Health Research Authority

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

July 2022

1. New Applications

a. 22/CAG/0022 - Patterns of Multiple Long-Term Vascular Conditions: A pilot study

Name	
Mr. Myer Glickman OBE	CAG member
Mr Andrew Melville	CAG member
Dr Murat Soncul	CAG alternative vice-chair
Ms Caroline Watchurst	HRA Confidentiality Advisor

Context

Purpose of application

This application from King's College London set out the purpose of medical research of linking data of patients with vascular (stroke and heart attack) episodes from national and local registries with their hospital and GP records to better understand patients health care journey and clinical outcomes, both mental and physical. This is part 2 of the project. There is a consented element, part 1, which does not require 's251' support.

Multimorbidity represents a significant health and societal burden, and commonly includes vascular risk factors and diseases. 32.4 million people annually suffer a stroke or heart attack worldwide, both being associated with significant mortality, morbidity and disabling conditions. Understanding the interrelationships between socio-demographics, vascular diseases, physical and mental outcomes, and early prevention and control of the development or progression of multimorbidity are all key to reducing the cumulative burden of these multiple long-term vascular conditions (MLTVCs) and their consequences. Gaps exist in effective prevention strategies in primary care; a recent analysis of 29,000 patients found that of 17,700 patients for whom a specific preventive treatment was clinically indicated before their first stroke, very few received the suitable treatments. linking of multiple health data sources has the potential to improve health outcomes among people with MLTVCs, as vascular events are largely preventable, and this linkage will help to identify which factors (social, biological, interventions) are associated with missed prevention opportunities and the data will aid in developing effective strategies for patients, their families, and clinical teams to reduce the likelihood of further vascular conditions.

Patients who have had a heart attack will be identified from the MINAP dataset by NICOR, who will disclose NHS number to NHS Digital in order to be linked with HES and ONS data. NHS Digital send the linked dataset back to NICOR, who will send this dataset, including NHS numbers, to the Clinical Data Linkage Service (CDLS) (hosted by SLaM). Clinical Record Interactive Search (CRIS) data including NHS numbers will also be disclosed to the CDLS. South London Stroke Register (SLSR), and Lambeth Data Network (LDN), will disclose only pseudonymised NHS number to CDLS, as they will use the same software which will change the NHS number into the same pseudonymised format, 's251' support is therefore not required for this disclosure. This will provide a complete picture of South London stroke patients.

CDLS will then use the same algorithm used by SLSR and LDN to pseudonymise the NHS numbers in the received datasets, and will then link together the MINAP, HES, ONS, CRIS, SLSR and LDN datasets using the pseudonymised NHS number. CDLS will then fully anonymise the data and retain the final dataset for analysis within SLaM, and the researchers from KCL will then be given permission to access the dataset.

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	Patient event between - 1st January 2003 to 31st March 2021 • All adults aged 18 and over admitted to hospital with a heart attack (MINAP data) • All adults aged 18 and over on South London Stroke Register • All adults aged 18 and over on Lambeth DataNet database • All adults aged 18 and over on The Clinical Record Interactive Search (CRIS) Applicants estimate this to be approximately 1.5 million individuals.
Data sources	1. Myocardial Ischaemia National Audit (MINAP) dataset, from National Institute for Cardiovascular Outcomes Research (NICOR), hosted at Barts Health NHS Trust, and controlled by HQIP. 2. NHS Digital – a. Hospital episode statistics (HES) b. Office for National Statistics (ONS) mortality data 3. Clinical Record Interactive Search (CRIS) data (at South London and Maudsley (SLaM) 4. Lambeth DataNet (LDN) – retained at South East London Clinical Commissioning Group 5. the South London Stroke Register (SLSR) - retained at Kings College London (KCL)

Identifiers required for linkage purposes	1. NHS number only between MINAP, HES and ONS 2. Pseudonymised NHS number between MINAP/HES/ONS, CRIS, SLSR, LDN 3. GP registration required regarding LDN data, to ensure catchment area, however this will not be linked to any direct identifier.
Identifiers required for analysis purposes	1. Gender 2. Occupation 3. Ethnicity The data is anonymous for analysis

Confidentiality Advisory Group advice

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

1. **Please provide the content of the patient notification which will be available on NICOR and KCL websites, which clearly sets out ways to raise objections, and includes contact details.**

   The applicant provided this document and the CAG were content.

2. **Please provide an updated report on patient and public involvement activity reflecting recent views of participants on this specific use of confidential patient information without consent.**

   The applicant provided feedback, which involved a small group of individuals, but covered the important topics. The CAG were content with this response.

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

The REC Favourable opinion was provided to the CAG inbox by the REC on 27 June 2022.

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 11 April 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 **20/21** DSPT reviews for **Barts Health NHS Trust (NICOR), NHS Digital, and South London and Maudsley NHS Foundation Trust** were confirmed as '**Standards Met'** on the NHS Digital DSPT Tracker (checked 14 February 2022)

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

Name	
Dr Tony Calland MBE	CAG Chair
Dr Martin Andrew	CAG member

Mr Andrew Melville	CAG member
Ms Caroline Watchurst	HRA Confidentiality Advisor

Context

Purpose of application

This application from Swansea University set out the purpose of medical research which 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. The applicant aims for the research to inform policy to address any differences in care, morbidity and mortality.

Injuries are a major public health problem which can lead to disability or death. In the United Kingdom (UK) six million Emergency Department (ED) visits a year are the result of accidental injuries. However, little is known about the incidence, management and outcomes related to injuries among people from ethnic minority groups in the UK. Studies from several countries have indicated that people from ethnic minority groups have poor experience of accessing care and poor satisfaction with care compared to their White counterparts. Poor experiences have been attributed to communication, cultural barriers, feeling excluded from vital decisions related to their care and perceived limited choice of care provision. The applicant aims for this research to support ambulance service and emergency departments to improve care and outcomes for ethnic minority people who experience injuries and inform injury surveillance resources where they exist, and to include ethnicity dimension in the reporting of injury.

This mixed methods study encompasses 5 work packages; ‘s251’ support is not sought for WP1, WP4 or WP5. The retrospective linkage element, WP2 does require ‘s251’ support. A questionnaire element (WP3), also requires ‘s251’ support for a linkage element. Invitation letters are sent out by direct care team, inviting the patient to consent to a questionnaire, but stating that linkage will be undertaken using ‘s251’. WP2 comprises of a split file design, where ambulance services disclose clinical data alongside a pseudonym to SAIL, and an identifiable data file alongside the pseudonym to NHS Digital, in order for NHS Digital to link with Hospital Episode Statistics (HES), emergency care data (ECDS), and Office for National Statistics (ONS) mortality data (for 6 months post presentation), and send a dataset to SAIL. This data set will include full date of death, however neither unit level postcode nor full date of birth is also disclosed in this flow, as the applicant has confirmed they are able to receive week of birth, and deprivation scores from NSH Digital. SAIL can then link the 2 files together. There is also a flow of Scottish data described for WP2, however this is out of scope for ‘s251’ 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	**WP2**: patients for whom a 999 call was made for an injury, recorded in ambulance dispatch data, from participating Ambulance services, between 1 August 2016 and 31 July 2021. (People of all ages; coded with injury; who contacted or were attended by the emergency ambulance service (including those not conveyed) or attended ED; who were located within the nominated ED area; classified as belonging to an ethnic minority group (using the 2011 ONS census classification, covering White minority Gypsy, Roma and Traveller groups) or classified as White British.) Estimated cohort size: n=550,000 **WP3**: Any adult (18 plus); coded with injury; who contacted the emergency ambulance service or were attended by emergency ambulance (including those not conveyed) or attended ED; who were located within the nominated ED area; classified as belonging to an ethnic minority group (as in WP2, above) or classified as White British, between 1 April 2022 – and 30 September 2022.

	Estimated cohort = 800
Data sources	1. **NHS Digital** – • Office for National Statistics (ONS) Civil Registration (Deaths) • Emergency Care Data Set (ECDS) • Hospital Episode Statistics (HES): Admitted Patient Care, Critical Care and Outpatient Care **Ambulance dispatch data from;** 2. East Midlands Ambulance Services 3. South East Coast Ambulance Service 4. Yorkshire Ambulance Service **A+E data from:** 5. Leicester Royal Infirmary – (University Hospitals of Leicester NHS Trust) 6. East Surrey Hospital, Redhill (Surrey and Sussex Healthcare NHS Trust) 7. Northern General Hospital, (Sheffield Teaching Hospitals NHS Foundation Trust)
Identifiers required for linkage purposes	4. Pseudonymous Study ID 5. Name 6. NHS number 7. Date of Birth 8. Postcode (unit level) 9. Gender 10. Ethnicity
Identifiers required for analysis purposes	1. Date of death 2. Gender 3. Ethnicity 4. Date of birth – modified to week of birth by NHS Digital

	5. Unit level post code – modified to deprivation score by NHS Digital

Confidentiality Advisory Group advice

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

1. **Please provide clarification regarding the use of the identifiers – Date of birth, date of death, and full post code. Please clarify if these are disclosed to SAIL, or if they are modified prior to this disclosure. If they are not modified, please confirm how long they are retained, and the justification for the use of the full data items.**

The applicant has confirmed they will be requesting Week of Birth, not full date of birth. They will also not request full postcode, but will receive deprivation scores via NHS Digital.

