Health Research Authority

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

**January 2023**

## 1. New Applications

### a. 22/CAG/0156 - General Health Outcomes in Subfertile Men: a UK register based cohort study

| Name | |
|---|---|
| Dr Patrick Coyle | CAG Vice Chair |
| Dr Martin Andrew | CAG Member |
| Dr Harvey Marcovitch | CAG Member |
| Mrs Diana Robbins | CAG Member |
| Ms Kathleen Cassidy | Confidentiality Advisor |

**Context**

**Purpose of application**

This application from UCL Institute of Child Health set out the purpose of medical research that seeks to establish whether men with known subfertility are at a greater

risk of developing chronic malignant and non-malignant health outcomes compared to men from the general population.

Infertility, defined as the inability of a sexually active couple to achieve pregnancy within one year, has substantial effects on human health at both population and individual levels. Assisted Reproductive Technology (ART) has increased the chances that infertile men will become fathers. However, the implications of the underlying infertility on the affected individuals remains uncertain. Research in the USA and Scandinavian countries has suggested that men's reproductive health may reflect their physical health, and male infertility may be a risk factor for the subsequent development of both malignant and non-malignant disease, as well as early death. Fertility evaluation could be an opportunity to improve men's overall health and identify risk factors for the development of diseases later in life. Little is known about how generalisable these findings are to other populations. The applicants seek to explore whether national administrative health data can be used to investigate the long-term health of men with fertility problems.

Staff at the Human Fertilisation and Embryology Authority (HFEA) will identify the male partners of women who have undergone ART from patient records that they hold. Confidential patient information will be disclosed to NHS Digital for linkage to Health Episode Statistics (HES) and ONS Mortality data, and the National Cancer Registration Dataset. The applicants confirmed that support under s251 was not required for the disclosure of confidential patient information from the HFEA to NHS Digital. Support was only required for disclosure of the linked dataset, pseudonymised by use of a unique study member number, from NHS Digital to the UCL Institute of Child Health.

NHS Digital will also identify a control group, of male individuals of similar age, from the Personal Demographics Services Dataset. Two controls will be identified for everyone patient in HFEA dataset. NHS Digital will conduct linkage to HES and ONS mortality data and the NCRAS dataset. A pseudonymised dataset will be disclosed to UCL Institute of Child Health. The pseudonymisation key will be held at NHS Digital, therefore the dataset held by UCL Institute of Child Health can be considered to be effectively anonymised. NHS Digital will retain a file containing confidential patient information for both cohorts.

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

## Confidential patient information requested

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

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

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| **Cohort** | Male partners of women who underwent non-donor assisted reproductive procedures for male subfertility in England and Wales between 01 August 1991- 31 September 2009.<br><br>Total sample size: 500,000 |
| **Data sources** | 1. NHS Digital held datasets:<br><br>a. Linked Health Episode Statistics (HES)<br><br>b. ONS Mortality data<br><br>c. National Cancer Registration Dataset<br><br>d. Personal Demographics Service<br><br>e. Civil Registration records |
| **Identifiers required for linkage purposes** | 1. Name<br><br>2. NHS number<br><br>3. Date of birth<br><br>4. Postcode – district level |
| **Identifiers required for analysis purposes** | 1. Date of birth<br><br>2. Postcode – district level<br><br>3. Gender<br><br>4. Ethnicity |

**Confidentiality Advisory Group advice**

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

1. **The patient notification materials need to be revised as follows:**

a. **The ‘de-anonymised’ typographical error needs to be amended.**

b. **The contradictory information about patient opt-out needs to be revised.**

The CAG noted this information and raised no further queries.

2. **The following needs to be undertaken, with regards to patient and public involvement:**

    a. **The patient and public involvement group needs to include individuals affected by infertility. Patient and public involvement needs to be conducted, via groups sessions and/or by individually targeted letters with questionnaires attached.**

The CAG noted this information and raised no further queries.

**Confidentiality Advisory Group advice conclusion**

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

## Specific conditions of support

The following sets out the specific conditions of support.

1. Favourable opinion from a Research Ethics Committee. **Favourable Opinion Confirmed 09 August 2022.**

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

below titled ‘security assurance requirements’ for further information.
**Confirmed:**

NHS Digital 2021/22 DSPT review for **NHS Digital** was confirmed as ‘Standards Met’ on the NHS Digital DSPT Tracker (31/10/2022)

The applicant and a representative from the HFEA confirmed that support under s251 was not required for the HFEA to disclosed confidential patient information to NHS Digital for linkage.

## b. 22/CAG/0147 - A Randomised Phase III Trial to Determine the Role of FDG-PET Imaging in Clinical Stages IA/IIA Hodgkin's Disease (FDG-PET Study): RAPID

| **Name** | |
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| Dr Malcolm Booth | CAG member |
| Mr Andrew Melville | CAG member |
| Ms Clare Sanderson | CAG alternative vice-chair |
| Ms Caroline Watchurst | HRA Confidentiality Advisor |

**Context**

### Purpose of application

This application from The Christie NHS Foundation Trust set out the purpose of medical research which aims to compare the late consequences, especially vital status, second cancers, and cardiovascular disease, of the different treatments used in the RAPID trial with a view to informing future patients and guiding national/international treatment policy.

The RAPID trial is a consented Randomised Controlled Trial (RCT) which compared standard treatment for limited stage Hodgkin lymphoma (chemotherapy + radiotherapy) with a new approach (chemotherapy alone) guided by PET scanning. Trial results

published in 2015 showed a good outcome for chemotherapy alone, however long term follow up, annually until 25 years after the first patient was registered to the trial (until 2028) is required, as it may take years for any long term outcomes to be detected. Follow up was consented and planned to be undertaken via participating hospitals. However the applicant has found that as patients are now mostly discharged from conventional care, they have been lost to conventional follow-up, and are requesting 's251' support for a new method of collecting follow up data which will be via NHS England (previously NHS Digital's) DigiTrials service.

Understanding the late consequences of chemotherapy and radiotherapy is of great importance when considering treatment options for patients and clinicians, and for policy makers. 's251' support is requested to enable UCL cancer trials centre to disclose RAPID ID, NHS number and date of birth to The Christie NHS Foundation Trust. The Christie NHS Foundation Trust with then disclose this list onwards to NHS England (previously NHS Digital) (via the NHS DigiTrials service) for linkage with HES, NCRAS, and to NHS Arden and Greater East Midland Commissioning Support Unit (Arden & GEM) & Redcentric (Harrogate) for linkage with the NICOR database. 's251' support is also required for the flow of data back to the applicant, at The Christie NHS Foundation Trust, as the dataset contains full date of death, and additionally the applicant retains identifiers and can re-identify the patients. The dataset will then be analysed at The Christie, by the statistician from UCL.

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** | Patients who participated in the RAPID FDG-PET study<br><br>88.9% of the rapid cohort are English and Welsh patients, and therefore relevant to this CAG application - This is 535 patients. |

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| **Data sources** | 1. RAPID trial database retained at the UCL Cancer trials centre<br>2. NHS England (previously NHS Digital) –<br>a. Hospital Episode Statistics (HES)<br>b. *National Cancer Registration and Analysis Service (N*CRAS)<br>3. *National Institute for Cardiovascular Outcomes Research (N*ICOR) database - (NHSE/I controllers, and processors are NHS Arden and Greater East Midland Commissioning Support Unit (Arden & GEM) & Redcentric (Harrogate) |
| **Identifiers required for linkage purposes** | 1. NHS number<br>2. Date of birth<br>3. RAPID participant ID |
| **Identifiers required for analysis purposes** | 1. Date of death |
| **Additional information** | Data linkage extracts will be provided by NHS England (previously NHS Digital) and NICOR twice. Once in 2022/2023 and again in 2028. |

**Confidentiality Advisory Group advice**

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

1. **Please clarify if the data can flow directly from and to UCL, instead of being required to flow though the Christie, to minimise the flows of confidential patient information. A new data flow diagram should be provided alongside this confirmation.**

The applicant provided an updated data flow diagram, however this was not to remove the flow between UCL and the Christie, as the applicant explained that there are long

term plans to move the dataset from UCL to the Christie anyway (which are outside the scope of this CAG application). Justification was provided that UCL do not have capacity to receive the linked data back due to resource issues, and the proposed data flow is still UCL to the Christie, and then onwards for linkage. The applicant has however confirmed that the linked data will not be sent from The Christie to UCL anymore, and that instead the UCL statistician will review the identifiable data on Christie servers. The CAG were content that the applicant had explored alternative routes that were less disclosive, and despite not being able to remove the 2 step process for both directions, the Members noted that the final proposed flow of identifiable data back from The Christie to UCL had been removed, and this was less disclosive than the original design.

2. **Please update the patient notification document to be suitable for display on the study website, to include the data flows, the use of 's251', and an opt out option. Please confirm where this will be displayed.**

The applicant provided an updated patient notification document, and confirmed that it will be displayed on the UCL CTC RAPID trial webpage. The CAG were content with this response.

**Confidentiality Advisory Group advice conclusion**

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

## Specific conditions of support

The following sets out the specific conditions of support.

