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

**December 2023**

*Please note, these minutes contain varying formats, as we work through a change of process regarding CAG outcomes.*

## 1. New Applications

### a. 23/CAG/0140 - Suicide Prevention in Probation: A mixed methods study

| Name | Capacity |
|---|---|
| Dr Pauline Lyseight-jones | CAG Lay Member |
| Mrs Sarah Palmer-Edwards | CAG Expert Member |
| Mr Dan Roulstone | CAG Lay Member |
| Ms Clare Sanderson | CAG Alternate Vice Chair |
| Mr Marc Taylor | CAG Expert Member |

## Context

### Purpose of application

This application from the University of Manchester sets out the purpose of examining death by suicide occurring under probation supervision in England and Wales to better identify prevention and intervention opportunities.

In order to build a comprehensive profile of suicide by people on probation, one of the central aims of the study is to establish (and test feasibility) of the national case series of suicide deaths by people on probation. The study will link information held by HM Prison & Probation Service on all individuals who were under probation supervision who have died by suicide in England & Wales since April 2019 up to March 2025 with information held by NCISH at the University of Manchester on all registered deaths by suicide in the general population and suicide deaths of people who had been in contact with health services prior to death (up to 12 months prior to death).

Support is requested to link identifiable NCISH data on registered suicides and open verdicts with identifiable HMPPS data on deaths under probation supervision to identify people who have died by suicide while under probation supervision since April 2019. The data linkage will also be used to identify deaths of people under probation supervision who were in contact with health services prior to death (up to previous 12 months). The linked dataset will be pseudonymised by HMPPS and sent from HMPPS back to NCISH. After the initial dataset is provided, NCISH will undertake an annual update to identify new suicide cases that have occurred in the last 12 months and identify reclassified cases for inclusion/ exclusion.

### 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.

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| **Cohort** | All individuals who were under probation supervision who have died by suicide in England & Wales since April 2019 up to March 2025 |
| **Data sources** | 1. National Confidential Inquiry into Suicide & Safety in Mental Health (University of Manchester) – registered morality data, clinical and health service contact prior to death, diagnosis, treatment<br>2. HM Prison & Probation Service:<br>a. nDelius - Offence & sentence details, supervision and contact prior to death<br>b. OASys - Offence details/ risk and criminogenic needs, prior self harm history |

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| | c. PNOMIS/DPS - Time spent in custody prior to release/ self-harming behaviours, ACCT, adjudications/ family contact<br>3. Other relevant reports (e.g. serious incident reports, Prison and Probation Ombudsman reports (where applicable and available) - Circumstances leading up to death, contact with services |
| **Identifiers required for linkage purposes** | 1. Name<br>2. Date of birth<br>3. Date of death<br>4. Postcode – sector level<br>5. Gender<br>6. Probation case reference number/prison number |
| **Identifiers required for analysis purposes** | 1. Date of birth<br>2. Postcode - sector level<br>3. Gender |
| **Additional information** | Estimated cohort number is 300 |

**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** |
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| 1. | Security assurances for 2022/23 are outstanding for the following organisations.<br><br>· *University of Manchester - National Confidential Inquiry into Suicide and Safety in Mental Health (NCISH)*<br><br>Please contact NHS England | Email confirmation received from NHS England (26/10/23)<br><br>*'I can confirm that the NHS England Data Security Centre has already completed its 22/23 Data Security and Protection Toolkit assessment review for* ***THE NATIONAL CONFIDENTIAL INQUIRY INTO SUICIDE AND SAFETY IN MENTAL HEALTH (NCISH) at The University of Manchester (8D594-ECC0020)*** *and has provided FULL DATA SECURITY ASSURANCE to CAG. This applies to any* |

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| | at exeter.helpdesk@nhs.net and provide the CAG reference number, the organisational names and references that require review, and ask NHS England to review the DSPT submissions due to a CAG application. | *CAG application using the DSPT for 8D594-ECC0020.'*<br><br>Publication status: **STANDARDS MET**<br><br>Confirmed: **12.10.2023** |
| 2. | Clarify who is the data controller for this application | The University of Manchester<br><br>The CAG were content with this response. |
| 3. | Please develop a new patient notification for the purposes of dissemination for family and friends, in line with advice in this letter, and provide to CAG for review.<br><br>a. Clearly describe the purpose and content of this application.<br><br>b. The notification should describe the use of confidential patient information for the purposes described in this application including the types of confidential patient information<br><br>c. Add a statement to disclose that 'section 251 support' is recommended by the Secretary of State | A public/ patient information sheet has been drafted and attached (V1; 25/10/23).<br><br>The CAG were content with this response. |

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| | for Health and Social Care, on advice from the Confidentiality Advisory Group (CAG).<br><br>d. Add a statement to disclose that National Data Opt-out will be respected. | |
| 4. | All notifications need to go on NCISH, HMPPS websites and other relevant website/platform such as suicide support groups. | A request has been submitted and agreed by UoM. A short summary brief, and public information sheet (attached separately) will be published on the University of Manchester Health & Justice Research Network page<br><br>https://research.manchester.ac.uk/en/projects/health-and-justice-research-network/projects/<br><br>A request has made to the Health Quality Improvement Partnership (HQIP) which requests access to the NCISH data. HQIP also need to give approval to add the summary brief and public information sheet to the NCISH research page under 'collaborations and associated projects.' (Decision pending as at 28/10/23).<br><br>An enquiry/ request has made to the HMPPS National Research Committee (who provide ethical approval) for routes to/ and where to publicise approved research on HMPPS/ MoJ webpages.<br><br>The response from the NRC (as of 28/10/23) has not confirmed whether this possible as it has not been done before. HMPPS and MoJ do not routinely publish information of research projects currently taking place so the |

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| | | request may take some time to action or could be denied.<br><br>There are no other relevant suicide support groups where publicising the study would be appropriate and/ or relevant to the probation population.<br><br>The CAG were content with this response. |
| 5. | Further patient and public involvement should be carried out in line with advice in this letter:<br><br>a. Further patient and public involvement should be undertaken, with NCISH and suicide support group, which is specific to the linkages and purposes described in this application.<br><br>b. Provide feedback on the outcomes of the recommendations that were discussed at the October meeting.<br><br>c. An ongoing patient and public involvement plan is to be provided. | A patient and public involvement plan has been drafted which sets out further activity (V1, 25/10/23 attached). This also includes drawing on the Centre for Mental Health and Safety at the University of Manchester has a dedicated Patient and Public Involvement and Engagement Group – Mutual Support for Mental Health Research (MS4MH-R), where appropriate and identifying relevant suicide support groups for example the National Suicide Prevention Alliance (Lived Experience Network - NSPA) for people on probation via probation Regional Deaths under Supervision Leads and engagement managers. A public/ patient information sheet has been drafted for publication on the NCISH and UoM website.<br><br>Feedback from the National Lived Experience team and Engaging with People on Probation engagement managers meeting that took place on 11/10/2023 included:<br><br>• Attendees collectively welcomed the proposed study, acknowledging the issue and lack of existing research and felt this would be a positive step in increasing knowledge |

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| | | • None of the attendees raised any concerns or objections when asked specifically about the acceptability of accessing data of deceased individuals without consent.<br>• There was discussion about the support and signposting to be made available post-interview for people on probation and for interviews to be trauma informed.<br>• They were supportive of the recruitment approach and offered additional options to strengthen these including signposting the study at women's centres and gambling and drug awareness groups that are set up for people on probation in particular regions across England and Wales.<br>• One member suggested that in Approved Premises it would be good to provide Key Workers with additional information about the study to accompany any material that might be shared with residents to aid any follow up questions or queries they might have.<br>• Several members have contacted the lead researcher separately following the meeting to offer their support and cascade advertising material when recruitment for this part of the study officially begins (2024).<br>The CAG were content with this response. |

**Confidentiality Advisory Group advice conclusion**

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

### Specific conditions of support

The following sets out the specific conditions of support.

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

The NHS England **23/2024** DSPT review for **University of Manchester NCISH** was confirmed as 'Standards Met' on the NHS England DSPT Tracker (checked 05 December 2023)

## b. 23/CAG/0143 - Development of the ISA classification system - PILOT

| Name | Capacity |
|---|---|
| Mr David Evans | CAG Expert member |
| Dr Murat Soncul | CAG Alternate vice chair |
| Mr Dan Roulstone | CAG Lay member |
| Dr Stephen Mullin | CAG Expert member |
| Dr Harvey Marcovitch | CAG Expert member |

**Context**

### Purpose of application

This application from the University of Leicester sets out the purpose of medical research to establish a classification system to accurately classify perinatal deaths. The research will also compare and evaluate the recently developed International Stillbirth Alliance (ISA) Classification System, in comparison to existing classification systems. The aim is to establish a cause of death (COD) coding system (either the ISA system, an existing system, or an adapted version of either) that allows the

collection of the highest quality data in respect to causes of perinatal death, thus allowing for data comparison between international settings and prioritisation for prevention strategies to minimise unexplained stillbirths and neonatal deaths.

For the purpose of this project, the applicant requires access to 100 mother and baby hospital notes for perinatal deaths occurring in July to December 2019 that have already been supplied to and processed by MBRRACE-UK under the terms of the Confidential Enquiry (CE) programme commissioned by HQIP. The processing of these records without consent for the purpose of the MBRRACE-UK Confidential Enquiry Programme has been undertaken using Section 251 approval (15/CAG/0119).

Support is requested for this specific project as the purpose of the data processing is research and is in addition to the Section 251 support for a non-research purpose for MBRRACE-UK for the CE programme.

