



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

April 2022

### 1. New Amendments

#### a. 20/CAG/0029 – Incidence of Chronic Recurrent Multifocal Osteomyelitis (CRMO) in the United Kingdom (UK) and Republic of Ireland (ROI)

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

### Context

#### Amendment request

The applicants have existing support to allow the disclosure of confidential patient information from reporting clinicians to the applicants at the Cambridge University Hospitals NHS Foundation Trust.

This BPSU surveillance study sought support to make two changes. The first change is to extend the surveillance sampling phase from 1 year to 2 years, until November 2022. This will therefore likely double the sample size. Applicants also sought support to extend the follow up duration of the entire cohort, requiring that patients are followed up for an additional year, until 2 years post diagnosis - until November 2024.

The applicants also seek to review all relevant radiological images taken within the surveillance and follow-up phases of the study. This will involve additional processing of confidential patient information. The process is as follows; scans (containing confidential patient information) will be sent to Addenbrooke's Hospital temporary PACS archive (TRAD). An anonymised copy of the images will be created using a unique study identifier. The patient identifiable data will then be deleted from PACS.

### **Confidentiality Advisory Group advice**

The amendment requested was considered by Chair's Action. The Chair recommended support for this amendment, noting that the cohort involved is still small numbers despite doubling, and that additional confidential patient information will be deleted after the transfer to Addenbrooke's Hospital.

### **Confidentiality Advisory Group advice conclusion**

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

### **Specific conditions of support**

The following sets out the specific conditions of support.

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

#### **Confirmed:-**

The NHS Digital 20/21 DSPT review for **Cambridge University Hospitals NHS Foundation Trust** was confirmed as 'Standards Met' on the NHS Digital DSPT Tracker (checked 07 April 2022)

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

## **b. 18/CAG/0124 – Automated Cancer Diagnosis and Prognosis Using Digital Images**

<b>Name</b>	<b>Capacity</b>
Ms Caroline Watchurst	HRA Confidentiality Advisor
Dr Murat Soncul	CAG alternative vice-chair

### **Context**

#### **Amendment request**

This application has support to enable the validation of a machine learning algorithm (a computer-based processing system) which has been developed to identify a range of cancers without human input.

This amendment sought support for three changes to the study which are detailed below. The first change requested is to obtain follow up data from patients treated initially at the main site - Leeds Teaching Hospitals NHS Trust, by extending 's251' support to access and collect clinical metadata and glass slides and/or tissue blocks from the following sites; The Mid Yorkshire Hospitals NHS Trust, Sheffield Teaching Hospitals NHS Foundation Trust, Hull University Teaching Hospitals, Airedale NHS Foundation Trust, Calderdale and Huddersfield NHS Foundation Trust, Harrogate and District NHS Foundation Trust and York and Scarborough Teaching Hospitals.

The second change requested is to increase the number of total cases from 12,000 to 80,000. This change is to support large scale clinical validation of our artificial intelligence platform which correctly identifies the presence of malignancy and its molecular subtype.

The final change requested is to add Panakeia Technologies Limited as an additional collaborator and funder to this study, however they will not be a processor under 's251' support, as they will receive anonymised data only (same as the previous collaborator - 4DPath). Therefore the specific change under 's251' is to amend the purposes of the study to allow data collected using 's251' to be transferred in anonymised format to Panakeia Technologies Limited. In order for them to validate a diagnostic algorithm, PANProfiler Breast, which can determine ER, PR and HER2 status of breast cancer specimens from a digitised image of H&E slides.

#### **Confidentiality Advisory Group advice**

The amendment requested was considered by Chair's Action. The Alternate Vice-Chair considered that the amendment request was reasonable. The AVC noted that the changes will help applicants to generate more data to develop other algorithms for other cancer types and less common entities, collect rare cancer types/molecular subtypes that are unavailable locally, and broaden the development of more diverse diagnostic technologies.

## Confidentiality Advisory Group advice conclusion

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

## Specific conditions of support

The following sets out the specific conditions of support.

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

### Confirmed:-

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

2. Confirmation of a favourable opinion from a Research Ethics Committee. **Confirmed 24 February 2022**

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

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

## Context

### Amendment request

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

In this amendment, the applicants are seeking support to extend the retention period of NHS number, date of birth and admission date for all study participants (only those covered by 's251' not consented patients), for a period of 5 years from the end of patient enrolment to the Avon CAP study. This is to enable future potential linkages with other datasets, not yet specified, however this amendment is purely for the retention. The applicants have confirmed that any changes to data flows, purposes, or additions of data sources, and data processors, will be submitted as an amendment to CAG for further support under 's251'.

