regain capacity. Support is required to include patients who die before consent can be sought. Confidential patient information will be disclosed to the University of Warwick. Individual level patient data will be disclosed to NHS Digital, PEDW and ICNARC for linkages to datasets these organisation hold, and a linked dataset returned to the University of Warwick.

The applicants noted that data linkage to Health Data Research UK (HDR UK) was planned. An amendment would be submitted before this was undertaken.

A recommendation for class 1, 2, 3, 4, 5 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 who experience an in-hospital cardiac arrest, are attended by the hospital cardiac arrest team and who require resuscitation with advanced airway management. 4190 patients will be included.
Data sources	1. Participant NHS hospital Trusts 2. NCAA (National Cardiac Arrest Audit), held by Intensive Care National Audit and Research Centre (ICNARC) 3. Patient Episode Database for Wales (PEDW), held by NHS Wales Informatics Service (NWIS)
Identifiers required for linkage purposes	1. Name 2. NHS Number 3. Date of birth 4. Postcode – district level
Identifiers required for analysis purposes	1. Date of birth 2. Date of death 3. Postcode – district level 4. Gender

	5. Ethnicity

Confidentiality Advisory Group advice

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

1. **The CAG request clarification on the Consent process. It was queried at what point consent was sought and whether consent was sought for only those who survived the cardiac arrest. Clarification on the consent process needs to be provided as follows:**

    a. **Clarify when consent would be sought and whether consent was sought for only those who survived the cardiac arrest.**

    The applicants advised that consent for follow-up would be sought from surviving patients, who had not registered a National Data Opt-Out, once they left intensive care. Consent would not sought from patients who did not survive to this point.

    b. **Confirmation that, should a patient who is approached for consent refuse, then their confidential patient information will be deleted.**

    All confidential patient information will be deleted if a person approached for consent refuses to participate in follow-up.

    The CAG noted the above information and raised no further queries.

2. **The poster needs to be revised to provide more information about the study.**

    The applicants provided a revised poster. The CAG reviewed this document and raised no further queries.

3. **Methods of promoting the study online need to be explored and feedback provided to the CAG.**

    A study website and a twitter account have been created, containing information about the study. Both were reviewed by the Patient and Public Trial Management Group member and Research and Audit Federation of Trainees Representative to ensure the information is suitable for patient viewing, and to provide trainees interested in the study with the correct information. A log will be kept of the feedback received. The CAG noted this information and raised no further queries.

4. **Methods of sign-posting those whose first language was not English to information about the study need to be explored and feedback provided to the CAG.**

The applicants are exploring ways of translating the poster provided at point 2 and other study information into the non-English languages spoken most often by the communities served by participating hospitals, including Welsh where appropriate, and will feed back to CAG as the study proceeds. The CAG noted this information and raised no further queries.

5. **Clarify whether the confidential patient information can be de-identified as the project is ongoing, or whether all confidential patient information will be held until 31 December 2026.**

The applicants confirmed that it will be possible to de-identify confidential patient information as the project proceeds, following data linkage and validation. 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 22 July 2022**

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

   The NHS Digital 21/22 DSPT review for**, Intensive Care National Audit and Research Centre (ICNARC)** was confirmed as 'Standards Met' on the NHS Digital DSPT Tracker (checked 13/09/2022)

   NHS Wales Informatics Service (NWIS) – CPIP in place

   The applicants confirmed that the University of the West of England would not process any confidential patient information under support, therefore a DSPT was not required for this organisation.

2. New Amendments

17/CAG/0176– A Risk-adjusted and Anatomically Stratified Cohort Comparison Study of Open Surgery, Endovascular Techniques and Medical Management for Juxtarenal Aortic Aneursyms: The UK Complex Aneurysm Study (UK-COMPASS).

Name	Capacity
Ms Caroline Watchurst	HRA Confidentiality Advisor
Ms Clare Sanderson	CAG Alternate Vice-Chair

Context

Amendment request

This application from the Royal Liverpool and Broadgreen University Hospitals NHS Trust was supported to examine how the different treatments for abdominal aortic aneurysm compare in terms of clinical benefit and the utilisation of NHS resources. The study will link data between NHS Digital, imaging data from Trusts and the National Vascular Registry for both initial collection and follow up over a five-year period. UK-COMPASS was designed to provide a comparison between operated and operation deferred/medically managed patients for cost effectiveness and mortality. The original design of the study allowed operated patients to be identified by both NHS Digital (with 's251' support) and participating sites. Patients identified by site would be identified prospectively by the direct care team, and consented, and would participate in a Quality of Life Study. These patients would also give permission for further information about their health care to be sought from NHS Digital.

This amendment sought support to include a further cohort of patients using a slightly altered data flow, to include;

- 's251' support for participating sites to retrospectively identify and disclose confidential patient information to Liverpool University Hospitals NHS Foundation Trust regarding operation deferred/ medically managed abdominal aortic aneurysm (AAA) patients from 01 November 2017. This is for baseline data and linkage with 2 year outcome data from NHS Digital, and the applicant confirmed that these patients will not be recruited to the Quality of Life study.

- ‘s251’ support for participating sites to retrospectively identify and disclose confidential patient information to Liverpool University Hospitals NHS Foundation Trust regarding those patients whose operations were delayed due to the COVID-19 pandemic, between 23 March 2020 and 31 December 2023. Again, this is for baseline data and linkage with 2 year outcome data from NHS Digital, and the applicant confirmed that these patients will not be recruited to the Quality of Life study.

This amendment has been requested as COVID-19 had an unanticipated effect on clinical studies, and it has therefore not been possible to recruit to target (55/300 patients currently recruited). Therefore, the applicant wishes to expand the ‘s251’ support they have, in order to identify these patients retrospectively at sites. An alteration to the Patient information sheet (PIS), and an update to the website wording, which are accepted as notifications to CAG.

Confidentiality Advisory Group advice

The amendment requested was considered by the Alternative Vice-Chair, who was content to recommend support for this amendment.

Confidentiality Advisory Group advice conclusion

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

Specific conditions of support

The following sets out the specific conditions of support.