## 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.

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| **Cohort** | 100 cases of perinatal death in England and Wales in 2019* |
| **Data sources** | 1. MBRRACE-UK Confidential Enquiry case notes<br>2. MBRRACE-UK Perinatal Surveillance data |
| **Identifiers required for linkage purposes** | 1. Date of birth – infant<br>2. Date of death – infant<br>3. Gender – infant and mother<br>4. Ethnicity – infant |
| **Identifiers required for analysis purposes** | 1. Date of birth – infant<br>2. Date of death – infant<br>3. Gender – infant and mother<br>4. Ethnicity – infant |
| **Additional information** | *cases already processed by MBRRACE-UK for the Confidential Enquiry Programme under 15/CAG/0119 |

**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.

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| 1 | Provide a clear explanation of the project specific opt-out in the patient notification materials | The applicant provided updated notification materials.<br><br>The CAG were content with this response. |
| 2 | Clarify how the National Data Opt-out will be applied, noting that this would only apply to parents. The CAG also requested that the patient notification materials should state that the National Data Opt-out will be respected | The data that will be used for this research is processed data from the recent confidential enquiry that has already been redacted and delinked from the original data. As a consequence it is not possible for MBRRACE-UK to identify either the NHS Trusts or individuals who were included in the confidential enquiry and so we cannot check if patients have requested that the National Opt-out should be applied.<br><br>Those wishing to apply the National Opt-out will already have done so at their individual NHS Trust.<br><br>MBRRACE-UK cannot confirm to parents whether or not their data was used for the confidential enquiry (and therefore the study), as doing so would breach the anonymity essential for the confidential enquiry process.<br><br>Parents who have already directly opted out of their data being used by MBRRACE-UK/PMRT do not form part of the cohort used for the study, as they would not have appeared in the original sample used for the confidential enquiry.<br><br>MBRRACE-UK has consulted bereaved parents directly as well as charities representing bereaved parents to find out how they feel about their records being used to help national learning |

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| | | around how to prevent similar deaths in the future. The response from the majority of parents we and they speak to, is that parents want to help stop these tragedies happening to other families and are willing to have their information used for this purpose.<br><br>The CAG were content with this response. |
| 3 | Explore additional websites, such as the International Stillbirth Alliance's website or any still birth charity/organisation to highlight the patient notifications materials. | We are discussing adding parent information to the ISA website and the Stillbirth and Neonatal Death charity SANDS.<br><br>The CAG were content with this response. |

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

## Specific conditions of support

The following sets out the specific conditions of support.

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

The NHS England **23/2024** DSPT review for **University of Leicester - College of Life Sciences** was confirmed as 'Standards Met' on the NHS England DSPT Tracker (checked 20 October 2023)

## c. 23/CAG/0069 - A study examining the outcomes of blood transfusions where "least incompatible blood" has been issued due to the rarity of available red cell units

| Name | Capacity |
|---|---|
| Dr Murat Soncul | CAG Alternate Vice Chair |
| Mrs Diana Robbins | CAG Lay member |
| Dr Martin Andrew | CAG Expert member |

**Context**

### Purpose of application

This application from NHS Blood and Transplant (NHSBT) set out the purpose of medical research that aims to follow up the transfusion outcomes of approximately 120 patients who have received "least incompatible" blood in England. The study will seek and examine hospital laboratory parameters to assess whether the transfusions, if given, led to an expected rise in haemoglobin (the oxygen carrying bit of the blood) and no reported reactions or rise in laboratory markers of haemolysis (destruction of red cells by antibodies).

Some patients have antibodies in their blood which makes finding perfectly matched, or compatible red blood cells for transfusion hard to find. These antibodies are often to red cell antigens that are found in the majority of the donor population, and therefore there is not compatible blood available. In these rare instances, the UK blood services select "least incompatible" (weakly reactive Vs the patient) blood for transfusion. As these instances are rare, very little is known about the outcomes of these transfusions, and whether the patient benefitted from the transfusion, if given. This study will help inform transfusion decision making when treating other patients with these rare antibodies in future, as it will provide additional information as to the clinical significance of the rare antibodies in question, and will inform future blood selection policies, which should improve patient care.

Patients who had an antibody to a high frequency antigen and whom NHSBT had issued red blood cells (RBC) for transfusion have been identified from the NHSBT clinical systems, retrospectively and dating back to around 10 years ago. The applicants currently do not know if these patients were actually transfused, and outcome data will only be collected for those that have received at least one unit of 'least incompatible' red cells issued by NHSBT as per inclusion criteria. However, the final fate of the units will be established for all patients, and ‘s251’ support is therefore required for all 120, as their confidential patient information will be processed regardless of whether or no they end up fitting the inclusion criteria. An enquiry will be made by the NHSBT research team, via telephone or secure nhs.net e-mail, to

hospital transfusion departments, as to the outcomes of the transfusion of least incompatible units. Data returned will include clinical data surrounding the transfusion, which will be linked back to the NHSBT data. Analysis will be undertaken on a pseudonymous dataset.

Support is requested to allow the disclosure of confidential patient information from NHS Blood and Transplant to referring hospital transfusion departments, for the purposes of linking with outcome data.

## 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.

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| **Cohort** | 120 patients who have been identified as having a rare antibody which led to the selection of 'least incompatible blood' issued by NHSBT |
| **Data sources** | 1. NHSBT - laboratory Information Management System (LIMS)<br>2. Referring hospital transfusion departments where least incompatible units sent to, and patients were transfused – medical records |
| **Identifiers required for linkage purposes** | 1. Name<br>2. Date of Birth<br>3. NHS number |
| **Identifiers required for analysis purposes** | 1. Analysis undertaken on a pseudonymous dataset |

### 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 develop a patient notification method that includes a study specific opt out mechanism, and provide to CAG for review.**

The applicant provided a notification document to be published on the NHSBT Research and Development Website. This included information on a study specific opt out.

The CAG were content with this.

**2. Please discuss the use of confidential patient information without consent with a patient and public involvement group, and provide feedback to CAG.**

The applicant provided a document detailing a patient and public engagement exercise where the use of confidential patient information without consent was discussed.

The CAG were content with this.

**3. Please provide clarity on when the data will be anonymised.**

The data will be pseudo anonymised once obtained. It will be kept in a pseudo anonymised format (identifiers in one location on secure NHSBT servers, with an allocated trial ID) and the outcome data in another secure location on NHSBT servers, pseudo anonymised to trial ID. Applicants intend to keep the data for analysis for 12 months post collection (collection will begin once CAG approval has taken place), now likely to be 31/07/2024. Applicants will delete the Patient Identifiable Data (patient names / DOB) once all the outcome data have been analysed for publication. No PID will be published.

The CAG were content with this.

**Confidentiality Advisory Group advice conclusion**
The CAG agreed that the minimum criteria under the Regulations appeared to have been met, and therefore advised recommending support to the 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 02 May 2023**

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

The NHS England 2022/23 DSPT review for **NHS Blood and Transplant** was confirmed as 'Standards Met' on the NHS England DSPT Tracker **(checked 07 December 2023)**

## d. 23/CAG/0134 - VIVALDI Social Care Database

**Present:**

| Name | Capacity |
|---|---|
| Professor William Bernal | CAG Alternate Vice Chair |
| Ms Clare Sanderson | CAG Alternate Vice Chair |
| Dr Sandra Duggan | CAG Lay Member |
| Dr Ben Gibbison | CAG Expert Member |
| Mr Andrew Melville | CAG Lay Member |
| C. Marc Taylor | CAG Expert Member |
| Professor James Teo | CAG Expert Member |

**Also in attendance:**

| Name | Position (or reason for attending) |
|---|---|
| Mr William Lyse | HRA Approval Administrator |
| Ms Emma Marshall | HRA Confidentiality Specialist |
| Ms Caroline Watchurst | HRA Confidentiality Advisor |
| Dr Angelika Kristek | External Observer (Clinical Research Facilitator at Royal Berkshire NHS Foundation Trust, and a member of Dulwich REC) |
| Jane Oakley | Internal Observer (Head of Public Involvement at the HRA) |
| Zoë Fry OBE | Engagement lead for VIVALDI Social Care, & the *Executive Director for* The Outstanding Society CIC |

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| Professor Laura Shallcross | Chief investigator |
| Dr Oliver Stirrup | Study statistician and senior post-doctoral research associate |

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

**Summary of application**

This application from University College London set out the purpose of medical research which aims to create a research database including data on infections, hospital attendances, vaccinations, antibiotic prescriptions, and deaths in older adults who live in care homes. Applicants will create the research database by collecting and linking data on residents in these homes. The aim is to collect data from at least 500 homes and up to 30,000 residents in England. This is a pilot project – if it is a success, the goal is to establish a long-term programme of research and surveillance for infection in care homes, informed by learning from this application.

Every year care home residents experience infections and outbreaks, which reduce their physical and mental health and well-being and cause avoidable hospital admissions and deaths. Many of these infections could be avoided with better evidence on 'what works in care homes' and systems to keep track of and therefore stop infection.

The research database will require confidential patient information to be collected from care homes and disclosed to Arden & GEM CSU, in order for NHS England to link to NHS and public health datasets, including records of vaccination, hospitalisation, and death. The database will then be effectively anonymised before it is shared with the applicants at University College London. It will be stored in the UCL Data Safe Haven. The effectively anonymous data collected will be used to measure and prevent infections in residents and stop them spreading. There is an associated non-research surveillance study, which has been submitted to CAG separately – 23/CAG/0135.