### **Confidentiality Advisory Group advice**

The amendment requested was considered by Chairs' Action. The CAG Vice-Chair agreed that the amendment was in the public interest, noting that the retention of the identifiers will allow for the possibility of future linkages to other databases as yet not specified. The Vice-Chair was satisfied that the applicant understood further amendments to 's251' support would be required to define these future linkages, when more information is known.

### **Confidentiality Advisory Group advice conclusion**

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

### **Specific conditions of support**

The following sets out the specific conditions of support.

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

#### **Confirmed:-**

The NHS Digital **2020/21** DSPT reviews for **University of Bristol (Bristol Medical School), University Hospitals Bristol and the Weston NHS Foundation Trust** were confirmed as 'Standards Met' on the NHS Digital DSPT Tracker (checked 11 April 2022)

The NHS Digital **2020/21** DSPT review for **North Bristol NHS Trust** was confirmed as 'Qualified Assurance – Trust has not achieved 95% staff undertaking security awareness training' on the NHS Digital DSPT Tracker (checked 11 April 2022). **Please note the specific condition of support. All staff at organisation that are involved in processing information under this application reference should have successfully completed local security awareness training before processing any information under support.**

2. Confirmation of a favourable opinion from a Research Ethics Committee.  
**Confirmed 11 March 2022**

## d. 19/CAG/0135 – Derby Monitoring Study of Self-harm

Name	Capacity
Ms Caroline Watchurst	HRA Confidentiality Advisor

### Context

#### Amendment request

The Derby Monitoring Study of Self-harm aims to undertake a series of studies on the epidemiology, clinical management, outcome and prevention of self-harm and suicide. The study includes all patients who present at the Derbyshire Healthcare NHS Foundation Trust having self-harmed.

This amendment sought to extend the duration of the study and is seeking support for an extension of study end date to 31st March 2023. It is important that the study is extended as it continues to provide important evidence used to inform National Strategy, Policy and Practices designed to reduce suicide and improve support for people who self-harm.

#### Confidentiality Advisory Group advice

The amendment requested was considered by the Confidentiality Advice Team. The CAT raised no queries and was content to support the amendment.

#### Confidentiality Advisory Group advice conclusion

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

#### Specific conditions of support

The following sets out the specific conditions of support.

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

#### Confirmed:-

The NHS Digital 20/21 DSPT review for **Derbyshire Healthcare NHS Foundation Trust, University Hospitals of Derby & Burton NHS Foundation Trust and NHS Digital**, were confirmed as 'Standards Met' on the NHS Digital DSPT Tracker (checked 11 April 2022).

2. Confirmation of a favourable opinion from a Research Ethics Committee. **Confirmed Non substantial 2 February 2022**

### **e. 18/CAG/0171 – Epidemiological studies of the Porton Down veterans: a ten-year update of mortality and cancer incidence**

<b>Name</b>	<b>Capacity</b>
Ms Caroline Watchurst	HRA Confidentiality Advisor

#### **Context**

##### **Amendment request**

This application aimed to undertake a 10 year update of mortality and cancer incidence of the patient cohort included in the 2002-07 Porton Down Veterans study. The previous study investigated whether military veterans who were exposed to chemical agents as part of the 'human volunteer programme' at the UK government's research establishment at Porton Down, had unusual rates of cancer incidence or mortality compared to veterans who did not attend Porton Down, and the general population.

This amendment sought to extend the duration of 's251' support until 1 November 2022, in order to complete analyses.

##### **Confidentiality Advisory Group advice**

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

##### **Confidentiality Advisory Group advice conclusion**

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

##### **Specific conditions of support**

The following sets out the specific conditions of support.

