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

**August 2020**

## 1. New Applications

### a. 20/CAG/0025 - SUPER (Southampton cardiac surgery Unit Performance Evaluation and Review Project)

| Name | Capacity |
|---|---|
| Dr Patrick Coyle | CAG Vice-Chair |
| Dr Katie Harron | CAG Member |
| Mr Andrew Melville | CAG Member |
| Ms Kathleen Cassidy | HRA Confidentiality Advisor |

**Context**

**Purpose of application**

This application from the University Hospital Southampton NHS Foundation Trust set out the purpose of an evaluation of survival rates following cardiac surgery at Southampton General Hospital in order to improve performance and service provision in the Southampton cardiothoracic surgery unit.

This project involving unconsented processing will allow an updated and accurate analysis of mortality rates following cardiac surgery and identify any patterns in this cohort. The long-term survival data of patients after cardiac surgery will be considered for different surgical procedures in order to develop benchmarks and assess performance in the form of a local audit, in order to improve future performance and patient-related outcomes. Reflection on these findings will be translated into better management and improved service provision.

The applicants sought support for the disclosure of confidential patient information from University Hospital Southampton NHS Foundation Trust to NHS Digital for linkage to their survival database. The dataset disclosed from University Hospital Southampton NHS Foundation Trust to NHS Digital will contain confidential patient information for all living and deceased patients within the cohort. NHS Digital will return confidential patient information only for deceased patients.

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

## Confidential patient information requested

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

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|---|---|
| **Cohort** | All patients undergoing cardiac surgery at Southampton General Hospital between 01/01/2000 and 01/07/2019. The applicants estimate that 21,200 patients will be included. |
| **Data sources** | 1. Mortality data held by NHS Digital |
| **Identifiers required for linkage purposes** | 1. Name<br>2. Date of birth<br>3. Hospital number<br>4. NHS number |
| **Identifiers required for analysis purposes** | 1. Date of death |

## Confidentiality Advisory Group advice

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

1. **Provide further information on how performance will be improved and how data will be analysed.**

The applicants explained that mortality data for the last two decades will be used to benchmark performance in conjunction with other postoperative quality indicators. Data analysis will include year-by-year comparisons for individual and specific procedures. The outcomes will be compared with current mortality rates and trends. The applicants will look at changes over these last two decades and identify indicators of performance that could be improved within the trust. The CAG noted this explanation and raised no further queries.

2. **Clarify how this local audit will complement the National Audit of Cardiac Surgery.**

The National Audit for Cardiac Surgery (NACS) does not presently provide outcome rates for specific procedures for individual trusts at present. NACS also does not return data quests for sample datasets anymore. The applicants advised that centres being unable to access their submitted data had meant that centres lack the opportunity to analyse their outcomes, except in the broadest of terms as published by NACS. Mortality data from NHS Digital would therefore complement and add to the outcome measures provided by NACS and include a granular analysis of mortality rates for each procedure. The CAG noted this explanation and raised no further queries.

3. **A patient notification strategy for living patients needs to be created. Patient information leaflets should be made available and public notices displayed in appropriate clinics and on relevant websites, and these should include clear information on how patients can dissent from the inclusion of their data. The text of these is to be provided to the CAG for review.**

The applicant advised that public notices had previously been displayed in clinics and wards. They also planned to publicise the study on the Trust website. The CAG reviewed the documents provided and asked that the poster was revised to include a telephone number and email address, in order to provide a local dissent mechanism, in addition to the National Data Opt-Out.

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

4. **Provide further information on what was discussed at the public meetings. This needs to include information on how many attended and the questions asked. It also needs to be clarified whether the issue of processing confidential patient information without consent had been discussed during these meetings.**

A copy of the minutes of the meeting, with list of attendees and questions asked, was provided to the CAG. The Group noted this and raised no further queries.

### Confidentiality Advisory Group advice conclusion

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

### Specific conditions of support

1. Confirmation provided from the IG Delivery Team at NHS Digital to the CAG that the relevant Data Security and Protection Toolkit (DSPT) submission(s) has achieved the 'Standards Met' threshold. See section below titled 'security assurance requirements' for further information. **(Confirmed: University Hospital Southampton NHS Foundation Trust (by NHS Digital email dated 29 November 2019) and NHS Digital (by NHS Digital email dated 10 June 2019) have confirmed 'Standards Met' grade on DSPT 2018/19).**

## b. 20/CAG/0033 - An anthropological study of the early detection of cancer

| Name | Capacity |
|---|---|
| Dr Tony Calland MBE | CAG Chair |
| Dr Martin Andrew | CAG Member |
| Ms Gillian Wells | CAG Member |
| Ms Kathleen Cassidy | HRA Confidentiality Advisor |

## Context

### Purpose of application

This application from the University of Cambridge set out the purpose of medical research that seeks to develop understanding of the practices, perceptions and experiences of scientists, health professionals and research volunteers, who are involved in scientific and clinical research studies related to the early detection of cancer in Cambridge.

The applicant will conduct interviews with clinical scientists, health professionals and research volunteers. The interviews will take place on a consented basis and support under s251 is not required for this activity. The applicants will also observe scientific practices and meetings in academic and clinical settings, shadow research dynamics in clinical research facilities and observe research volunteers outside clinical spaces. During the observation of health professionals in clinical research meetings and multi-disciplinary team meetings, where the researchers and clinicians may discuss aspects of research volunteers' participation in relevant studies, the applicant may be exposed to confidential patient information and support is sought for these incidental disclosures.

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

### Confidential patient information requested

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

| | |
|---|---|
| **Cohort** | Male and female healthy volunteers and patients diagnosed with cancer, who have finished cancer treatment but are at risk of recurrence. |
| **Data sources** | 1. Confidential patient information for patients discussed during clinical research meetings and multi-disciplinary team meetings at Cambridge University Hospitals NHS Foundation Trust |

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|---|---|
| **Identifiers required for linkage purposes** | No identifiers will be required for linkage purposes |
| **Identifiers required for analysis purposes** | No identifiers will be retained for analysis purposes |

## Confidentiality Advisory Group advice

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

1. **Information about the application, including the observation of clinical research meetings and multi-disciplinary team meetings, should be made available on appropriate websites.**

The applicant advised that a newsletter would be created and made available on the study website. The newsletter was provided for review. The CAG noted this information and raised no further queries.

2. **A newsletter, with information about this aspect of the study, is to be created and made available to those included in the other, consented, aspects of the study.**

A newsletter was provided for review. This would be displayed on the study website. The CAG was satisfied by this clarification.

3. **The specific issue of access to confidential patient information by those outside of the direct care team without consent being sought by individual patients needs to be explored during patient and public involvement and engagement, and feedback from these discussions provided to the CAG.**

The applicant provided details on the patient and public involvement which had been carried out, both to explore the use of confidential patient information without consent and to seek feedback on the newsletter. The applicant approached members of the public who had

previously offered feedback on the Patient Information Sheets and Consent Forms. This included, “People in Research” members, the Patient Representative from the research clinic in which the study would take place, and the NIHR Patient and Public coordinator, who facilitates engagement with the Addenbrooke’s PPI panel. Details on the responses received were provided with the response. The CAG noted this information and raised no further queries.