The applicants anticipate the research database will be used for research on infectious diseases, outbreaks, and Antimicrobial Resistance (AMR), subject to approval by the study Data Access Committee (DAC). Researchers will be required to access the data for analysis within the UCL Data safe haven. If this pilot is successful, applicants anticipate that the scope of the research database could be extended to support research on infectious and non-infectious diseases. The DAC

will include representation from residents, families, care providers and policymakers.

**Confidential information requested**

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| **Cohort** | The cohort will include approximately 15,000-30,000 residents from 500-1500 care homes for adults older than 65 years in England.<br><br>The data will be collected prospectively between 01 October 2023 and 31 March 2025 (but will be for a maximum of 12 months at each care home) |
| **Data sources** | 1. Participating care homes records<br>2. NHS England – Linked routine datasets:<br><br>-COVID-19 / Influenza tests<br><br>-NIMS vaccination data<br><br>-APC / ECDS hospital attendances data<br><br>-ONS mortality data<br><br>-SGSS microbiology and virology results<br><br>-Antimicrobial prescriptions<br><br>-HPZone, care home level data on outbreaks |
| **Identifiers required for linkage purposes** | 1. NHS number<br>2. Care home post code based on care home CQC-ID (only the first 3 characters)<br>3. National Commissioning Data Repository (NCDR) pseudo-identifier |
| **Identifiers required for analysis purposes** | 1. Applicants are linking to mortality data but are only receiving date of death in MM/YY format.<br>2. Gender<br>3. Ethnicity<br>4. Age |

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| | 5. Care home post code based on care home CQC-ID (only the first 3 characters)<br><br>Therefore data will be pseudonymised (effectively anonymised) for analysis |
| **Additional information** | The pseudonymisation key will be held by NHS England.<br><br>Data will be linked daily. |

**Confidentiality 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

| # | **Action required** | **Response from the applicant** |
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| 1. | Please revise the notification materials:<br><br>a. Amend the current description surrounding CAG having 'approved' the study, as the role of CAG is advisory, and research is approved by the Health Research Authority on advice from CAG.<br><br>b. Provide further detail with regards to the research database purpose.<br><br>c. Clarify a start date for data collection on the notification materials.<br><br>d. Please provide reference to feeding back the results to residents and relatives, as well as the care homes. | Applicants have amended the poster, residents' leaflet, relatives' leaflet, and detailed information sheet in line with these suggestions. CAG were content with these responses. |

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| 2. | Confirm whether the National Data Opt Out can be applied at the point of data extraction from care homes. | Applicants have discussed this with the digital software suppliers - (Nourish and Person Centred Software). They have confirmed that they will be able to apply the National Data Opt Out in addition to the study-specific opt-out (described in the CAG application and protocol) before residents' NHS numbers are sent to NHS England. The Data Flow Diagram has been updated accordingly (see Data Flow Diagram V2). CAG were content with this response. |
| 3. | Please provide a breakdown of membership to the data access committee (DAC) as well as the terms of reference. These should evidence how the medical purpose and public interest for applications to use the data will be assessed. | Applicants have included a Data Access Committee Terms of Reference and membership list (VIVALDI Social Care Data Access Committee ToR V4). Membership will include five resident & relative representatives, three care providers, four member of care home staff, four researchers including a mix of academic experience, and representatives from each of the three data controllers (OS, Care England, UCL).<br><br>Applicants have also included an Oversight Diagram (V4 171023) which summarises how the study will be overseen by operational, advisory, and oversight groups including the DAC.<br><br>CAG were content with this response. |
| 4. | Support cannot be issued until a Favourable opinion from a Research Ethics Committee is in place. | Confirmed 07 December 2023 |

**Confidentiality Advisory Group advice: Conditionally supported**

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. Increase the number of care home residents in further patient and public involvement undertaken over the next year and report these discussions to CAG at annual review.
2. Favourable opinion from a Research Ethics Committee. **Confirmed 07 December 2023**
3. Confirmation provided from the DSPT Team at NHS England to the CAG that the relevant Data Security and Protection Toolkit (DSPT) submission(s) has achieved the 'Standards Met' threshold. **Confirmed:**

The NHS England **22/23** DSPT reviews for **NHS England & Arden and GEM Commissioning Support Unit** (AGEM CSU/DSCRO) were confirmed as 'Standards Met' on the NHS England DSPT Tracker (checked 20 November 2023)

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

**e.**

| **23/CAG/0165** | **2023 Adult Inpatient Survey** |
|---|---|
| Contact: | Tamantha Webster |
| Data controller: | Care Quality Commission |
| Application type: | Non-research |

| **Name** | **Capacity** |
|---|---|
| Dr Murat Soncul | Alternate Vice Chair |
| Dr Sandra Duggan | CAG Lay Member |

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| Mr Umar Sabat | CAG Expert Member |

**Also in attendance:**

| Name | Position (or reason for attending) |
|---|---|
| Mr Dayheem Sedighi | HRA Approvals Administrator |
| Ms Caroline Watchurst | HRA Confidentiality Advisor |

**Summary of application**

This non-research application submitted by Picker Institute Europe on behalf of the Care Quality Commission, sets out the purpose of conducting the 2023 NHS Adult Inpatient Survey.

The Adult Inpatient Survey started in 2002 and falls within the NHS Patient Survey Programme (NPSP). The NPSP was initiated in 2002 by the then Department of Health, and is now overseen by the Care Quality Commission (CQC), the independent regulator of health and social care in England.

The 2023 Adult Inpatient survey will be the twenty-first carried out to date, and the fourth mainstage to be completed using a mixed method approach.

All eligible trusts (131) will be asked to conduct the survey, with preparations expected to begin in the autumn of 2023 and fieldwork expected to start from January 2024. Trusts will collect information of all eligible patients and, following suitability checks, will share confidential patient information with the coordination centre (Picker Institute Europe) and one of the approved contractors (Picker Institute Europe, Quality Health, Patient Perspective or Explain). The contractors will distribute questionnaires to patients using the approach detailed below:

| | Mode of contact |
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| Contact 1 | Postal letter inviting the patient to take part online (and a paper questionnaire included for those over 80 years old) |
| Contact 1.1 | Four days later an SMS reminder will be sent, including a direct link to the online survey |
| Contact 2 | In week 2, a reminder letter will be sent to non-responders |
| Contact 2.2 | Four days later an SMS reminder will be sent, including a direct link to the online survey |
| Contact 3 | Final postal reminder sent, along with a paper questionnaire |

Ahead of each reminder mailing, it will be necessary to remove all respondents who have completed the survey already, and to conduct a DBS or local check on

the full sample. If anyone has requested to be opted out of further reminders, they should also be removed at these timepoints.

## Confidential information requested

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| **Cohort** | Inpatients aged 16 years old or over who were discharged from acute and specialist NHS hospitals in November (and earlier for smaller trusts), having had at least one overnight stay in hospital.<br><br>A list of reasons for exclusion, such as deceased patients and those under 16 years of age at the time of sampling, was included in the application.<br><br>1,250 patients per Trust |
| **Data sources** | 1. Electronic patient records with acute and specialist trusts in England (131).<br><br>2. NHS England - NHS Spine Personal Demographics Service (PDSS) |
| **Identifiers required for contact purposes** | 1. Name<br>2. Address fields including postcode<br>3. Mobile phone number<br>4. Patient unique identifier |
| **Identifiers required for deceased check purposes** | 1. NHS Number<br>2. Full date of birth |
| **Identifiers required for analysis purposes** | 1. Unique identifier (a three digit Trust code and 4 digital serial number related to sampled patient)<br>2. Postcode<br>3. Trust code<br>4. Year of birth<br>5. Gender<br>6. Ethnic category<br>7. Date of admission<br>8. Date of discharge<br>9. Length of Stay<br>10. Treatment Function Code<br>11. ICD-10 Chapter Code<br>12. Treatment Centre Admission<br>13. Admission method |

| | |
|---|---|
| | 14. NHS Site code-Admitted<br>15. NHS Site code-Discharged<br>16. 'Decided to admit' date<br>17. Virtual ward indicator |
| **Additional information** | Trusts may also choose to collect additional sample variables outside of those detailed in the Survey Handbook. This can be valuable to trusts in enabling them to make greater use of their survey locally to target quality improvements.<br><br>Sample and mailing data will be submitted by trusts to approved contractors in a single file. The file which contains both mailing and sample information will be split into separate files by the contractor before submitting only the sample information to the Coordination Centre for checking and approval.<br><br>Please note that the Survey Coordination Centre does **not** receive any names or full addresses |

**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. | Security assurances for 2022/23 are outstanding for the following organisations.<br>• Picker Institute Europe<br>• Patient Perspective<br>• Explain<br><br>Please contact NHS England at exeter.helpdesk@nhs.net and provide the CAG reference number, the organisational names and references that require review, and ask NHS England to review the DSPT submissions due to a CAG application. | These were provided as per standard condition of support. |

**Confidentiality Advisory Group advice: Conditionally supported**

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 standard conditions of support.

### Specific conditions of support

The following sets out the specific conditions of support.

1. Please provide the additional full set of communication toolkit materials that are being developed, as soon as they are ready, and confirm that Trust's will be strongly advised to use the communication toolkit.

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

The NHS England **22/23** DSPT reviews for **Picker Institute Europe, Patient Perspective, Quality Health Limited, & Explain** were confirmed as 'Standards Met' on the NHS England DSPT Tracker (checked 11 December 2023)

## f. 23/CAG/0062 - Exploring determinants of pregnancy intention and relationships between pregnancy intention and outcome using routine data

| **Name** | **Capacity** |
|---|---|
| Dr Sandra Duggan | CAG member |
| Professor Lorna Fraser | CAG member |
| Dr Murat Soncul | CAG alternative vice-chair |
| Ms Katy Cassidy | HRA Confidentiality Advisor |
| Dr Paul Mills | HRA Confidentiality Advice Service Manager |

## Context

### Purpose of application

This application from Imperial College London set out the purpose of medical research to explore the relationships between pregnancy intention and adverse pregnancy outcomes.