1. Favourable opinion from a Research Ethics Committee. **Confirmed via Substantial Amendment 9 on 29 April 2022**

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

   The NHS Digital **21/22** DSPT reviews for **The Christie NHS Foundation Trust, University College London – School of Life and Medical Sciences, NHS Digital,** & on behalf of NICOR**; NHS Arden and Greater East Midland**

**Commissioning Support Unit (Arden & GEM) and Redcentric (Harrogate)** were confirmed as '**Standards Met'** on the NHS Digital DSPT Tracker (checked 03 November 2022)

### c. 22/CAG/0154 - Evaluating the clinical and cost-effectiveness of a conservative approach to oxygen therapy for invasively ventilated adults in intensive care: UK-ROX

| Name | |
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| Dr Sandra Duggan | CAG member |
| Mr David Evans | CAG member |
| Mr Tony Kane | CAG member |
| Dr Harvey Marcovitch | CAG member |
| Ms Rose Payne | CAG member |
| Ms Diana Robbins | CAG member |
| Mr Dan Roulstone | CAG member |
| Ms Clare Sanderson | CAG alternative vice-chair |
| Dr Murat Soncul | CAG alternative vice-chair |
| Ms Caroline Watchurst | HRA Confidentiality Advisor |

**Context**

**Purpose of application**

This application from The Intensive Care National Audit & Research Centre (ICNARC) set out the purpose of medical research which aims to evaluate the clinical effectiveness of conservative versus usual oxygen therapy on 90-day all-cause mortality. The UK-ROX trial is a multi-centre randomised clinical trial (RCT), and has already begun without the need for a CAG application. However the applicants have submitted an amendment to the REC to introduce the need for 's251' support.

184,000 patients annually are admitted to NHS intensive care units (ICUs) and over 30% require a ventilator. Giving oxygen through the ventilator is essential. However, it is not known how much oxygen should be given to optimise recovery. Both too much, and too little oxygen may cause harm. This study will look at the effect of a small reduction in oxygen. Results will have a large and immediate impact on ICU clinical practice and on patient outcomes throughout the NHS. Data from the 16,500 patients in this study will also contribute to a larger global study of 40,000 patients. The global study will answer similar questions about oxygen therapy in ICU patients but from an international perspective.

The purpose of linkage to the Case Mix Programme national clinical audit of patients screened but not enrolled into UK-ROX, is to review whether certain subgroups of patients are being excluded, and to ensure equality, diversity and inclusiveness of the trial population.

The purpose of linking outcome data for participants from whom patient consent, or consultee opinion, was unable to be obtained, is because excluding data from these cohorts of patients may introduce substantial bias and impact upon the safety monitoring/reporting and, ultimately, the scientific validity of the trial and may prevent evidence of significant clinical benefit from being detected.

All patients will be unconscious at the time of treatment, as by definition they become eligible once mechanical ventilation has started, and therefore patients will be recruited under a research without prior *consent* (RWPC) model, in accordance with the Mental Capacity Act 2005. The applicants are seeking ‘s251’ support to process confidential patient information for all patients from the end of the emergency event until patient death or until either patient consent or a consultee opinion is obtained. For non-survivors, support is needed for the collection of confidential patient information from the treating hospital, and linkage to ICNARC CMP, and NHS England (previously NHS Digital) and DHCW datasets. For surviving patients, confidential patient information will be collected until either the patient or a consultee explicitly refuses agreement to the processing of their confidential patient information. If the patient survives but the researchers are unable to contact the patient or a consultee to seek consent, support will also be needed to continue to collect confidential patient information and link to other data sources. This is in line with other applications of this type. In addition, the applicants require ‘s251’ support to link data for those patients who were screened but not enrolled into the UK-ROX trial

to the CMP. This is undertaken with the ICNARC Case Mix Programme admission number, which is pseudonymous, disclosed to ICNARC from participating Trusts, however as applicants retain confidential patient information linked to the ICNARC CMP ID, and therefore have the ability to re-identify, 's251' support is also required for this disclosure and linkage.

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

## Confidential patient information requested

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

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| **Cohort** | The study will include 16,500 patients from 100 UK NHS ICUs<br><br>But 's251' support is only relevant to:<br><br>patients receiving mechanical ventilation in participating critical care units who were screened but not enrolled to UK-ROX, ~53,000 patients<br><br>And participants included in UK-ROX from whom patient consent, or consultee opinion, was unable to be obtained (e.g. because the patient died or was discharged prior to regaining capacity) ~300 patients. |
| **Data sources** | 1. Participating ICU's (across England and Wales)– UK-ROX collected study data and secure electronic case report form<br><br>2. Intensive Care National Audit & Research Centre (ICNARC) - Case Mix Programme dataset |

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| | 3. NHS England (previously NHS Digital):<br>a) Civil Registrations (deaths) dataset<br>b) Hospital Episodes Statistics (HES)<br><br>4. Digital Health and Care Wales (DHCW)<br>a) Patient Episodes Data for Wales (PEDW) |
| **Identifiers required for linkage purposes** | Regarding patients who were screened but not included in UK-ROX;<br>1. ICNARC Case Mix Programme admission number<br><br>Regarding those included in UK-ROX but were discharged or died prior to consent or consultee opinion being obtained:<br><br>1. UK-ROX Trial ID<br>2. ICNARC Case Mix Programme admission number<br>3. NHS Number<br>4. date of birth<br>5. sex<br>6. postcode |
| **Identifiers required for analysis purposes** | 2. Date of death<br>3. Sex<br>4. Ethnicity |
| **Additional information** | Linked extracts will be received quarterly. |

**Confidentiality Advisory Group advice**

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

1. **Please confirm that the global sharing of data collected under 's251' support would only be relevant to the estimated 300 patients included in UK-ROX from whom patient consent, or consultee opinion, was unable to be obtained. Please confirm what data would be shared, and please confirm that the data would be considered effectively anonymous.**

The applicant confirmed this would only apply to the patients enrolled in the trial, and confirmed the data would be effectively anonymous. After further queries, the applicant confirmed the data would be anonymised according to the principles and procedures in the ICO anonymisation code of practice or other ICO guidance that is current at the time. The CAG were content with this response.

2. **Please alter the patient notification document sent to those who are discharged prior to consent or consultee advice being gained, to ensure it is not asking for explicit consent, and stating that linkage to outcome data would be undertaken with 's251' as the legal basis under common law, and include details of how the participant could opt out of this. The letter should also say the patient could call for further information, at which stage the patient could then be consented if they get in touch with the study team. This updated document should be provided to CAG for review.**

The enrolment cover letter has been modified into a patient notification letter and all suggested content has been added. The Members were content with this response, and with the documentation provided.

3. **Regarding any patient who is included in the study with 's251' support because they were discharged prior to either consent or consultee advice being gained, please advise if it would be possible for the initial treating clinician to seek consent at any in-hospital follow up?**

The applicant confirmed that the use of critical care follow-up clinics is not routine, and varies across hospitals. In cases where participating sites routinely invite patient to attend a critical care follow-up clinic, sites will be instructed to try to seek consent at this opportunity. The CAG were content with this response.

4. **Please clarify if sex is required for analysis rather than gender?**

Applicants confirmed that sex is required for analysis. The CAG were content with this response.

5. **Please provide assurance that the sharing of anonymised data regarding any patient registering an NDOO will be undertaken via the standard of anonymisation as outlined in the ICO code of practice, and that this is undertaken by staff who are considered direct care team.**

The applicant confirmed that the sharing of anonymised data for screened patients with an NDOO will be undertaken as outlined in the ICO code of practice. Only anonymised data on inclusion/exclusion criteria met will be included on the screening log and submitted to ICNARC. The CAG were content with this reassurance.

6. **The poster, leaflet and website text should be revised in line with advice in this letter. The cohort and the specific breach of confidentiality should be described, along with what data items will be shared, between which organisations for which purposes. The role of CAG should be described, regarding the need for 's251' support, and an opt out option specifically for the data flows covered by 's251' should be offered. The updated patient notification documents should be discussed with patients and the public.**

The poster, leaflet, and website text have been revised with the suggested content. The updated documents have been reviewed by and discussed with patients and their family members. The applicant clarified that the privacy notice is displayed on the UK-ROX website and a link to the website is included in the patient information sheets. The CAG were broadly content with these, asking only that the applicant improve the poster by including The Intensive Care National Audit & Research Centre in full, rather than just the word ICNARC. The applicant completed this change, and the CAG were content with this response.

7. **Further patient and public involvement should be undertaken to establish the acceptability of this use of confidential patient information without consent.**

The applicant explained that further to the PPI activities conducted prior to submitting the application, the team have approached ICU Steps, the national intensive care patient support charity, to discuss the use of confidential patient information without consent. Further engagement/involvement work is planned with their patient group to be commenced in January 2023. Applicants are also in contact with a number of local/regional patient and public groups where there are plans to present the scenarios where 's251' support is requested, and discuss the acceptability of this. Following these

consultations, applicants will update the processes and/or patient documents, as required, and submit as an amendment for consideration of the CAG. Applicants will also provide evidence of these further PPI activities, as required, at the end of Quarter 1 in 2023. The CAG were content with this response, and are content to receive the outcome of any discussions as part of any further amendments that are required due to the discussions, as suggested by the applicant.

8. **Please provide Favourable opinion from a Research Ethics Committee regarding the amendment that introduced the need for CAG, as per standard condition of support below.**

The REC favourable opinion for substantial amendment 5, which introduces the need for CAG, was provided, as per standard condition of CAG support.