They will request full Date of Death. Date of death is needed to define specific study outcomes, such as death within 24 hours of an ED attendance. 's251' support is therefore requested until SAIL deletes the full date of death.

This will be stored in SAIL in a separate database, and will be retained by SAIL for a maximum of 5 years in line with other data and will be deleted at that time point. The CAG were content with this response.

2. **Please provide some information about which 3rd sector organisations will host the WP2 notification on their websites/social media.**

Examples of organisations applicants are working with are below. They will host the WP2 notification on their website (where available) and display the notification on their public notice boards:

- Sheffield - Refugee Council
- Leicester - Race Equality Network
- Surrey – Healthwatch Surrey

The CAG were content with this response.

3. **Please provide any notification posters for CAG review.**

No posters have been provided, but the CAG were content with the available notification documents.

4. **Please provide updated versions of the patient notification materials for WP2 and WP3. These should take into account the advice provided in this letter, and should be reviewed by lay individuals.**

These have been provided, and extensively reviewed by lay people. The CAG were content with this.

5. **Please undertake further patient and public involvement with at least 10 more individuals, who are representative of the cohort (general population). Please focus on the use of confidential patient information without consent, and the content of the patient notification, and feedback to CAG.**

The applicant has began discussions with two PPI groups; the SAIL Consumer Panel consisting of 15 people, and the PRIME Super groups consisting of 20 people. Both groups include PPI members living in England and from various age groups, genders, sexualities, and class and ethnic backgrounds (including White-British). The CAG were content that there will be ongoing discussions with these groups.

6. **The exit strategy for 's251' support is to be clarified, and this will be aided by the response to point 1, above.**

The exit strategy is now clarified, and the CAG were content with the response provided in point 1.

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 5th April 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.**

   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.

   The relevant organisations are;

   1. NHS Digital
   2. SAIL (8WG95)

<u>English Ambulance services</u>

   3. East Midlands Ambulance Services
   4. South East Coast Ambulance Service
   5. Yorkshire Ambulance Service

<u>English Trusts</u>

   6. Leicester Royal Infirmary – (University Hospitals of Leicester NHS Trust)
   7. East Surrey Hospital, Redhill (Surrey and Sussex Healthcare NHS Trust)
   8. Northern General Hospital, (Sheffield Teaching Hospitals NHS Foundation Trust)

c.22/CAG/0019 - CUREd+: Centre for Urgent and Emergency Care Research Database - refresh

Name	
Dr Tony Calland MBE	CAG Chair
Dr Martin Andrew	CAG Member
Ms Sophie Brannan	CAG Member
Mr. Myer Glickman OBE	CAG Member
Mr Tony Kane	CAG Member
Dr Rachel Knowles	CAG Member
Ms Rose Payne	CAG Member
Ms Diana Robbins	CAG Member
Ms Clare Sanderson	CAG Alternative Vice-Chair
Ms Natasha Dunkley	HRA Head of Confidentiality Advice Service
Ms Emma Marshall	HRA Confidentiality Specialist
Dr Paul Mills	HRA Confidentiality Advice Service Manager
Mr Michael Pate	HRA Confidentiality Advisor
Ms Caroline Watchurst	HRA Confidentiality Advisor

Context

Purpose of application

This application from University of Sheffield (UoS) set out the purpose of medical research of updating and extending the CUREd Research Database (18/CAG/0126), to include more recent data and to extend the geographical area covered by the dataset. The CUREd Research Database refresh will expand the hospital data to cover all of England, update the linked ambulance service data, add death registration data, reduce variation within the hospital data, reduce the amount of confidential patient information processed and retained by UoS, and enable further research on a number of Urgent and Emergency Care (UEC) related topics.

The CUREd Research Database allows research from a UEC system perspective to examine patient flow through the whole system, from point of contact (e.g. call to 999/NHS 111) through different parts of the system, including the emergency department (ED) and into hospital. Understanding the system and how patients use it is key to developing appropriate patient-focused interventions that can lead to a sustainable, safe and cost-effective system of care. The CUREd database refresh will ensure that the data held reflects changing practices and continues to be useful for analyses.

Updated clinical data from NHS Digital and from Yorkshire Ambulance Service (YAS) will be combined with existing YAS data taken from the CUREd Research Database, which was originally created under ‘s251 support’ by UoS using data from YAS and a number of NHS Hospital Trusts in Yorkshire and the Humber. The existing CUREd Research Database contains clinical and operational data, and the patient identifiers used during its creation are encrypted and stored separately. NHS Digital will act as the Trusted Third Party for linkage and provide an updated dataset back to the applicants.

Access to the environment containing the pseudonymised health data will be restricted to experienced data management personnel involved in the processing of the database. Research will focus on specific cohorts of patients, pathways through the UEC services, and trends over time of service use. Limited, de-identified extracts containing only the necessary data will be prepared as needed for analysis, and transferred to separate secure computing environments where analysis will take place. Analysis will be according to the research question of interest but will focus on how the UEC system is used. Researchers who are not part of the Applied Research Collaboration (ARC) will require approval from the UoS CUREd+ Data Release Committee to obtain data from the refreshed CUREd Research Database.

A recommendation for class 1, 2, 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	Patient episodes of care between 1st April 2011 and 31st March 2023 Cohort A: Patients who 1) contacted or received care from the emergency ambulance service provided by Yorkshire Ambulance Service (YAS) NHS Trust, or 2) contacted the NHS 111 telephone triage service provided by YAS Cohort B: Patients who 1) received unscheduled care at a Walk-in Centre, Minor Injuries Unit, Urgent Care Centre or Emergency Department in England, or, 2) received inpatient or outpatient NHS hospital care in England, or 3) received care from Mental Health Services in England Cohort C:

	Patients who 1) are in cohort A, or 2) are in cohort B, and whose care was provided by a Trust in the Yorkshire and Humber region Approximate number of patients estimated as 80 million in Cohort B, plus additional minimal numbers in cohort A and C. (however the 80 million figure is based on number of unique NHS Digital identifiers, and this may represent a lower number of individual patients)
Data sources	8. University of Sheffield - School of Health and Related Research (ScHARR) a. the YAS clinical data (999 and NHS111) extracted from CUREd Research Database", between 2011 and 2017 b. patient identifiers for the existing YAS cohort of patients from the CUREd database 9. NHS Digital a. **For cohort B**: i. Hospital Episode Statistics (HES); 1. Emergency Care Data Set (ECDS) 2. Accident & Emergency (A&E) 3. Outpatient (OP) 4. Admitted Patient Care (APC) ii. Mental Health Services Data Set (MHSDS) iii. Demographic, and iv. Civil Registration – death data (ONS Mortality) b. **For cohort C:** i. Medicines Dispensed in Primary Care data, ii. and address information iii. Demographic, and

	iv. Civil Registration – death data (ONS Mortality) 10. Yorkshire Ambulance Service – (2017-2023) (cohort A) a. electronic Patient Records (ePR), b. Computer Aided Dispatch (CAD) and c. NHS111
Identifiers required for linkage purposes	1. Unique common pseudo-identifier 2. Name 3. NHS number 4. Date of birth 5. Postcode
Identifiers retained but separated from CUREd+ database	1. Address (cohort C) 2. Date of death
Identifiers required for analysis purposes	6. GP registration 7. Year of birth 8. Date of death – this is always modified for analysis 9. Output Area LSOA 10. Ambulance incident location postcode 11. Gender 12. Ethnicity 13. non-identifiable pseudonymised Unique Property Reference Number (UPRN) Effectively anonymous to researchers
Additional information	Dates of death will not be stored within the CUREd+ database, but stored separately (within University of Sheffield) and used to generate non-identifiable death-related variables such as 'death occurred within X days of Y event'. Address data for cohort C will also be stored in a separate computing environment, and only used for generation of pseudo-UPRN data and identification of institutional addresses (e.g. care homes).