### Confidentiality Advisory Group advice conclusion

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

### Specific conditions of support

1. Favourable opinion from a Research Ethics Committee. **Confirmed 19 February 2020.**

2. Confirmation provided from the IG Delivery Team at NHS Digital to the CAG that the relevant Data Security and Protection Toolkit (DSPT) submission(s) has achieved the ‘Standards Met’ threshold. See section below titled ‘security assurance requirements’ for further information. **Confirmed – Cambridge University NHS Foundation Trust has a confirmed ‘Standards Met’ grade on DSPT submission 2018/19 by NHS Digital email dated 19 September 2019.**

## c. 20/CAG/0046 - An evaluation of a water fluoridation scheme in Cumbria: population based comparative cohort studies of topical fluoride exposure alone

| Name | Capacity |
|---|---|
| Dr Tony Calland MBE | CAG Chair |
| Ms Sophie Brannan | CAG Member |
| Dr Katie Harron | CAG Member |
| Dr Simon Kolstoe | CAG Member |
| Dr Harvey Marcovitch | CAG Member |

| | |
|---|---|
| Ms Gillian Wells | CAG Member |
| Ms Kathleen Cassidy | HRA Confidentiality Advisor |

## Context

### Purpose of application

This application from the University of Manchester set out the purpose of medical research that seeks to assess the effects and costs of systemic and topical exposure to water fluoridation following a reintroduced Water Fluoridation scheme on a cohort of contemporary children.

Tooth decay is the commonest disease of childhood. Fluoride can prevent tooth decay. Water fluoridation has a 70-year history. Unfortunately the scientific evidence demonstrating how well water fluoridation works and how cost-effective it is in the current climate of falling decay levels is lacking. A new plant opened in May 2013, giving the applicants an opportunity to study the impact of water fluoridation in West Cumbria. The applicant will investigate the effects of a new water fluoridation scheme on young children by recruiting groups of children born over the period of a year and following up over a five to six-year period. All children born from September 2014 to September 2015 were recruited and their teeth examined at 3 and 5 years of age to assess the affects of fluoridation on the deciduous teeth. The number of children who developed tooth decay in fluoridated and non-fluoridated areas.

Support is sought for the applicants to link the previously collected confidential patient information collected for the study to dental health data from NHS Business Services Authority (BSA) and HES data from NHS Digital. NHS BSA and NHS Digital had deemed the existing consent obtained in 2013 to be insufficient for this planned data linkage. The applicants also seek support to obtain anonymised data from NHS BSA for children born between September 2014 and September 2015, within the same geographic location, Cumbria East and West, as the children consented into the study.

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

### Confidential patient information requested

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

| | |
|---|---|
| **Cohort** | 3200 children aged 4 -12 years and living in West Cumbria; Cornhow and Ennerdale |
| **Data sources** | 1. Dental Health Data held by NHS BSA<br>2. HES data held by NHS Digital |
| **Identifiers required for linkage purposes** | 1. Name<br>2. Date of birth<br>3. Postcode |
| **Identifiers required for analysis purposes** | 1. Date of birth<br>2. Postcode<br>3. Gender |

## Confidentiality Advisory Group advice

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

1. **Further information on the cohorts recruited for each application is required, including the differences between each cohort**

The applicant explained that there were two cohorts involved in the study. Patients in Cohort 1 were children born between 1st September 2014 and 31st August 2015 in Cumbria. Children were seen around the age of 3 and 5 years old. This cohort would be used to examine the systemic and topical effects of water fluoridation. Cohort 2 will include children who started Reception at school in September 2013, in Cumbria (and therefore would have been born between 1st September 2008 to 31st August 2009). Children were seen around the ages of 5, 7 and 11. This cohort would be used to examine the topical only effect of water fluoridation.

The key difference between the two cohorts is their age. Water fluoridation plants were turned on in 2013. Patients in Cohort 1 will therefore have received fluoridated water from conception. Patients in Cohort 2 will have begun to receive fluoridated water at 4-5 years of age. The CAG noted this clarification and raised no further queries.

2. **Provide clarification on which patients in the cohort would be included in the data linkage, whether this was the whole population who originally consented or only those still active in the study.**

The applicant advised that those involved in the patient linkage will only be those who have originally consented, but any participants who have opted out or withdrawn from the study will be excluded. The CAG noted this information and raised no further queries.

3. **Justification needs to be provided on why consent for the proposed data linkages cannot be sought, particularly from those who are still actively participating in the study.**

The applicant explained that it was not possible to seek consent from patients, as a number may have moved away from the area or the applicants may not have up to date contact details available. Participants in the study had been identified via their schools. The applicants noted that they no longer had the same opportunities to recruit participants. The CAG noted this information and raised no further queries.

4. **A patient notification strategy needs to be devised. Any materials, such as posters, leaflets and website text, need to be provided for review.**

The applicant explained that it was not possible to send the patient notification with the questionnaire as suggested, as the questionnaires had already been sent. Patient and public involvement had already been undertaken around this feedback and the applicants planned to notify as many patients as possible by sending information via post or email to participants that they have current contact details for. This information will be a link to the CATFISH website (and University of Manchester website where possible). Further information regarding access to data will be replicated on the CATFISH website and University of Manchester websites. All participants were given the CATFISH website details each time they were contacted over the last 5 years and therefore for those who are not sent a notification directly the information will be available online.

Information on the CATFISH and university website will detail the University's privacy notice for research participants. A link to the University's privacy notice for research participants was

provided. In addition the CATFISH website will provide access to the original leaflets and information provided to participants. The CAG was satisfied by this information.

5. **Patient and public involvement and engagement needs to be undertaken around the proposed usage of confidential patient information as proposed in the application.**

The applicant explained that patient and public involvement had been undertaken around the access to dental data and the impact of this dental data in relation to the public. This included seeking feedback from both those taking part in the study and also members of the public who are not taking participants, but who are similar to the participant group. A summary of the feedback was provided with the response. The CAG was satisfied by this information.

## Confidentiality Advisory Group advice conclusion

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

## Specific conditions of support

1. Favourable opinion from a Research Ethics Committee. **Confirmed 29 July 2020.**

2. Confirmation provided from the IG Delivery Team at NHS Digital to the CAG that the relevant Data Security and Protection Toolkit (DSPT) submission(s) has achieved the 'Standards Met' threshold. See section below titled 'security assurance requirements' for further information. **Confirmed – University of Manchester (by NHS Digital email dated 04 October 2019), NHS Digital (by NHS Digital email dated 10 June 2019) and NHS Business Services Authority (by NHS Digital email dated 06 September 2019) have a confirmed 'Standards Met' grade on DSPT submission 2018/19.**

## d. 20/CAG/0038 - The C3 Study - Version 1 (The short and long-term cardiovascular consequences of critical illness: The C3 Study)

| Name | Capacity |
|---|---|
| Dr Tony Calland MBE | CAG Chair |
| Ms Clare Sanderson | CAG Alternative Vice-Chair |
| Dr Malcolm Booth | CAG Member |
| Mr Marc Taylor | CAG Member |
| Dr Lorna Fraser | CAG Member |
| Dr Rachel Knowles | CAG Member |
| Ms Kathleen Cassidy | HRA Confidentiality Advisor |

**Context**

### Purpose of application

This application from the University of Oxford set out the purpose of medical research which aims to establish if it is possible to predict who is at risk of subsequent strokes and heart attacks and their likelihood of survival, and to discover if there is any association between these adverse events and the care patients have received whilst they were unwell.