**Confidentiality Advisory Group advice conclusion**

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

## Specific conditions of support

The following sets out the specific conditions of support.

1. Favourable opinion from a Research Ethics Committee. **Confirmed 25 November 2022**

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

   The NHS Digital **21/22** DSPT reviews for **The Intensive Care National Audit & Research Centre (ICNARC) and NHS Digital** were confirmed as 'Standards Met' on the NHS Digital DSPT Tracker (checked 23 November 2022)

Digital Health and Care Wales (DHCW) has a valid CpiP in place as confirmed by the Welsh Information Governance team.

Due to the number of participating ICU's involved it is the responsibility of ICNARC, as controller, to ensure that these participating organisations meet the minimum required standard in complying with DSPTs, and take remedial action if they become aware of any that fall below this, or where any concerns are raised.

## d. 22/CAG/0145 - Safety and Efficacy of Managing Acute Heart Failure without Hospital Admission (SAFE v6.0)

| Name | |
|---|---|
| Mr Tony Kane | CAG member |
| Mr Umar Sabat | CAG member |
| Ms Clare Sanderson | CAG alternative vice-chair |
| Ms Caroline Watchurst | HRA Confidentiality Advisor |

**Context**

### Purpose of application

This application from Blackpool Teaching Hospitals NHS Foundation Trust (BTH) set out the purpose of medical research which aims to better understand short term outcomes, 60 days post treatment with intravenous furosemide in patients with heart failure (HF), in order to support feasibility of recruitment into a future multicentre randomised controlled trial (RCT) into the effectiveness and safety of out-patient based services for the management of Acute Heart Failure (AHF).

100,000 patients are admitted to hospital for AHF each year in the UK. HF is a progressive syndrome associated with substantial morbidity and mortality, and is the most common cause of hospitalisation for individuals aged 65 years and older in UK. AHF is usually managed in hospital, and is associated with 7-11% mortality rate. The

NHS Long Term Plan recommended better, personalised planning for patients with the hope to reduce nights spent in hospital and reduce drug spend. Accelerated by the COVID pandemic, some hospitals are now developing out-patient based services for the management of AHF. Out-patient management (OPM) of AHF has gained popularity in the UK, however, the effectiveness and safety of this strategy is uncertain. There are no substantial randomised trials in order to inform clinicians, patients or clinical practice guidelines. A substantial multi-centre RCT to determine safety and cost-effectiveness is therefore needed to obtain robust evidence to justify more widespread investment in out-patient based treatment of AHF, and this application is testing the feasibility of a future RCT.

Eligible patients are retrospectively identified at participating sites by the direct care team from existing clinical databases. Data will be collected via excel spreadsheet. Names, postcodes, hospital/NHS numbers will be removed, but pertinent dates (of admission, discharge and death) remain. These dates mean that the data is not fully anonymised at this point, and therefore 's251' support is required for this transfer of confidential patient information to the applicant. Once at BTH, the Trust statistician will fully anonymise the data after using the dates to calculate the required period of risk – "days alive and out of hospital within 60 days" measure – before analysis. Full dates will then be deleted.

A recommendation for class 1 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 consecutive patients who have had acute/decompensated/worsening heart failure with a requirement for IV diuretics at participating sites (including inpatient stays and outpatient clinic visits)<br><br>for the period 01 August 2019 to 31 January 2021.<br><br>~3000 (however possibly more, and exact number not yet known) |

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| **Data sources** | 1. Participating Trusts existing clinical databases;<br>a. Buckinghamshire Healthcare NHS Trust<br>b. Liverpool University Hospitals NHS Trust<br>c. Manchester University hospitals NHS Foundation Trust<br>d. North Tees & Hartlepool NHS Foundation Trust<br>e. Croydon Health Services NHS Trust<br>f. Lancashire Teaching Hospitals NHS Trust<br>g. Oxfordshire University Hospitals NHS Foundation trust<br>h. Dudley Group NHS Foundation Trust |
| **Identifiers required to be disclosed from participating Trusts** | 1. Date of admission<br>2. Date of discharge<br>3. Date of death |
| **Identifiers required for analysis purposes** | 1. N/A - Analysis will be undertaken on an anonymised dataset |
| **Additional information** | A second readmission from the same patient is classed as a new episode if the admission is more than 60 days from the previous episode, else it is classed as a readmission within 60 days. |

**Confidentiality Advisory Group advice**

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

1. **Please develop a notification poster for clinical areas of participating Trusts, that could also be displayed on trust websites, as per the advice in this letter.**

The applicant has developed a poster as per advice. The CAG were content with the notification provided.

2. **Please provide confirmation that it will be made clear to participating Trusts that the NDO should be applied before they submit their data to the applicant.**

The applicant confirmed that this will be made clear to participating Trusts, and it is added to the data flow chart and site introduction checklist that will be provided to sites. The checklist has been provided for CAG review. Members were content with this response.

3. **Please provide further details on exactly how the Patient and Public Involvement group was involved, and in particular how the 'design' was supported by the group.**

The applicant explained that the Heart Failure Patient and Public Involvement (PPI) group from the Lancashire cardiac centre are supportive of the study methodology. For this specific application, the PPI group consisted of 7 members, diverse in terms of age, gender, ethnicity, consisting of patients with heart failure and other cardiac condition, carers as well as members of the public. Applicants met with 4 members of the PPI group on 17 November as part of an online focus group, to discuss whether the unconsented activity should go ahead. The group unanimously agreed applicants should perform this study involving processing confidential information without consent, due to the nature of the condition. The PPI group agreed it is not feasible or kind to contact carers and patients, many of whom with severe heart failure may have already died. The remaining three PPI participants (who were unable to attend the meeting), unanimously agreed with this plan via a phone call on 15 November. The CAG were content that this response was sufficient.

4. **Please confirm that the original spreadsheets containing dates received in full format from Trusts will be deleted after calculations have been undertaken by the BTH statistician.**

Applicants confirmed that the original spreadsheets containing identifiable data (dates) will be deleted as soon as calculations to anonymise the data have been made by the statistician. The CAG were content with this response.

5. **Please provide Favourable opinion from a Research Ethics Committee, as per standard condition of support below.**

The applicant provided this on 16th January 2023, as per standard condition of CAG support.

**Confidentiality Advisory Group advice conclusion**

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

### Specific conditions of support

The following sets out the specific conditions of support.

1. Favourable opinion from a Research Ethics Committee. **Confirmed 16 January 2023.**

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

The NHS Digital **21/22** DSPT review for **Blackpool Teaching Hospitals NHS Foundation Trust** was confirmed as '**Standards Met'** on the NHS Digital DSPT Tracker (checked 03 November 2022)

## e. 22/CAG/0168 - Opioid use after surgery in opioid-naive patients: a qualitative study

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| **Name** | |

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| Dr Patrick Coyle | CAG Vice Chair |
| Dr Sandra Duggan | CAG Member |
| Dr Harvey Marcovitch | CAG Member |
| MsRose Payne | CAG Member |
| Mr Umar Sabat | CAG Member |
| Ms Kathleen Cassidy | Confidentiality Advisor |

**Context**

## Purpose of application

This application from University College London set out the purpose of medical research that seeks to explore the themes and experiences of previously opioid-naïve patients who were discharged with opioids for pain control after surgery, the barriers to opioid taper and cessation, and drivers for continued use.

Long-term opioid use for pain carries various risks and can affect patients' quality of life. The likelihood and intensity of these risks tends to increase as dosage and duration of therapy increases. Many patients who use opioids develop a tolerance to their analgesic effects and some become dependent on them. Population surveys have found that long-term opioid use is associated with increased side effects, worse health outcomes and no improvement in pain relief. Prescription of opioids increased by 34% and the total oral morphine equivalent dose increased by 127% between 1998 and 2016. In 2017 – 2018, 12.8% of England's population had an opioid prescription dispensed, with approximately 50% taking opioids for at least one year. There is no consensus about the most acceptable and effective way of tapering opioid use. The applicants seek to follow-up previously opioid-naïve patients' surgical patients three months after surgery and discharge with a prescription for opioids.

A list of patients aged 18 years and over who underwent any elective surgical procedure within University College London Hospitals NHS Foundation Trust (UCLH) will be created from the electronic patient record system via an automated process. A list of eligible patients and their contact details will be disclosed to the researchers. Patients will be contacted by email with information about the study and an invitation to participate. The email will be followed by telephone call after 2-7 days. Those who accept the invitation will have their eligibility status assessed and consent taken. Their participation will then proceed on a consented basis.

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

## Confidential patient information requested

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

| | |
|---|---|
| **Cohort** | Patients aged 18 years and over who underwent an elective surgical procedure at UCLH in the three-month period before the report is run, were not taking opioids prior to surgery and were prescribed opioids at discharge.<br><br>60 patients will be included. |
| **Data sources** | 1. Electronic patient records at University College London Hospitals NHS Foundation Trust |
| **Identifiers required for linkage purposes** | 1. Name<br><br>2. Date of birth<br><br>3. Email address<br><br>4. Telephone number |
| **Identifiers required for analysis purposes** | 1. Gender<br><br>2. Ethnicity |

### Confidentiality Advisory Group advice

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

1. **Clarify whether date of birth needs to be included in the data disclosed to the research team in order to facilitate contact and, if so, provide justification on why it is needed.**

The applicants clarified that patients' dates of birth had been included in the proposed data to be disclosed to the research team to conform potential participant identity. This item can be omitted from the data disclosed prior to participant consent, and confirmation of identity can take place after the patient has been recruited to the study. The protocol will be amended to include this change.