1. Confirmation provided from the 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 **Liverpool University Hospitals NHS Foundation Trust and NHS Digital** were confirmed as ‘Standards Met’ on the NHS Digital DSPT Tracker (checked 29 September 2022)

2. Confirmation of a favourable opinion from a Research Ethics Committee.
   Confirmed 06 September 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 also sought support for the addition of five new participating sites (Royal Berkshire NHS Trust, Mid Cheshire Hospitals NHS Foundation Trust, Countess of Chester Hospital NHS Foundation Trust, Blackpool Teaching Hospitals NHS Foundation Trust, Newham Hospital (Barts Health NHS Trust)), as data processors. Applicants will also include an additional site in Scotland but this is outside the scope of support for ‘s251’, and the applicant is seeking PBPP approval for this.

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 29 September 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 28 September2022**

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 also sought support for the addition of four new participating sites (Airedale NHS Foundation Trust, West Suffolk NHS Foundation Trust, Doncaster and Bassetlaw Teaching Hospitals NHS Foundation Trust, United Lincolnshire Hospitals NHS Trust) as data processors.

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 29 September 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 28 September 2022**

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

Name	Capacity
Ms Caroline Watchurst	HRA Confidentiality Advisor

Context

Amendment request

This application to test whether a digital platform can efficiently identify patients who have suffered a bleeding event, has 's251' support to allow members of the research

team to access confidential patient information for patients identified as having met the study criteria, so that patients can be approached for consent.

The prospective cohort that applicants currently have ‘s251’ support for is; Adults aged 16-110 years of age who were admitted to, or attended the emergency department at, Oxford University Hospitals NHS Trust between 01 October 2021 and 31 August 2022.

This amendment sought support to change the dates for the prospective cohort, due to delays caused by covid-19. Therefore the prospective cohort that applicants will now have ‘s251’ support for is; Adults aged 16-110 years of age who were admitted to, or attended the emergency department at, Oxford University Hospitals NHS Trust between 01 October 2021 and 31 August 2023.

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

Confidentiality Advisory Group advice

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

Confidentiality Advisory Group advice conclusion

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

Specific conditions of support

The following sets out the specific conditions of support.

1. Confirmation provided from the 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 **Oxford University Hospitals NHS Foundation Trust** is confirmed (by check of the NHS Digital DSPT tracker on 29 September 2022)

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

17/CAG/0015 – Antibiotic Reduction and Conservation in Hospitals (ARK-Hospital)

Name	Capacity
Ms Caroline Watchurst	HRA Confidentiality Advisor

Context

Amendment request

This application from Oxford University Hospitals NHS Foundation Trust set out the purpose of a research project which will test whether a package of strategies can help doctors, nurses, pharmacists and patients stop antibiotics in hospital when they are no longer needed.

This amendment sought support to extend the duration of ‘s25’1 support until 31 August 2023, in order to complete analyses.

Confidentiality Advisory Group advice

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

Confidentiality Advisory Group advice conclusion

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

Specific conditions of support

The following sets out the specific conditions of support.

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

   The NHS Digital **21/22** DSPT review for **Oxford University Hospitals NHS Foundation Trust** was confirmed as 'Standards Met' on the NHS Digital DSPT Tracker (checked 29 September 2022)

2. Confirmation of a favourable opinion from a Research Ethics Committee. **confirmed non substantial 30 August 2022**

18/CAG/0131 – Inflammatory Bowel Disease Registry

Name	Capacity
Ms Caroline Watchurst	HRA Confidentiality Advisor

Context

Amendment request

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

This amendment sought support to include additional data items in the 's251' supported data collection, (the 2021_K dataset) to align with the consented research database. This does not include any additional items of confidential

patient information, however clarifies that sex is collected, as an alternative for the previous field of gender, and now includes IBD audit code which is a site identifier only. All other data collected is clinical and not identifiable.

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 **Civica - (previously CIMS), AIMES management service, IBD Registry Limited and NHS Digital** were confirmed as 'Standards Met' on the NHS Digital DSPT Tracker (checked 29 September 2022).

   DHCW (previously NWIS) has a valid CPiP Outturn report.

22/CAG/0076 – Suicide by patients in contact with drug and alcohol services in the year prior to death

Name	Capacity

Ms Caroline Watchurst	HRA Confidentiality Advisor

Context

Amendment request

This application aims to identify the characteristics and antecedents of suicide in people in contact with substance misuse services. ‘s251’ support is in place for a number of flows, but pertinent to this amendment, support is already in place for the disclosure of confidential patient information from University of Manchester (UoM) to the Office for Health Improvement and Disparities (OHID), part of the Department of health and Social Care (DHSC), Digital health and Care Wales (DHCW) (previously NWIS), and Public Health Scotland (PHS), in order to link to National Drug Treatment Monitoring System (NDTMS), Welsh National Database for Substance (WNDSM), and Drug and Alcohol Information System (DAIsy). ‘s251’ support is also in place to allow the disclosure of confidential patient information from UoM to third sector and NHS services organisations providing publicly funded drug and alcohol services, in order to request an Serious Incident Report (SUI) report, which is then redacted and disclosed back in pseudonymised format. ‘s251’ support is also required for flow back, as NCISH can re-identify.

Identifiers currently required to send to OHID, DHCW, PHS are as follows;

1. Name
2. Date of birth
3. Date of death
4. NHS number (DHCW only)
5. unique NCISH ID number

This amendment sought support to include sex and outward postcode for England and Wales (OHID & DHCW) and CHI Number for Scotland (PHS). This is at the request of the data controllers to ensure accurate linkage.

This amendment also sought support to additionally access local investigation reviews (also referred to as Mortality Case Review Documents/Incident Reviews/Structured Judgement Reviews, depending upon the service), in addition or instead of an SUI. Following further conversations with professionals from NHS and third sector organisations providing alcohol and drug services, applicants have learnt that local investigation reviews (also referred to as Mortality Case Review Documents/Incident Reviews/Structured Judgement Reviews, depending upon the service) are undertaken following the death of a patient by suicide. These Reviews determine the levels of preventability. They trigger a Serious Incident Investigation should there be any

concerns with the treatment provided or are conducted if the death has not met the criteria for a Serious Incident Investigation. The Reviews are not as detailed as a Serious Incident Investigation but applicants would like to collect these documents in addition to the SUI or, in the place of an SUI, (should one not have been undertaken) , to enable applicants to capture detailed clinical information on more patients who had contact with alcohol and drug services in the year prior to suicide, increasing the clinical data within the study and improving the validity of any recommendations.