Confidentiality Advisory Group advice

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

1. **Please provide a justification for the retention of institutional addresses indefinitely, or commit to pseudonymising before deleting at a defined timepoint.**

The retention of institutional (care homes, hospices) addresses is solely to enable subsequent linkage of institutional information, such as staffing levels, CQC ratings and, potentially, bespoke surveys or other data collections relating to the operation of institutions. This retention of address is required as it is not possible to identify these institutions by other means. Data will only be collected at an institutional level, not at an individual patient level. The CAG were content with this response, noting the justification seems reasonable, and the safeguards appropriate.

2. **Please provide updated patient notification to CAG;**
   a) **Provide CAG with CUREd website text, and a CUREd poster regarding opting out of CUREd+,**
   b) **Update YAS website text to provide more description, and more information around legal basis/CAG, and provide YAS privacy notice.**
   c) **The CUREd and YAS notifications should be consistent with each other (consider creating YAS poster which matches the CUREd poster, and can be accessed via YAS website)**
   d) **At least a phone number and email address should be included for people to opt out**
   e) **Ensure clarity surrounding role of CAG**
   f) **Ask patient and public involvement group to review the updated CUREd+ and YAS notifications**

Applicants have provided this updated patient notification, and the CAG were content with the documents provided. Applicants have extended the date that is possible for people to opt-out of the CUREd+ research database from 1st July 2022 to 1st September 2022. The Members noted that the posters are good.

3. **Please consider implementing a communications strategy across local or national media, and provide feedback on any plans to publicise the database.**

Applicants will investigate using the CURE group and School's social media accounts (Twitter and Facebook) to post about the research database, and direct to the poster and webpage if people would like more information. Applicants are also investigating writing a news story that would be hosted on the ScHARR webpage. Applicants are working with the University's Media and Social Teams to identify and maximise any opportunities to promote the project through the press and communicate to the general public at relevant points. This may include, but is not limited to, using the Faculty and University social media accounts to post about the research database. The CAG were content with this response and happy to see that plans are in hand.

4. **Please undertake further patient and public involvement as described in this letter;**
   a) **with a bigger group/more lay individuals,**
   b) **discuss the use of confidential patient information without consent,**
   c) **discuss the inclusion of mental health data and information about children and young people,**
   d) **and ask for feedback on the patient notification materials**

Further Patient and Public Involvement and Engagement was undertaken, consisting of three separate focus groups, and the applicant took into account everything requested by CAG. The Members were content with this response, noting that good PPI had been undertaken, which provided interesting, relevant, verbatim feedback.

5. **Please confirm there will be more than one lay individual recruited to the data release committee.**

Applicants confirmed there will be at least 2 lay individuals, and the CAG were content with this response.

6. **Please confirm that the data release committee will assess the medical purpose of specific projects prior to the release of data.**

Applicants confirmed this point, and the CAG were content with this response.

7. **Please clarify how many individuals in the cohort, and confirm if the reference to 80 million relates to care records rather than individuals.**

The applicants confirmed that these estimates are based on the number of unique NHS Digital generated patient identifiers, it is acknowledged that patients may be linked to more than one patient identifier across the study period leading, hence this is an overestimate of cohort size. The CAG were content with this response.

Amendment

As part of the response to provisional, the applicant also submitted an amendment to allow them to collect Demographics and Mortality data from NHS Digital for cohort C also. The applicant has reasoned that date of death for all patients in cohort C means that applicants can look at the time between an index event (such as an ambulance journey), and death for all in the Yorkshire and Humber region, and not be excluding a sub-set of patients who did not end up in A&E or inpatients care. The CAG were content with this amendment, and this information is now included in the data sources in the table in this letter.

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

1. Support provided for 5 years initially. A duration amendment will be required at this time to extend support.

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

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

The NHS Digital **20/21** DSPT reviews for **University of Sheffield - School of Health and Related Research (8D715 – SHRR), Yorkshire Ambulance Service (RX8), and NHS Digital** were confirmed as '**Standards Met'** on the NHS Digital DSPT Tracker (checked 14 March 2022)

d.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	
Professor William Bernal	CAG alternative vice-chair
Ms Sophie Brannan	CAG member
Professor Lorna Fraser	CAG member
Dr Rachel Knowles	CAG member
Dr Pauline Lyseight-Jones	CAG member
Dr Harvey Marcovitch	CAG member
Ms Rose Payne	CAG member
Professor Sara Randall	CAG member
Ms Diana Robbins	CAG member
Dr Murat Soncul	CAG alternative vice-chair
Ms Emma Marshall	HRA Confidentiality Specialist
Dr Paul Mills	HRA Confidentiality Advice Service Manager
Mr Michael Pate	HRA Confidentiality Advisor
Ms Caroline Watchurst	HRA Confidentiality Advisor

Context

Purpose of application

This application from NAMSA on behalf of Lima Corporate is submitted to undertake medical research to prospectively and retrospectively collect data from the medical records of patients who were treated with either the polyethylene glenosphere shoulder replacement compared to the cobalt chromium metal glenosphere shoulder replacement between 1st January 2013 and 1st January 2020 at Wrightington, Wigan and Leigh NHS Foundation Trust.

The purpose of the research is to gather data from assessments and images collected at hospital visits performed as per standard of care from pre-op to 2-year follow-up. Data will be analysed to measure the safety and effectiveness of the devices, both of which are CE-marked and widely used in Europe. The data may be used to submit to other geographies where the device is not currently approved for use. Measure of the safety and effectiveness of the device will determine if the device is in the continued public interest to be used in shoulder replacement surgery. The data may be submitted to other markets with a view to improving patient care in those countries.

Clinical data from an estimated 140 medical records will be extracted by the research delivery team. Support is requested for the direct care team to provide NHS numbers of patients who are deceased and for patients for whom 2-year patient reported outcome measures (PROMs) were provided before February 2016 (where consent for use was not provided). Support is also requested for the research delivery team (who are not considered part of the direct care team) to access medical records to extract the data.

The research will also collect data on patients for whom 2-year PROMs were provided under consent after February 2016, and all patients where 2-year PROMS are not available (patients will be contacted, and consent requested). Both these data flows are outside the scope of support, as is the provision of effectively anonymised data to the sponsor.

A recommendation for class 1 and 3 support was requested to cover access to the relevant unconsented activities as described in the application.

Confidential patient information requested

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

Cohort	All patients treated with the SMR Reverse Shoulder System device (either with 36-mm CoCrMo (cobalt chromium molybdenum alloy) glenosphere or 40-mm cross-linked UHMWPE (ultra-high molecular weight

	polyethylene) glenosphere) at Wrightington Hospital between 01 January 2013 and 01 January 2020 where either: 1. The patient is deceased, or 2. The patient completed PROMs before February 2016
Data sources	Medical Records at the Wrightington Hospital
Identifiers required for linkage purposes	NHS number
Identifiers required for analysis purposes	None

Confidentiality Advisory Group advice

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

Number	Action Required	Response from the applicant
1.	CAG requires the applicant to clearly demonstrate how there will be a clear public benefit arising from the use of information without consent. CAG members were unclear about how this activity (which is based on the use of NHS data) would be of benefit to the NHS. • Please provide further clarity on how this activity will be of benefit to the NHS.	Applicant stated that this study will benefit the NHS by the nature of international collaboration, to ensure the safety and performance of new joint replacements and their component parts by pooling all available and relevant data. The CAG were content with this response.
2.	It should be clearly demonstrated that steps have been taken to minimise the use of identifiable data to conduct the activity.	Applicant confirmed that no names or addresses will be given to the manufacturer, these are purely for ease of data collection

	• Please confirm if the collection and retention of names and addresses could be reduced from the entire study cohort to the prospective cohort of patients only.	within the Upper Limb Unit at Wrightington Hospital and would not need to be stored in a separate database as lists can be specified on the Hospital Information System (HIS). A record of the pseudonymisation code linked to the NHS number would be sufficient to allow data queries to be addressed if they arise. The CAG were content with this response.
3.	Members considered whether a practicable alternative to the disclosure of confidential patient information without consent existed in accordance with Section 251 (4) of the NHS Act 2006, taking into account the cost and technology available. The CAG highlighted that the data required for this study could already exist in the National Joint Registry (NJR). • Please confirm with the NJR if the data required is available and provide evidence of their response.	Applicant confirmed that the NJR does not directly store the responses to outcome scores and revision in relation to specific patients or to specific components of the shoulder replacements. The CAG were content with this response.
4.	The CAG considers date of death as an identifier and therefore noted concerns with sharing the date of death with the sponsor. • Please confirm that date of death could be reduced to either month or year of death.	The applicant agreed to reduce the date of death to record only the month and year to avoid being fully identifiable. The CAG were content with this response.
5.	Please provide further clarity on which identifiers are being retained and the length of time for retention.	The applicant confirmed that the Research Delivery Team will retain only the pseudonymisation key (Subject ID Log) and that it will be stored securely within the study files and archived for 15 years. The CAG were content with the response.
6.	It is a general principle of CAG support for reasonable measures to be taken to inform the relevant population of the activity and to provide a right to object and mechanism to respect that objection, where appropriate.	The applicant confirmed that since February 2016, pre-operative shoulder replacement patient reported outcome scores (PROMs) leaflets have been provided to patients attending for shoulder replacement. The leaflet