There is evidence of linkage between unplanned pregnancies and poor pregnancy outcomes, such as pre-term birth or low birthweight and postnatal depression. This may be due to additional stress and anxiety that an unplanned pregnancy may cause or because women whose pregnancy is unplanned may be less likely to have prepared for pregnancy or accessed pregnancy related services later. The applicants seek to include questions in antenatal care to develop understanding of the relationships between unplanned pregnancy and pregnancy outcomes, with the aim of identifying those at increased risk of worse outcomes.

The applicants seek to use data already collected as part of routine antenatal care to investigate the links between pregnancy intention and adverse pregnancy outcomes. Information will be extracted from patient records by those with an existing legal basis to process the information and also by research midwives. A pseudonymised dataset will be extracted and transferred to the Data Safe Haven at University College London for analysis.

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

### Confidential patient information requested

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

| | |
|---|---|
| **Cohort** | All pregnant people who completed their booking appointment at UCLH, Homerton or Guy's and St Thomas' Hospital from October 2020 onwards (UCLH), May 2020 (Homerton) and November 2022 (GSTT) until mid-2025.<br><br>Approximately 52500 patients. |
| **Data sources** | 1. Patient records held at:<br>a. University College London Hospitals NHS Foundation Trust<br>b. Homerton Healthcare NHS Foundation Trust<br>c. Guy's and St Thomas' NHS Foundation Trust |

| | |
|---|---|
| **Identifiers required for linkage purposes** | 1. NHS number<br>2. Postcode |
| **Identifiers required for analysis purposes** | 1. Postcode<br>2. Occupation<br>Ethnicity |

**Confidentiality Advisory Group advice**

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

| Number | Action required | Response from the applicant |
|---|---|---|
| 1. | Please develop a patient notification method that includes a study specific opt-out option. The notifications should be included on the websites of participating organisations and in relevant clinical areas. Please provide to CAG for review. | The applicant provided a notification method, including materials, to CAG for review. Following further clarifications to make the materials clearer and provide multiple routes to opt out CAG accepted the materials.<br><br>However, CAG still felt that the breach of confidentiality could be better described and added a condition of support to review and return to CAG within 3 months. |
| 2. | The postcodes are to be converted to Index of Multiple Deprivation prior to transfer using one of many online lookup tables, or please justify why this is not practicable. | The applicant confirmed that postcodes will be converted to either Index of Multiple Deprivation (IMD) or Lower Super Output Area (LSOA) prior to transfer into the data safe haven.<br><br>CAG accepted this response. |

| | | |
|---|---|---|
| 3. | Please provide the NHS England 2021/22 DSPT review for Homerton Healthcare NHS Foundation Trust, as per standard condition of support below. | The 22/23 NHS England DSPT review for Homerton Healthcare NHS Foundation Trust was provided. |

**Confidentiality Advisory Group advice conclusion**

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

## Specific conditions of support

The following sets out the specific conditions of support.

1. Review and update the notification material to ensure it accurately describes the breach of confidentiality. Provide a response and any updated materials within 3 months.

2. Favourable opinion from a Research Ethics Committee. **Confirmed 15 June 2023**

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

   The NHS England **22/23** DSPT review for **University College London, University College London Hospitals NHS Foundation Trust and Guy's and St Thomas' NHS Foundation Trust and Homerton Healthcare NHS Foundation Trust** were confirmed as 'Standards Met' on the NHS England DSPT Tracker (checked 13 December 2023)

## g.

| | |
|---|---|
| **23/CAG/0148** | Aspirin Esomeprazole Chemoprevention Trial – EXtension Long-term Clinical Study : A cohort follow up of a phase III randomised study of Aspirin and Esomeprazole Chemoprevention in Barrett's Metaplasia |
| Chief Investigator: | Professor Janusz Jankowski |
| Controller: | University College London |
| Application type: | Research |

| Name | Capacity |
|---|---|
| Professor William Bernal | CAG Alternate Vice Chair |
| Dr Pauline Lyseight-Jones | CAG Lay Member |
| Dr Harvey Marcovitch | CAG Expert Member |

**Also in attendance:**

| Name | Position (or reason for attending) |
|---|---|
| Mr William Lysé | HRA Approvals Administrator |
| Ms Caroline Watchurst | HRA Confidentiality Advisor |

**Summary of application**

This application from University College London (UCL) set out the purpose of medical research that aims to collect the health status of previously consented AspECT participants (alive and deceased), to confirm if aspirin and proton pump inhibitor (PPI)s effectiveness increases long term, to see if aspirin effectiveness increases, and to see if any complications from PPI use occur over a longer period of follow up.

AspEXT EXceL is a follow up trial to the original AspECT consented trial which tested 2 drugs – a high and low dose PPI, with and without aspirin in patients with Barrett's oesophagus (a condition which can develop into oesophageal cancer many years later), with the aim of investigating the benefits in reducing the risk of cancer in these patients. The results from the original trial showed that high dose PPI significantly reduced the occurrence of cancer. In addition, high dose PPI with aspirin appeared to be more effective than when used alone. However, the trial was not long enough to determine whether conversion to oesophageal cancer was significant for each/both drugs.

Most of the patients will be alive, and data collection will be undertaken with consent, and is not relevant for 's251' support. Some of the patients, however, may have died and will therefore not be able to consent. Participating sites will be asked to provide as much information as possible regarding oesophageal adenocarcinoma diagnosis, cause of death and PPI and Aspirin use prior to death using hospital notes, and this will be entered into an electronic case report form (eCRF) called OpenClinica (hosted by Amazon Web Services). 's251' support is not required for this as there is no confidential patient information uploaded to OpenClinica. Full date of death will be uploaded to the UCL Data Safe Haven, and 's251' support is required for this.

Where this information is missing, sites will send confidential patient information (AspECT ID, NHS number, date of birth and sex at birth) regarding deceased

participants to the UCL Data safe haven (DSH). ‘s251 support is also required for this.

If the participating sites cannot provide the NHS number or date of birth, then UCL will request this information from the original AspECT sponsor (Oxford Clinical Trials Unit) using AspECT ID. ‘s251’ support is also required for this flow and the flow back, as the pseudo-ID will be used to re-identify the patient, and provide confidential patient information to UCL. UCL will in turn disclose NHS number and date of birth to NHS England, in order for NHS England to link to the listed datasets, and return the data back to UCL for analysis. Once in UCL-DSH, the data will be linked back to clinical data from the original AspEXT trial, using the using AspECT ID, that will have been separately disclosed to UCL. Once analysis is complete, NHS number, date of birth, and date of death will be deleted from UCL DSH.

**Confidential information requested**

| | |
|---|---|
| **Cohort** | 1587 AspECT participants in total (alive and deceased) (across all of UK)<br><br>‘s251’ support only relevant regarding the deceased patients on England and Wales, however the applicant cannot yet estimate how many people this is relevant for. |
| **Data sources** | 1. 20-35 Participating Aspect sites in England and Wales – (high recruiting AspECT sites with at least 20 participants)<br>a. AspECT screening/enrolment logs<br>b. medical records<br>2. University of Oxford<br>a. original AspECT database<br>3. NHS England<br>a. Hospital Episode Statistics (HES)<br>b. Admitted Patient Care (APC)<br>c. Emergency Care Data Set (ECDS)<br>d. Civil Registrations (Deaths) data set |
| **Identifiers required for linkage purposes with original AspECT trial** | 1. original AspECT trials ID number (to identify NHS number and date of birth if missing from trust data, and to link to AspECT data) |
| **Identifiers required for linkage purposes with NHS England** | 1. NHS number<br>2. Date of birth<br>3. sex |

| | |
|---|---|
| **Identifiers required for analysis purposes** | 1. Date of death<br>2. Date of birth<br>3. sex<br><br>Cause of death, diagnosis of oesophageal cancer or dysplasia at time of death, date of diagnosis and PPI and Aspirin use prior to death will also be provided back to the applicant. |
| **Additional information** | The identifiable patient data will be held separately to the clinical data. This separation happens at the point of data entry at a site/trust level. OpenClinica will hold the clinical data, and UCL DSH will hold confidential patient information |