The benefit of care in Intensive Care Units (ICU) has historically been measured as survival. Over the last three decades, the survival of patients admitted to ICU has improved markedly and attention is now focused on the long-term health problems related to ICU care in survivors. Many of these problems significantly impact patients' lives and the associations with the ICU stay are poorly understood, partly as they may occur many years later.

The applicants will study strokes and diseases of the heart and blood vessels, conditions that are common after treatment on ICU. Evidence from other countries suggests that these may be more common after care on ICU, possibly due to the patients' underlying illnesses and the long-term effects of ICU treatments during critical illness. It is not currently possible to identify which patients are at risk of heart attacks and strokes. There are well established treatments

to avoid these conditions in the community and this research will help decide who should be considered for these treatments following a critical illness.

The applicants will create a new database, containing data routinely collected in ICU, such as patients' vital signs, treatments and blood tests. These records will be linked to NHS long-term follow-up data, so that it can be established which patients are at risk of heart attacks and strokes up to several years after discharge from ICU. How much the treatments patients received on ICU contributed to this risk will also be explored. Support is sought for the applicants to link confidential patient information from six participating Trusts to the National Institute for Cardiovascular Outcomes Research (NICOR) Audit database and linkages to HES and ONS data at NHS Digital.

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

## Confidential patient information requested

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

| | |
|---|---|
| **Cohort** | Patients aged 16 years and over, admitted to an intensive care unit for greater than 24 hours. Two cohorts were included, a retrospective cohort of patients treated between 01 January 2006 and 31 October 2020. The prospective cohort will include patients treated between 1 November 2020 to 31 July 2023<br><br>120,000 patients were expected to be included. |
| **Data sources** | 1. Intensive care Clinical Information System (CIS) at 6 participating Trusts<br>2. Hospital electronic patient records at 6 participating Trusts<br>3. HES and ONS data at NHS Digital<br>4. National Institute for Cardiovascular Outcomes Research Audit database, hosted by Barts Health NHS Trust on behalf of HQIP |

| | |
|---|---|
| **Identifiers required for linkage purposes** | 1. Name<br>2. NHS number<br>3. Date of birth<br>4. Date of death<br>5. Postcode – unit level |
| **Identifiers required for analysis purposes** | 1. Date of death<br>2. Postcode – unit level<br>3. Gender<br>4. Occupation<br>5. Ethnicity |

## Confidentiality Advisory Group advice

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

1. **Clarify if the research team will access confidential patient information at participating Trusts in order to identify suitable patients and extract the data required for linkage, or whether the participating Trusts will identify suitable patients.**

The applicant clarified that the research team will access confidential data at the participating Trusts. Patients' will be identified through a record of admission being present in the individual Trust's ICU Clinical Information System (CIS). Data extraction and some processing (such as pseudo-anonymisation and natural language processing) will be performed on site to avoid the transport of unnecessary confidential information. This will be performed by members of the study team. The CAG noted this information and raised no further queries.

2. **Clarify whether the free text would be anonymised before it left the participating Trust and if the data was checked to ensure it was anonymised. If so, clarification on who would do this checking is needed.**

The applicant explained that free text will be anonymised prior to transfer. Where natural language processing is used only the diagnostic codes will be transferred. Where free text has to be transferred, then each field will be separately screened by two members of the study team. Each column/field will then be certified as anonymous prior to any transfer occurring. The CAG noted this information and raised no further queries.

3. **Provide further information on the value of including a prospective cohort, given that no follow-on data was available for this group.**

The applicant advised that one of the objectives of this study is to develop a model to estimate a patient's risk of developing new-onset atrial fibrillation during an ICU stay. This will both allow identification of modifiable variables and allow targeted treatment in future prevention trials. Including a prospective cohort will allow us to build a model using all available data in the retrospective cohort. This could then be validated on the prospective cohort. Given the constantly developing nature of ICU care, a contemporaneous cohort is important to establish the clinical utility of this model, and future predictive models that may be developed for in-ICU events. The CAG noted this information and raised no further queries.

4. **Clarify why the hospital number is required for linkage.**

The hospital number is only required for linkage to other electronic heath care records within the participating Trust. Hospital numbers will not be used for external linkage and will not be transferred to NHS Digital nor into the study database. The CAG noted this information and raised no further queries.

5. **Advise if NHS Digital can undertake the calculation, thereby removing the need to hold the complete postcode.**

The applicants explained that they could request that NHS Digital provide per patient level LSOA codes as an alternative to the unmasked postcode in full. The LSOA codes will allow the applicants to then reference the local deprivation data as well as local census data and other key information collected by ONS at the time of analysis. The CAG noted this information and raised no further queries.

6. **A patient notification and project-specific dissent process needs to be developed, separate to the privacy statement, and submitted to CAG for review. Participating Trusts also need to agree to display the notification appropriately.**

The applicant explained that the Research Ethics Committee had suggested that advertising the study to the visitors of patients on ICU could be both distressing and burdensome on ICU staff and that this request contradicted the request from the CAG to develop a patient notification and dissent process.

7. **Advise if it is necessary to hold both the ledger of dissenting patients at participating sites and whether NHS Digital applying the National Data Opt-out is sufficient.**

The applicant explained that the ledger held at the participating sites will only consist of a list of patients whose data has been sent to NHS Digital. This will serve as an audit trail whilst the study is running. NHS Digital are optimally placed to apply the National Data Opt-Out and, when notified of dissent, will erase the patient's data from the pseudonymised database and mark the ledger accordingly, so no future admissions or data are ever extracted for this individual. At the end of the study this ledger will be destroyed. The CAG noted this information and raised no further queries.

8. **Further patient and public involvement and engagement needs to be carried out to devise the patient notification strategy. Feedback from this needs to be provided to the CAG.**

A patient notification strategy was provided, which was reviewed and accepted by the CAG.

9. **Confirm that an amendment will be submitted to include the further two sites that will take part in the study.**

The applicant confirmed that an amendment would be submitted when the further two sites are in full agreement of participation. The CAG noted this information and raised no further queries.