	The CAG noted that patient notification specific to the study did not appear to be in place. The CAG also noted that although the National Data Opt-out will be applied a local opt-out mechanism was not in place. • Taking these points into account please provide details of plans to implement study specific notification and a local opt-out mechanism, including copies of any new or updated patient notification materials.	explains that Wrightington Hospital is a research active site and that a variety of patient data is collected for means of patient education, research, training of doctors and professional colleagues and for presentation and publication. On these forms, patients ticked 'I agree' to the points on the form. The CAG were content with this approach and agreed with the applicant's decision that CAG support was not required for this cohort of patients. The applicant confirmed that for the cohort of patients from 2013-Jan 2016 (when the PROMS leaflet was not in use) they would include a statement on the Trust website to explain the study and provide details on how patients could opt out of this specific study. Text was provided by the applicant for the website. The CAG were content with this approach.
7.	Meaningful engagement with patients, service users and the public is considered to be an important factor for the CAG in terms of contributing to public interest considerations as to whether the unconsented activity should go ahead. The CAG noted that although PPI work had been undertaken this should be broadened to seek the views of patients with experience of joint replacement surgery. The CAG also noted a high proportion of negative responses in relation to accessing confidential patient without consent for this study but felt that this may be linked to the way that the questions had been presented to the group. • Taking these points into account please provide details	The applicant provided a copy of a survey and responses carried out with patients with lived experience. The applicant also confirmed that they intend to use the surveys to ask joint replacement patients attending Wrightington Hospital for follow-up visits to complete them. The CAG were content with this response.

	of plans to undertake further PPI with patients with experience of joint replacement. The CAG suggests exploring different methods of undertaking PPI to enable the group to understand the questions being asked. The CAG also suggests that approaching arthritis research charities or the National Orthopaedic Centre could be helpful in finding patients with relevant experience.	

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 13 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**
3. 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 02 May 2022)

e.22/CAG/0078 - EXTEND study – Needs Assessed Care for Early Psychosis

Name	

Dr Tony Calland MBE	CAG Chair
Dr Martin Andrew	CAG member
Dr Patrick Coyle	CAG vice-chair
Dr Sandra Duggan	CAG member
Mr David Evans	CAG member
Mr Tony Kane	CAG member
Mr Andrew Melville	CAG member
Mr Umar Sabat	CAG member
Ms Clare Sanderson	CAG alternative vice-chair
Ms Katy Cassidy	HRA Confidentiality Advisor
Ms Emma Marshall	HRA Confidentiality Specialist
Dr Paul Mills	HRA Confidentiality Advice Service Manager
Mr Michael Pate	HRA Confidentiality Advisor
Ms Caroline Watchurst	HRA Confidentiality Advisor

Context

Purpose of application

This application from the University of Oxford (with the controller for the activity confirmed to be the same) set out the purpose of medical research which aims to develop a more tailored approach to participants undergoing Early Intervention in Psychosis (EIP) treatment, based on the needs of each individual and understand the health, social, and cost benefits of this approach.

The study will use data from the annual National Clinical Audit of Psychosis that measures aspects of care that individuals receive from every EIP service across England. The study will link audit data to routinely collected NHS hospital records. By identifying differences between people who receive longer or shorter EIP treatment, the research team can see whether differences in length of EIP care lead to different

outcomes. They will also find out how differences in duration of EIP influence the short- and long-term cost-effectiveness of the service.

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	Those aged between 14 yrs and 65 yrs who took part in the 2019, 2020 and 2021 National Clinical Audit of Psychosis – approx. 30,000 records, though the same person may have taken part in all 3 audits, thus the number of people taking part will be less than 30,000.
Data sources	11. Royal College of Psychiatrists National Clinical Audit of Psychosis (NCAP) 2. NHS Digital Hospital Episode Statistics (HES) Mental Health Services Dataset (MHSDS)
Identifiers required for linkage purposes	11. NHS number 12. Gender 13. Age 14. Partial postcode

Identifiers required for analysis purposes	14. Date of Death 15. District-level postcode will be used to produce local area-based deprivation measures (IMD), but the postcode will then be destroyed.

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 if full date of death could be redacted to month and year of death in order to conduct the data analysis.

The full date of death increases the risk of identification within the linked analysis dataset; however, as we outline below, there is also a clear motivation for analysing mortality at the daily level as these analyses may yield results with strong potential policy implications. For these reasons, we have proposed the initial transfer of full date of death from NHS Digital to the ONS Secure Research Service, at which point it will be transformed to a less identifiable format that nonetheless requires ongoing S251 support. Findings from the National Confidential Inquiry into Suicide and Safety in Mental Health based at the University of Manchester (https://sites.manchester.ac.uk/ncish/) indicate an elevated risk of suicide in the weeks following discharge from psychiatric in-patient care. The highest number occurred on day 3 after leaving hospital, leading to the recommendation (adopted by NICE and NHS England & Improvement) of following up all patients within 72 hours of discharge. The purpose of the EXTEND study is to understand how the timing of discharge from Early Intervention in Psychosis care impacts–among other outcomes –mortality. In this context, knowing whether an individual died in the days or weeks immediately following discharge is informative and will influence the policy implications of our work (e.g. extending EIP care vs. improving EIP step-down transitions).The important variables for the purpose of our analysis are not the exact dates themselves (which can be identifying) but relative dates, measuring the time between events (e.g. referrals, discharge, relapse, death). For that reason, we will, upon receipt of the data from NHS Digital, recode the full date of

death variable as days between relevant events (days since referral and discharge from EIP, CMHT and in-patient care), along with a date of death redacted at the year and month level. However, the approach laid out does not eliminate the risk of identification. The full date of death could be reconstructed by researchers by adding the days between discharge and death to the date of discharge. The date of discharge could in turn be redacted to year and month of discharge along with days between referral and discharge, but this will considerably increase the complexity and risk of error in the redaction process given the large number of services involved. It would also ultimately remain identifiable due to the measurement of duration between events (e.g. referral) and publicly available but relevant dates (specifically the NCAP census dates).

The CAG accepted this explanation.

2. Please confirm the length of support required, depending upon whether full date of death is redacted prior to analysis or not.

Because the risk of identification cannot be eliminated by our strategy while maintaining the relevant information for research purposes, ongoing S251 support for the duration of the project and retention of the analysis dataset would be required. Part of the annual review of S251 support would include providing evidence that no researchers had attempted to reconstruct the full date of death variable, for example by sharing statistical outputs or the code used in analysis.

The CAG was content with this.

3. Please provide a patient notification document, which clearly explains both the National Data Opt-Out and the local opt-out mechanisms.

The participant information and opt-out sheet has been revised in collaboration with the PPI co-investigators, and in consultation with the EXTEND-InG. The following changes points were considered when revising the document:

- **More clarity and explanation on what "patient data" is and how it is used. Initial feedback suggested confusion regarding what "individual data" means in this context, figures explaining how data are collected and analysed have therefore been added.**

- **Condensing the information to a single page. A single page document is likely to be easier to read and share, but more importantly is less difficult to print and put up in physical locations that affected individuals might come across. Other relevant information will be placed on a study website for individuals interested in learning more.**

- **Adding a "positive" reason for sharing. In the prior version of the patient information sheet, we hoped that individuals would see and share the notice without acting on it in any way (as they would not feel the need to opt out). Instead, we felt the opportunity to opt out would be likely to have more reach if there was a positive reason to share, which is why we have added the opportunity to sign up and hear about events and engagement events via the study website.**

- **Simplifying the opt-out procedure. While the NHS National Data Opt-out will result in opting out from the study, as will opting out of the NCAP via your trust, it was confusing to have multiple options for opting out to achieve the same thing. Instead, we have included the central option for opting out (via the RCPsych email address) while clarifying that we will be respecting national data opt-outs.**

- **General changes to the language for clarity and accessibility. We have made it clear that carers can opt out on behalf of an affected individual using their NHS Number, we have added language to justify why the study is important, and clarified distinction between the matching and analysis parts of the proposed research. The submitted version of the patient information and opt-out sheet are final except for the study website URL (which is assigned by the University of Oxford system when published) and the first possible date of data transfer (which will depend on the receipt of final ethical approvals and publishing of the information sheet).**

The CAG wished for an easy-read version of the notification to be created and placed on the website. This will be part of conditional support.