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

**Confirmed:-**

The NHS Digital 20/21 DSPT review for **King's College London - King's Centre for Military Health Research (KCMHR), and NHS Digital** were confirmed as 'Standards Met' on the NHS Digital DSPT Tracker (checked 11 April 2022)

2. Confirmation of a favourable opinion from a Research Ethics Committee.  
**Confirmed non notifiable by email 22 February 2022**

**f. 21/CAG/0173 – Establishing the burden of vaccine preventable acute lower respiratory tract infections in primary care, UK: Avon-CAP GP2**

<b>Name</b>	<b>Capacity</b>
Dr Tony Calland MBE	CAG Chair
Ms Caroline Watchurst	HRA Confidentiality Advisor

**Context**

**Amendment request**

This application aims to describe the incidence of acute lower-respiratory tract infection (aLRTI) in adults who present to primary care, and to estimate the proportion caused by vaccine preventable infections, including *Streptococcus pneumoniae*, Respiratory Syncytial Virus (RSV) and SARS-CoV-2. 's251' support is currently in place to allow disclosure of confidential patient information from participating GP practices to the University of Bristol, for those eligible patients that cannot be approached for consent, and also to allow research nurses/practitioners, who are not considered to be part of the direct care team, to access confidential patient information in patient records, and out of hours discharge letters from Brisdoc at participating GP practices, to screen patients for eligibility and approach patients for consent, into both the surveillance study and the sampling study.

The current cohort of patients relating to 's251' support is; *'Adults presenting to participating GP practices in Bristol (including out of hours provider Brisdoc) with acute lower respiratory tract disease, including pneumonia, lower respiratory tract infection and heart failure. Maximum of 4000 patients, however 's251' support will not extend to those instances where the direct care team have screened and approached the patient.'*

This amendment sought support to widen the cohort of patients to include those who attended the Emergency Department (but were not admitted to hospital), as the applicants realised these patients were an important subgroup that were currently not included. The eligible cohort for 's251' support is therefore requested to be extended to; *'Adults registered with participating GP practices in Bristol who have presented to in-hours primary care, out-of-hours primary care*

*(Brisdoc) or the Emergency Department, with acute lower respiratory tract disease, including pneumonia, lower respiratory tract infection and heart failure*'. The applicant has confirmed that this additional inclusion will not increase the total number of patients that require 's251' support, as the original number provided was an estimate. The patient inclusion criteria is being updated in the protocol to correspond to this addition, and the updated protocol will be provided to the CAG in due course.

The applicant also explained that this additional data capture of patients attending the emergency department is not currently collected by sister study AVON CAP, as they are currently only registering patients who are actually admitted to the hospital. AVON CAP may also extend 's251' support to those patients who attend the emergency department, but are not admitted, and double counting will be prevented as applicants retain confidential patient information, and this will be able to be checked at a later date between the 2 studies.

Therefore the widening of the cohort means a corresponding change in 's251' support to allow access to confidential patient information in patient records, out of hours discharge letters from Brisdoc, **and discharge letters from the emergency department**, at participating GP practices, to screen patients for eligibility and approach patients for consent, into both the surveillance study and the sampling study. This does not represent a change to the data sources or data flows, as this data is disclosed from Trusts to GPs, in the form of the emergency department discharge letter for the purposes of clinical care, which then becomes part of the GP record – therefore the data sources remain GP records at participating practices.

This amendment also sought support to extend 's251' support from solely 'research nurses/practitioners' to include the wider research team, as staffing is short. The applicants wish for 's251' support to be extended to 'pre-specified suitably trained members of the research team'.

Therefore, incorporating both changes, 's251' support is now extended to allow pre-specified suitably trained members of the research team, who are not considered to be part of the direct care team, to access confidential patient information in patient records, and out of hours discharge letters from Brisdoc, and discharge letters from the emergency department, at participating GP practices, to screen patients for eligibility and approach patients for consent, into both the surveillance study and the sampling study.

### **Confidentiality Advisory Group advice**

The amendment requested was considered by Chair's Action. The Chair was content to recommend support for this amendment, and welcomed the clarifications of the applicant surrounding the prevention of double counting with the sister study AVON-CAP.

### **Confidentiality Advisory Group advice conclusion**

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

## Specific conditions of support

The following sets out the specific conditions of support.

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

### Confirmed:-

The NHS Digital **20/21** DSPT reviews for **University of Bristol - Bristol Medical School (EE133799-BRMS)** and **NHS Bristol, North Somerset & South Gloucestershire CCG** (to cover the 6 participating GPs), were confirmed as '**Standards Met**' on the NHS Digital DSPT Tracker (checked 12 April 2022).

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

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

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

## 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 Digital, in order for NHS Digital 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.