### Confidentiality Advisory Group advice conclusion

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

## Specific conditions of support

1. Favourable opinion from a Research Ethics Committee. **Confirmed 02 April 2020.**

2. Confirmation provided from the IG Delivery Team at NHS Digital to the CAG that the relevant Data Security and Protection Toolkit (DSPT) submission(s) has achieved the 'Standards Met' threshold. See section below titled 'security assurance requirements' for further information. **(Confirmed: Oxford University Hospitals NHS Foundation Trust (by NHS Digital email 08 November 2019), Imperial College Healthcare NHS Trust (by NHS Digital email dated 21 November 2019), Barts Health NHS Trust (NHS**

**Digital DSPT Tracker checked 10 March 2020) Royal Berkshire NHS Foundation Trust (by NHS Digital DSPT Tracker checked 10 August 2020) and NHS Digital (by NHS Digital email 10 June 2019) have confirmed 'Standards Met' grade on DSPT 2018/19).**

- **Confirmed: Kings College Hospital NHS Foundation Trust - NHS Digital have confirmed qualified assurance against the organisation's 2018/19 DSPT submission on the basis that the Trust has not met the 95% standard relating to staff security awareness training.**

  **As a result, the following specific condition of support has been added: all staff involved in processing data under this section 251 support must have successfully completed local security awareness training before processing any data.**

## e. 20/CAG/0105 - National Clinical Audit of Psychosis

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

### Amendment scope

1. This submitted information represented a new application in relation to an existing activity under application reference 19/CAG/0083. As a result of a change in the commissioning of the programme the primary change is that of an addition of a controller, from solely HQIP to joint controllership between HQIP and NHS England. The intention is to replace 19/CAG/0083 with this new application once support is in place

2. The submitted information also requests an extension duration of support to August 2021.

### Confidentiality Advice Team advice conclusion

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

The Confidentiality Advice Team therefore recommended to the Secretary of State for Health and Social Care that the activity be conditionally supported, subject to compliance with the specific and standard conditions of support as set out below.

## Specific conditions of support

The following sets out the specific conditions of support.

1. 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 – NHS Digital and the Royal College of Psychiatrists (12/08/2019) have received 'Standards Met' grade for 18/19).**

## 2. New Amendments

### a. 18/CAG/0049 - Using primary care to increase uptake of the Bowel Scope Screening Programme in Yorkshire: evaluating paper and telephone-based interventions

| Name | Capacity |
|---|---|
| Ms Kathleen Cassidy | HRA Confidentiality Advisor |

**Context**

**Amendment request**

The applicants are seeking to extend the end date of the study from 01 October 2019 until 01 January 2020.

The applicants have experienced difficulties in recruiting patients into the trial, due to delays in the roll-out of bowel scope screening, which has meant that fewer general practices have been offering screening during the course of the trial. The trial funder, Yorkshire Cancer Research, have therefore granted a three-month no-cost extension. The applicants note that, even with the extension, they are unlikely to recruit the sample size they had originally planned for, in order to test for differences between trial arms 1, 2 and 3. The applicants would not be able to determine which of the three interventions is more effective than the other, but the extension would allow them to test for a difference between arm 1, and arms 2 and 3 combined. This will enable the researchers to determine whether receiving either of the interventions is more effective than usual care.

**Confidentiality Advisory Group advice**

The amendment requested was considered by the Confidentiality Advisory Group. The Group agreed that the extension was in the public interest.

**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 – University College London, School of Life and Medical Sciences. has a confirmed 'Standards Met' grade on DSPT submission 2018/19 by check of the NHS Digital DSPT tracker on 20 July 2020)**

2. Confirmation of a favourable opinion from a Research Ethics Committee **Confirmed 26 November 2019.**

## b. ECC 2-03(c)/2012 - National Paediatric Diabetes Audit (NPDA)

| Name | Capacity |
|---|---|
| Ms Kathleen Cassidy | HRA Confidentiality Advisor |

### Context

### Amendment request

In this amendment, the applicants sought support to include a new organisation as data processor. This change was required as the provider of recovery back-up services for the Royal College of Paediatric and Child Health had changed from Plan B to SysproPLC.

### Confidentiality Advisory Group advice

The amendment requested was considered by the Confidentiality Advice Team. The Team agreed that the amendment was in the public interest and did not require review by the CAG.

### 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 Royal College of Paediatrics and Child Health has a confirmed 'Standards Met' grade on DSPT submission 2018/19 by NHS Digital DSPT Tracker checked 24 July 2020).**

- **Confirmed – SysGroup PLC has a confirmed 'Standards Met' grade on DSPT submission 2019/20 by NHS Digital email dated 07 August 2020).**

## c. 17/CAG/0055 - CRIS Linkage with DWP Employment and Benefits Data

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

### Context

### Amendment request

This application was provided support to link data of patients seen by South London and Maudsley NHS Foundation Trust between 01 January 2007 and 31 December 2016, with data held by the Department for Work and Pensions (DWP). This linkage has encountered unforeseen delays and has not yet happened. Prior to this linkage being

undertaken, the applicants request amended support to extend the timeframe of the linkage between 01 January 2007 and 01 July 2019.

This study is looking at a number of potentially rare exposures and outcomes. Because of this, the study team wish to link the maximum possible number of cases to provide meaningful data.

### Confidentiality Advisory Group advice

The amendment requested was considered by the Confidentiality Advisory Group. The CAG were content with the request and the justification provided.

### 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 – South London and Maudsley NHS Foundation Trust (by email dated 06 December 2019) and Department for Work and Pensions (by email dated 27 July 2020) have a confirmed 'Standards Met' grade on DSPT submission 2018/19 by NHS Digital email dated 06 December 2019).**

2. Confirmation of a favourable opinion from a Research Ethics Committee. **Confirmed 24 July 2020**

## d. 16/CAG/0096 - Therapeutic Assessment (TA) of Adolescents Presenting with Self Harm versus Standard Psychosocial Assessment and Risk Management. Randomised Controlled Trial Long-term Follow Up

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

### Context

### Amendment request

This amendment requests support for King's College London to share pseudonymised data collected under 'section 251' support with the University of Leeds RISA-IPD research team to perform a meta-analysis. The shared data will not include direct patient identifiers, but the data set will include age, gender, ethnicity and other sensitive information surrounding self-harm events. The meta-analysis aims to identify subgroups of those who self-harm who may respond differently to therapeutic interventions, thus paving the way for further targeted treatment trials.

### Confidentiality Advisory Group advice

The amendment requested was considered by the Chair's Action. The Chair noted the use of the data in a meta-analysis will be very much in the public interest.

### 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**

    - **King's College London - Institute of Psychiatry, Psychology & Neuroscience - Child and Adolescent Psychiatry (EE133874-IOPPN-CAP) – Confirmed by email to CAG inbox from NHS Digital 07 August 2020**
    - **University of Leeds – Clinical Trials Research Unit (ECC0010) and NHS Digital have confirmed 'Standards Met' on DSPT 2018/19 (by check of DSPT Tracker 25 June 2020).**

2. Confirmation of a favourable opinion from a Research Ethics Committee **Confirmed 29 May 2020**

# e. 15/CAG/0207 - NHS Cancer Screening Programmes: National Coordination and Quality Assurance

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

## Context

## Amendment request

The NHS Cancer Screening Programmes run by Public Health England (PHE) enable cases of bowel, breast and cervical cancer to be identified and treated at the earliest possible stage in order to improve patient outcomes. There is currently support under the Regulations to enable PHE to process confidential patient information for those components of the programmes (for which it is responsible and accountable to the Secretary of State for Health for as part of its core remit) that depend on the processing of confidential patient information without consent.

There is support currently in place to process confidential patient information to enable the NHS bowel cancer screening programme to screen a cohort age ranging from 60-74 years old.