4. Please confirm that the additional proposed Patient and Public Involvement will commence before the study begins, and provide evidence of this.

The first meeting of the EXTEND Involvement Group (EXTEND-InG), referred to in parts of the study protocol as the Patient Advisory Group (PAG), occurred on 6th June 2022. In addition to the two PPI co- investigators and co-chairs, the group is composed of 7 individuals with experiences of psychosis and psychosis care. Five members have direct personal experience of psychosis, while the remaining 2 have experience as carers. Our members include individuals who have experienced range of relevant diagnoses, socio-economic and demographic backgrounds, and points along the early intervention referral/discharge pathway. The minutes of this meeting are attached alongside this letter. Additional activities, such as the consensus workshops, EXTEND-InG commentary on study outputs and "town hall" events, will be planned based on discussions taking place within the EXTEND-InG.

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

1. That an easy-read version of the notification to be created and placed on the website.

2. Favourable opinion from a Research Ethics Committee. **Confirmed: 26 July 2022**

3. Confirmation provided from the IG Delivery Team at NHS Digital to the CAG that the relevant Data Security and Protection Toolkit (DSPT) submission(s)

has achieved the ‘Standards Met’ threshold. See section below titled ‘security assurance requirements’ for further information. **Confirmed**:

The NHS Digital 20/21 DSPT review for **Royal College of Psychiatrists** was confirmed as ‘Standards Met’ on the NHS Digital DSPT Tracker (checked 16 May 2022)

The NHS Digital 20/21 DSPT review for **NHS Digital** was confirmed as ‘Standards Met’ on the NHS Digital DSPT Tracker (checked 16 May 2022)

2. New Amendments

ECC 2-03(c)/2012 – National Paediatric Diabetes Audit (NPDA)

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

Context

Amendment request

The amendment sought support for the removal of Rackspace as a data processor, due to National Paediatric Diabetes Audit (NPDA) Data Platform Server migration back into the Royal College of Paediatrics and Child Health (RCPCH) own environment. (Microsoft Azure is a sub-processor). The amendment also sought support for a change of physical storage location within the RCPCH for storage of NPDA files used for data processing and analysis – to the Microsoft Cloud in Microsoft UK data centres based in Cardiff, Durham and London with data back up provided at the Microsoft UK South (London) data centre.

Confidentiality Advisory Group advice

The amendment requested was considered by Chairs’ Action. The Chair was content with the changes requested.

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 **20/21** DSPT reviews for **Royal College of Paediatrics & Child Health, Net Solving Limited, and SysGroup PLC** were confirmed as '**Standards Met'** on the NHS Digital DSPT Tracker (checked 09 June 2022)

   The NHS Digital **21/22** DSPT reviews for **Microsoft UK** was confirmed as '**Standards Met'** on the NHS Digital DSPT Tracker (checked 09 June 2022)

21/CAG/0033 – Risk of Aneurysm Rupture Study. Short Title: ROAR

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

Context

Amendment request

This application from University Hospitals Southampton NHS Foundation Trust aims to explore whether the PHASES (Population, Hypertension, Age, Size, Earlier subarachnoid haemorrhage, and Site) rupture risk tool provides accurate estimates of

rupture risk over 5 years for unruptured intra-cranial aneurysms in a UK population. ‘s251’ support is in place to allow the disclosure of confidential patient information from participating Trusts to the coordinating centre at University Hospitals Southampton NHS Foundation Trust, the onwards disclosure to NHS Digital and NHS Wales Informatics Service (NWIS), now the Department of Health & Care Wales (DHCW) for the purposes of linkage with HES, ONS and PEDW data, the return of identifiable data to University Hospitals Southampton NHS Foundation Trust, and for the retention of identifiers until the final linkage is requested (as the 25 trusts will be sending their datasets in at different timepoints).

This amendment sought support to include renal units as a data source to identify individuals with unruptured intra cranial aneurysms - who will still fulfil the original inclusion criteria. This would be in addition to the current identification sources which are neurosurgical units. The identification would still be undertaken by direct care team. ‘s251’ support is therefore required for the same flows as are already supported – to send confidential patient information to the applicant, and for linkage, and retention, as per the original application.

Confidentiality Advisory Group advice

The amendment requested was considered by Chair’s Action. The Vice Chair was content to recommend support for this amendment to include patients identified from renal units. This additional source of subjects for the study will use a similar data flow to those identified from neurosurgery units. Patients with polycystic kidneys have a high incidence of intracranial aneurysms many of which would not be identified from neurosurgery units. This will increase the number of subjects for study. It will also give the opportunity to study this subgroup to assess whether it behaves differently. All this will enhance the study.

The Vice-Chair noted that the applicant has mentioned linkage with a Scottish database in the amendment form, however as per the original application, any processing of Scottish data is out of scope and PBPP should be in place. The applicant is therefore reminded that the CAG can only recommend support for England and Wales.

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

   The NHS Digital **20/21** DSPT reviews for **University Hospitals Southampton NHS Foundation Trust** and the DSPT equivalent for **NHS Digital** were confirmed as 'Standards Met' on the NHS Digital DSPT Tracker (checked 15 July 2022).

   DHCW has a valid Caldicott Principles into Practice (CPiP) outturn report

   As there are more than 5 organisations processing confidential patient information without consent, the CAT team has not individually checked the DSPTs; this is the responsibility of the applicant to ensure these are in place.

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

20/CAG/0133 – Yorkshire Specialist Register of Cancer in Children and Young People

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

Context

Amendment request

The applicants have existing support to allow the disclosure of confidential patient information between University of Leeds and Local NHS Trusts, EMIS, TPP, NHS Digital, Public Health England, Department of Education and Department of Work and Pensions, to examine delays in diagnosis and long-term morbidity using routine NHS datasets.

In this amendment, the applicants are seeking support to extend the inclusion criteria of their current research, which examines the outcomes of patients diagnosed with cancer during their childhood and adolescent years. The applicants wish to expand the definition of the inclusion criteria for the Yorkshire Register from "*All individuals between 0-29 diagnosed with a malignant (or benign central nervous system) tumour whilst resident in the area contiguous with the former Yorkshire and the Humber SHA region" to specifically* include any benign tumour, not just those which originate in the Central Nervous System. The applicants also wish to clarify the different age range inclusion criteria dependent on the date of diagnosis, a point which may not be clear in the current scope of support. Support should cover all those diagnosed under the age of 30 years from 1st January 1990.

The full inclusion criteria are proposed to be as follows and will apply to both retrospective and prospective individuals:

- All individuals who have a malignant or benign tumour diagnosis;
- That were aged under 15 years at the time of their diagnosis from 01/01/1974 until 31/12/1989 or under 30 years if diagnosed from 01/01/1990 onwards;
- That were resident in Yorkshire (defined as having a postcode contiguous with the former Yorkshire and the Humber Strategic Health Authority) at the time of their diagnosis.

The applicant has provided updated patient notification leaflets.

Confidentiality Advisory Group advice

The amendment requested was considered by Chair's action. The Chair was content to recommend support, and found the amendment to be justified.

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 **20/21** DSPT submission for **University of Leeds – Laser, was confirmed as 'Standards Met' by NHS Digital (by check of DSPT tracker on 26 May 2022).**

   Security assurances are required for the organisations where processing of confidential patient information will take place. Support will be based on confirmation that the DSPT at the site will be complied with. However, as this is 5 or more organisations, these will not be individually checked by the Confidentiality Advice Team, and it is the responsibility of the applicant to ensure that appropriate security assurances are in place. This includes NHS Digital, EMIS, TPP, NHS Digital, Department for Education and Department for Work and Pensions, and participating NHS Trusts.

2. Confirmation of a favourable opinion from a Research Ethics Committee. **Confirmed 22 June 2022**

22/CAG/0004 – Mass evaluation of lateral flow immunoassays for the detection of SARS-CoV-2 antibody responses in immunosuppressed people: Melody

Name	Capacity
Ms Caroline Watchurst	HRA Confidentiality Advisor

Context

Amendment request

This application from Imperial College London aims to evaluate the detection of SARS-CoV-2 antibodies at a population level in immunosuppressed individuals. 's251' support is currently in place to allow the disclosure of confidential patient information (full name, address including postcode, mobile phone number and date of birth) from NHS Digital to Ipsos Mori for the purpose of inviting individuals to the study.

This amendment sought support to extend the duration of 's251' support until 30 September 2022. This is to allow the applicants to meet their recruitment target.