The letters of invitation to participants and participant information sheet have been updated to reflect the change of data sources and variables requested.

Confidentiality Advisory Group advice

The amendment requested was considered by the Confidentiality Advice Team, who raised no queries with this amendment, as the flows are already supported. This amendment is to include additional data items within the supported flows.

Confidentiality Advisory Group advice conclusion

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

Specific conditions of support

The following sets out the specific conditions of support.

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

   The NHS Digital **21/22** DSPT reviews **for University of Manchester NCISH - 8D594-ECC0020, and UKHSA** (on behalf of NDTMS) were confirmed as **'Standards Met'** on the NHS Digital DSPT Tracker (checked 05 October 2022)

   - DHCW – a valid CPiP in currently in place.

- Third sector and NHS services organisations providing publicly funded drug and alcohol services – more than 5, and therefore this is the responsibility of the applicant to ensure.

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

22/CAG/0064 – Building an understanding of Ethnic minority people's Service Use Relating to Emergency care for injuries (BE SURE)

Name	Capacity
Ms Caroline Watchurst	HRA Confidentiality Advisor

Context

Amendment request

This application aims to understand how people from minority ethnic backgrounds present to Emergency Ambulance Services and Emergency Departments with injuries, the care they receive and what happens to them, compared to the White British population.

This amendment sought support to clarify the data flow diagram for WP2, that no confidential patient information was disclosed to NHS Digital from East Surrey Redhill Hospital; The Royal Infirmary Leicester; Sheffield Northern General regarding patients who attended with injury to Emergency Department. The data flow diagram has been amended to show that this outcome data is available via NHS Digital, from Hospital Episode Statistics and Office for National Statistics. This is less disclosive than the original data flow diagram.

This amendment also sought support for an updated version of WP3 data flow diagram, but there is no change to the 's251' support provided, and this is accepted as notification. The applicant has separated the responding and non-responding Study IDs for questionnaires.

The applicant has ‘s251’ support for the collection of ‘Ambulance dispatch data’ from East Midlands Ambulance Services, South East Coast Ambulance Service, and Yorkshire Ambulance Service. However as data controllers they have requested the applicant to be more specific about the data requested. Therefore it has been clarified that the applicants refer to AMPDS (999 computer aided dispatch) data and on scene data collected by paramedics in the Patient Care Record (PCR). This amendment therefore sought support to clarify that they are requesting both AMPDS and PCR data.

Confidentiality Advisory Group advice

The amendment requested was considered by the Confidentiality Advice Team, who raised no queries regarding this amendment, noting this change is no more disclosive than the original request.

Confidentiality Advisory Group advice conclusion

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

Specific conditions of support

The following sets out the specific conditions of support.

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

   Due to the number of organisations involved it is the responsibility of University of Swansea, as controller for this application, to ensure that organisations processing confidential patient information without consent for the purposes of this application, meet the minimum required standard in complying with DSPTs, and take remedial action if they become aware of any that fall below this, or where any concerns are raised.

2. Confirmation of a favourable opinion from a Research Ethics Committee.
   Confirmed no REC review required 13 September 2022

22/CAG/0068 – Childhood outcomes after perinatal brain injury: a population-based linkage study

Name	Capacity
Ms Caroline Watchurst	HRA Confidentiality Advisor

Context

Amendment request

This application aims to conduct a population-based matched cohort study of children born in England 2008-2020, to investigate differences in long-term health, mortality and educational outcomes in children with perinatal brain injury compared to those without brain injury. The initial estimated sample size for cohort 1 (infants with brain injury) was 40, 166 infants.

This amendment sought support to clarify the sample size, as cohort 1 has now been extracted and includes 54,733 infants with brain injury. This will in turn also increase the size of the comparator cohort 2 from 14, 911 to 24, 612 and comparator cohort 3 from 75, 765 to 90, 363 infants. The overall sample size has therefore increased from an estimated 130, 842 to 169, 708 infants.

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 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 review for the following organisations were confirmed as 'Standards Met' on the NHS DSPT Tracker (checked 05 October 2022)

   - **University College London – School of Life and Medical Sciences (standards met for DSPT 2020/21)**
   - **Office for National Statistics (standards met for DSPT 2020/21)**
   - **Department for Education (standards met for DSPT 2021/22)**
   - **NHS Digital (standards met for DSPT 2020/21)**
   - **Chelsea & Westminster Hospital NHS Foundation Trust (standards met for DSPT 2020/21)**

2. Confirmation of a favourable opinion from a Research Ethics Committee. **Confirmed 26 September 2022**

CAG 8-03(PR2)/2013 – UK Register of Fatal anaphylactic reactions

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

Context

Amendment request

This service evaluation application from Manchester University NHS Foundation Trust aims to review deaths from anaphylactic reactions, evaluating whether treatment was given, if so what treatment and why it was ineffective. A recommendation for class 2, 4 and 6 support was requested to cover linking data on an existing locally held database of deceased patients with data held by coroners. 's251' support was provided broadly, and it was assumed that 's251' support was in place for certain data sources, however, the applicant is now required to clarify specific data sources to ensure 's251' support is in place for the data flows.

This amendment sought support to change the previous name of Central Manchester University Hospital Trust, as the Trust is now called Manchester University NHS Foundation Trust.

The amendment also sought support to clarify that 's251' support is in place for the applicant to receive data of deceased individuals from anaphylactic reactions, from the following organisations as data sources;

- PICANet - Paediatric Intensive Care Audit Network (via Universities of Leeds & Leicester)
- ICNARC – Intensive Care National Audit and Research Centre
- NCEPOD - National Confidential Enquiry into Patient Outcome and Death
- NHS Digital (Hospital Episode Statistics)
- National Reporting and Learning ("NRLS") and the Learning from Patient Safety Events (LFPSE) Systems
- Office of National Statistics for Wales (*in addition to the existing Office of National statistics in England*)

To ensure completeness of data for UK, the applicant is also liaising with PBPP for permissions to receive data from Scotland and trying to establish links with Northern Ireland. This is outside of the scope of CAG support.