The CAG noted this and was content that patients date of birth will no longer be collected by the research team prior to consent being sought.

2. **Please produce a simplified lay summary of information sheet, with signposting to access the full version, should the participant wish.**

A simplified lay summary of the patient notification was provided. The CAG noted this and raised no further queries.

3. **Confirm that a maximum of 3 phone calls to the applicant will be attempted, instead of the proposed 5.**

The applicant confirmed that a maximum of three telephone calls will be made to attempt contact with potential participants. The protocol had been amended to reflect this. The CAG noted this and raised no further queries.

4. **Please confirm that the notification material will be updated to reflect the position around the National Data Opt-out.**

The applicant confirmed that the National Data Opt-Out will be applied to the study, and the patient notification will include a statement reflecting this in the last section. The CAG 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 Health Research Authority, subject to compliance with the specific and standard conditions of support as set out below.

## Specific conditions of support

The following sets out the specific conditions of support.

1. Favourable opinion from a Research Ethics Committee. **Confirmed 19 December 2022.**

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

The NHS Digital **21/22** DSPT reviews for **University College London** & **University College London Hospitals NHS Foundation Trust** were confirmed as 'Standards Met' on the NHS Digital DSPT Tracker (checked 12 November 2022)

## f. 22/CAG/0105 - Improving patient outcomes in the 'hot zone' during major incidents

| **Name** | |
|---|---|
| Dr Murat Soncul | CAG Alternate Vice Chair |
| Mr Anthony Kane | CAG Member |
| Mr Andrew Melville | CAG Member |
| Professor Sara Randall | CAG Member |
| Mrs Diana Robbins | CAG Member |
| Ms Kathleen Cassidy | Confidentiality Advisor |

**Context**

### Purpose of application

This application from Barts Health NHS Trust set out the purpose of medical research that seeks to investigate the causes and timeline associated with pre-hospital death following terrorism incidents, and the pre-hospital interventions associated with decreasing pre-hospital mortality.

During the initial phase of terrorist incidents, a "hot zone" is created, where there may be on-going terrorist activities and active threats to life. Currently policy is that emergency medical services are unlikely to enter the hot zone until it has been made safe enough, which may take several hours. Most deaths caused by these events occur at the scene before emergency services can enter the hot zone and autopsy evidence from mass shootings in the US suggests that some patients die from injuries that could

have been survivable had treatment been given at the scene. If these findings are consistent across other types of events and healthcare systems, providing trauma care in the hot zone could dramatically reduce deaths in terrorist events. However, to send emergency personnel into an area where there is an active terrorist threat to their own life is a major decision. Limited data is currently available as most of the information is military in origin, which is difficult to translate to civilian data due to the differences in body armour worn by military personnel and the resultant injury pattern and injury prevention, or from US active shooter mass casualty incidents. A key area highlighted by many of the authors reflected on how the presence of a persistent and active threat, such as a shooter, prevented access of trained medical personnel into the hot zone. A retrospective cohort analyses of available datasets will be undertaken in addition to the use of an expert panel to determine, from the presented data sets, whether 'death/cardiac arrest' on scene was likely preventable or not with timely interventions.

Data will cumulatively be extracted from terror events in the UK and from London's Air Ambulance (LAA) pre-hospital trauma deaths (non-terrorist incident).

For Cohort 1, the Pre-Hospital Trauma deaths (non-terrorist incident), members of the research team will extract confidential patient information from LAA. Additional patient data will be collected from London Ambulance Service (LAS). Records dating back to 2000 will be accessed to capture a minimum of 150 pre-hospital trauma deaths which have the required sequence of data and information accessible. Confidential patient information will be shared with HM Coroner Services in London and the Metropolitan Police (MPS). The complete data set will include LAA data, the forensic report and CCTV and/or body worn video (BWV) footage. Once the dataset is linked, confidential patient information will be removed and the anonymised data presented to an expert panel, which will determine whether the death was likely preventable.

For Cohort 2, Terrorist event data, members of the research team will extract confidential patient information from LAS and LAA patient records for deaths related to terrorist incidents. This data will be linked to additional sources, of information, including HM Coroners forensic reports, inquest reports, judicial reports, CCTV and BWV footage. Confidential patient information will be shared with HM Coroner Services in London and the Metropolitan Police (MPS) to facilitate this linkage. Once the dataset is linked, confidential patient information will be removed and the anonymised data presented to an expert panel, which will determine whether the death was likely preventable.

The applicants have advised that the project aims to capture data from all terror attacks across the UK since 2000. There have been a number which have only involved one or two patients who have died and, although these would ideally be included, it was decided that the initial sites would be the NHS trusts who have attended the larger events in the first instance. This is London and Manchester / North-West Ambulance Service (NWAS). Having approached NWAS, they were not able to participate until after the Chairman for the Manchester Arena Inquiry publishes his conclusions and recommendations. This has been delayed beyond the initial anticipated timings and is now not likely to occur until at least November of this year. After this time, colleagues working in Manchester who are collaborators on this NIHR grant will assist in bringing the appropriate NHS Trust colleagues together to add as additional sites in the

region. The applicants understand that an amendment will need to be submitted to include this data.

In terms of police data (from where the original patient identification will occur for the patients from terrorist events), the applicants have the agreement from counterterrorism policing to do so for all terrorist events in the UK since 2000 (as all counter-terrorism policing ultimately comes under the Metropolitan Police Service, this can be done with one data sharing agreement).

The confidential information will be held on a password protected spreadsheet that will be held by the Metropolitan Police Service (MPS), and as such the MPS will be the legal entity responsible for it. The MPS have requested that, as the applicants are extracting data from their data sources that has been collected for policing purposes, that this is where the confidential information extracted for both groups of patients, the crime and counter-terrorist patients will be held. As their servers are secure QMUL, Barts Health and London Ambulance Service are all happy with this.

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

### Confidential patient information requested

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

| | |
|---|---|
| **Cohort** | Male and female patients, aged 0 years and over, who meet the following criteria:<br><br>Cohort 1: Traumatic pre-hospital deaths (non-terrorist incident): prehospital or on hospital arrival death (cardiac arrest), traumatic injury causing death, patient attended by the LAS and/or LAA between 2000 and 2020.<br><br>Cohort 2: Terror incident data: Patient went into cardiac arrest prior to reaching hospital, UK terror event since 2000. |

| | |
|---|---|
| | The applicants estimate that 250 patients will be included. |
| **Data sources** | 1. Electronic patient record system air ambulance and paper record patient forms from London Air Ambulance Service (part of Barts Health NHS Trust) and electronic call log for ambulance service call times<br>2. London Ambulance Service NHS Trust<br>3. Forensic and post-mortem reports from HM Coroner<br>4. Judicial documents, such as inquest reports from previous terror attacks<br>5. CCTV and Body Worn Camera (BWV) footage, witness statements and police reports from the Metropolitan Police Service<br>6. Counter Terrorist Investigation sequence of events accessed via the Senior Investigating Officer |
| **Identifiers required for linkage purposes** | 1. Name<br>2. NHS number<br>3. Hospital ID number<br>4. Date of birth<br>5. Date of death<br>6. Postcode<br>7. Age<br>8. Gender |
| **Identifiers required for analysis purposes** | 1. Date of death<br>2. Gender<br>3. Age |

**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. **Confirm that the National Data Opt-Out will be applied to the non-terrorist cohort.**

The applicants confirmed that the National Data-Optout will be applied for the non-terrorist (crime) data for the project. The CAG noted this information and raised no further queries.

2. **Work needs to be undertaken to explore ways of publicising the study and a communications strategy provided to the CAG.**

The applicants provided further details on how the study would be publicised. This included the publication of relevant details in the QMUL Joint Research Management Office Research News Bulletin, provision of information to the Survivors Against Terror (SAT) Network, engagement with the Barts Health Research Engagement and Diffusion Team regarding providing general information about the study on their social media channel, and engagement with the Counter Terrorist Advisory Network (CTAN). The applicants will also liaise with the St. Giles Trust, a charitable trust with a partnership with Barts Health NHS Trust, helping young victims of serious violence, particularly knife crime. The CAG noted this information and raised no further queries.

### Confidentiality Advisory Group advice conclusion

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

### Specific conditions of support

The following sets out the specific conditions of support.

1. Favourable opinion from a Research Ethics Committee. Confirmed **05 September 2022.**

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

   The NHS Digital 21/22 DSPT reviews for **London's Air Ambulance (part of Barts Health NHS Trust), The London Ambulance Service NHS Trust, Queen Mary University London (QMUL)** and **The Metropolitan Police**

**(MPS)** (the applicant confirmed via email that the DSPT for MPS also covered HM coroner reports) were confirmed as 'Standards Met' on the NHS Digital DSPT Tracker (checked 20/01/2023).