Confidentiality Advisory Group advice

The amendment requested was considered by 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 **20/21** DSPT reviews for **Ipsos Mori and NHS Blood and Transplant** were confirmed as '**Standards Met'** on the NHS Digital DSPT Tracker (confirmed by email to CAG inbox 31 December 2021)

2. Confirmation of a favourable opinion from a Research Ethics Committee.
   Confirmed no requirement for REC review 23 June 2022

21/CAG/0061 – British Paediatric Surveillance Study of Neonatal Stroke in the United Kingdom and the Republic of Ireland presenting/diagnosed in babies in the first 90 days of life. Short title: UK and Republic of Ireland Neonatal Stroke Surveillance

Name	Capacity
Ms Caroline Watchurst	HRA Confidentiality Advisor

Context

Amendment request

This application from University of Nottingham aims to determine the number of new cases of Neonatal stroke in the UK and Republic of Ireland over 13 months, as well as determining the proportion of neonatal stroke subtypes.

Due to delays caused by the Covid-19 pandemic, this amendment sought support to extend the duration of ‘s251’ support until 03 November 2025.

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 **University of Nottingham E133856-RGD** was confirmed as '**Standards Met'** on the NHS Digital DSPT Tracker (checked 18 July 2022)

   Security assurances are required for the submitting clinicians. Support will be based on confirmation that the DSPT at the site will be complied with. However, as this is 5 or more organisations, these will not be individually checked by the Confidentiality Advice Team, and it is the responsibility of the applicant to ensure that appropriate security assurances are in place.

2. Confirmation of a favourable opinion from a Research Ethics Committee. **Confirmed no REC review required 02 July 2022**

20/CAG/0138 – Avon Community Acquired Pneumonia Study (Avon CAP): A Pan-Pandemic Acute Lower Respiratory Tract Disease Surveillance Study

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

Context

Amendment request

The applicants have existing support to allow the disclosure of confidential patient information from North Bristol NHS Trust and University Hospitals Bristol and Weston

NHS Foundation Trust to the University of Bristol. A recent amendment was supported to extend the retention period of NHS number, date of birth and admission date for all study participants covered by ‘s251’ (not consented patients), for a period of 5 years from the end of patient enrolment to the Avon CAP study, to enable future potential linkages with other datasets, not yet specified. The applicants confirmed that any changes to data flows, purposes, or additions of data sources, and data processors, would be submitted as an amendment to CAG for further support under ‘s251’.

This amendment sought support to collect GP practice details - an additional identifier, for those patients whose data is collected under ‘s251’ support. This is to help ensure that linkage between AvonCAP and AvonCAP GP2 is as accurate as possible.

This amendment also sought support for an additional method of transferring data, for already supported data flows. The applicants propose to use an encrypted USB key to transfer data into an encapsulated virtual machine (EVM). The study already has ‘s251’ support to securely share participant identifiers with the "sister study" AvonCAP GP2. Sharing of identifiers and subsequent linkage will take now place within an encapsulated virtual machine (EVM), a secure folder created by the University of Bristol.

Confidentiality Advisory Group advice

The amendment requested was considered by Chairs’ Action. The Vice-Chair was content to recommend support for all changes requested, noting that the data transfer using an encrypted USB key is secure, with all the safeguards prescribed. The Vice-Chair noted that CAG have already previously recommended support for the retention of date of birth as a secondary identifier for future linkages, as yet not specified, which was also requested in this amendment. This has therefore not been processed as a change to ‘s251’ support as part of this current amendment. The applicant is reminded that they must submit a further amendment if they decide to actually undertake these unspecified future linkages, to confirm the datasets being linked with, and to therefore ensure the scope of support is clear regarding any additional data flows or data sources.

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 **2020/21** DSPT reviews for **University Hospitals Bristol and the Weston NHS Foundation Trust** & **North Bristol NHS Trust** were confirmed as 'Standards Met' on the NHS Digital DSPT Tracker (checked 18 July 2022)

   The NHS Digital **2021/22** DSPT review for **University of Bristol (Bristol Medical School)** was confirmed as 'Standards Met' on the NHS Digital DSPT Tracker (checked 18 July 2022)

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

20/CAG/0027 – Congenital Heart Audit: Measuring Progress In Outcomes Nationally

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

Context

Amendment request

This application originally gained support to link data from 130,000 children and adults with congenital heart disease with a number of datasets.

This amendment sought support to update the dataset with data extracts involving an additional cohort, to include new patients registered in National Congenital Heart Disease Audit (NCHDA) who have had their first procedure from March 2017, up to and including March 2021, or March 2022 if available. Applicants estimate the new extract will increase the dataset size by approximately 50,000 patients, and by 62,500 records. Applicants will request that NICOR will provide a second data extract from the NCHDA, and send corresponding identifiers to NHS Digital for linkage with updated ONS mortality outcome data. Both NICOR and NHS Digital will provide pseudonymised data regarding the updated dataset to the applicant, as per the current design. This amendment also sought support to link NCARDRS (National Congenital Anomaly and Rare Disease Registration Service) data to NCHDA and ONS. Applicants will also be applying to NHS Digital for the year 2019 of NCARDRS data and also requests 's251' support to link 2018 (already held at UCL) and 2019 NCARDRS data to NCHDA and ONS data.

Confidentiality Advisory Group advice

The amendment requested was considered by Chairs' Action. The Vice-Chair was content to recommend support for this amendment to this project which aims to develop tools for routinely measuring congenital heart disease outcomes. The applicants wish to include data over an extended period of time almost to the present to include many more subjects. In addition, they want to update the PRAiS (Partial Risk Adjustment in Surgery) risk model. This will enhance the project without causing any greater risk to patient confidentiality. The Vice-Chair also noted that the addition of the NCARDS data is relevant to the purpose and will be pseudonymised using the project ID before transfered to the investigators.

Confidentiality Advisory Group advice conclusion

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

Specific conditions of support

The following sets out the specific conditions of support.

1. Confirmation provided from the IG Delivery Team at NHS Digital to the CAG that the relevant Data Security and Protection Toolkit (DSPT) submission(s) has achieved the 'Standards Met' threshold:
   Confirmed: The NHS Digital 21/22 DSPT reviews for University College London - School of Life and Medical Sciences and NHS Digital were confirmed as 'Standards Met' on the NHS Digital DSPT Tracker (checked 15 July 2022)

2. Confirmation of a favourable opinion from a Research Ethics Committee.
   Confirmed 20 June 2022

PIAG 1-05 (j) 2007 - A national population-based case-control study of the genetic, environmental and behavioural causes of breast cancer in men

Name	Capacity
Ms Caroline Watchurst	HRA Confidentiality Advisor

Context

Amendment request

This amendment sought support to change the chief investigator from the inaugural Chief Investigator (Professor Swerdlow) to Professor Richard Houlston, as Professor Swerdlow has retired.

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 **202/21** DSPT review for **The Institute of Cancer Research was** confirmed as 'Standards Met' on the NHS Digital DSPT Tracker (checked 19 July 2022)

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

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

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

Context

Amendment request

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

In this amendment, the applicants are seeking to include an additional alternative data flow of confidential patient information (NHS number) from Yorkshire Ambulance Service (YAS) to the study team at Sheffield University, for The Northern General Hospital (NGH) in Sheffield only. YAS will apply the National Data Opt Out prior to this disclosure. The research team at Sheffield then identify the first attendance for each patient, and discloses the NHS numbers and dates of attendance to the PI at NGH. The NHS number and attendance dates will be used by the PI and the hospital Information Services Team to link with records from the Northern General Hospital in Sheffield, to identify any patients who were admitted or died in the ED and had an admission ICD10 diagnosis or cause of death compatible with sepsis. These patients will be selected for research nurse screening for the reference standard as per the original application. Data is then sent back in pseudonymous format to the research team at University of Sheffield.

This option is a last resort for applicants, as it will only generate estimates from a single site, however even as a single site study the research will still be able to make a substantial contribution to the knowledge of prediction of sepsis in the adult population in a pre-hospital setting, where time-critical treatment is so important. The additional optional data flow is requested as it is the only feasible option within the available timeframe, and is requested as a ‘plan B’ in case the ‘plan A’ of linked NHS Digital data is not received before the study funding ends. ‘s251’ support is therefore still required for the original data flow also, this amendment does not replace, but is in addition to the original data flow. As a back up.

Confidentiality Advisory Group advice

The amendment requested was considered by Chairs’ Action. The Alternate Vice-Chair was content to recommend support for the amendment, after reviewing the communications between NHS Digital and the applicant.