Confidentiality Advisory Group advice

The amendment requested was considered by Chair's Action. The Vice-Chair recommended support for this amendment, stating that this is fully justified, as these sources of data are essential for complete ascertainment.

Confidentiality Advisory Group advice conclusion

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

Specific conditions of support

The following sets out the specific conditions of support.

1. Confirmation provided from the IG Delivery Team at NHS Digital to the 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 **Manchester University NHS Foundation Trust** was confirmed as 'Standards Met' on the NHS Digital DSPT Tracker (checked 05 October 2022)

19/CAG/0096 – A randomised pilot study of a pharmacist-led retrospective review of prescribing by general practitioners in training (REVISiT) intervention

Name	Capacity
Ms Caroline Watchurst	HRA Confidentiality Advisor

Context

Amendment request

This application gained support under the Regulations to legitimise access to confidential patient information on site at GP practices by the Pharmacist undertaking the review of the GP trainee prescribing practices. The confidential patient viewed is about patients who have been prescribed medication by a GP Trainee within a participating practice during the study duration.

This amendment sought support to extend the duration of ‘s251’ support until 31 March 2023.

Confidentiality Advisory Group advice

The amendment requested was considered by the Confidentiality Advice Team who raised no issues with the 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: Not checked due to the number of research sites involved. Support is recommended on the basis that the applicant ensures the required security standards are in place at each site prior to accessing confidential patient information with support under the Regulations.**

2. Confirmation of a favourable opinion from a Research Ethics Committee. **Confirmed no review required 09 September 2022**

17/CAG/0081 – UK Women's Cohort Study – HES

Name	Capacity
Ms Caroline Watchurst	HRA Confidentiality Advisor

Context

Amendment request

This application involves a database, generated from an existing consented cohort held by the applicants as part of the UK Women's Cohort Study, linked with data held by NHS Digital. The applicants have existing support for the disclosure of confidential patient information from the established cohort to the University of Leeds Integrated Research Campus (IRC). The IRC will then send this information to NHS Digital in order for the dataset to be linked with HES and ODR data for the cohort. This will be returned by NHS Digital to the IRC, whereby the research team will access the information via a Virtual Research Environment.

This amendment sought support to confirm an administrative change in data processor from the University of Leeds Integrated Research Campus (IRC) to University of Leeds -LASER (Leeds Analytic Secure Environment for Research). An associated DSPT has been provided.

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 **University of Leeds - LASER** was confirmed as 'Standards Met' on the NHS Digital DSPT Tracker (checked 05 October 2022)

2. Confirmation of a favourable opinion from a Research Ethics Committee. Confirmed no need for REC review **21 September 2022**

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

Name	Capacity
Professor William Bernal	CAG alternative vice-chair
Dr Sandra Duggan	CAG member
Mr David Evans	CAG member
Dr Rachel Knowles	CAG member
Ms Rose Payne	CAG member
Mr Dan Roulstone	CAG member
Mr Umar Sabat	CAG member
Dr Murat Soncul	CAG alternative vice-chair
Ms Caroline Watchurst	HRA Confidentiality Advisor

Context

Amendment request

This study from the Leeds Teaching Hospitals NHS Trust was supported in April 2018, and aims to test targeted Low Dose Computed Tomography (LDCT) scans screening

in community settings concentrating on deprived areas of Leeds. The intention was to randomise 55-80 year old smokers or ex-smokers to intervention or usual care groups prior to approach. The intervention group were invited to an assessment for a Lung Health Check (including LDCT screening for high-risk people) framed as a pilot health service. The applicants intended to compare outcomes between the invited group and a usual care group, who weren't invited to take part or know that they were in a research study. By comparing outcomes with a control population, the true benefits (of reducing number of late stage cancers, and therefore lives saved) and possible harms (of over-diagnosis) of introducing screening in the UK will be assessed. It was noted by CAG that this study is designed in the style of a screening programme, and that consent and an introduction to the research study does not come up until the patient turns up for the screening scan.

Multiple amendments have been supported, but the most relevant is an amendment supported in 2021 to allow applicants to re-contact by phone, 1000 high risk individuals who had stopped responding, but had initially responded.

This amendment sought support for 3 changes to 's251' support;

- **Change 1**: Identification of newly-eligible participants for screening
- **Change 2**: Pathway navigation (PN) for repeat non-responders
- **Change 3**: Recontacting people disengaging from screening programme using patient navigation (PN)
- This amendment also formally confirms an administrative change - the data processor name at University of Leeds has changed from 'University of Leeds-IRC' to 'University of Leeds-LASER', and this is reflected in the name of the DSPT required.

Change 1

Change 1 is the introduction of re-screening for individuals who may have become eligible since the initial screening for eligibility. Eligibility for lung screening relates largely to age and smoking history and thus changes over time. Those people who may have become newly-eligible would be contacted by telephone to undertake a repeat telephone triage assessment. If this confirmed eligibility, then an appointment would be

made to attend the mobile screening unit. The research nature of the YLST would then be explained at this appointment alongside an informed consent conversation.

Change 2

Change 2 is requested as only 50% of people receiving a postal invitation asking them to make contact with a Lung Health Check service for risk assessment took up that offer. Furthermore, uptake was skewed towards those from more affluent areas, and towards those people who had quit smoking. Applicants propose to randomise individuals who ignored a previous invitation for lung screening, into a PN sub-study. Those allocated the intervention arm would receive an advanced notification letter three weeks before their scheduled telephone appointment time. This is because provision of a scheduled appointment was shown to increase participation in other screening programmes. This notification would include dissent information and an opt-out telephone number should participants not wish to receive a subsequent phone call. At the pre-arranged time, a Pathway Navigator would contact the participant to discuss lung screening. The aim of this is to understand the barriers to screening and to try and help individuals to attend. The PN intervention will be tested using a service demonstration design which frames the intervention as usual care to those receiving it. This means participants will be unaware of the research nature of the Yorkshire Lung Screening Trial until they attend for a Lung Health Check appointment at which fully informed consent will be collected for their participation.