## g. 22/CAG/0174 - UNderstanding the Causes of hyperglycaemia in pRegNancy

| **Name** | |
|---|---|
| Dr Murat Soncul | CAG Alternate Vice Chair |
| Dr Harvey Marcovitch | CAG Member |
| Mr Umar Sabat | CAG Member |
| Dr Sandra Duggan | CAG Member |
| Mr Andrew Melville | CAG Member |
| Ms Kathleen Cassidy | Confidentiality Advisor |

**Context**

### Purpose of application

This application from King's College London set out the purpose of medical research to characterise the pathophysiological subtypes of gestational diabetes and to define mechanistic pathways. Gestational diabetes (GDM) is a condition causing high blood glucose (hyperglycaemia) and results from an imbalance between decreasing insulin sensitivity during pregnancy and beta-cell compensation. This description came from early studies in small numbers of high-risk women and used thresholds of diagnosis for GDM that are now outdated. As a result, current therapy in the UK is to counsel women for dietary change. If their glucose levels do not improve, metformin is prescribed, followed by insulin if the GDM is still not controlled. This process can take several weeks, and it is not known which therapy is most appropriate for individuals' patients. The method of undertaking the oral glucose tolerance test (OGTT), the main test for GDM diagnosis and which is undertaken at 24-28 weeks of pregnancy, is not standardised. This makes global interpretation of research difficult. Practical issues also make the OGTT an unreliable and outdated method of diagnosis.

Patient medical records will be screen by the research team to identify eligible patients. The research team will then make contact by telephone, text message or email in advance of their scheduled appointment. Patients will be sent a copy of the Patient Information Sheet and Consent Form as part of an invitation email. Contact may then continue via phone, email or in person. The applicants noted that patients may be approached by researchers in clinic, if the invitation was missed or the patients do not use email or telephone. Should patients consent, their participation will proceed on a consented basis.

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

## Confidential patient information requested

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

| | |
|---|---|
| **Cohort** | 750 pregnant women of white or South Asian descent with a singleton pregnancy. |
| **Data sources** | 1. Electronic medical records held at University Hospitals of Leicester NHS Trust<br>2. Electronic medical records held at Guy's and St Thomas' NHS Foundation Trust |
| **Identifiers required for linkage purposes** | 1. Name<br>2. NHS number<br>3. Hospital ID<br>4. Date of Birth<br>5. Postcode<br>6. Ethnicity<br>7. Contact details (phone number, email and postal address) |

| | |
|---|---|
| **Identifiers required for analysis purposes** | 1. N/A as any identifiers for analysis included with consent as the legal basis under common law |

**Confidentiality Advisory Group advice**

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

1. **Please provide clarity on how the research team access patient records, as well as clarify, whether staff have been appropriately trained and how the access will be controlled throughout the duration of the study.**

The applicant explained that patient records will be accessed electronically by members of the research team who are employed by, or have honorary contracts with, the respective Trusts. Prior to access being granted, staff will need to complete relevant training modules as well as have up to date information governance training. Only individuals who fulfil these criteria will have access. The CAG noted this information and raised no further queries.

2. **Please create a new notification, including the following:**

    a. **An explanation that patient data may be accessed**

    **Explain section 251 and the role of CAG.**

    b. **Clearly explain the local and National Data Opt-out mechanisms in place.**

The application provided a revised patient notification document.

The CAG reviewed the patient notification document. Members asked that a heading and an explanation of who the study team are, to enable better contacts for the local opt-out mechanism, were included on the document. A further revised document was received. This was reviewed and accepted.

3. **Confirm that the patient notifications will be displayed in relevant waiting areas and clinics.**

The applicants confirmed that patient notifications will be placed in appropriate clinical or waiting areas. The CAG noted this information and raised no further queries.

### Confidentiality Advisory Group advice conclusion

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

### Specific conditions of support

The following sets out the specific conditions of support.

1. Favourable opinion from a Research Ethics Committee. **Confirmed 17 January 2023**

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

   The NHS Digital **21/22** DSPT reviews for **King's College London**, **University Hospitals of Leicester NHS Trust** & **Guy's and St Thomas' NHS Foundation Trust** were confirmed as 'Standards Met' on the NHS Digital DSPT Tracker (checked 12 November 2022)

## h. 22/CAG/0157 - Do we miss a common subset of Primary Aldosteronism in which there is cyclical or exaggerated diurnal variation in secretion?

| **Name** | |
|---|---|
| Dr Patrick Coyle | CAG Vice Chair |
| Dr Malcolm Booth | CAG Member |

| | |
|---|---|
| Dr Rachel Knowles | CAG Member |
| Mr Andrew Melville | CAG Member |
| Mrs Diana Robbins | CAG Member |
| Ms Kathleen Cassidy | Confidentiality Advisor |

**Context**

## Purpose of application

This application from Queen Mary University of London set out the purpose of medical research to determine whether a form of primary aldosteronism exists which causes a cyclical or exaggerated diurnal variation in secretion and whether 24-hour urine measurements help in detecting people with PA.

Hypertension (high blood pressure) can lead to heart attacks and stroke. Many people with hypertension have 'essential' hypertension, for which no underlying cause has been identified. Around 10% of patients with hypertension have primary aldosteronism (PA), an excess production of the hormone aldosterone, which causes the body to inappropriately retain salt. PA can be treated with surgery or medications, however only around 1% of patients with PA are diagnosed with the condition and better ways of identifying the condition need to be developed. Gene mutations in the adrenal gland affect the rhythm with which aldosterone is produced and may cause fluctuations in aldosterone production throughout the day. PA may have been missed in patients whose aldosterone levels fluctuate. The applicants aim to identify patients with a potentially missed diagnosis of PA by studying 24-hour urine samples.

Patients will be consented into the study. Suitable participants will be recruited from endocrinology and hypertension clinics, either referred from their responsible clinicians or by interrogation of the databases of patients in these clinics. This will be undertaken by the direct care team and is outside the scope of support. Patients who had taken part in previous research but did not meet the criteria for PA may also be recruited. Similarly, some participants will also be recruited from previous results sourced from laboratory databases. These two recruitment methods will require processing of confidential patient information by research staff. Once suitable patients have been identified, they will be contacted by post for consent to take part in the research. If patients do not respond to the postal contact within one month, they will be followed up by telephone. Patients participation will proceed on a consented basis.

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

## Confidential patient information requested

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

| | |
|---|---|
| **Cohort** | Patients with suspected PA who did not meet the diagnostic threshold for PA<br><br>Patients with diagnosed PA and with previous aldosterone samples of <277 pmo/L<br><br>Patients with fluctuating aldosterone results that indicate variability in production<br><br>Total sample size: 100 |
| **Data sources** | 1. Patient records, records from previous research and laboratory databases held at Barts Health NHS Trust |
| **Identifiers required for linkage purposes** | 1. Name<br><br>2. NHS number<br><br>3. Hospital ID number<br><br>4. Full postcode |
| **Identifiers required for analysis purposes** | 1. Name<br><br>2. Date of birth<br><br>3. Gender<br><br>4. Ethnicity |

### Confidentiality Advisory Group advice

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

1. **Clarify whether the participants recruited from the endocrinology and hypertension clinics are the same as the lab group.**

The applicants advised that they are two separate groups.

The people recruited from the endocrinology and hypertension clinics are referred from their responsible clinicians and would have their blood tests done around the time of their clinic visits.

The people recruited from the laboratory databases are those who had historical blood test results. Although most would have had their blood tests ordered from the above clinics, they may no longer be receiving follow-up if their blood tests did not meet current screening criteria for primary aldosteronism.

The CAG noted this information and raised no further queries.

2. **Clarify why patients need to be recruited from previous studies.**

The applicant explained that recruiting patients from previous studies would not provide the total number needed to meet the recruitment target of 77-100 participants, but will help in achieving the target.

The CAG noted this information and raised no further queries.

3. **A patient and public group needs to be created. The CAG also advised contacting cardiovascular and heart disease charities and request that they review the information.**

The applicants sought advice from Trials Connect during a hypertension study day. 12 out of 12 patients all agree that this is important research that would be beneficial to the participants. They agree that data can be accessed without consent and for contact to be done only to those who meet the study criteria.

4. **The patient notification materials need to be reviewed by the Chief Investigator, Academic Supervisor and Patient and Public Involvement group, to help simplify the language used.**

A revised patient notification was provided. This had been reviewed by the Chief Investigator and Academic Supervisor.

### Confidentiality Advisory Group advice conclusion

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

### Specific conditions of support

The following sets out the specific conditions of support.

1. The second paragraph on the Outpatient Notification documents needs to be revised. The paragraph currently reads, “This will involve looking at historical blood test results. If the results meet our research criteria, we will contact them and invite them to join our study if they wish to.” The references to “them” need to be revised to clarify who is being referred to. The revised patient notification is to be provided within one month of the issuing of this letter.

2. Favourable opinion from a Research Ethics Committee. **Confirmed:** 04 January 2023

3. Confirmation provided from the IG Delivery Team at NHS Digital to the CAG that the relevant Data Security and Protection Toolkit (DSPT) submission(s) has achieved the ‘Standards Met’ threshold. See section below titled ‘security assurance requirements’ for further information.
   **Confirmed:**
   NHS Digital 2021/22 DSPT reviews for **Barts Health NHS Trust** and **Queen Mary University of London** were confirmed as ‘Standards Met’ on the NHS Digital DSPT Tracker (31/10/2022)

## i. 22/CAG/0141 - Do patients with autoimmune hepatitis (AIH) have an excessive incidence of cardio- and cerebrovascular disease and is this related to corticosteroid treatment?

| **Name** | |
|---|---|
| Dr Murat Soncul (AVC) | CAG Alternate Vice Chair |
| Dr Malcolm Booth | CAG Member |
| Dr Katie Harron | CAG Member |
| Dr Pauline Lyseight-jones | CAG Member |
| Professor Sara Randall | CAG Member |

### Context

#### Purpose of application

This application from Sheffield Teaching Hospitals NHS Foundation Trust set out the purpose of medical research that seeks to investigate whether the rate of new hospital admissions and/or deaths is higher after a diagnosis of autoimmune hepatitis (AIH) than that in a general population cohort.