**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

| # | Action required | Response from the applicant |
|---|---|---|
| 1 | Please undertake further patient and public involvement to specifically address the use of confidential patient information without consent and outside the direct care team. | Applicants sent an email to the PPI group explaining the reasons for collecting confidential data without consent and how it will be stored. There were been no objections raised. The CAG queried how many people had responded, and initially it was 1 out of a PPI group of 4. CAG were not content with this response and requested further responses from the existing PPI group.<br><br>The applicants provided a further response to say that from their original 4 PPI members: 1 has now deceased and 1 has moved.<br><br>The 2 remaining members have both confirmed that they are happy with the justification of collecting data on deceased patients and how the data will be stored. Applicants have also had support from another trustee of the Oesophageal Patients Association (OPA).<br><br>The Members felt the responses were acceptable, and proportionate to the application, however as there are now 2 less |

| | | |
|---|---|---|
| | | members of the PPI group, CAG has applied an additional condition, for the applicant to continue ongoing patient and public involvement with additional participants, and report back with further feedback at annual review. The CAG noted that the medical purpose is clear and important and they do not want to delay supporting the application any further, but additional PPI is required at the next annual review. |
| 2. | Please confirm an estimated timepoint for the deletion of identifiers required for linkage – NHS Number and data of birth. | NHS number and date of birth will be deleted once applicants have completed the database lock, and completed analysis and publication.<br><br>Applicants will update CAG to any changes in the end date and will then be able to give an estimated timepoint for deletion of the data.<br><br>CAG were content with this response. |
| 3. | Please confirm whether full dates of birth and full dates of death are required to be retained for analysis. If these are required for analysis in full format, this should be clearly justified, and a clear timepoint for deletion should be provided. | Full date of birth and death is required for analysis as this would allow applicants to accurately calculate overall survival. Once the analysis is complete the data will be deleted as per date of birth and NHS number above.<br><br>CAG were content with this response. |
| 4. | Please confirm a timepoint when full date of death will be deleted by OpenClinica, and also by UCL-DSH. | Following discussion within the trial team, applicants will not be collecting date of death in OpenClinica. they will request this information to be sent with NHS number and date of birth which will be stored within UCL Data Safe Haven.<br><br>Full date of death will be deleted from the DSH upon completion of analysis and publication.<br><br>CAG were content with this response. |
| 5. | Please provide assurance that no confidential patient information will be disclosed outside of the UK, and confirm that any data disclosed outside of the UK will be | All confidential data will be stored within UCL Data Safe Haven within the UK. This will not be transferred outside of the Data Safe Haven. If any data is disclosed outside the UK, then it will be anonymised in line with ICO guidance. |

| | | |
|---|---|---|
| | anonymised in line with ICO guidance. | CAG were content with this response. |

**Recommendations**

| | | |
|---|---|---|
| 1. | If the applicants can foresee undertaking further linkage with this cohort in the future, then the applicants should consider appropriate language in the current study consent documentation, as part of the consent process of the current alive population, in order for applicants not to have to re-visit this aspect, and potentially prevent the need for a future application to CAG | Applicants responded that the following statement is in the current consent form: *I give permission for UCL CCTU to store my NHS number (or equivalent in Scotland/ Northern Ireland) and date of birth for the collection of future follow-up data for research purposes.*<br><br>CAG accepted the comment but is unable to provide any advice on whether or not this will be sufficient for any data controller in the future to release outcome data, as this will be the decision of the data controller as to whether that consent is specific enough for any future purpose. |

**Confidentiality Advisory Group advice: Conditionally supported**

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.

**Specific conditions of support**

The following sets out the specific conditions of support.

1. Continue ongoing patient and public involvement with additional participants, and report back with further feedback at annual review.

2. Favourable opinion from a Research Ethics Committee. **Confirmed 19 May 2023**

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

   Due to the number of participating organisations involved it is the responsibility of the applicant, as controller, to ensure that all organisations processing confidential patient information meet the minimum required standard in complying with DSPTs, and take remedial action if they become aware of any that fall below this, or where

any concerns are raised about an organisation. These will not be individually checked by the CAT team due to the number of organisations involved.

## 2. New Amendments

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

| Name | Capacity |
|---|---|
| Ms Caroline Watchurst | Confidentiality Advisor |

**Context**

**Amendment request**

This amendment sought 's251' support to revise the dataset used for data collection in the National Hip Fracture Database (NHFD), following review of the dataset by the National Hip Fracture Database (NHFD) advisory group. These changes will be effective from 1 January 2024, and the details are in the submitted amendment form.

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

**Confidentiality Advisory Group advice**

The amendment requested was considered by the Confidentiality Advice team (CAT). CAT reviewed the information provided, and as the amendment was not making any changes to the confidential patient information being processed without consent, no queries were raised regarding this amendment.

**Confidentiality Advisory Group advice conclusion**

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

### Specific conditions of support

The following sets out the specific conditions of support.

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

   The NHS England **22/23** DSPT reviews for **Royal College of Physicians, Crown Informatics, & University of Bristol - Bristol Medical School** were confirmed as 'Standards Met' on the NHS England DSPT Tracker (checked 23 November 2023)

## 21/CAG/0004 – Neonatal Complications of Coronavirus Disease (COVID-19) Study

| Name | Capacity |
|---|---|
| Dr Tony Calland, MBE | CAG Chair |
| Ms Clare Sanderson | CAG Alternate vice chair |

**Context**

### Amendment request

This application from the University of Oxford aimed to determine, via the British Paediatric Surveillance Unit (BPSU) methodology, the incidence of neonatal COVID-

19, including hospital acquired infection, and the incidence of transmission from mother to baby during pregnancy, labour and birth by setting up a national surveillance programme.

This application was originally for 13 months surveillance with 6 months follow-up to ensure ascertainment of all outcomes, from the end of March 2020 until the end of April 2021. The identifiable data was planned to be held until 31 October 2021. An amendment was submitted by the applicant 24 March 2022, to extend the duration

of ‘s251’ support until April 2023, in order to properly be able to establish the complete eligible cohort, ensure the data for each eligible patient is complete, and undertake linkages.

This amendment sought to extend the duration of ‘s251’ support in order to retain the confidential patient information collected from this study. This is requested to allow the applicant to carry out longer-term follow-up of this unique national cohort of babies infected or affected by SARS-CoV-2. Given the novel nature of this virus, the long-term impact of infection and in-utero exposure is not yet known. It is important therefore that applicants have the capacity to follow-up unbiased population based cohorts of children who were exposed to SARS-CoV-2 in utero and in the neonatal period. This cohort of children are now aged between 1y and 3yrs old which, for many of them, is too early to assess the impact on development and respiratory function. Applicants are therefore seeking to retain identifiers for 5 more years, until April 2028, until the cohort reach an age where applicants can be confident of identifying any adverse impacts on development, respiratory function and other organ systems. At that point, a full new REC and CAG application will be made to carry out the relevant study/studies.

**Confidentiality Advisory Group advice**
The amendment requested was considered by Chair’s Action. Both the Chair and the Alternate Vice-Chair were in agreement to recommend support to retain the data for further use in the future for this defined specific research.

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

## Specific conditions of support

The following sets out the specific conditions of support.

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

   The NHS England **22/23** DSPT review for **The University of Oxford - Medical Sciences Division - Nuffield Department of Population Health (EE133863-MSD-NDOPH-NDPH)** was confirmed as ‘**Standards Met’** on the NHS England DSPT Tracker (checked 11 May 2023)

2. Confirmation of a favourable opinion from a Research Ethics Committee. **Confirmed 07 December 2023**

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

| Name | Capacity |
|---|---|
| Paul Mills | Confidentiality Advice Service Manager |

**Context**

### Amendment request

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

This amendment sought support for the University of Dundee (UofD) Health Informatics Centre (HIC) to migrate its servers to a cloud service named AWS by Amazon. There is no change to the data flow, nor the data being collected, nor the timeframe of the study, nor the pseudonymisation, nor the dissemination of results.

**Confidentiality Advisory Team advice**

The amendment requested was considered by the Confidentiality Advice Team. No concerns were raised.

**Confidentiality Advisory Team advice conclusion**

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

### Specific conditions of support

The following sets out the specific conditions of support.

1. Security assurances regarding University of Dundee evidenced in the form of Public Benefit and Privacy Panel for Health and Social Care (HSC-PBPP) approval on 01 June 2022.

2. Confirmation provided from the IG Delivery Team at NHS England 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 England 22/23 DSPT review for Amazon AWS was confirmed as 'Standards Met' on the NHS England DSPT Tracker (checked on 08 December 2023)

3. Confirmation of a favourable opinion from a Research Ethics Committee. **Confirmed 12 December 2022**

## 23/CAG/0117 – Hertfordshire and West Essex Integrated Care Board (QM7) - Disclosure of combined commissioning data sets and GP data for risk stratification purposes to Integrated Care Boards and Data Processors.

| Name | Capacity |
|---|---|
| Paul Mills | Confidentiality Advice Service Manager |

**Context**

### Amendment request

This application was supported in September 2023 for the flow of confidential patient information from GP suppliers to the risk stratification supplier and to link this information with national datasets through NHS number for risk stratification purposes.

This amendment requests support to change the data processor from Arden and GEM Commissioning Support Unit to Cerner. No other changes to the application were made.

### Confidentiality Advisory Group advice

The amendment requested was considered by the Confidentiality Advice Team. No concerns were raised.

### Confidentiality Advisory Group advice conclusion

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

### Specific conditions of support

The following sets out the specific conditions of support.

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

   The NHS England 22/23 DSPT reviews for **Prescribing Services Ltd and Cerner** were confirmed as 'Standards Met' on the NHS England DSPT Tracker (checked 08 December 2023)

## 23/CAG/0073 – CompreHensive GeriAtRician led MEdication Review (CHARMER) - Work Package 4 Definitive Trial

| Name | Capacity |
|---|---|
| Dr Murat Soncul | Alternative Vice Chair |
| Dr Paul Mills | Confidentiality Advice Service Manager |

## Context

### Amendment request

This application was supported in July 2023 to test the effectiveness of the refined CHARMER intervention developed in the feasibility study, which is an intervention to support geriatricians and hospital pharmacists to proactively deprescribe for older people whilst they are in hospital, by measuring the impact proactive deprescribing has on readmission rates to hospital.

Support was granted for Confidential Patient Information to flow from participating sites to the Norfolk and Norwich University Hospitals NHS Foundation Trust, for the onwards disclosure to NHS England for the purposes of linkage with HES, ONS, and the Prescription Dataset, and for the flow of date of death back to Norwich Clinical Trials Unit.

This amendment seeks support to additionally request A&E and outpatient data from NHS England. This information will inform the cost analysis of patient NHS resource use post discharge in relation to the CHARMER intervention.