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

2. Confirmation of a favourable opinion from a Research Ethics Committee.
Confirmed 20 July 2022

21/CAG/0085 – The Child Health Clinical Outcome Review Programme (CH-CORP)

Name	Capacity
Ms Kathleen Cassidy	HRA Confidentiality Advisor

Context

Amendment request

This application has 's251' support for a core methodology of data collection for The Child Health Clinical Outcome Review Programme (CH-CORP). Confidential patient information regarding all eligible cases is disclosed from participating healthcare providers to the National Confidential Enquiry into Patient Outcome and Death (NCEPOD), a sample is selected, and confidential patient information is used to follow-up with clinicians involved in the patients care by way of questionnaire (completed online in pseudonymised format), and relevant copies of

extracts from the patient's case notes are also disclosed from treating clinicians to NCEPOD.

HQIP commission one topic each year. This year the topic is Testicular Torsion. The standard methodologies for retrospective case identification, sending of questionnaires to clinicians and anonymous case note review will be followed.

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 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 2020/21 DSPT review for National Confidential Enquiry into Patient Outcome and Death (NCEPOD) was confirmed as 'Standards Met' on the NHS Digital DSPT Tracker (checked 13 July 2022).

PIAG-4-08(b) 2003 - National Confidentiality Enquiry into Patient Outcome and Death

Name	Capacity

Ms Kathleen Cassidy	HRA Confidentiality Advisor

Context

Amendment request

In line with the original application, the applicant had been commissioned by HQIP to undertake two confidential reviews of case notes every year. This amendment covered the first of the reviews due to take place in 2022, which will investigate endometriosis. The standard methodology for NCEPOD reviews will be followed.

Confidentiality Advisory Group advice

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

Confidentiality Advisory Group advice conclusion

In line with the considerations above, the CAT agreed that the minimum criteria under the Regulations appeared to have been met for this amendment, and therefore advised recommending support to the 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 2020/21 DSPT review for National Confidential Enquiry into Patient Outcome and Death (NCEPOD) was confirmed as 'Standards Met' on the NHS Digital DSPT Tracker (checked 13 July 2022).

CAG 5-07(d)/2013 - National Emergency Laparotomy Audit

Name	Capacity
Ms Kathleen Cassidy	HRA Confidentiality Advisor

Context

Amendment request

The National Emergency Laparotomy Audit (NELA) was set up in 2012 in response to a high incidence of death and wide variation in the provision of care and mortality for patients who receive emergency laparotomy (abdominal surgery) in England and Wales. NELA is delivered under contract to the Healthcare Quality Improvement Partnership (HQIP) by the Royal College of Anaesthetists and the Clinical Effectiveness Unit of the Royal College of Surgeons of England. From December 2022, the scope of the audit will also include patients who could undergo surgery but do not, due to either extreme illness or surgery not being in the patients' best interest.

The applicants seek to add a new data flow and data processor, in the form of a cloud backup provider for NELA data. Data had previously been backed up by tales, but the Royal College of Anaesthetists (RCoA) have moved to cloud-based backups, which includes backups of NELA data. Personally identifiable data will not be backed up to the cloud and this change in backup provision only affects pseudonymised data.

Personally identifiable data is only stored on RCoA servers for short periods of time to enable data linkage and is then securely deleted, thus missing the nightly backup schedule. Personally identifiable data submitted on the NELA webtool will continue to be hosted by UKFast, per the original CAG application.

The change to cloud-based backup will reduce the risk is that all NELA data could be lost in the event of technological or physical disruption to the RCoA.

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 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 2020/21 DSPT reviews for Royal College of Anaesthetists and Royal College of Surgeons of England were confirmed as 'Standards Met' on the NHS Digital DSPT Tracker (checked 13 July 2022).

3. Amendments – Response to Provisional Outcome

a. 18/CAG/0146 – National Joint Registry (NJR) National Data Opt-Out (NDO) deferral request

Name	
Dr Tony Calland MBE	CAG Chair
Dr Malcolm Booth	CAG member
Dr Patrick Coyle	CAG vice-chair
Dr Sandra Duggan	CAG member
Professor Lorna Fraser	CAG member

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

Scope of NDO deferral request

Productive discussions prior to the CAG meeting had identified that the deferral request paper also referenced 19/CAG/0182. This is a linked research application that utilises non-research data collected under 18/CAG 0146 for research purposes. It was mutually agreed prior to the CAG meeting that the justifications given for NDO deferral did not have the same issues and weighting for the processing for research purposes and would therefore be excluded from the current request. The advice and decision set out in this letter relate only to the non-research uses detailed in 18/CAG/0182.

The NJR (jointly controlled by HQIP and NHS England & Improvement) is the largest joint replacement register in the world with over 3 million records that collects, analyses and disseminates data on hip, knee, elbow, shoulder and ankle joint replacement surgery. It is a primarily consented registry and operates under a model where patient consent is recorded in three ways. The first is ‘yes’ where the patient has provided consent, the second is ‘no’ where the patient has not consented and anonymised surgical data is used, and the third is where patient consent status is ‘unknown’.

Regulation 5 support relates only to the third category and provides a legal basis for patient identifiers to be uploaded to the NJR database by participating hospitals. Support also provides a legal basis to link HES, ONS and PROMS data from NHS Digital to that held in the NJR for this cohort of patients. It is for those patients where consent status is ‘unknown’ that a deferral request from the NDO is sought.

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. Set out clearly the various communication routes that will be used to inform the patient population that the National Data Opt-Out will not be applied to the NJR audit activity for those patients whose consent status is recorded as ‘unknown’. Approach/dissemination/communication methods should be proportionate to the requested change with all relevant text provided for review.

The applicants provided a communications plan and the proposed text for the various forms of communication proposed. This was reviewed by the CAG, who raised no further queries.

Confidentiality Advisory Group advice conclusion

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

Specific conditions of support

1. The National Data Opt-Out does not apply to the non-research activities specified in 18/CAG/0146.

2. The National Data Opt-Out must be applied in relation to processing for research purposes and specifically in relation to 19/CAG/0182.

3. A local patient objection mechanism must continue to be used in relation to 18/CAG/0146.

4. 4. Communication and notification – the communications plan presented to CAG is to be followed. Any changes in the communications plan should be notified to the CAG.

b. 22/CAG/0114 (previously 17/CAG/0071) – NHS England (NICOR) National Cardiac Audit Programme (NCAP) (Supersedes Barts Health (NICOR) National Cardiac Audit Programme (NCAP))

Name	Capacity
Professor William Bernal	CAG Alternate Vice-Chair
Mr Tony Kane	CAG member
Dr Harvey Marcovitch	CAG member
Mr Andrew Melville	CAG member
Dr Sandra Duggan	CAG member
Ms Katy Cassidy	HRA Confidentiality Advisor

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

Context

Amendment request

This is a request to defer the national data opt out for 22/CAG/0114 (17/CAG/0071), non-research application. The Healthcare Quality Improvement Partnership (HQIP) commissions the cardiac audits on behalf of the Department of Health and Social Care (DHSC).

22/CAG/0114 superseded 17/CAG/0071 due to a change of data controller from HQIP/Barts Health NHS Trust to NHS E/I, and a change in data processor from Barts Health Trust to Arden & GEM CSU. 17/CAG/0071 previously superseded ECC 1-06(d)/2011 due to a change of data controller from University College London (UCL) to Barts Health NHS Trust. ECC 1-06(d)/2011 superseded ECC 1-06 (c)/2009 when responsibility for managing six national cardiac audits transferred from the NHS Information Centre (NHS IC) to NICOR/UCL in early 2011. The National Cardiac Audit programme (NCAP) has been supported since 2009 (through various data controller changes), with consistent submission of annual reviews since that time.

Support is in place for clinical teams to provide the audit team with confidential patient information, which is linked with NHS Digital outcome data.

The applicants submitted this request in relation to 2 non-research applications, 22/CAG/0114 (17/CAG/0071) and 22/CAG/0116 (17/CAG/0152) (which is provided as a separate outcome letter). The ensuing paper provided by the applicants mentioned research. This outcome letter relates only to the non-research activities undertaken under CAG reference 22/CAG/0114 (17/CAG/0071).

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. **Set out clearly into a communications strategy, the various communication routes that will be used to inform the patient population that the National Data Opt-Out will not be applied to the NICOR audit activity. Approach/dissemination/communication methods should be proportionate to the requested change.**

The CAG were broadly content with the communications strategy provided, however they noted that a sentence in one of the sections should be altered for accuracy. In the draft Communications Notice to Patients, section 5.5, which regards a section to be posted on the website, the top of the 3rd paragraph states; '*The NHS Health Research Authority has granted NICOR permission to collect information from hospitals without patient consent. '*

This should be altered to; '*NICOR has support from the Secretary of State for Health and Social Care, on advice from the Confidentiality Advisory Group (CAG), (https://www.hra.nhs.uk/aboutus/committees-and-services/confidentiality-advisory-group/, to collect information from hospitals without patient consent'*

The CAG are content to recommend support whilst including this as a condition, to avoid delaying the applicant in this case.