This amendment seeks support to extend the cohort age range to age 47-74 years, to screen a cohort age range of 50-74. Data from all eligible people will be processed from age 47, with an aim to screen everybody from age 50. This is in line with the government commitment in the NHS long-term plan to lower the age for bowel cancer screening to 50 years, by April 2021. Lowering the starting age for bowel cancer screening will help detect more cancers early enabling more effective treatment but without increasing the risks significantly.

## Confidentiality Advisory Group advice

The amendment requested was considered by the Confidentiality Advisory Group. The Group noted that in line with the government commitment to lower the age at which bowel screening is offered to 50, that it will be essential to work on software requirements to enable the change to be implemented by April 2021. The Group were happy to recommend support to allow this software development to begin.

There are 3 cancer screening programmes supported under CAG reference 15/CAG/0207. It was noted that this amendment was specific to the bowel cancer screening programme. The Group were aware that Hitachi Consulting does not currently have security assurances provided from NHS Digital. However the Group were content to recommend support for this amendment, given that the organisation in question does not process any confidential patient information as part of the bowel screening programme. All security assurances are in place for the bowel screening programme.

The Group also noted that although the CAG did not receive any patient information materials, this was due to the amendment being implemented in the future. The CAG trust that any relevant materials will be supplied when they are developed, and the Group are happy to recommend support without making this a specific condition, due to the excellent track record of the applicant in this area.

## 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 for the Bowel screening programme** (All security assurances are in place for the bowel screening programme, which is one of three cancer screening programmes which are supported under CAG reference 15/CAG/0207)

- **The NHS Digital DSPT 2018/19 review for Public Health England was confirmed as 'Standards Not Fully Met (Plan Agreed)' on the NHS Digital DSPT Tracker (checked 16 July 2020).**
  **Support is conditional upon Public Health England achieving the security assurance action plan as agreed with NHS Digital. All staff involved in processing information under this application reference should be aware of the precise scope of support and its boundaries and have successfully completed local security awareness training before processing any information under support.**

- **NHS Digital has confirmed 'Standards met' 2018/19 by check of the NHS Digital DSPT tracker (20 July 2020)**

**Members were content that security assurances were not required for the below organisations regarding this amendment which regards bowel screening only -**

- **NHS North of England Commissioning Support Unit has confirmed 'Standards met' 2019/20 by check of the NHS Digital DSPT tracker (20 July 2020) (Runs the Cervical Screening Administration Service and does not require security assurances for bowel screening).** It is understood that NHS North of England Commissioning Support Unit are a new data processor, and an amendment will be sent regarding this.
- **Hitachi Consulting - Pending (Runs the breast screening service and does not require security assurances for bowel screening)**

## f. 16/CAG/0058 - National Maternity and Perinatal Audit (NMPA)

| Name | Capacity |
|---|---|
| Ms Kathleen Cassidy | HRA Confidentiality Advisor |

### Context

### Amendment request

The applicants have existing support to allow the disclosure of confidential patient information from English & Welsh NHS Trusts to the Royal College of Obstetricians and Gynaecologists, in order to link this data with data contained in other national databases for the purpose of conducting a national, prospective, clinical audit of maternity services in England and Wales, in order to improve the quality of services and the outcomes achieved for mothers and new-borns.

The amendment request set out a number of changes to the scope of support as detailed below:

1. The NMPA team will no longer receive identifiers for the neonatal data, which were previously required for linkage purposes. NHS Digital will instead link the English ONS register of live births and stillbirths with the ONS mortality register, Personal Demographics Service (PDS) birth notification dataset, Maternity Services Data Set (MSDS), Maternity Information System (MIS), National Neonatal Research Database (NNRD), HES and English mental health datasets. The NMPA project team will be provided with pseudonymised data, containing the NMPA ID only, for analysis

2. The applicant clarified that the MSDS will provide maternity data for the NMPA, where appropriate, to meet the existing deliverables and reporting requirements. The applicant noted that MIS data may still temporarily be used to supplement the MSDS data where coverage and quality is not sufficient.

3. The applicant clarified that 4 individuals within the audit team will be able to access confidential patient information or pseudonymised data; 1 x data manager; 2 x statisticians; 1 senior methodologist.

### Confidentiality Advisory Group advice

The amendment requested was considered by the Confidentiality Advice Team, who accepted the clarifications to the data sources and flows.

### Confidentiality Advisory Group advice conclusion

In line with the considerations above, the CAT agreed that the minimum criteria under the Regulations appeared to have been met for this amendment, and therefore advised recommending support to the 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 Royal College of Obstetricians and Gynaecologists (NHS Digital DSPT Tracker checked 08 July 2020) has a confirmed 'Standards Met' grade on DSPT 2018/19).**

## g. 16/CAG/0134 - Follow-up of the Hertfordshire Cohort Study through Hospital Episode Statistics

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

### Context

### Amendment request

The applicants have existing support to continue to hold and process confidential patient information for 2997 patients born between 1931-1939 who attended baseline clinics during 1998-2004. An extract from HES, covering the period between the attendance at baseline clinics and 31 March 2010, had been obtained. Patients had also been followed up by repeat

clinics and postal questionnaires. These activities had taken place on a consented basis. Support for the continued holding and processing of data had been sought in 2016, as NHS Digital had determined that the consent given by patients was no longer valid, as the consent referred to GP data only. Patients could not be re-contacted for consent as a significant number were deceased or otherwise lost to contact.

The applicants are now seeking support to undertake a further data linkage to HES, covering the period 01 April 2010 and 31 March 2019, with updates at yearly intervals. The applicants anticipate that the inclusion of data for a further ten years will add to the value of the database. The additional data will be used to enable the description of and identification of risk factors, for longitudinal patterns of hospital admission between the ages of 60 and 90 years in a contemporary ageing cohort, and to provide sufficient cases of individual diagnoses and procedures to allow exploration of causal pathways. The data will also be used to provide a source of cohort-wide follow-up prior to death in a group of people whose mortality rate is rising fast.

### Confidentiality Advisory Group advice

The amendment requested was considered by the Confidentiality Advisory Group. It was noted that there is a clear medical purpose and public interest in the requested amendment for a further 10 years of HES data. The Group were supportive of the amendment to increase the data collection period from 01 April 2010 to 31 March 2019, with the condition that the data items requested from HES are the same as the original and not including additional data. The applicant has confirmed that this is the case. The Group were also supportive of annual updates, however the Group felt that they could only offer support for a period of five years from 2019. After five years more data updates taking the applicant to March 2024, the CAG will require a further amendment application to offer support after this time period.

### 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 – MRC Lifecourse Epidemiology Unit (by check of the DSPT tracker on 09 June 2020) have confirmed 'Standards Met' grade on DSPT submission 2019/20). NHS Digital (by check of the DSPT tracker on 09 June 2020) have confirmed 'Standards Met' grade on DSPT submission 2018/19).**

2. Confirmation of a favourable opinion from a Research Ethics Committee:
   **Confirmed 5 August 2020**

3. The applicant is required to submit a further amendment request for support for any further annual data collection updates from HES after 5 years from 2019.