The applicants confirmed they have identified 14,960 people who will be eligible for randomisation as part of the PN study. The control arm would receive a further written invitation to contact the team for lung cancer risk assessment. This written invitation would be the same as they received in the baseline round of screening and mimics the recall of existing screening programmes. There are no plans to collect any additional information regarding these participants. The data that was extracted at the start of the study remains on file, and will be used to describe differences between those who participate in the PN study and those who do not.

The applicants confirmed that none of the 1000 individuals who were contacted as part of the 2021 amendment would be re-contacted for any part of this amendment, as they are a different sub-group of individuals.

The applicants also confirmed that the following groups of people will not be contacted for the purposes of this amendment;

1) People who had requested no further contact from the Lung Health Check team
2) People in whom screening was previously considered not appropriate for medical reasons (dementia, frailty, significant comorbidity making screening inappropriate)
3) People who were deemed unable to consent to the study
4) People who were unable to proceed with screening (e.g. unable to lie flat for the scan)

The justification provided for this amendment in queries answered prior to the meeting, is that it is in the public benefit - lung cancer screening has been shown to reduce lung cancer deaths, and the UK National Screening Committee is considering whether to introduce a nationwide screening programme currently. Participation in lung cancer screening remains lower than other established screening programmes, and data from the YLST indicates that those from more deprived communities were 42% less likely to respond to participate in lung cancer screening, and those people who continue to smoke are 56% less likely to take part than comparator groups. Both deprivation and continued smoking are major risk factors for lung cancer, thus the people at highest risk of this disease appear less able or inclined to participate in screening. There is therefore an urgent need to address barriers to participation in these populations in order to maximise the lives saved by lung cancer screening and ensure equitable access to services in those most at risk of lung cancer. By increasing participation in screening from individuals from deprived populations and who continue to smoke, will offer the possibility of preventing lung cancer deaths through earlier detection for the population who are most at risk of this disease. This amendment aims to address and overcome the inequities that appear to exist in current participation in lung cancer screening, and therefore to maximise the health benefits of screening for more deprived populations. Applicants hope this will help to reduce the significant health inequalities that persist in the UK population and provide strategies for equitable implementation of any future national lung cancer screening programme.

The applicants also reasoned that the design of YLST has always aimed to mimic a possible future nationwide screening programme (and therefore to gain information to inform what that programme might look like). This randomised study seeks to gather evidence to see if PN is a worthwhile and cost-effective intervention to add to a possible future nationwide programme.

The applicant has provided specific justification and detail relating to contacting non-responders for this purpose;

1. Prior invitation letters have always included a clear method for individuals to dissent from the use of their data and to opt-out of any further contact. The small minority who have dissented will not be contacted and are excluded from the repeat non-responder group.

2. Prior invitation letters have not sought explicit consent at the invitation stage. Consent is sought during the subsequent face-to-face Lung Health Check appointment should they choose to attend. The letters simply ask individuals to telephone to begin the process of eligibility assessment and appointment booking. The applicant reasons that those not responding to prior invitations therefore cannot be considered a failing to explicitly consent as they were not asked to do so (in line with guidance: https://s3.eu-west-2.amazonaws.com/www.hra.nhs.uk/media/documents/managing-non-response-guidance-v1-2.pdf).

3. There are different reasons for non-response beyond informed personal choice, as evidenced by research implicating practical and motivational barriers to participating in lung cancer screening which underpin inequalities in participation.
    a) Prior invitation letters not received/understood. Applicants do not know how many of those who did not respond a) received the postal invitation (e.g., incorrect address, difficulty receiving post at multi-resident address) and b) were able to read or understand the contents (due, for example, to literacy, English language, sight difficulties). The PN intervention will use a timed phone call to support effective contact of individuals and strategies which support comprehension to not only support participation, but also informed consideration of the offer.
    b) Inclined to respond but do not. These individuals may be interested in screening or intended to respond previously but did not. Reasons are wide-ranging with examples ranging from conflicting/competing priorities (eg, work/caring responsibilities) and issues with access (e.g. transport, cost, disability) to procrastination or forgetfulness. In the context of cervical cancer screening, research in England suggests that half of women who have not participated do actually intend to do so and that women from lower socioeconomic backgrounds are more likely to not realise their intention to participate. The PN intervention will use strategies to support access and planning should they personally choose to participate.
    c) Misinformed non-response. These individuals may hold misconceptions about their eligibility for lung cancer screening (e.g. I have smoked too long), their likelihood of benefitting from early detection and the efficacy of treatment (e.g. having known close others die of lung cancer when diagnosed late), may fear being diagnosed at screening or may believe

they will be stigmatised due to their tobacco dependence. Research shows these perceptions are more common among those living in areas experiencing socioeconomic deprivation and those who currently smoke. The aim of PN is to help overcome emotional barriers and misconceptions based on deep-rooted personal experience of the disease and offer strategies to support their response and attendance should they personally choose to do so.

d) Informed non-response. These individuals have made an informed choice not to respond but have not dissented from data use nor further contact. Applicants respect their right to do so but cannot practicably identify which individuals they are in order to remove them from invitation to the third screening round. They may continue not to actively dissent, may not respond to their invitation to the third screening round (if in the control arm), or decline to participate during a timed phone call (if in the intervention arm). This letter will be sent approximately 2 years after their prior invitation and is routine activity for a NHS service to re-invite the eligible population periodically. If applicants do achieve contact with someone in this group, they will fully respect any choice to decline participation.

4. There is evidence that repeat contact strategies for cancer screening are more effective at engaging those experiencing socioeconomic deprivation (eg, reminders, advance notification).

In addition, the applicants state that they have undertaken a patient and public involvement exercise to understand the acceptability of this observational approach to collecting ‘anonymous’ data for analysis without seeking individual informed consent.

Change 3

Change 3 is requested to allow the recontacting of people who disengaged from the screening programme by using PN. In YLST, of 7,954 people found to be at high risk of Lung Cancer following telephone triage assessment, 1,304 people did not proceed to screening. Some were appropriately excluded, however, the commonest reason for not attending, was failing to attend on the day (DNA) or contacting to cancel their appointment. Continued participation in screening is essential to achieve the mortality benefits demonstrated in the randomised studies. People with potentially reversible reasons will be contacted by telephone and offered an opportunity to reengage with the Lung Health Check programme should they wish. Change 3 therefore aims to explore reasons for non-attendance/adherence in previously eligible participants. The same PN approach described above will be used to elicit, and where possible overcome, barriers to attendance.