2. **Please provide all associated patient notification materials, which should be layered, and made clearer than the current draft.**

The applicant provided these and the CAG were content.

Confidentiality Advisory Group advice conclusion

The CAG would like to note that the decision to overrule patient's wishes expressed through their enrolment in the NDO, is not taken lightly, and that the Group is only minded to do so in exceptional circumstances. The CAG recommendation is based on the documentation provided. Following thorough review of the request rationales, members agreed that the patient safety rationale and bias issues were very strong and provided appropriate rationale for advising why the NDO should not be applied to this data flow.

Whilst a patient notification strategy and draft notification materials were provided, the CAG felt that the applicant could improve the wording of the communications plan, and CAG should have oversight of these as soon as possible.

Given that the applicants have provided a notification strategy and draft documentation, CAG therefore recommended, in this specific instance, to the Secretary of State for Health and Social Care that the National Data Opt-Out deferral request be conditionally approved.

Specific conditions of support

The following sets out the specific conditions of support.

1. This outcome confirms a change to the original conditions of support. The National Data Opt-Out is not to be applied to patients included in the activities specified in
   22/CAG/0114 (prev 17/CAG/0071)
2. The National Data Opt-Out must be applied in relation to processing for research purposes, specifically in relation to 22/CAG/0118 (Prev 17/CAG/0078)
3. A local patient objection mechanism must continue to be used in relation to 22/CAG/0114 (Prev 17/CAG/0071)
4. The applicant is requested to submit full refreshed applications in relation to 22/CAG/0114 (17/CAG/0071) and 22/CAG/0018 (17/CAG/0078) to ensure to scope of support is clear regarding research and non-research activity. This should be submitted in lieu of the next due annual review.
5. Please provide evidence of discussions with patients and the public, surrounding the non-application of the National Data Opt-Out, within 3 months from the date of this letter
6. Please provide the updated communications plan regarding Communications Notice to Patients, section 5.5, as per the advice in this letter, as soon as possible to avoid any incorrect versions of text being uploaded to websites.

c. 22/CAG/0116 (Previously 17/CAG/0172) – NHS England (NICOR): UK Transcatheter Aortic Valve Implantation (TAVI) (Supersedes Barts Health (NICOR) UK Transcatheter Aortic Valve Implantation (TAVI))

Name	Capacity
Professor William Bernal	CAG Alternate Vice-Chair
Mr Tony Kane	CAG member

Dr Harvey Marcovitch	CAG member
Mr Andrew Melville	CAG member
Dr Sandra Duggan	CAG member
Ms Katy Cassidy	HRA Confidentiality Advisor
Dr Paul Mills	HRA Confidentiality Advice Service Manager
Ms Caroline Watchurst	HRA Confidentiality Advisor

Context

Amendment request

This is a request to defer the national data opt out for 22/CAG/0116 (17/CAG/0152), non-research application. The Healthcare Quality Improvement Partnership (HQIP) commissions the cardiac audits on behalf of the Department of Health and Social Care (DHSC).

22/CAG/0116 superseded 17/CAG/0172 due to a change of data controller from HQIP/Barts Health NHS Trust to NHS E/I, and a change in data processor from Barts Health Trust to Arden & GEM CSU. 17/CAG/0152 previously superseded CAG 5-07(c)2013 due to a change of data controller from University College London (UCL) to Barts Health NHS Trust. TAVI has been supported since 2014 (through various data controller changes), with consistent submission of annual reviews since that time.

Support is in place for clinical teams to provide the audit team with confidential patient information, which is linked with NHS Digital outcome data.

The applicants submitted this request in relation to 2 non-research applications, 22/CAG/0116 (17/CAG/0152) and 22/CAG/0114 (17/CAG/0071) (which is provided as a separate outcome letter). The ensuing paper provided by the applicants mentioned research. This outcome letter relates only to the non-research activities undertaken under CAG reference 22/CAG/0116 (17/CAG/0152).

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. **Set out clearly into a communications strategy, the various communication routes that will be used to inform the patient population that the National Data Opt-Out will not be applied to the TAVI audit activity. Approach/dissemination/communication methods should be proportionate to the requested change.**

The CAG were broadly content with the communications strategy provided, however they noted that a sentence in one of the sections should be altered for accuracy. In the draft Communications Notice to Patients, section 5.5, which regards a section to be posted on the website, the top of the 3rd paragraph states; '*The NHS Health Research Authority has granted NICOR permission to collect information from hospitals without patient consent. '*

This should be altered to; '*NICOR has support from the Secretary of State for Health and Social Care, on advice from the Confidentiality Advisory Group (CAG), (https://www.hra.nhs.uk/aboutus/committees-and-services/confidentiality-advisory-group/, to collect information from hospitals without patient consent'*

The CAG are content to recommend support whilst including this as a condition, to avoid delaying the applicant in this case.

It is noted that informaiton about TAVI is included in the information sheets for NCAP, rather than having 2 separate communications. The CAG were content with this.

2. **Please provide all associated patient notification materials, which should be layered, and made clearer than the current draft.**

The applicant provided these and the CAG were content.

Confidentiality Advisory Group advice conclusion

The CAG would like to note that the decision to overrule patient's wishes expressed through their enrolment in the NDO, is not taken lightly, and that the Group is only minded to do so in exceptional circumstances. The CAG recommendation is based on the documentation provided. Following thorough review of the request rationales, members agreed that the patient safety rationale and bias issues were very strong and provided appropriate rationale for advising why the NDO should not be applied to this data flow.

Whilst a patient notification strategy and draft notification materials were provided, the CAG felt that the applicant could improve the wording of the communications plan, and CAG should have oversight of these as soon as possible.

Given that the applicants have provided a notification strategy and draft documentation, CAG therefore recommended, in this specific instance, to the Secretary of State for Health and Social Care that the National Data Opt-Out deferral request be conditionally approved.

Specific conditions of support

The following sets out the specific conditions of support.

1. This outcome confirms a change to the original conditions of support. The National Data Opt-Out is not to be applied to patients included in the activities specified in
   22/CAG/0116 (prev 17/CAG/0152).
2. A local patient objection mechanism must continue to be used in relation to 22/CAG/0116 (prev 17/CAG/0152).
3. Please provide evidence of discussions with patients and the public, surrounding the non-application of the National Data Opt-Out, within 3 months from the date of this letter.
4. Please provide the updated communications plan regarding Communications Notice to Patients, section 5.5, as per the advice in this letter, as soon as possible to avoid any incorrect versions of text being uploaded to websites.

3. Annual Review Approvals

14/CAG/1029	DECS - Diabetic Eye disease in Children Study: incidence, detection / presentation, clinical characteristics and outcomes of diabetic eye disease in childhood in the UK
20/CAG/0027	Congenital Heart Audit: Measuring Progress In Outcomes Nationally (CHAMPION)
ECC 2-03(c)/2012	National Paediatric Diabetes Audit (NPDA)
16/CAG/0071	Benchmarking CLinical Quality Healthcare Measures
20/CAG/0013	Correlates of cognitive changes in epilepsy
21/CAG/0085	Child Health Clinical Outcome Review Programme
20/CAG/0021	Breast Reconstruction: Investigating long-term clinical and cost-effectiveness in the National Mastectomy and Breast Reconstruction Audit cohort
20/CAG/0067	Learning Disabilities Mortality Review (LeDeR)
CR17/2014	Epidemiological Study of BRCA1 and BRCA2 Mutation Carriers
19/CAG/0012	Long-term outcomes in Hirschsprung's and anorectal malformations
15/CAG/0115	UKCTOCS UK Collaborative Trial of Ovarian Cancer Screening
19/CAG/0109	Suicide by middle-aged men
20/CAG/0034	Detecting clinical deterioration in respiratory hospital patients using machine learning
15/CAG/0148	Improving Care in the NHS

21/CAG/0089	Evaluating the integration of the Recommended Summary Plan for Emergency Care and Treatment (ReSPECT) into primary care and its impact on patient treatment and care
PIAG 2-07 (b) /2004	The Oxford Monitoring System for Attempted Suicide
21/CAG/0081	neoWONDER: Neonatal Whole Population Data linkage to improving long-term health and wellbeing of preterm and sick babies

Signed – Chair		Date
Minutes signed off as accurate by CAG Chair Dr Tony Calland MBE, Vice Chair Dr Patrick Coyle, and Alternate Vice Chairs Ms Clare Sanderson, Dr Murat Soncul, and Professor William Bernal		*31 August 2022*
Signed – Confidentiality Advice Team		Date
Ms Caroline Watchurst, HRA Confidentiality Advisor		*04 August 2022*