The original application requested that sites provide data through two distinct data flows: A and B. For Dataflow A, individual NHS organisations were to provide Information including pseudonymised NHS Number following application of NoE DSCRO pseudonymisation at source tool. For Dataflow B individual NHS organisations were to provide information to include: pseudonymised NHS number; diagnostic group and details of contacts with services, following application of NoE DSCRO pseudonymisation at source tool. Following discussion

with NHS Digital and NECS (North East Commissioning Service) it has been requested that dataflow B include the month and year of birth of each patient in addition to the previously requested data.

This amendment therefore sought to clarify that month and year of birth would be included in dataflow B as additional data items, in order to improve the quality of data linkage.

### **Confidentiality Advisory Group advice**

The amendment requested was considered by Chairs' action. The CAG Vice-Chair was content to recommend support for this amendment, noting it is for an extra data item which is not on its own disclosive, but will add to the accuracy of linkage.

### **Confidentiality Advisory Group advice conclusion**

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

### **Specific conditions of support**

The following sets out the specific conditions of support.

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

#### **Confirmed:-**

The NHS Digital **2020/21** DSPT review for **North of England Commissioning Support Unit (NECS)** was confirmed as 'Standards Met' on the NHS Digital DSPT Tracker (checked 11 April 2022).

2. Confirmation of a favourable opinion from a Research Ethics Committee. **Confirmed 6 April 2022.**

## **h. 21/CAG/0067 – Derivation and narrow validation of a clinical decision rule for paramedics to triage older adults with a traumatic brain injury**

<b>Name</b>	<b>Capacity</b>
Kathleen Cassidy	Confidentiality Advisor

### **Context**

#### **Amendment request**

This application from South East Coast Ambulance Service NHS Foundation Trust set out the purpose of medical research that aims to develop and test a clinical decision rule (CDR) that paramedics could use to aid triage of patients aged 60 years or older who could be at risk of a traumatic brain injury (TBI), to a hospital with neurosurgical services onsite. Support is already in place to allow data extraction from emergency departments patient records to be undertaken by Intelligent information specialists (who are not considered part of the direct care team) at participating hospitals (part of East Kent Foundation Hospitals Trust for SELKaM Trauma network and part of University Hospitals Sussex NHS Foundation Trust for Sussex Trauma network), and for the onwards disclosure of confidential patient information to SECAMB.

In this amendment, the applicants are seeking support to extend the data collection period from 30 April 2022 until 30 June 2022. The additional time is required as Covid-19 related illness has delayed data collection.

#### **Confidentiality Advisory Group advice**

The amendment requested was considered by the Confidentiality Advice Team. The Team was satisfied that the extension to the data collection period was in the public interest.

#### **Confidentiality Advisory Group advice conclusion**

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

## Specific conditions of support

The following sets out the specific conditions of support.

1. Confirmation of a favourable opinion from a Research Ethics Committee. **Confirmed - REC review is not required**
2. Confirmation provided from the IG Delivery Team at NHS Digital to the CAG that the relevant Data Security and Protection Toolkit (DSPT) submission(s) has achieved the 'Standards Met' threshold: **Confirmed: As there are more than 5 organisations processing confidential patient data these will not be individually checked by the CAT team, and it is the responsibility of the applicant to ensure the DSPTs for the following organisations have been assessed as 'standards met' by NHS Digital;**
  - South East Coast Ambulance Service NHS Foundation Trust
  - King's College Hospital
  - East Kent Foundation Hospitals Trust
  - University Hospitals Sussex NHS Foundation Trust (new merged Trust, should currently be covered by the below;
  - Brighton & Sussex university Hospital NHS Trust and
  - Western Sussex Hospitals NHS Trust
  - Medway Maritime Hospital NHS Foundation Trust

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

Name	Capacity
Ms Clare Sanderson	CAG Alternate vice-chair
Ms Caroline Watchurst	HRA Confidentiality Advisor

## Context

### Amendment request

The applicants have existing support to allow the disclosure of confidential patient information from participating trusts 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 data capture to not only include NHS providers but also independent healthcare providers. Patients use both NHS and independent providers for treatment, and therefore all healthcare providers should be given the opportunity to be able to monitor the quality of care.

### **Confidentiality Advisory Group advice**

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

### **Confidentiality Advisory Group advice conclusion**

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

### **Specific conditions of support**

The following sets out the specific conditions of support.