Confidentiality Advisory Group advice

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

1. **Please confirm the evidence that shows that the characteristics of the non-responders are the same as those who are at more high risk of lung cancer.**

The applicant has clearly described the evidence to show this in the response provided. It is well known that lung cancer risk is higher in current versus ex-smokers. The link between deprivation and lung cancer risk is also well described. Data from the baseline round of the Yorkshire Lung Screening Trial (YLST) showed that current smoking status and socio-economic deprivation were both strongly linked to non-response. The CAG were content with the evidence provided.

2. **Please provide evidence of specific support form patients and the public, surrounding the contacting of non-responders for the purpose of change 2.**

The applicant provided thorough feedback surrounding patient and public involvement undertaken with 12 respondents from various sources. None expressed any concerns or reticence about approaching non-responders. Whilst all respondents gave broad affirmative feedback that the overall research design was acceptable, some also specifically picked up on the importance of reaching people who had previously not responded. The CAG were content with this response.

3. **Please provide the Favourable Opinion of the REC, as per standard condition of support**

This was provided by the applicant alongside the response to CAG.

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 **Leeds Teaching Hospitals NHS Trust, University of Leeds – Laser, CFH Docmail LTD, Reed Wellbeing Ltd, and NHS Digital** were confirmed as 'Standards Met' on the NHS Digital DSPT Tracker (checked **26 September 2022**)

2. Confirmation of a favourable opinion from a Research Ethics Committee; **Confirmed 05 October 2022**

21/CAG/0120 – NHS England Hepatitis C Virus Case Finding in Primary Care Pilot (HepCAPP)

Name	Capacity
Ms Caroline Watchurst	HRA Confidentiality Advisor

Context

Amendment request

The applicants have existing support to allow the disclosure of confidential patient information from participating GP practices to UKHSA (previously Public Health England) so that eligible patients can be contacted to seek consent for participation in the study.

The original application stated that a reminder letter would be sent. This amendment sought support to reduce the 's251' support provided to only one initial contact, and remove the sending of the reminder letter from the application. The applicants have

found uptake better than expected, and do not wish to contact patients twice when it is not required.

The updated associated documents (with references to the second reminder contact removed) have been accepted as notifications to CAG.

Other changes made to the REC approval within this IRAS amendment do not relate to any changes to ‘s251’ support and are therefore accepted as notification only.

Confidentiality Advisory Group advice

The amendment requested was considered by the Confidentiality Advice Team, who agreed that the amendment was in the public interest, noting that the study design was now less disclosive.

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 05 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 **Confirmed:**

   The NHS Digital 21/22 DSPT reviews for the **University of Bristol - Bristol Medical School and UKHSA** were confirmed (confirmed by check of the NHS Digital DSPT tracker on 20 October 2022).

22/CAG/0075 – Clinical and Radiographic outcomes of reverse shoulder arthroplasty performed with 36-mm CoCrMo vs 40-mmcross-linked UHMWPE glenospheres at minimum 2-years follow-up.

Name	Capacity
Ms Caroline Watchurst	HRA Confidentiality Advisor

Context

Amendment request

Support is currently in place to allow the direct care team to provide NHS numbers of the patients meeting the eligibility criteria to the research delivery team, and for the research delivery team to subsequently access medical records to extract clinical data. The supported data flow currently includes the redaction and pseudonymisation of radiographic images, and burning these to disc to transfer to a radiographic CoreLab for interpretation by independent radiographers. The flow of this data remains the same, but will now take place by electronic transfer rather than by the posting of discs to the CoreLab.

Therefore this amendment sought support to change the process whereby the radiographic images are extracted, as the pseudonymous data flow will now be undertaken using electronic data transfer, and therefore the extraction process (which requires ‘s251’ support) has changed to remove the need to burn scans to disc . The applicant has confirmed there is no change to the data flow or data sources.

Confidentiality Advisory Group advice

The amendment requested was considered by the Confidentiality Advice Team, who raised no queries with this amendment, noting there was no change to data flows or sources, and was therefore no more disclosive than the current ‘s251’ support.

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 **20/21** DSPT review for **Wrightington, Wigan and Leigh NHS Foundation Trust** was confirmed as 'Standards Met' on the NHS Digital DSPT Tracker (checked 20 October 2022)

2. Confirmation of a favourable opinion from a Research Ethics Committee. **Confirmed 13 October 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 also sought support for the addition of five new participating sites (Worcestershire Acute Hospitals NHS Trust, Hampshire Hospitals NHS Foundation Trust, Wrightington, Wigan and Leigh Teaching Hospitals NHS Foundation Trust, Hywel Dda University Health Board and Cardiff and Vale University Health Board) as data processors, 3 of which are in England, and 2 in Wales. There is an additional site being included from Scotland, which does not fall under 's251' remit, and the applicant is seeking PBPP approval for this.

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 20 October 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 21 October 2022

15/CAG/0158 – The Fracture Liaison Service Database

Name	Capacity
Ms Caroline Watchurst	HRA Confidentiality Advisor

Context

Amendment request

This amendment sought support for a clarification regarding one of the data items collected as part of the application. The FLS-DB currently collect ‘gender’ with ‘male’ and ‘female’ response options. This amendment sought support to change the field ‘gender’ to ‘sex’, but keep the response options the same.

There is no change to data flows or any other change to confidential patient arrangements.

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 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 Royal College of Physicians of London, Crown Informatics, and University of Bristol – Bristol Medical School** were confirmed as **'Standards Met'** on the NHS Digital DSPT Tracker (checked 20 October 2022).

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

Name	Capacity
Ms Kathleen Cassidy	Confidentiality Advisor

Context

Amendment request

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

The applicants are seeking to revise the notification materials sent to patients. This is required as the NCA Salford Integrated Record (SIR) Board have asked that the application was split into three separate applications, one for each research question. The applications for research questions 1 and 2 have been submitted to the SIR Board. In order to begin work on the first two research questions, the applicants have created two notifications. The first will inform patients of the use of their data to answer queries 1 and 2, and will be displayed for two weeks before the work commences.