**Confidentiality Advisory Group advice**

The amendment requested was considered by the Chair's Action. No concerns were raised about the amendment as the additional datasets requested will support the cost analysis.

**Confidentiality Advisory Group advice conclusion**

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

### Specific conditions of support

The following sets out the specific conditions of support.

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

   **Confirmed:** The NHS England 22/23 DSPT review for **Norfolk and Norwich University Hospital NHS Foundation Trust, NHS England, & Norwich Clinical Trials Unit** was confirmed as 'Standards Met' on the NHS England DSPT Tracker (checked 08 December 2023)

2. Confirmation of a favourable opinion from a Research Ethics Committee. **Confirmed 06 December 2023**

## 23/CAG/0019 – CLEOPATRAA Trial (Breast cancer molecular typing and grading trial)

| Name | Capacity |
|---|---|
| Ms Caroline Watchurst | HRA Confidentiality Advisor |

### Context

### Amendment request

This application aims to determine whether 4D Path's Technology Q-Plasia OncoReader Breast, that has been developed in the research setting, works robustly and reproducibly in the clinical diagnostic environment, to confirm its real-life clinical utility, in terms of breast carcinoma grading and molecular subtyping. Support is in place to allow the disclosure of confidential patient information to researchers who are not considered direct care team, at Leeds Teaching Hospitals NHS Trust, during the process of extracting and pseudonymising image data for disclosure to 4D Path Inc, and extracting a clinical/pathological dataset for analysis which will be retained by the direct care team, and also during the unblinding and comparison of the case diagnostic output. In the original study design, eligible cases will be identified by the direct care team within the pathology laboratory system CoPath. At this stage, the National Data Opt Out (NDOO) would be applied, by the Trusts Data Access Committee. 's251' support was then required as the research team, who are not considered direct care team, will extract the digital images, clinical and pathological data required from the Trust digital pathology server, Sectra, and electronic patient records, which will require the research team to view confidential patient information.

This amendment sought support for a minor alteration to the timing of processes undertaken along the data flow, however, the organisations processing data, and the data items remain the same. The first step of the pathway has been amended to support earlier image extraction. The images will now be extracted earlier within the digital workflow and before the NHS National Data Opt Out checks are complete. The case identification and its corresponding data and image extraction will only be done by the direct care team, rather than the research team, as the National Data Opt Out (NDOO) will be applied after this timepoint. Therefore the requirement for 's251' support to allow the research team to initially extract the digital images will no longer be required.

These images will be stored in a secure file within the NHS IT system and the process for checking the National Data Opt-Out status for all identified cases will then be carried out – ie. a list of identified patients will be sent by the direct care team to the Data Access Committee who will perform the NDOO check and will return cases eligible for the study. Any cases identified as applying an NDOO will have all corresponding digital images, along with the data collected to enable to opt-out check, deleted and the case will take no further part in the study.

After this point, eligible patient records will still need to be accessed by the research team to collect the relevant pathology report/clinical data. In parallel, images from this subset of cases will be shared in an anonymised format with 4D Path who will return a case-specific report. As per the original design, both the data collection and the matching of 4D Path's report to that of the pathologist may be done by a non-direct clinical team member to maintain blinding – hence needs for ongoing CAG support.

After review of the pre-existing protocol to incorporate the above changes, a new, precautionary measure has been implemented. Researchers will now back-up the anonymised images used in the trial. They will be backed up using a 256 bit ACS encrypted hard drive and this will be kept in a locked office on NHS premises. Regarding the receipt of algorithm results, the PDF reports for each case will now be sent to the secure Microsoft Azure datalake and then downloaded to the secure NHS server. Lastly, 4D Path will also provide researchers a with a supplementary Microsoft Excel spreadsheet of all results generated. These changes are not relevant to 's251' support as these do not involve the processing of confidential patient information. The updated protocol incorporating all changes has been provided.

**Confidentiality Advisory Group advice**

The amendment requested was considered by the Confidentiality Advice Team, who noted that this amendment in fact reduced the processing of 's251' support.

**Confidentiality Advisory Group advice conclusion**

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

### Specific conditions of support

The following sets out the specific conditions of support.

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

   The NHS England 22/23 DSPT review for **Leeds Teaching Hospitals NHS Trust** was confirmed as 'Standards Met' on the NHS England DSPT Tracker (checked 10 October 2023)

2. Confirmation of a favourable opinion from a Research Ethics Committee. **Confirmed non substantial 13 December 2023**

## 23/CAG/0021 - CSOR: Children's Surgery Outcome Reporting Research Database

| Name | Capacity |
|---|---|
| Ms Caroline Watchurst | HRA Confidentiality Advisor |

**Context**

### Amendment request

This application is a research database containing data relating to children treated for necrotising enterocolitis (NEC), Hirschsprung's disease (HD), gastroschisis, posterior urethral valves (PUV), congenital diaphragmatic hernia (CDH) and oesophageal atresia (OA). 's251' support is in place to allow the disclosure of confidential patient information

from participating NHS trusts to Oxford University Hospitals NHS Foundation Trust, onward disclosure to NHS England for linkage to HES, and the return of a linked dataset. An amendment has also been supported to use the NHS England communications service vital status check to confirm fact of death of infants. Since then, NHS England have now advised that the communications service can only be used to provide fact of death if it is also used to provide parental contact details.

This amendment therefore sought support to use the communications service vital status check, as an additional specified data source at NHS England, in order to provide the applicant with additional specific data items – Parental/next of kin name (s), Parental/next of kin postal address (es), Parental/next of kin telephone numbers (including mobile numbers), and Parental/next of kin email address(es).

Support is already in place for NHS England to provide a linked dataset back to the applicant, and this amendment is to include the additional listed identifiers in that flow.

**Confidentiality Advisory Group advice**

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

**Confidentiality Advisory Group advice conclusion**

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

## Specific conditions of support

The following sets out the specific conditions of support.

1. Confirmation provided from the DSPT Team at NHS England to the CAG that the relevant Data Security and Protection Toolkit (DSPT) submission(s) has achieved the ‘Standards Met’ threshold **Confirmed: Due to the number of participating organisations involved it is the responsibility of University of Oxford as controller, to ensure that participating organisations meet the minimum**

**required standard in complying with DSPTs, and take remedial action if they become aware of any that fall below this, or where any concerns are raised.**

2. Confirmation of a favourable opinion from a Research Ethics Committee.
   **Confirmed no REC review required via email 08 November 2023**

## 16/CAG/0053 – Prolonged Effects of ART: A Record Linkage study (PEARL)

| Name | Capacity |
|---|---|
| Emma Marshall | Confidentiality Specialist |

**Context**

### Amendment request

This study from University of Oxford aims to create a linked dataset combining data on fertility treatment from the Human Fertilisation and Embryology Authority (HFEA) and primary care and hospitalisation data from the Clinical Practice

Research Datalink (CPRD), and to use the linked dataset to assess the effect of Assisted reproductive technologies (ART) on the health of women and their children after successful fertility treatment.

This amendment sought to extend the duration of support to 31st December 2024. Without a duration amendment the applicants would be unable to finalize results and to respond to reviewer comments as needed to all the publication of results.

**Confidentiality Advisory Group advice**

The amendment requested was considered by the Confidentiality Advice Team. The Team considered the justification for the amendment to be reasonable.

**Confidentiality Advisory Group advice conclusion**

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

### Specific conditions of support

The following sets out the specific conditions of support.

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

**Confirmed** – 2022/23 DSPT for **University of Oxford – Medical Science Division – Nuffield Department of Population Health** was confirmed as 'Standards Met' by NHS Digital (by check of DSPT tracker 18 December 2023)

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

**Confirmed non substantial 18 December 2023**

## 22/CAG/0103 – Supporting the NHS Long Term Plan: An evaluation of the implementation and impact of NHS-funded tobacco dependence services

| Name | Capacity |
|---|---|
| Emma Marshall | Confidentiality Specialist |

**Context**

### Amendment request

The applicants have existing support to allow research staff at participating trusts to access confidential patient information in order to identify eligible patients and extract a pseudonymised dataset. Hospital records will be accessed to determine

the number of smokers who have been offered and used tobacco dependence services and to calculate the cost of providing the service.

This amendment sought to add to the project as a data processor. Avon and Wiltshire Mental Health Partnership NHS Trust. This site will collect the confidential patient data detailed in the original application to share with Newcastle University, as detailed in the original application.

**Confidentiality Advisory Group advice**

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

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

### Specific conditions of support

The following sets out the specific conditions of support.

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

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

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

**Confirmed 05 December 2023**

## 21/CAG/0164 – Recovery, Renewal and Reset of Services to Disabled Children

| Name | Capacity |
|---|---|
| Ms Caroline Watchurst | Confidentiality Advisor |

**Context**

### Amendment request

This application has 's251' support in place to allow the disclosure of confidential patient information from individual NHS organisations to NECS, on to North of England DSCRO, and on to NHS England (previously NHS Digital), in order for NHS

England to undertake linkage with HES and MHSDS data, in order to establish which reconfiguration of services, practices and strategies for disabled children made during the coronavirus pandemic worked well.

This amendment sought support to extend the duration of 's251' support until 31 May 2024, and to clarify that civil registrations – deaths is required as a data source from NHS England. The original application stated: '*patient-level data on identified children from NHS datasets: Hospital Episode Statistics - (accident and emergency care, admitted patient data, outpatient data, linked to civil registration) and Mental Health Services Data Set'*.

### Confidentiality Advisory Group advice

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

### Confidentiality Advisory Group advice conclusion

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

## Specific conditions of support

The following sets out the specific conditions of support.