Autoimmune hepatitis (AIH) is a chronic inflammatory liver disease that affects about 11,000 people in the UK and is becoming more common. It can affect all populations and age groups, although most patients are female. Untreated, AIH is a serious and fatal disease. Drug treatments, such as steroids, are effective in improving outcomes, but have side effects such as weight gain, diabetes, and increases in blood pressure and fat levels in the blood and liver. Patients with other steroid treated conditions, such as rheumatoid arthritis, have a higher rate of vascular disease compared to the general population. The applicants seek to establish whether this is also true of patients with AIH and if there is a link to steroid therapy, in order to inform the development of newer, non-steroid treatments.

The three participating trusts, Sheffield Teaching Hospitals NHS Foundation Trust, Kings College Hospital NHS Foundation Trust and University Hospitals Birmingham will disclose confidential patient information, collected from the autoimmune hepatitis patient datasets they hold, to NHS Digital. NHS Digital will generate a control group, consisting of 10 controls per patient, matched to the patient group in age, sex and

postcode (LSOA). NHS Digital will then link data for both the patients and controls with the HES Admitted Patient Care Dataset and ONS Mortality Dataset. The dataset will then be disclosed to the Chief Investigator at Sheffield Teaching Hospitals NHS Foundation Trust. The dataset for the case data will be pseudonymised, as the name, NHS number, date of birth, sex and post code will be replaced by the unique Study ID. The control dataset will be completely anonymous, with each patient identified only by their corresponding "case" Study ID.

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

### Confidential patient information requested

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

| | |
|---|---|
| **Cohort** | Patients aged 18 years and over who were diagnosed with AIH between 1989 and 2021, and who are under the care of the Liver Units at Sheffield Teaching Hospitals, Kings College Hospital NHS Foundation Trust or University Hospitals Birmingham.<br><br>In total there will be 8580 patients involved: 780 "cases" and 7800 "controls". |
| **Data sources** | 1. Electronic patient records at:<br><br>a. Sheffield Teaching Hospitals NHS Foundation Trust<br><br>b. Kings College Hospital NHS Foundation Trust<br><br>c. University Hospitals Birmingham<br><br>2. The HES Admitted Patient Care Dataset and ONS Mortality Dataset, held by NHS Digital |
| **Identifiers required for linkage purposes** | 1. Name<br><br>2. NHS Number<br><br>3. Date of birth |

| | |
|---|---|
| | 4. Postcode – sector level |
| **Identifiers required for analysis purposes** | 1. Date of death<br>2. Postcode – sector level<br>3. Gender<br>4. Ethnicity |

**Confidentiality Advisory Group advice**

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

1. **The term 'general population' should not be used to describe the study population in any of the patient-facing materials**

The applicants confirmed that they have removed the term 'general population' from the patient notification letter. The revised version was provided for review.

The CAG noted this and raised no further queries.

2. **The CAG query whether the applicant trusts the reliability of ethnicity data and whether it could cause a problem when performing linkage.**

The applicants noted that relatively little information is available on the accuracy of HES data and cited 2021 study which found that 91.3% of patients had complete information regarding ethnicity in HES. When compared with self-declared records, the accuracy of this data was found to be more than 90%. The applicants were content that this is sufficient for the purposes of the study.

The applicants noted that the purpose of requesting ethnicity data was to check for and avoid demographic bias between the case and control groups.

The CAG noted this and raised no further queries.

3. **Provide clarification on whether the research team are using the full postcode for linkage and then obtaining the lower super output area.**

Cases and controls would be matched by Lower Super Output Area (LSOA). The full postcode of the AIH patients will be sent to NHS Digital for linkage to maximise the accuracy of doing this. Only the direct clinical care team will have access to the patients' full post code. Data returned from NHS Digital will contain the LSOA only, for both patients and controls. The CAG noted this and raised no further queries.

4. **The CAG requested for the use of SPSS to be only used on University resources (laptops/network) rather than personal devices.**

The applicants explained that, when personal devices are used to access SPSS, this will be done using the University Network via a VPN. All data will be saved on the encrypted university shared drive, never on the personal devices' hard drive. The CAG noted this and raised no further queries.

5. **The CAG wishes to inform the applicant that HES refers to a data set held within NHS Digital.**

The applicants noted that they understood that HES is a data set held within NHS Digital and had updated the Patient Notification Letter to make this clearer. The CAG noted this and raised no further queries.

6. **Please clarify where the key is going to be held for pseudonymisation.**

Each participating centre will hold their own pseudonymisation key. This will be stored in a file on a secure trust computer, which is password protected and uses an encrypted network. Only members of the patient's direct care team will have access to this file. The CAG noted this and raised no further queries.

7. **Please include a sentence within the patient notification letter, explaining that the participant would not be opted out should they not to respond to the letter.**

The applicants provided an updated patient notification letter. The CAG noted this and raised no further queries.

8. **Notifications need to be displayed at hospital sites**

The applicants provided a patient notification poster which will be displayed at each hospital site. Printed copies of the poster in leaflet form will be provided for patients to take home. The CAG noted this and raised no further queries.

9. **The CAG note that the patient and public involvement group is too small and should include patients and the public from different areas of the country, to reflect the study population.**

The applicants sought views from the PPI Group on the Study Protocol, Patient Notification Letter and Patient Notification Poster. The patient notification letter and poster have been updated in accordance with the comments received.

The CAG noted this and raised no further queries.

10. **The possibility of holding patient and public involvement meetings more frequently than annually should be explored. If this is not feasible, please provide justification as to why.**

The applicants propose to hold a patient and public involvement meeting every 6 months via video conference. The CAG 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 Health Research Authority, subject to compliance with the specific and standard conditions of support as set out below.

### Specific conditions of support

The following sets out the specific conditions of support.

1. Favourable opinion from a Research Ethics Committee. **Confirmed 01 November 2022.**

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

   The NHS Digital 2021/22 DSPT reviews for **Sheffield Teaching Hospitals NHS Foundation Trust, University Hospitals Birmingham NHS Foundation Trust, Kings College Hospital NHS Foundation Trust and NHS Digital** were confirmed as 'Standards Met' on the NHS Digital DSPT Tracker (30/01/2022)

## j. 23/CAG/0010 - The SHIPS Study: Sharing Information at the Primary / Secondary care interface – improving patient care by ensuring that GPs get the information they need when someone is discharged from hospital

| **Name** | |
|---|---|
| Dr Malcolm Booth | CAG Member |
| Dr Patrick Coyle | CAG Vice Chair |
| Mr Anthony Kane | CAG Member |
| Mr Dayheem Sedighi | HRA Approvals Administrator |
| Ms Caroline Watchurst | HRA Confidentiality Advisor |

## Context

### Purpose of application

This application from University of Bristol – Bristol Medical School set out the purpose of medical research that seeks to explore the communication of poor prognosis between secondary care and primary care when a patient is discharged from hospital. The aim is to understand what information should be shared with General Practitioners (GPs) after a hospital stay, and how it might best be shared. GPs find it challenging to identify patients with advanced illness, who might have limited life expectancy, and would welcome clear communication from hospital specialists concerning these patients. Communication of this information to GPs enables better continuity and coordination of care. Advance care planning discussions can then enable patients' wishes to be identified and respected, including preferences for place of care and death, and future admission avoidance.

On average, people dying in Britain spend three weeks of their last year of life in hospital as a result of one or more emergency admissions. The SHIPS study is relevant, and needed now, as emergency admissions in the last year of life are predicted to translate to a need for 8000 extra hospital beds by 2038. Strategies that improve Summary of application for CAG continuity of care lower hospital admissions, potentially improving the quality of end of life care, while reducing its cost. To ensure the delivery of well-coordinated and continuous care by GPs, applicants need to establish how primary and secondary care can communicate effectively and efficiently.

Part 1 of The SHIPS study is already underway regarding a literature review to inform part 2. Part 2 includes a number of different methodologies at 2 participating Trusts, including consented interviews and reviewing anonymised discharge information. These elements do not require 's251' support. However the applicant is also undertaking ethnographic observations, of multidisciplinary team meetings, board round meetings, observed daily at each site, informal interactions between HCPs on hospital wards, and observations of clinicians preparing discharge communications about patients on the ward. Support under Regulation 5 is required for this aspect of the study as the applicants may be exposed to confidential patient information when undertaking the observations. Observations will be recorded via handwritten field notes. Identifiable patient information will not be recorded, but the researcher may record age, gender and ethnicity, which would be effectively anonymous to the researcher.

The researcher will spend approximately 48 days in total on six wards (three wards per study site), conducting interviews and 80-100 hours of observations. The study sites are Great Western Hospitals NHS Foundation Trust and North Bristol NHS Trust. The wards will be purposively sampled focusing on respiratory, oncology and care of the elderly wards, as these wards are most likely to be caring for patients in the last year of life. Other wards, including surgery and cardiology may also be selected, to include

wards who are known to be effectively identifying and communicating limited life expectancy at discharge, and wards who may have development needs in this area.