A later amendment will be submitted to provide the patient notification for research question 3.

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:

The NHS Digital **2020/21** DSPT reviews for the **University of Manchester** and **the Northern Care Alliance** were confirmed as ‘Standards Met’ on the NHS Digital DSPT Tracker (checked 27 January 2022).

2. Confirmation of a favourable opinion from a Research Ethics Committee.

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

Name	Capacity
Ms Kathleen Cassidy	Confidentiality Advisor

Context

Amendment request

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

The applicants are now seeking to expand the cohort to include patients at Nottingham University Hospitals NHS Trust when under the care of any specialty, not just respiratory medicine. The same data flows will be followed, i.e. confidential patient information will be accessed by research staff at the Trust to access an anonymised dataset for analysis at the University of Nottingham.

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 the **University of Nottingham** and **Nottingham University Hospitals NHS Trust** were confirmed as 'Standards Met' on the NHS Digital DSPT Tracker (checked 03 March 2022)

2. Confirmation of a favourable opinion from a Research Ethics Committee. **Confirmed 31 August 2022**.

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

Name	Capacity
Ms Kathleen Cassidy	Confidentiality Advisor

Context

Amendment request

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

The amendment set out a request to include locally held Patient Administration System (PAS) data from each of the participating trusts for all patients in the study. This additional data source has been added to aid the collection of readmissions data.

The applicants also seek to include additional items from the HES dataset. These data items did not include any additional items of confidential patient information therefore support was not needed to collect these.

Confidentiality Advisory Group advice

The amendment requested was considered by the Confidentiality Advice Team, who 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:

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

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

22/CAG/0062 – ASCEND PLUS

Name	Capacity
Ms Kathleen Cassidy	Confidentiality Advisor

Context

Amendment request

The applicants have existing support to allow the disclosure of confidential patient information from NHS Digital to Paragon Customer Communications to facilitate contact with patients meeting the eligibility criteria and seek their consent to take part.

The amendment request set out a number of changes to the protocol and participant facing materials, that did not impact on the scope of support.

The amendment also included a change to the data disclosed from NHS Digital to Paragon Customer Communications Ltd. Instead of including patients' NHS numbers

in the disclosure from NHS Digital, a unique identifier will be used to pseudonymise the data.

Confidentiality Advisory Group advice

The amendment requested was considered by the Confidentiality Advice Team. The Team agreed that the use of a unique identifier in place of patients' NHS number will minimise the disclosure of confidential patient information. The CAT noted that support was still required as Paragon Customer Communications Ltd would be able to re-identify patients to make contact, therefore there was still a breach in the Common Law Duty of Confidentiality.

Confidentiality Advisory Group advice conclusion

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

Specific conditions of support

The following sets out the specific conditions of support.

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

   Confirmed: The NHS Digital 2021/22 DSPT review for University of Oxford and Paragon Customer Communications Ltd were confirmed as 'Standards Met' on the NHS Digital DSPT Tracker (checked 19 October 2022).

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

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

Name	Capacity
Ms Clare Sanderson	CAG Alternate Vice Chair
Sara Randall	CAG Member

Dr Harvey Marcovitch	CAG Member
Ms Kathleen Cassidy	Confidentiality Advisor

Context

Amendment request

This is a request to defer the National Data Opt-Out for ECC 1-03(d)/2012, the National Bowel Cancer Audit (NBOCA). A request was also received to defer the National Data Opt-Out for ECC 1-06(c)/2011, the National Oeosphago-Gastric Cancer Audit (NOGCA). A separate outcome letter had been produced for NOGCA. Both audits are part of the Gastrointestinal Cancer Audit Programme (GICAP). GICAP was commissioned by HQIP on behalf of NHS England and the Welsh Government as part of the National Clinical Audit and Patient Outcomes Programme (NCAPOP). The Programme aims to evaluate and improve the care of NHS patients with bowel or oeosphago-gastric cancer. The applicants have submitted annual reviews for each application, as required.

Confidentiality Advisory Group advice

1. **Further information is required to evidence that application of the National Data Opt-Out would have an adverse effect on patient safety.**

The GICAP's work in detecting statistical outliers for key outcome indicators enables the identification of potential patient safety issues, leading to local improvement activities where necessary. There are many examples from across both audits of the impact of outlier reporting on patient safety. The applicants provided summaries of a selection of case studies. The CAG noted this information and raised no further queries.

2. **The patient notification documents need to be provided. A layered approach to patient notification also needed to be adopted, including posters and leaflets as well as online information. The patient notification documents need to include:**

    a. **An explanation of deferral the National Data Opt-Out.**
    b. **An explanation that other items of confidential patient information, in addition to their NHS Number, would be collected.**

The applicants provided revised patient leaflets, explaining the National Data Opt-out (NDO) deferral. These documents explained that identifiable data items other than NHS Number were collected by the audits.

Posters, explain the National Data Opt-Out and links to further information, had been created. The posters will be distributed to all hospitals participating in GI audits. Both posters have been also shared with Patient Groups and the feedback was positive. For both audits, an National Data Opt-out specific page, called Patient Choices, had been included within the audit's web site, to provide or direct to the information about the National Data Opt-Out deferral and the process of opting-out from individual audits.

The applicants also engaged with the Enquiries team at NHS Digital to discuss the potential National Data Opt-Out deferral for GICAP and what it meant for handling patients' enquiries. The Enquiries team has also agreed with us the process for managing opt-outs from individual audits.

The CAG noted this information and was largely satisfied by the information provided. Members noted that the leaflets contained the statement "Not everyone is comfortable for their information being used…" and asked that this was revised for grammar.

3. **Patient and public involvement needs to be undertaken specifically around the deferral of the National Data Opt-Out. Feedback from this activity needs to be provided to the CAG.**

The applicants provided details of the patient and public involvement carried out and the feedback received. The CAG noted this information and raised no further queries.

Specific conditions of support

The following sets out the specific conditions of support.

1. The statement "Not everyone is comfortable for their information being used…" in the leaflets needs to be revised

2. Application of the National Data Opt-Out is to be deferred for the non-research activities specified in ECC 1-03(d)/2012.