## h. CAG 8-06(b)/2013 - National Asthma and Chronic Obstructive Pulmonary Disease (COPD) Audit Programme

| Name | Capacity |
|---|---|
| Ms Kathleen Cassidy | HRA Confidentiality Advisor |

### Context

### Amendment request

The applicants have existing support for Crown Informatics to periodically securely transfer identifiable data, patients' NHS number, Date of Birth, Postcode and Name, to NHS Digital, DARS and NHS Wales Informatics Service (NWIS) to link data and provide appropriate HES, ONS and PEDW (NWIS) data. The linked data is then returned to Crown Informatics, who combine the validated identifiers, NHS Digital data, NWIS data and the COPD audit data, before pseudonymising the data and transferring the dataset to Imperial College London and the Royal College of Physicians for analysis and to facilitate management of the audit, respectively.

An amendment was given support on 04 February 2020 to allow the collection of audit data for all adults aged 16 years and over admitted to hospital with asthma attacks and adults over 35 years of age with acute exacerbation of COPD in England, Scotland and Wales.

This current amendment has been submitted to seek support to make changes to the non-identifiable data items currently collected for the adult asthma secondary care audit only. The applicants provided the data items currently collected as part of the adult asthma audit in appendix 2 and a list of the revised items in the dataset in appendix 3.

This amendment was submitted as, after conducting the first-round of continuous data collection for the adult asthma audit and receiving the results from the first data download and report, the applicants had noted that there were further areas of care which required improvements. Changes to the dataset in order to record the relevant metrics were therefore required in order to assist in making improvements in the quality of care and services. The applicants anticipated that these amendments would remain in place until the end of the programme. The programme was currently planned to end in February 2021, however the applicants noted that this may be extended.

### Confidentiality Advisory Group advice

The amendment requested was considered by the Confidentiality Advisory Group. The CAG agreed that the revisions made were in the public interest.

### Confidentiality Advisory Group 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

1. Confirmation of suitable security arrangements via IG Toolkit submission.
   **Confirmed:**
   **Royal College of Physicians (by NHS Digital email 09 August 2019), Imperial College London (by check of the NHS Digital DSPT tracker on 07 August 2020) Crown Informatics (by NHS Digital email 16 August 2019), and NHS Digital (by NHS Digital email 10 June 2019) have confirmed 'Standards Met' grade on DSPT 2018/19).**

## i. CAG 8-06(b)/2013 - National Asthma and Chronic Obstructive Pulmonary Disease (COPD) Audit Programme

| Name | Capacity |
|---|---|
| Ms Kathleen Cassidy | HRA Confidentiality Advisor |

### Context

### Amendment request

The applicants have existing support for Crown Informatics to periodically securely transfer identifiable data, patients' NHS number, Date of Birth, Postcode and Name, to NHS Digital, DARS and NHS Wales Informatics Service (NWIS) to link data and provide appropriate HES, ONS and PEDW (NWIS) data. The linked data is then returned to Crown Informatics, who combine the validated identifiers, NHS Digital data, NWIS data and the COPD audit data, before pseudonymising the data and transferring the dataset to Imperial College London and the Royal College of Physicians for analysis and to facilitate management of the audit, respectively.

The current support in place includes the collection of audit data for all admissions of children aged 1 – 18 years admitted to hospital with asthma attack in England and Wales for the National Children and Young People's Asthma Audit's secondary care data flows. The data flows were described in appendix 1 of the amendment. In this amendment, the applicants are seeking support to revise the flow of linked outcome data. Data will be sent by NHS Digital and NWIS to Imperial College London in a pseudonymised, patient-level format. This means that Crown Informatics Ltd will no longer receive the returned linked data from NHS Digital and NWIS, and the revised data flow will be as follows:

1. Crown Informatics Ltd will securely transfer identifiable data (NHS number, date of birth and postcode + a unique audit identifier for the cohort [for which we require linked data] to NHS Digital and NWIS.
2. NHS Digital link the data to HES and ONS datasets and NWIS link the data to the PEDW dataset.
3. NHS Digital and NWIS will pseudonymise the linked data at source as follows:
4. NHS number replaced with unique audit identifier
5. Date of birth replaced with age at admission
6. Postcode replaced with Lower Super Output Area (LSOA)
7. NHS Digital and NWIS return the pseudonymised linked data to Imperial College London for analysis. This data file will include date of death which is now a Civil

Registration Data Item and no longer considered patient identifiable as an independent data item.

8. Imperial College London will use the unique audit identifier to link the pseudonymised data files with the NACAP children and young people's secondary care dataset
9. Once this process has been completed Imperial College will transfer the national, country and service level aggregated data to RCP for production of the reports and drafting of commentary.

The applicant confirmed that Imperial College London and Royal College of Physicians will not have access to patient identifiable information. A similar amendment was given support in February 2020. The outcome letter for this amendment was supplied.

### Confidentiality Advisory Group advice

The amendment requested was considered by the Confidentiality Advisory Group. The CAG agreed that the revisions made were in the public interest.

### Confidentiality Advisory Group 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

1. Confirmation of suitable security arrangements via IG Toolkit submission.
   **Confirmed:**
   **Royal College of Physicians (by NHS Digital email 09 August 2019), Imperial College London (by check of the NHS Digital DSPT tracker on 07 August 2020) Crown Informatics (by NHS Digital email 16 August 2019), and NHS Digital (by NHS Digital email 10 June 2019) have confirmed 'Standards Met' grade on DSPT 2018/19).**

## j. 19/CAG/0040 (Replacement of CAG 4-09(a)/2013) – Translational Research in Pulmonary Hypertension at Imperial College (TRIPHIC)

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

### Context

### Amendment request

The TRIPHIC research database received a recommendation of support under the Regulations on 18 September 2013 (CAG 4-09(a)/2013), and for a further 5 years on 26 April 2019 (19/CAG/0040). The research database linked established datasets at Imperial College Healthcare Trust with datasets at NHS Digital. The database includes data on consented patients prospectively, which does not require support under the Regulations.

Support under the Regulations currently extends to the use of data from retrospective living patients, as well as deceased patients. The applicants agreed to pilot an approach of consenting 40 retrospective patients, to determine if this was a viable means of exiting support. It was also agreed where the non-response rate was high, the applicants would revert to an opt out approach. As a condition of support, the applicants were to report back at the first annual review.

This amendment:

- Reports on this condition of support. A pilot of 48 patients was undertaken, with 23 responding to the consent. As such the applicant, in line with the initial support letter, details that the non-response rate was too high, and that a move to use an opt-out method with retrospective living patients has been undertaken.
- Updates the affiliations of the Chief Investigator and named personnel.
- Details the modernisation of the TRIPHIC information system infrastructure (but does not change data flows or storage of information).
- Details the installation of PAHTool software as part of the clinical management of patients with pulmonary hypertension at Hammersmith hospital, which will link to the research database (but does not change data flows or storage of information).
- Details minor updates to the TRIPHIC Protocol

### Confidentiality Advisory Group advice

The amendment requested was considered by the Confidentiality Advisory Group, who were content with the way the amendment was presented. The Group considered the applicants attempts to seek consent from and inform living patients regarding the use of their data in TRIPHIC exemplary, and the public facing notification documents excellent. The Group considered all elements of the amendment to be necessary and of public benefit.