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

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

2. Confirmation of a favourable opinion from a Research Ethics Committee. **Confirmed non substantial 30 November 2023**

## 21/CAG/0044 – UK Longitudinal Linkage Collaboration (Study to NHS identifier flow v1)

| Name | Capacity |
|---|---|
| Dr Tony Calland MBE | CAG Chair |
| Professor William Bernal | Alternate Vice Chair |
| Dr Malcolm Booth | CAG Expert Member |
| Mr David Evans | CAG Expert Member |
| Mr Andrew Melville | CAG Lay Member |
| Professor Sara Randall | CAG Lay Member |
| Dr Joanne Bailey | CAG Expert Member |
| Dr Ben Gibbison | CAG Expert Member |
| Ms Emma Marshall | HRA Confidentiality Specialist |
| Dr Paul Mills | HRA Confidentiality Advice Service Manager |
| Mr Dayheem Sedighi | HRA Approvals Administrator |

**Context**

### Amendment request

This application has ‘section 251 support’ to create a pseudonymised research database - The UK Longitudinal Linkage Collaboration (UK LLC) - which will bring together data from UK longitudinal population studies (LPS), linked to data from national central datasets, into one secure 'Trusted Research Environment' (TRE), initially with a focus on COVID-19 research. Support is only required regarding participating studies which have current support under Regulation 5. Studies using a consented model do

not require support. The LLC research database is UK wide but Regulation 5 support does not extend to Scotland or Northern Ireland.

The current ‘section 251’ support for LLC allows;

- the disclosure of confidential patient information from UK Longitudinal Population Studies (LPS) which currently operate under Regulation 5 support (named as NHS ENgland, TWINSUK, ALSPAC, with any additional studies requiring an amendment to LLC application) to NHS Digital Health & Care Wales (DHCW) (previously NHS Wales Informatics service (NWIS) as a trusted third party.
- for DHCW to onwardly disclose identifiers to NHS England (previously NHS Digital) for the purposes of flagging patients as LLC participants and linking with relevant English covid-19 related datasets, in order to supply the LLC database with pseudonymised linked data.
- and for DHCW to retain the identifiers relating to the LPS study cohorts to ensure de-duplication, and also to retain the key between the link ID and the key ID.

The applicants submitted an amendment request to cover three changes:

1. Add EPIC Norfolk (The European Prospective Investigation into Cancer Norfolk Study) as a supported.

2. Extension of support until June 2028.

3. Expand the UK LLC Research from only COVID-19 research to ALL research.

**Confidentiality Advisory Group advice**

The amendment requested was considered by a full meeting of the CAG on **07 December 2023**.

The CAG noted that this activity fell within the definition of medical research and was therefore assured that the application described an appropriate medical purpose within the remit of section 251 of the NHS Act 2006.

Having reviewed the application and considered the risks and benefits involved, the

CAG was also assured that the proposed activity was in the public interest.

The CAG requested that any additional data set that was going to be added to this collaboration data set where consent is not sufficient, should come to CAG as an amendment. This should provide clear detail on how these participants will be informed of the new use. **(Condition 1)**

The CAG noted that the amendment was aiming to expand the UK LLC Research from COVID-19 research to all research. From the information provided to CAG members found it difficult to understand the intended purpose of the LLC. The CAG felt the submission was still looking for a purpose, rather than having a clear a vision how the LLC will contribute to furthering medical research. Therefore, the CAG requested that more details to be provided on the types of research that the data access panel has considered and supported/rejected six months from the date of approval of this amendment. **(Condition 2)**

Members agreed that Section 251 can only be provided where there is a medical purpose, and wished to remind the applicants that any request to use the data should be for a medical purpose. **(Condition 3)**

Members agreed that the provided notifications were overcomplicated and too technical for the intended reader. The CAG requested for these to be revised, and recommended review by the Patient and Public Involvement and Engagement Group. **(Action 1a)**

The CAG also requested that the notifications to provide a clear explanation on how patients can request removal of their data for this application. This would also need to be reviewed by the Patient and Public Involvement and Engagement Group. **(Action 1b)**

The CAG noted the submitted guidance to ensure that each participating study informs their participants of the extended purpose. Members requested confirmation that the applicant has contacted each participating study with the guidance and that clear information is provided on study websites. Examples should be provided. **(Action 2)**

The CAG noted that the response to initial conditions (in 2021) anticipated that the planned Patient and Public Involvement (PPI) was anticipated to complete in spring 2022. No further feedback was specifically requested by CAG on the outcome of this PPI, and none was provided in the 2023 annual review. Further information was provided by the applicant regarding this initial PPI, and PPI around the change in purpose from COVID-19 to all research. On reviewing the provided information, it was not clear whether the participants were asked their views on the extended use of their confidential patient information for the purposes of the LLC (particularly as extending from COVID-19 to all research), without consent. Considering the potential scale of the LLC members also felt that the scale of PPI was insufficient. Therefore, the CAG requested an extensive and proportionate specific patient and public involvement was undertaken with representative groups, to discuss the acceptability of this use of confidential patient information without consent for the expanded purpose of LLC. **(Action 3)**

**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 for **changes 1 and 2**.

The CAG agreed that there was a public interest in this **change 3**, were supportive in principle of this activity proceeding, and therefore recommended to the Health Research Authority that **change 3 be provisionally supported**. However, further information and actions would be required prior to confirming that the minimum criteria and established principles of support have been adequately addressed.

**Request for further information for Change 3**

1. Update the patient notification materials as follows and provide to CAG for review:
    a. Please update the notifications in a lay language that is easily understood.
    b. An explanation on how patients can request removal of their data for this application should be included.

c. All updated patient notification materials should be reviewed by a patient and public involvement group.

2. Provide confirmation that each participating study has been provided with the guidance and that clear information is displayed on study websites. Examples should be provided.

3. Further proportionate patient and public involvement, particularly around the specific issue of use of confidential patient information without consent is to be undertaken across the longitudinal studies and feedback provided to the CAG for review.

## Specific conditions of support

The following sets out the specific conditions of support.

1. The CAG requested that any additional longitudinal data set that is going to be added, where consent is not sufficient, should be submitted as an amendment to CAG. This should provide clear detail on how these participants will be informed of the new use.

2. The CAG requested that more details to be provided on the types of research that the data access panel has considered and supported/rejected within six months from the date of approval of this amendment.

3. Section 251 can only be provided where there is a medical purpose. The applicants should ensure that any request to use the data should be for a medical purpose

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

   **The applicant must ensure that NHS England confirmation of 'standards met' for organisations processing confidential patient information is in place. As there are more than 5 organisations, the DSPTs will not been individually checked by the Confidentiality Advice Team (CAT). This will be the responsibility of the applicant.**

5. Confirmation of a favourable opinion from a Research Ethics Committee. **Confirmed 16 October 2023**

## 20/CAG/0116 – Quality and Outcomes in Oral and Maxillofacial Surgery (QOMS)

| Name | Capacity |
|---|---|
| Dr Paul Mills | HRA Confidentiality Advice Service Manager |
| Dr Tony Calland, MBE | CAG Chair |

### Context

### Amendment request

The applicants have existing support to allow the disclosure of confidential patient information from participating trusts in England and Wales to the Barts Cancer Care (BCC) Safe Haven Environment, in order for the QOMS project to produce benchmarks for oral and maxillofacial surgery (OMFS) practice and provider-level comparative data for quality of care.

This amendment sought support to expand the QOMS Oncology & Reconstruction workstream to include restorative dentistry and patient-specific implants for mandible reconstruction. No further processing of confidential patient is required as the patients will be within the existing QOMS cohort, but this amendment seeks to confirm an extension in purpose.

### Confidentiality Advisory Group advice

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

### Confidentiality Advisory Group advice conclusion

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

### Specific conditions of support

The following sets out the specific conditions of support.

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

   **Confirmed:** The NHS England **22/23** DSPT review for **Barts CR-UK Centre** was confirmed as '**Standards Met'** on the NHS England DSPT Tracker (checked 7 December 2023).

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

## 20/CAG/0116 – Quality and Outcomes in Oral and Maxillofacial Surgery (QOMS)

| Name | Capacity |
|---|---|
| Dr Paul Mills | HRA Confidentiality Advice Service Manager |
| Dr Tony Calland, MBE | CAG Chair |

**Context**

### Amendment request

The applicants have existing support to allow the disclosure of confidential patient information from participating trusts in England and Wales to the Barts Cancer Care

(BCC) Safe Haven Environment, in order for the QOMS project to produce benchmarks for oral and maxillofacial surgery (OMFS) practice and provider-level comparative data for quality of care.

This amendment sought support to receive full postcode as part of an anonymised retrospective data collection for the audit. On receipt postcode will be immediately converted into LSOA, index of multiple deprivation and distances, and then deleted. No other patient identifiers are collected, and this use of postcode is expected to happen once per patient.

**Confidentiality Advisory Group advice**

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

**Confidentiality Advisory Group advice conclusion**

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

## Specific conditions of support

The following sets out the specific conditions of support.

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

   **Confirmed:** The NHS England **22/23** DSPT review for **Barts CR-UK Centre** was confirmed as '**Standards Met'** on the NHS England DSPT Tracker (checked 7 December 2023).

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

## CAG 5-07 (d) 2013 – National Emergency Laparotomy Audit (NELA)

| Name | Capacity |
|---|---|
| Dr Paul Mills | HRA Confidentiality Advice Service Manager |
| Dr Tony Calland, MBE | CAG Chair |
| Dr Patrick Coyle | CAG Vice Chair |

### 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.

This amendment seeks to add a new group of patients with pathologies indicative for emergency laparotomy but who do not undergo surgery (the 'no-lap' cohort). The rationale is to identify best practice for this cohort of patients to reduce morbidity and mortality. Standards of care will be defined for this cohort and associated questions will be drafted and implemented in the data collection instrument. The initial application has been exempted from the national data opt out and the applicants requested that this exemption is extended to the new cohort.