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

Name	Capacity

Ms Clare Sanderson	CAG Alternate Vice Chair
Sara Randall	CAG Member
Dr Harvey Marcovitch	CAG Member
Ms Kathleen Cassidy	Confidentiality Advisor

Context

Amendment request

This is a request to defer the National Data Opt-Out for ECC 1-06(c)/2011, the National Oeosphago-Gastric Cancer Audit (NOGCA). A request was also received to defer the National Data Opt-Out for ECC 1-03(d)/2012, the National Bowel Cancer Audit (NBOCA). A separate outcome letter had been produced for NBOCA.

Both audits are part of the Gastrointestinal Cancer Audit Programme (GICAP). GICAP was commissioned by HQIP on behalf of NHS England and the Welsh Government as part of the National Clinical Audit and Patient Outcomes Programme (NCAPOP). The Programme aims to evaluate and improve the care of NHS patients with bowel or oeosphago-gastric cancer. The applicants have submitted annual reviews for each application, as required.

Confidentiality Advisory Group advice

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

1. **Further information is required to evidence that application of the National Data Opt-Out would have an adverse effect on patient safety.**

The GICAP's work in detecting statistical outliers for key outcome indicators enables the identification of potential patient safety issues, leading to local improvement activities where necessary. There are many examples from across both audits of the impact of outlier reporting on patient safety. The applicants provided summaries of a selection of case studies. The CAG noted this information and raised no further queries.

2. **The patient notification documents need to be provided. A layered approach to patient notification also needed to be adopted, including posters**

and leaflets as well as online information. The patient notification documents need to include:

a. **An explanation of deferral the National Data Opt-Out.**
b. **An explanation that other items of confidential patient information, in addition to their NHS Number, would be collected.**

The applicants provided revised patient leaflets, explaining the National Data Opt-out (NDO) deferral. These documents explained that identifiable data items other than NHS Number were collected by the audits.

Posters, explain the National Data Opt-Out and links to further information, had been created. The posters will be distributed to all hospitals participating in GI audits. Both posters have been also shared with Patient Groups and the feedback was positive. For both audits, an National Data Opt-out specific page, called Patient Choices, had been included within the audit's web site, to provide or direct to the information about the National Data Opt-Out deferral and the process of opting-out from individual audits.

The applicants also engaged with the Enquiries team at NHS Digital to discuss the potential National Data Opt-Out deferral for GICAP and what it meant for handling patients' enquiries. The Enquiries team has also agreed with us the process for managing opt-outs from individual audits.

The CAG noted this information and was largely satisfied by the information provided. Members noted that the leaflets contained the statement "Not everyone is comfortable for their information being used…" and asked that this was revised for grammar.

3. **Patient and public involvement needs to be undertaken specifically around the deferral of the National Data Opt-Out. Feedback from this activity needs to be provided to the CAG.**

The applicants provided details of the patient and public involvement carried out and the feedback received. The CAG noted this information and raised no further queries.

Confidentiality Advisory Group advice conclusion

The CAG agreed that insufficient justification had been provided to justify a deferral of application of the National Data Opt-Out in relation to the non-research activities contained within ECC 1-06(c)/2011. The CAG therefore recommended to the Secretary of State for Health and Social Care that the National Data Opt-Out deferral request be provisionally approved. The CAG would make a final recommendation on whether the deferral request should be supported once responses to the below queries had been provided and considered.

Specific conditions of support

The following sets out the specific conditions of support.

1. The statement "Not everyone is comfortable for their information being used…" in the leaflets needs to be revised

2. Application of the National Data Opt-Out is to be deferred for the non-research activities specified in ECC 1-03(d)/2012.

3. Annual Review Approvals

16/CAG/0053	Prolonged Effects of ART: a Record Linkage study (PEARL)
20/CAG/0073	Styrene cohort study
20/CAG/0133	Yorkshire Specialist Register of Cancer in Children and Young People
21/CAG/0048	STAMPEDE
15/CAG/0139	Life course pathways to ageing in the MRC NSHD
21/CAG/0104	Enhancing Pre-hospital Chest Pain Telephone-triage
19/CAG/0055	Triage Heart Failure
PIAG 3-07(j)/2002	Study into the long-term consequences of chronic diseases and their treatments
PIAG 2-10(f)/2005	ICNARC Case mix programme (CMP)
19/CAG/0135	Derby Monitoring Study of Self-harm
21/CAG/0120	NHS England Hepatitis C Virus Case Finding in Primary Care Pilot
19/CAG/0139	Routine testing for Group B Streptococcus
17/CAG/0081	UK Women's Cohort Study - HES
19/CAG/0144	Infections in Oxfordshire: a Research Database (IORD)
16/CAG/0043	BADBIR
20/CAG/0084	PIONEER
21/CAG/0088	BSIR
ECC 7-04(j)2010	Long term risks of paediatric fluoroscopic cardiology
ECC 5-07 (b)/ 2009	Prescription Event Monitoring
15/CAG/0158	The fracture liasion service database
20/CAG/0056	PEARL s251 Sensitive Health Records Template b3010

20/CAG/0057	PEARL s251 Sensitive Health Records Template b2172
19/CAG/0118	Collection of genito-urinary tissue
16/CAG/0121	Epidemiology of Cancer after solid organ transplantation
18/CAG/0180	LAUNCHES QI
20/CAG/0116	BAOMS - QOMS
21/CAG/0127	Oxford Vascular Study
19/CAG/0172	Population based study of genetic predisposition to endometrial cancer
19/CAG/0171	A population-based study of genetic predisposition to breast cancer
18/CAG/0142	A population-based study of genetic predisposition to Ovarian cancer
20/CAG/0071	BALLETS First Year Follow Up
19/CAG/0024	The Sub30 Feasibility Trial
ECC 1-05(b)/2012	ALSPAC Study Young Adults: Enrolment and Consent for Record Linkage

Signed – Chair	Date
Dr Tony Calland, MBE, CAG Chair, Dr Patrick Coyle, CAG Vice-Chair, Ms Clare Sanderson, Dr Murat Soncul & Professor William Bernal, CAG Alternate Vice-Chairs	*15 December 2022*

Signed – Confidentiality Advice Team	Date
Ms Kathleen Cassidy, HRA Confidentiality Advisor	*05 December 2022*