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

**Confirmed:-** The NHS Digital **2020/21** DSPT review for **Barts CR-UK Centre** was confirmed as '**Standards Met**' on the NHS Digital DSPT Tracker (checked 11 April 2022).

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

### **j. 18/CAG/0018– Pre-Hospital Emergency Medicine (PHEM) Feedback**

<b>Name</b>	<b>Capacity</b>
Ms Caroline Watchurst	HRA Confidentiality Advisor

## **Context**

### **Amendment request**

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

This amendment sought support to include additional data processors in the form of the new sites listed below;

- 1) West Suffolk NHS Foundation Trust
- 2) James Paget University Hospitals NHS Foundation Trust
- 3) East and North Hertfordshire NHS
- 4) North Middlesex University Hospital NHS Trust
- 5) Norfolk and Norwich University Hospitals NHS Foundation Trust
- 6) Bedfordshire Hospitals NHS Foundation Trust
- 7) The Queen Elizabeth Hospital King's Lynn NHS Foundation Trust
- 8) Barking, Havering and Redbridge Hospitals NHS Trust

This amendment also sought support to confirm that Ambulance or Air Ambulance Service Trust email addresses are no longer NHS.net, however the flows of data remain the same and NHS Digital have confirmed that these remain security accredited domains.

This amendment also clarified that the applicant will use NHS numbers to check if a patient has opted out via the National Data Opt Out via the MESH system, and this procedure remains a standard expectation of all applications under 's251' support.

The amendment also sought support to extend the duration of 's251 support' by 2 years to April 2025. This is to account for time lost during the pandemic.

### **Confidentiality Advisory Group advice**

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

### **Confidentiality Advisory Group advice conclusion**

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

## Specific conditions of support

The following sets out the specific conditions of support.

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

### Confirmed:-

- a. **Not checked due to the number of additional research sites to be included within the scope of support.**
- b. **Support is recommended on the basis that the applicant ensures the required security standards are in place at each site prior to any processing of confidential patient information with support under the Regulations – see section below titled 'security assurance requirements' for further information.**
- c. **Where NHS Digital confirms confirmed qualified assurance against the organisation's 2020/21 DSPT submission on the basis that the Trust has not met the 95% standard relating to staff security awareness training: the applicant must ensure that all staff involved in processing data under this section 251 support must have successfully completed local security awareness training before processing any data.**

## k. ECC 6-02(FT3)/2012 – Sentinel Stroke National Audit Programme

Name	Capacity
Ms Caroline Watchurst	HRA Confidentiality Advisor

### Context

#### Amendment request

The Sentinel Stroke National Audit Programme (SSNAP) commissioned by the Healthcare Quality Improvement Partnership (HQIP) has 's251' support in place for Kings College London to process confidential patient information without consent. The initial application however specified there were internal processes in place to ensure that named individuals did not view any items of confidential patient information.

The applicant is now finalising internal processes to comply with the National Data Opt-Out. In order to be fully compliant with the NDOO regulations, applicants wish to check identifiable data against the NDOO list via the MESH system, which will require the named individuals to view confidential patient information.

Therefore, this amendment sought support to clarify that this internal process will be lifted, and named individuals at Kings College London will view confidential patient information in order to perform a check against the National Data Opt Out, for the purposes of linkage.

### **Confidentiality Advisory Group advice**

The amendment requested was considered by the Confidentiality Advice Team, who raised no queries regarding this amendment, and noting this appears to be covered by the 's251' support already in place. This amendment was to formalise the changes in internal processing.

### **Confidentiality Advisory Group advice conclusion**

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

### **Specific conditions of support**

The following sets out the specific conditions of support.

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

The NHS Digital **20/21** DSPT review for **King's College London - Sentinel Stroke National Audit Programme, Net Solving Limited, and NHS Digital** were confirmed as 'Standards Met' on the NHS Digital DSPT Tracker (checked d11 April 2022)

## I. 21/CAG/0149 – Legacies and Futures: Gestational Parents' Experiences with Vulnerability and Resilience as it Influences Parent and Neonatal Health

Name	Capacity
Ms Caroline Watchurst	HRA Confidentiality Advisor

### Context

#### Amendment request

This application aims to research what roles resilience and vulnerability play in the health and wellbeing of LGBTQ+ gestational parents, as compared to their cis-heterosexual peers, during their antenatal care and their neonates. 's251' support is in place to allow the disclosure of confidential patient information from 4 participating hospital trusts to the Data Safe Haven at University College London, where the researcher will access the information in order to email information about the study to patients.