### Confidentiality Advisory Group 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

1. 1. All pre-existing conditions of support related to CAG 4-09(a)/2013 remain applicable.

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 – Imperial College Healthcare NHS Trust has a confirmed 'Standards Met' grade on DSPT submission 2018/19 by check of NHS Digital DSPT tracker on 16 July 2020).**

3. Confirmation of a favourable opinion from a Research Ethics Committee. **Confirmed 16 July 2020**

## k. 17/CAG/0020 - Clinical and Biological factors associated with relapse and length of survival following relapse in UK neuroblastomas

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

## Context

### Amendment request

This research study from Newcastle University is a retrospective epidemiologic and genetic study into Neuroblastoma, which is an embryonal childhood tumour derived from cells which go on to form the sympathetic nervous system.

The applicants currently have support under the regulations to allow the relevant data extraction at the identified sites to be undertaken by clinical data co-ordinators, who are not be part of the direct care team. The applicants also have support to further analyse the DNA of three children for whom consent has not been obtained.

This amendment sought support to extend the duration of the study until 31 March 2023, to align with further funding secured. The amendment also is updating the study leaflets to reflect these changes.

### Confidentiality Advice Team advice

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

### Confidentiality Advice Team 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

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

   **Confirmed** - The NHS Digital DSPT 2018/19 review for **Newcastle Upon Tyne Hospitals NHS Foundation Trust** was confirmed as **'Standards Not Fully Met**

**(Plan Agreed)'** on the NHS Digital DSPT Tracker (checked 7 August 2020). Please note the updated specific condition of support below.

**Newcastle Upon Tyne Hospitals NHS Foundation Trust** should achieve the security assurance action plan as agreed with NHS Digital. All staff involved in processing information under this application reference should be aware of the precise scope of support and its boundaries and 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 Non-Substantial 21 April 2020**

## I. 19/CAG/0201 – The PREDICT Study

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

### Context

### Amendment request

This research study from the North East Ambulance Service NHS Foundation Trust seeks to determine if a lactate measurement, taken by a paramedic during an out of hospital cardiac arrest, can predict survival to hospital. Support is in place as patients are enrolled prior to consent being taken, due to the emergency nature of the cardiac arrest.

In this amendment, the applicant sought to extend the study duration to finish recruitment on 31 March 2021, and complete data collection on 30 April 2021. Patient facing documentation has been updated accordingly to reflect this.

The applicant confirmed that there were no other changes to the study, and the request was to enable sufficient recruitment to the study.

## Confidentiality Advice Team advice

The amendment requested was considered by the Confidentiality Advice Team, who agreed that the request to extend the study duration was reasonable and in the public interest.

## Confidentiality Advice Team 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

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 DSPT 2018/19 review for **Gateshead Health NHS Foundation Trust** was confirmed as **'Standards Met'** on the NHS Digital DSPT Tracker (checked 7 August 2020)
    - The NHS Digital DSPT 2018/19 reviews for **Newcastle Upon Tyne Hospitals NHS Foundation Trust and North East Ambulance Services NHS Foundation Trust** were confirmed as **'Standards Not Fully Met (Plan Agreed)'** on the NHS Digital DSPT Tracker (checked 7 August 2020). Please note the updated specific condition of support below.

    **Newcastle Upon Tyne Hospitals NHS Foundation Trust and North East Ambulance Services NHS Foundation Trust** should achieve the security assurance action plan as agreed with NHS Digital. All staff involved in processing information under this application reference should be aware of the precise scope of support and its boundaries and 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 non substantial 10 July 2020**

## m. 18/CAG/0185 - At-Risk Registers Integrated into primary care to Stop Asthma crises in the UK (ARRISA-UK): A pragmatic cluster randomised trial with nested economic and process evaluations examining the effects of integrating at-risk asthma registers into primary care with internet-based training and support

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

### Context

### Amendment request

This study from the University of East Anglia aims to assess whether care provided to patients with asthma, who are at greater risk of hospital admissions and dying from their condition, can be improved via a GP-practice led intervention. Support under the Regulations is currently in place to allow the disclosure of specified confidential patient information from participating GP practices in England to Harvey Walsh prior to onward disclosure to NHS Digital for linkage with HES and ONS datasets.

This amendment sought support to extend the duration of the study in line with an approved funding extension to the overall study of 15 months. The revised end of study date is 31 October 2021.

### Confidentiality Advice Team advice

The amendment requested was considered by the Confidentiality Advice Team. The CAT considered the duration request reasonable and in the public interest.

### Confidentiality Advice Team 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

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 - NHS Digital and Harvey Walsh Ltd. have confirmed Standards Met grade on the DSPT 2018/19** (By check of the DSPT tracker 11 August 2020)

2. Confirmation of a favourable opinion from a Research Ethics Committee.
   **Confirmed Non-substantial 21 July 2020**

## n. 18/CAG/0054 - Lung cancer screening study using low dose CT to support the development of blood tests for early cancer detection

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

### Context

### Amendment request

This study investigates the feasibility of introducing low dose computed tomography (LDCT) screening to a group of adults at high risk of lung cancer. The study has support to allow the research team access to GP record systems in order to identify and invite potential participants to the study. The study also has support to analyse the data of both those who attend and those who do not.

This amendment sought support for three external contractors to access the trial database for the purpose of system maintenance, which may lead to confidential patient information becoming visible as fixes are processed. The contractors are appointed via honorary contracts with UCL which bind these individuals to the same duty of confidence as substantive UCL staff.

### Confidentiality Advice Team advice

The amendment requested was considered by the Confidentiality Advice Team, as a previous amendment request for maintenance of the trial database was considered by a Sub-Committee and supported on 14 October 2019. The CAT recognised that the maintenance of the trial database was an essential element to ensuring the supported project can successfully proceed.

It was noted that the Confidentiality Advisory Group (CAG) had already determined that the project had a medical research purpose which was strongly in the public interest. The CAT recognised that the Sub-Committee had previously determined that database maintenance was not listed as a medical purpose in its own right within section 251(12) of the NHS Act 2006, however the Group was assured that the necessary processing for this task was essential to achieving the overarching medical research purpose of the study.

The CAT understood the rationale provided and were content to provide a recommendation of support to the project.

### Confidentiality Advice Team 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

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 – DSPT 2018/19 have been confirmed with 'Standards Met' grades for University College London Hospitals NHS Foundation Trust, University College London - School of Life and Medical Sciences, CFH Docmail Ltd., and Amazon Web Services (by check of the DSPT tracker on 16 June 2020).**

2. Confirmation of a favourable opinion from a Research Ethics Committee
   **Confirmed within the scope of existing ethical opinion**

## o. 19/CAG/0214 - Understanding the scale and nature of avoidable harm in prison healthcare (Phases 2 & 3: Case note review and qualitative interviews)

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

## Context

### Amendment request

This study from University of Manchester aims to determine the frequency and nature of avoidable patient harm in prison healthcare. There is currently support under the Regulations for researcher access to confidential patient information within electronic and paper-based medical records, managed by a number of healthcare providers delivering services at 17 named prisons in England. This will be the records of approximately 15,000 patients. Pseudonymised information will be extracted into an electronic case report form for analysis.