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

## Confidential patient information requested

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

| | |
|---|---|
| **Cohort** | Individual observation of secondary care clinicians: 30-40 clinicians, each clinician observed up to 1-3 times<br><br>Out of scope for 's251':<br>Secondary care clinician interviews: 24-28 interviews<br>GP interviews: 18-22 interviews<br>Interviews with patients and carers: 24-28 interviews<br>Anonymised discharge documentation: 30-40 items<br><br>The researchers undertaking observations of MDT meetings may be exposed to confidential patient information relating to patients discussed at the MDT meetings. It is these patients who are the cohort for 's251' support. |
| **Data sources** | 1. Clinical meetings recorded via written field notes, at the following Trusts;<br><br>• Great Western Hospitals NHS Foundation Trust<br>• North Bristol NHS Trust |

| | |
|---|---|
| **Identifiers required for linkage purposes** | No items of confidential patient information will be recorded for linkage purposes |
| **Identifiers required for analysis purposes** | 1. Age<br>2. Gender<br>3. Ethnicity<br><br>This is effectively anonymous to the researcher |

**Confidentiality Advisory Group advice**

The Confidentiality Advice Team (CAT) considered the applicant's response to the request for further information detailed in the provisionally supported outcome in correspondence.

1. **Please provide an updated ward information sheet to include a brief explanation regarding 'Section 251' support and why it is required.**

The applicant provided an updated information sheet as per CAG advice, and CAT were satisfied with the response.

2. **Please provide an updated poster to include a brief explanation regarding 'Section 251' support and why it is required, and also include information on how to opt out.**

The applicant provided an updated poster as per CAG advice, and CAT were satisfied with the response.

**Confidentiality Advisory Group advice conclusion**

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

### Specific conditions of support

The following sets out the specific conditions of support.

1. Favourable opinion from a Research Ethics Committee. **Confirmed 20 December 2022**
2. Confirmation provided from the IG Delivery Team at NHS Digital to the CAG that the relevant Data Security and Protection Toolkit (DSPT) submission(s) has achieved the 'Standards Met' threshold. See section below titled 'security assurance requirements' for further information. **Confirmed:**

   The NHS Digital **21/22** DSPT reviews for **Great Western Hospitals NHS Foundation Trust** & **North Bristol NHS Trust** were confirmed as 'Standards Met' on the NHS Digital DSPT Tracker (24 January 2023)

## 2. New Amendments

## 18/CAG/0040 - The eLIXIR project/ eLIXIR: Early Lifecourse data Cross-Linkage in Research: a Multidisciplinary partnership - linked data for research into maternal and child health

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

**Context**

### Amendment request

The applicants have existing support to link maternity and neonatal data from King's College Hospital NHS Foundation Trust and Guys and St Thomas' NHS Foundation Trust, with the South London and Maudsley (SLaM) NHS Foundation Trust mental

health Clinical Record Interactive Search (CRIS), further linkage to HES data at NHS Digital and to link with the Lambeth DataNet (LDN) GP patient record data.

In this amendment, the applicants seek support for the disclosure of confidential patient information from the eLIXIR dataset to the UK Government Human Fertilisation and Embryology Authority (HFEA) and the National Immunisation Management System (NIMS) databases.

For the linkage to HFEA, patient NHS numbers and eLIXIR IDs will be extracted from the eLIXIR database. The information will be run through OpenPseudonymiser software and a unique anonym will be created for each patient. The HFEA will have access to the same anonyms to match patients. The linked dataset will then be returned to South London and Maudsley NHS Foundation Trust and linked to the eLIXIR dataset.

For linkage to NIMS, SLaM CDLS will create an eLIXIR Identifiers Table, which contains patients first name, last name, gender, DOB, NHS number and eLIXIR ID (patient-level anonym used with the eLIXIR data). This Table will be disclosed to NHS Digital for linkage to NIMS and the linked dataset returned to SLaM.

**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.

**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: South London and Maudsley NHS Foundation Trust, NHS Digital,** and the **UK Government Human Fertilisation and Embryology Authority** have confirmed ‘Standards Met’ grades on DSPT submission 2021/22 (checked 22 December 2022).

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

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

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

### Context

### Amendment request

The applicants have existing support to allow research staff at participating trusts to access confidential patient information in order to identify eligible patients and extract a pseudonymised dataset. Hospital records will be accessed to determine the number of smokers who have been offered and used tobacco dependence services and to calculate the cost of providing the service.

In this amendment, the applicants are seeking to make three changes. The first request is to extend the duration of support until 31 December 2023.

Sandwell and West Birmingham NHS Trust have withdrawn from the study prior to commencing data collection. Great Western Hospitals NHS Foundation Trust have been included as a data processor.

### 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.

### Confidentiality Advisory Group advice conclusion

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

### Specific conditions of support

The following sets out the specific conditions of support.

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

   **Confirmed:** The NHS Digital 2021/22 DSPT review for Great Western Hospitals NHS Foundation Trust was confirmed as 'Standards Met' on the NHS Digital DSPT Tracker (checked 06 January 2023).

2. Confirmation of a favourable opinion from a Research Ethics Committee. Confirmation that the amendment did not require REC review was provided on **22 December 2022.**

## 19/CAG/0150 – Long-term vascular complications in young people with childhood-onset type 1 diabetes

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

**Context**

### Amendment request

This amendment sought support to change the Chief Investigator from Professor David Dunger, to Dr Loredana Marcovecchio.

The protocol, and corresponding patient notification information placed on websites and social media accounts have been updated correspondingly.

**Confidentiality Advisory Group advice**

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

### Confidentiality Advisory Group advice conclusion

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

### Specific conditions of support

The following sets out the specific conditions of support.

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

   The NHS Digital 21/22 DSPT reviews for **University of Cambridge (School of Clinical Medicine) and NHS Digital** were confirmed as 'Standards Met' on the NHS Digital DSPT Tracker (checked 09 January 2023)

2. Confirmation of a favourable opinion from a Research Ethics Committee. **Confirmed 15 November 2021**

## 19/CAG/0139 – The clinical and cost-effectiveness of testing for Group B Streptococcus: a cluster randomised trial with economic and acceptability evaluations (GBS3)

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

### Context

### Amendment request

This application from the University of Nottingham aims to evaluate two testing approaches to identify Group B Streptococcus in pregnant women.

The applicants have existing support to process data from; electronic health records from participating maternity units in England and Wales, the National Neonatal Research Database, Patient Episodes Dataset Wales held by the DHCW (previously NHS Wales Informatics Service), Group Strep B Infant Sepsis reports held by Public Health England, Group Strep B Infant Sepsis reports held by Health Protection Wales, and the English Maternity Services Dataset and HES data held by NHS Digital, the Paediatric Intensive Care Audit Network (PICANet) and Badgernet (Maternity and Neonatal). Data from these sources will be processed in order to create a dataset for analysis.

The amendment sought support for the addition of two new participating sites (Bedfordshire Hospitals NHS Foundation & Manchester University NHS Foundation Trust) as data processors, both of which are in England.

**Confidentiality Advisory Group advice**
The amendment requested was considered by the Confidentiality Advice Team (CAT), who raised no queries regarding this amendment.

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

## Specific conditions of support

The following sets out the specific conditions of support.

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

The NHS Digital **21/22** DSPT review for **the University of Nottingham and the DSPT equivalent for NHS Digital** were confirmed as 'Standards Met' on the NHS Digital DSPT Tracker (checked 13 December 2022)

Due to the number of organisations involved it is the responsibility of University of Nottingham, as controller, to ensure that all organisations processing confidential patient information without consent meet the minimum required standard in complying with DSPTs, and take remedial action if they become aware of any that fall below this, or where any concerns are raised. These will not be individually checked by CAT as there are more than 5 organisations.

**Health Informatics Centre at the University of Dundee – HSC-PBPP approval confirmed 04 November 2021**

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

## 17/CAG/0096 – A population based study of pre-disposition to breast cancer: SEARCH Breast

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

**Context**

### Amendment request

This research study from the University of Cambridge investigates the role of inherited genetic variation in breast cancer risk and clinical outcomes.

This amendment sought support to change the Chief Investigator from Professor Paul Pharoah, to Professor Antonis Antoniou. Professor Paul Pharoah has left the University of Cambridge and Professor Antonis Antoniou has taken over as Chief Investigator for SEARCH. Professor Paul Pharoah will continue involvement with the studies as a collaborating investigator.

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

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

### Specific conditions of support

The following sets out the specific conditions of support.

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

   The NHS Digital 21/22 DSPT reviews for **University of Cambridge (School of Clinical Medicine)** (8F331) and NHS England (previously NHS Digital) were confirmed as 'Standards Met' on the NHS Digital DSPT Tracker (checked 11 January 2023)

2. Confirmation of a favourable opinion from a Research Ethics Committee. **Confirmed 03 January 2023**

## 17/CAG/0098 – Population based study of genetic predisposition to endometrial cancer: SEARCH Endometrial

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

**Context**

### Amendment request
This research study from the University of Cambridge investigates the role of inherited genetic variation in endometrial cancer risk and clinical outcomes.