This amendment sought support to include further participating Trusts into the application, as additional data processors. The additional sites are;

- Barts Health NHS Trust (inclusive of The Royal London, Barkantine Birth centre, Newham Hospital, Whipps Cross Hospital, and Barking Birth Centre),
- Guy's and St Thomas' NHS Foundation Trust,
- Homerton University Hospital,
- Kingston Hospital NHS Foundation Trust,
- Royal Free London NHS Foundation Trust,
- West Hertfordshire Hospitals NHS Trust,
- Whittington Hospitals

The applicant confirmed that Brighton and Sussex Hospital has changed name to University Hospitals Sussex, as the Trusts have merged.

This amendment also lists grammatical changes to the protocol and other documents, and also lists further changes which are not relevant to 's251' support. The applicant has confirmed that any patient notification documents are changed only to address the additional sites.

#### Confidentiality Advisory Group advice

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

## **Confidentiality Advisory Group advice conclusion**

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

## **Specific conditions of support**

The following sets out the specific conditions of support.

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

### **Confirmed:-**

Due to the number of organisations involved it is the responsibility of University College London, 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.

2. Confirmation of a favourable opinion from a Research Ethics Committee. **Confirmed non-substantial 29 March 2022.**

## 2. Annual Review Approvals

21/CAG/0025	Retrospective Review of the Use of Simplex High Viscosity Bone Cement for Joint Arthroplasty
ECC 5-04(g)/2011	Extended follow-up of three occupational cohorts exposed to styrene, phenoxy herbicides and formaldehyde
18/CAG/0003	FAST- Febuxostat versus Allopurinol Streamlined Trial A prospective, randomised, open-label, blinded endpoint (PROBE) clinical trial evaluating long term cardiovascular safety of febuxostat in comparison with allopurinol in patients with chronic symptomatic hyperuricaemia
14/CAG/1030	Cluster randomised trial of the clinical and cost effectiveness of the i-gel supraglottic airway device versus tracheal intubation in the initial airway management of out of hospital cardiac arrest - Airway Management in cardiac arrest patients (AIRWAYS2)
19/CAG/0047	Development and validation of a risk assessment tool for self-harm in prisoners
19/CAG/0001	National Asthma and COPD Audit Programme (NACAP): Children and young people (CYP) Asthma Clinical Audit
18/CAG/0207	Defining delirium and its impact in Parkinson's Disease (DELIRIUM PD)
21/CAG/0010	Peritoneal Mesothelioma Retrospective Sample Collection (Short title: Peritoneal Mesothelioma TMA)
21/CAG/0026	High intensity treatment at the end of life in children with cancer: retrospective, national, data linkage study
19/CAG/0154	The CANDID study: Understanding how to improve making, communicating and recording a medical (differential) diagnosis in the acute care setting through institutional, legal and ethical drivers.  (Short title: Differential diagnosis in the acute care setting)
18/CAG/0184	Using National Congenital Heart Diseases Audit data to explore the impact of non-medical risk factors on late post-operative outcomes for children with complex congenital heart defects
18/CAG/0063	National Early Inflammatory Arthritis Audit (NEIAA)

17/CAG/0010	NRCT Research Database V1.0
19/CAG/0079	IBIS – International Breast Cancer Intervention Study Epidemiological Cohort Study (IBIS-I)
18/CAG/0021	The incidence of hydroxychloroquine retinopathy in England - a prospective case-finding study
19/CAG/0189	Barts Gynae Tissue Bank
CAG 9-08(c)/2014	Mesobank Retrospective Sample Collection
19/CAG/0160	Evaluation of the NHS Breast Screening Programme – an individual-based cohort study of mortality
15/CAG/0120	National investigation into suicide in children and young people

Signed – Chair

Date

*Minutes signed off as accurate by CAG Chair Dr Tony Calland MBE, Vice Chair Dr Patrick Coyle, and Alternate Vice Chairs Ms Clare Sanderson and Dr Murat Soncul*

18 May 2022

Signed – Confidentiality Advice Team

Date

*Laura Gordon, Confidentiality Advisory Group Assistant*

18 May 2022