This amendment sought support for an additional method of remote data collection via a locally agreed protocol with each prison/healthcare provider. This will be possible via the healthcare providers who can arrange access to prison-based records through their wider Trust/organisational secure servers. This may not be possible for some sites.

For each prison site, the link person at the prison/healthcare provider will generate a screening list of prisoners on the study provided census date. This link person will be someone who already has access to prisoner data as part of their job as a healthcare member of staff. The list will include prisoner names, dates of birth and/or NHS numbers/prison numbers. A unique Patient Study Number will be allocated to each case as per protocol. For data collection that takes place at the prison, the list will be stored electronically at the prison. This is as per the original support. For remote data collection, where possible, the link person will generate this list directly from S1. Where that is the case, the list will then be stored electronically on healthcare provider computers/servers. If for any reason it is not possible to generate it directly via S1, it will be done via the link person at the prison and shared by secure NHS to NHS email. This will be password protected. This is done by the same person as originally planned, but altering the method slightly so remote access is enabled. For both methods of data collection, the list will only be accessed by authorised study personnel, on prison/NHS/healthcare provider computers/servers.

Research GP/nurse reviewers will then use the generated pseudonymised lists to extract data from the medical records of eligible prisoners.

Prisons will be contacted at the end of data collection to confirm that they have deleted the internal list, and when data is accessed remotely the list is also permanently deleted by researchers.

This change has been requested due to the unknown delay in data collection due to Covid-19. An additional method of data collection will potentially allow applicants to re-start the study where it is possible to use a remote data collection method.

All data processors and levels of access to the confidential data, including the pseudo-anonymised data remain unchanged.

The protocol has been updated to reflect that data collection may take place 'in person' at the prison or remotely via access to healthcare servers.

## Confidentiality Advisory Group advice

The amendment requested was considered by the Confidentiality Advisory Group. The Group understood the rationale behind the amendment request, and noted that the applicants had a need for support under the Regulations in principle, so that arrangements could be made with each prison involved, and the study could begin to collect some data. The Group were happy to support the amendment, with some clarification around the 'link person'. The applicant was queried surrounding who the link person at each site was, and it was confirmed that the link person would be a healthcare professional within each prison who would have access to confidential identifiable information as part of their clinical role. The study design of a link person extracting lists containing identifiable information is the same design as originally supported, but the methods of extraction are changing in line with enabling remote working.

## Confidentiality Advisory Group 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

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

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

2. Confirmation of a favourable opinion from a Research Ethics Committee.
   **Confirmed non-substantial by email 5 August 2020**

# p. ECC 5-04(e)/2011 - SIGGAR1 (Special Interest Group in Gastrointestinal and Abdominal Radiology): CT colonography, colonoscopy or barium enema for the diagnosis of colorectal cancer in older symptomatic patients

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

## Context

## Amendment request

This study from Imperial College London has support in place to process identifiable patient information in order to receive mortality and cancer information for people who were eligible to participate in the SIGGAR 1 trial but did not take part. Support is not in place for people who declined the study. These linkages have now taken place, but the SIGGAR cohort database is still being used as part of an ongoing study - SOCCER.

This amendment sought support to extend the duration of support under the Regulations to retain the SIGGAR database until 31 December 2032. This is due to additional analyses

being undertaken as part of the SOCCER study until 31 December 2022 (which uses the SIGGAR cohort), and the trial database then being retained for 10 years until 2032.

This amendment also sought support for a change in Chief Investigator to Professor Amanda Cross.

### Confidentiality Advice Team advice

The amendment requested was considered by the Confidentiality Advice Team. It was noted that this amendment was given REC favourable opinion in December 2019, but the applicants did not realise that CAG were also required to give support until the submission of their 2020 annual review. The CAT raised no queries regarding this amendment.

### Confidentiality Advice Team 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

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 2019/20 DSPT review for **Imperial College London - Faculty of Medicine - Cancer Screening and Prevention Research Group (**8HL46-FOM-CSPRG) was confirmed as 'Standards Met' on the NHS DSPT Tracker (checked 18 August 2020)

2. Confirmation of a favourable opinion from a Research Ethics Committee.
   **Confirmed 13 December 2019**

## 3. Annual Review Approvals

| CAG Reference | Application Title |
|---|---|
| PIAG 2-08(e)/2002 | Linked de-identified research database for congenital anomaly outcomes |
| 19/CAG/0160 | Evaluation of the NHS Breast Screening Programme - an individual-based cohort study of mortality |
| CAG 8-03(PR2)/2013 | UK Register of Fatal Anaphylactic Reactions |
| ECC 6-02(FT3)/2012 | Sentinel Stroke National Audit Programme (SSNAP) |
| 15/CAG/0120 | National investigation into suicide in children and young people |
| 17/CAG/0103 | West Midland's Regional Children's Tumour Registry |
| 15/CAG/0120 | National investigation into suicide in children and young people |
| 17/CAG/0096 | SEARCH: A population based study of genetic predisposition to breast cancer |
| 17/CAG/0098 | SEARCH: A population based study of genetic predisposition to endometrial cancer |
| 17/CAG/0097 | SEARCH: A population based study of genetic predisposition to ovarian cancer |
| 18/CAG/0142 | SEARCH: A population based study of genetic predisposition to breast, ovarian and endometrial cancer |
| ECC 5-04(e)/2011 | SIGGAR1: CT colonography, colonoscopy or barium enema for the diagnosis of colorectal cancer in older symptomatic patients |
| 18/CAG/0018 | Pre-Hospital Emergency Medicine (PHEM) Feedback |
| 16/CAG/0006 | UK National Flap Registry (UKNFR) |
| 17/CAG/0045 | Hospice-led innovations for end of life care |
| 16/CAG/0048 | LATTE: Long Term Anastrozole vs Tamoxifen Effects |
| 16/CAG/0096 | Therapeutic Assessment (TA) of Adolescents Presenting with Self Harm versus Standard Psychosocial Assessment and Risk Management. Randomised Controlled Trial Long-term Follow Up. |

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|---|---|
| 18/CAG/0041 | Liverpool Lung Project |
| 19/CAG/0109 | Suicide by middle-aged men |
| 19/CAG/0092 | The 'OxMIV' violence risk assessment tool: an external validation study in patients referred to Early Intervention in Psychosis services using routine documentation in Electronic Patient Records |
| 17/CAG/0075 | Incidence of JSLE in CYP and their access to care in the UK and ROI |
| 15/CAG/0005 | Research to identify measures of quality and safety of healthcare |
| 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) |
| 15/CAG/0123 | aTTom: Adjuvant Tamoxifen Treatment - Offer More? (aTTom) trial |
| 16/CAG/0071 | Benchmarking clinical quality healthcare measures |
| 19/CAG/0040 | Translational Research in Pulmonary Hypertension at Imperial College (TRIPHIC) |
| 17/CAG/0076 | The Invasive Dentistry – Endocarditis Association (IDEA) Study: A Study of the link between invasive dental procedures and critical medical events including infective endocarditis, myocardial infarction, stroke, pulmonary embolus and spontaneous pre-term birth |

| Signed – Chair | Date |
| --- | --- |
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| Signed – Confidentiality Advice Team | Date |
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