The amendment also informed CAG that their hardware server provider, UKFast, has merged with ANS Group Limited and now trade under that name.

### Confidentiality Advisory Group advice

The amendment requested was considered by a sub-committee of the CAG. Members felt that the inclusion of the no-laparotomy group is extremely important, and may have a high mortality rate.

Given the potential high mortality rate and the potential for significant safety issues members agreed to advise support for the inclusion of the 'no-lap' cohort, and for the exemption of the national data opt out to be extended to this cohort.

### Confidentiality Advisory Group advice conclusion

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

### Specific conditions of support

The following sets out the specific conditions of support.

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

   **Confirmed:** The NHS England 22/23 DSPT reviews for **Royal College of Anaesthetists and Royal College of Surgeons of England & UKFAST** were confirmed as 'Standards Met' on the NHS Digital DSPT Tracker (checked 14 December 2023).

## 19/CAG/0177 – The Child Death Review Programme

| Name | Capacity |
|---|---|
| Dr Paul Mills | HRA Confidentiality Advice Service Manager |

## Context

### Amendment request

Support was initially granted in October 2021 to allow the disclosure of confidential patient information from a number of specified data sources to Public Health Wales to enable linkage and to inform analysis for the purposes of the child death review programme.

Some of the data sources included datasets from Digital Health and Care Wales – DHCW. This amendment seeks to add a new dataset held by DHCW – the Welsh Clinical Portal. No other changes to data items or data flows are requested.

The amendment also informed CAG that the programme is also collecting identifiable information on living individuals that have been incidentally included in documentation provided to the Child Death Review Programme. The programme has reviewed with their Information Governance Team as to whether they should continue to receive this information. The programme and IG team have determined collection is justified, but Section 251 support is not requested as it is not considered to be ‘ confidential patient information’.

### Confidentiality Advisory Group advice

The amendment requested was considered by the Confidentiality Advice Team who raised no concerns about the addition of a new data source. The team noted the information collected on living individuals included in the documentation, but no support is required given the programme has stated that this is not confidential patient information and therefore outside the remit of regulation 5 of the Health Service (Control of Patient Information Regulations) 2002.

### 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. **Confirmed:** Security assurances for Public Health Wales have been confirmed by DHWC (July 2023)

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

| Name | Capacity |
|---|---|
| Dr Paul Mills | HRA Confidentiality Advice Service Manager |

### 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.

This amendment seeks to clarify in the protocol that notes requested for the Juvenile Idiopathic Arthritis topic will include any pre-diagnosis discharge summaries, referral letters and correspondence which relate to the JIA diagnosis. This will provide information to the case reviewers assessing the case notes for the overall quality of care, particularly in relation to the referral process.

### Confidentiality Advisory Group advice

The amendment requested was considered by the Confidentiality Advice Team. No concerns were raised.

### Confidentiality Advisory Group advice conclusion

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

### Specific conditions of support

The following sets out the specific conditions of support.

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

   **Confirmed:** The NHS England 22/23 DSPT review for **National Confidential Enquiry into Patient Outcome and Death (NCEPOD)** was confirmed as 'Standards Met' on the NHS England DSPT Tracker (checked 14 December 2023).

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

| Name | Capacity |
|---|---|

| | |
|---|---|
| Ms Caroline Watchurst | HRA Confidentiality Advisor |

**Context**

## Amendment request

This application aims to identify the characteristics and antecedents of suicide in people in contact with substance misuse services.

This amendment sought to extend the duration of ‘s251’ support until 31 May 2024.

**Confidentiality Advisory Group advice**

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

**Confidentiality Advisory Group advice conclusion**

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

## Specific conditions of support

The following sets out the specific conditions of support.

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

   The NHS England **22/23** DSPT reviews **for University of Manchester NCISH - 8D594-ECC0020, and UKHSA** (on behalf of NDTMS) were confirmed as **‘Standards Met’** on the NHS England DSPT Tracker (checked 19 December 2023)

- DHCW – a valid CPiP in currently in place.
- Third sector and NHS services organisations providing publicly funded drug and alcohol services – more than 5, and therefore this is the responsibility of the applicant to ensure.

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

## 24/CAG/0021 (supersedes 16/CAG/0049) – National cohort study of late effects of Hodgkin lymphoma treatment

| Name | Capacity |
|---|---|
| Ms Caroline Watchurst | HRA Confidentiality Advisor |

**Context**

### Amendment request

This submitted information represented a new application in relation to an existing activity under application reference 16/CAG/0049. The main change is that of a change of data controller, from the Institute of Cancer Research to The Royal Marsden NHS Foundation Trust. The Chief Investigator has changed from Professor Anthony Swerdlow, to Professor David Cunningham, who is based at the Royal Marsden.

The confidential patient information collected will be transferred to the Royal Marsden from the ICR. Active recruitment to the trial has ceased, however should any follow-up activity be undertaken, then data would flow to the Royal Marsden NHS Foundation Trust. The changes in the relevant infrastructure, security, governance, legal and other necessary requirements have been detailed in a revised application form. The applicant confirmed that no other changes to the purpose, data sources, data items and data flows have been made.

The intention is to replace 16/CAG/0049 with this new application (24/CAG/0021).

**Confidentiality Advisory Group advice**

It was noted that no other changes to people, purposes, data and flows were flagged to the CAG by the applicant. The annual review remains on the same cycle as 16/CAG/0049. This was informed to CAT in 2021, and supported at the time, however no new study reference was created at that time. This letter is to provide the new reference in line with new data controllership.

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

**Confidentiality Advisory Group advice conclusion**

The Health Research Authority, having considered the advice from the Confidentiality Advice Team as set out below, has determined the following:

1. The amendment, via a new research application, to amend the data controller from the Institute of Cancer Research to The Royal Marsden NHS Foundation Trust, is supported, subject to compliance with the standard conditions of support outlined below.

## Specific conditions of support

The following sets out the specific conditions of support.

1. 16/CAG/0049 is superseded from the date of this letter.

2. Favourable opinion from a Research Ethics Committee. **Confirmed 27 October 2021**

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

   The NHS England **22/23** DSPT review for **Royal Marsden Hospital NHS Foundation Trust** was confirmed as 'Standards Met' on the NHS England DSPT Tracker (checked 29 December 2023)

## 3. Annual Review Approvals

| CAG reference | Application Title |
|---|---|
| 18/CAG/0168 | Clinical outcomes of a PPS program undertaken in a large UK cohort |
| 18/CAG/0189 | Helicobacter pylori Screening Study: a randomised stomach cancer prevention trial |
| 22/CAG/0026 | Covid impact on RSV Emergency Presentations: BronchStart |
| 16/CAG/0153 | Renal Association (trading as the UK Kidney Association) |
| 21/CAG/0071 | Congenital Hypothyroidism with Gland in Situ: establishing risk factors and outcomes using population-based data linkage methods |
| 22/CAG/0152 | 2022 NHS Adult Inpatient Main Stage Survey – Mixed Methods |
| 20/CAG/0116 | Quality and Outcomes in Oral and Maxillofacial Surgery |
| 19/CAG/0177 | The Child Death Review Programme |
| 20/CAG/0064 | Health, education and social outcomes of children with visual impairment and blindness (VI/SVIBL) |
| 20/CAG/0087 | Research database for Cambridgeshire & Peterborough NHS FT (CPFT) |
| 18/CAG/0100 | HPS-4/TIMI 65/ORION-4: A double-blind randomized placebo controlled trial assessing the effects of inclisiran on clinical outcomes among people with atherosclerotic cardiovascular disease |

| | |
|---|---|
| 21/CAG/0164 | Recovery, Renewal and Reset of Services to Disabled Children |
| 21/CAG/0078 | Cancer Survivorship Studies |
| ECC 8-02(FT5)/2010 | SABRE Study: Ethnic Differences in Cardiometabolic Risk |
| 22/CAG/0116 | NHS England (NICOR) UK Transcatheter Aortic Valve Implantation (TAVI) Registry |
| 18/CAG/0146 | National Joint Registry |
| 21/CAG/0088 | Barts Structural Interventional Registry (BSIR) |
| 20/CAG/0136 | A randomised controlled trial assessing the effectiveness and cost effectiveness of thrice weekly, extended, in-centre nocturnal haemodialysis versus standard care using a mixed methods approach. |
| 19/CAG/0188 | A POPULATION BASED STUDY OF GENETIC PREDISPOSITION AND GENE-ENVIRONMENT INTERACTIONS IN PROSTATE CANCER |
| 20/CAG/0125 | A POPULATION BASED STUDY OF GENETIC PREDISPOSITION AND GENE-ENVIRONMENT INTERACTIONS IN COLORECTAL CANCER |
| 20/CAG/0126 | A POPULATION BASED STUDY OF GENETIC PREDISPOSITION AND GENE-ENVIRONMENT INTERACTIONS IN (MULTI) CANCER |
| ECC 7-04(j)/2010 | Long term risks of paediatric fluoroscopic cardiology |

| Signed – Chair | Date |
| --- | --- |
| *Dr Tony Calland, MBE, CAG Chair, Professor William Bernal, & Dr Murat Soncul, CAG Alternate Vice-Chairs* | *31 January 2024* |

| Signed – Confidentiality Advice Team | Date |
| --- | --- |
| *Ms Caroline Watchurst*<br>*HRA Confidentiality Advisor* | *25 January 2024* |