This amendment sought support to change the Chief Investigator from Professor Paul Pharoah, to Professor Antonis Antoniou. Professor Paul Pharoah has left the University of Cambridge and Professor Antonis Antoniou has taken over as Chief Investigator for SEARCH. Professor Paul Pharoah will continue involvement with the studies as a collaborating investigator.

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

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

### Specific conditions of support

The following sets out the specific conditions of support.

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

   The NHS Digital 21/22 DSPT reviews for **University of Cambridge (School of Clinical Medicine)** (8F331) and NHS England (previously NHS Digital) were confirmed as 'Standards Met' on the NHS Digital DSPT Tracker (checked 11 January 2023)

2. Confirmation of a favourable opinion from a Research Ethics Committee. **Confirmed 29 November 2022**

## 17/CAG/0097 – A population based study of genetic predisposition to ovarian cancer: SEARCH Ovarian

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

## Context

### Amendment request

This research study from the University of Cambridge investigates the role of inherited genetic variation in ovarian cancer risk and clinical outcomes.

This amendment sought support to change the Chief Investigator from Professor Paul Pharoah, to Professor Antonis Antoniou. Professor Paul Pharoah has left the University of Cambridge and Professor Antonis Antoniou has taken over as Chief Investigator for SEARCH. Professor Paul Pharoah will continue involvement with the studies as a collaborating investigator.

### Confidentiality Advisory Group advice

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

### Confidentiality Advisory Group advice conclusion

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

### Specific conditions of support

The following sets out the specific conditions of support.

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

   The NHS Digital 21/22 DSPT reviews for **University of Cambridge (School of Clinical Medicine)** (8F331) and NHS England (previously NHS Digital) were confirmed as 'Standards Met' on the NHS Digital DSPT Tracker (checked 11 January 2023)

2. Confirmation of a favourable opinion from a Research Ethics Committee. **Confirmed 30 November 2022**

## 19/CAG/0188 – A population based study of genetic predisposition and gene-environment interactions in prostate cancer in east anglia, trent and west midlands: SEARCH Prostate

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

### Context

#### Amendment request

This research study from the University of Cambridge investigates the role of inherited genetic variation in prostate cancer risk and clinical outcomes.

This amendment sought support to change the Chief Investigator from Professor Paul Pharoah, to Professor Antonis Antoniou. Professor Paul Pharoah has left the University of Cambridge and Professor Antonis Antoniou has taken over as Chief Investigator for SEARCH. Professor Paul Pharoah will continue involvement with the studies as a collaborating investigator.

#### Confidentiality Advisory Group advice

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

#### Confidentiality Advisory Group advice conclusion

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

### Specific conditions of support

The following sets out the specific conditions of support.

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

The NHS Digital 21/22 DSPT reviews for **University of Cambridge (School of Clinical Medicine)** (8F331) and NHS England (previously NHS Digital) were confirmed as 'Standards Met' on the NHS Digital DSPT Tracker (checked 11 January 2023)

2. Confirmation of a favourable opinion from a Research Ethics Committee. **Confirmed 30 November 2022**

## 20/CAG/0125 – A population based study of genetic predispositions and gene-environment interactions in colorectal cancer - SEARCH Colorectal

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

**Context**

### Amendment request

This research study from the University of Cambridge investigates the role of inherited genetic variation in colorectal cancer risk and clinical outcomes.

This amendment sought support to change the Chief Investigator from Professor Paul Pharoah, to Professor Antonis Antoniou. Professor Paul Pharoah has left the University of Cambridge and Professor Antonis Antoniou has taken over as Chief Investigator for SEARCH. Professor Paul Pharoah will continue involvement with the studies as a collaborating investigator.

**Confidentiality Advisory Group advice**

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

**Confidentiality Advisory Group advice conclusion**

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

### Specific conditions of support

The following sets out the specific conditions of support.

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

   The NHS Digital 21/22 DSPT reviews for **University of Cambridge (School of Clinical Medicine)** (8F331) and NHS England (previously NHS Digital) were confirmed as 'Standards Met' on the NHS Digital DSPT Tracker (checked 11 January 2023)

2. Confirmation of a favourable opinion from a Research Ethics Committee. **Confirmed 30 November 2022**

## 20/CAG/0126 – A Population-based Study of Genetic Predisposition to Cancer (SEARCH) (Oesophageal Cancer, Pancreatic Cancer, Brain tumours, Non-Hodgkins, Lymphoma, Melanoma, Kidney Cancer, Bladder cancer - SEARCH Multi

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

**Context**

### Amendment request

This research study from the University of Cambridge investigates the role of inherited genetic variation in multi cancer risk and clinical outcomes.

This amendment sought support to change the Chief Investigator from Professor Paul Pharoah, to Professor Antonis Antoniou. Professor Paul Pharoah has left the University of Cambridge and Professor Antonis Antoniou has taken over as Chief Investigator for SEARCH. Professor Paul Pharoah will continue involvement with the studies as a collaborating investigator.

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

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

### Specific conditions of support

The following sets out the specific conditions of support.

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

   The NHS Digital 21/22 DSPT reviews for **University of Cambridge (School of Clinical Medicine)** (8F331) and NHS England (previously NHS Digital) were confirmed as 'Standards Met' on the NHS Digital DSPT Tracker (checked 11 January 2023)

2. Confirmation of a favourable opinion from a Research Ethics Committee. **Confirmed 30 November 2022**

## 19/CAG/0171 – A population based study of genetic predisposition and gene-environment interactions in breast cancer: SEARCH breast

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

## Context

### Amendment request

This research study from the University of Cambridge investigates the role of inherited genetic variation in breast cancer risk and clinical outcomes, and this CAG application is regarding the facilitation of the invitation process.

This amendment sought support to change the Chief Investigator from Professor Paul Pharoah, to Professor Antonis Antoniou. Professor Paul Pharoah has left the University of Cambridge and Professor Antonis Antoniou has taken over as Chief Investigator for SEARCH. Professor Paul Pharoah will continue involvement with the studies as a collaborating investigator.

### Confidentiality Advisory Group advice

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

### Confidentiality Advisory Group advice conclusion

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

## Specific conditions of support

The following sets out the specific conditions of support.

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

   The NHS Digital 21/22 DSPT reviews for **University of Cambridge (School of Clinical Medicine)** (8F331) and NHS England (previously NHS Digital) were confirmed as 'Standards Met' on the NHS Digital DSPT Tracker (checked 11 January 2023)

2. Confirmation of a favourable opinion from a Research Ethics Committee. **Confirmed 03 January 2023**

## 18/CAG/0142 – a population based study of genetic predisposition and gene-environment interactions in ovarian cancer

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

### Context

#### Amendment request

This research study from the University of Cambridge investigates the role of inherited genetic variation in ovarian cancer risk and clinical outcomes, and this CAG application is regarding the facilitation of the invitation process.

This amendment sought support to change the Chief Investigator from Professor Paul Pharoah, to Professor Antonis Antoniou. Professor Paul Pharoah has left the University of Cambridge and Professor Antonis Antoniou has taken over as Chief Investigator for SEARCH. Professor Paul Pharoah will continue involvement with the studies as a collaborating investigator.

**Confidentiality Advisory Group advice**

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

**Confidentiality Advisory Group advice conclusion**

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

#### Specific conditions of support

The following sets out the specific conditions of support.

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

   The NHS Digital 21/22 DSPT reviews for **University of Cambridge (School of Clinical Medicine)** (8F331) and NHS England (previously NHS Digital) were confirmed as 'Standards Met' on the NHS Digital DSPT Tracker (checked 11 January 2023)

2. Confirmation of a favourable opinion from a Research Ethics Committee. **Confirmed 30 November 2022**

## 19/CAG/0172 – a population based study of genetic predisposition and gene-environment interactions in endometrial cancer

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

**Context**

### Amendment request

This research study from the University of Cambridge investigates the role of inherited genetic variation in endometrial cancer risk and clinical outcomes, and this CAG application is regarding the facilitation of the invitation process.

This amendment sought support to change the Chief Investigator from Professor Paul Pharoah, to Professor Antonis Antoniou. Professor Paul Pharoah has left the University of Cambridge and Professor Antonis Antoniou has taken over as Chief Investigator for SEARCH. Professor Paul Pharoah will continue involvement with the studies as a collaborating investigator.

**Confidentiality Advisory Group advice**

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

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

### Specific conditions of support

The following sets out the specific conditions of support.

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

   The NHS Digital 21/22 DSPT reviews for **University of Cambridge (School of Clinical Medicine)** (8F331) and NHS England (previously NHS Digital) were confirmed as 'Standards Met' on the NHS Digital DSPT Tracker (checked 11 January 2023)

2. Confirmation of a favourable opinion from a Research Ethics Committee. **Confirmed 29 November 2022**

## 17/CAG/0048 – Long-term follow-up of the East London Sickle Cell Disease Neonatal Cohort

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

**Context**

### Amendment request

This application from the Royal London Hospital (part of Barts Health NHS Trust) aims to follow-up patients previously entered into the Sickle Cell Disease database which was established in East London in 1983. This cohort, referred to as the East London Newborn cohort, was a unique cohort of patients diagnosed with universal newborn screening in the London Boroughs of Hackney since 1983. The cohort is under continuous clinical follow up at The Royal London Hospital, although a minority have

transferred care to other clinics or become lost to follow-up. Data on patients under current follow-up at Royal London Hospital is maintained on a secure clinical database at site. Information on patients in other clinics was sought from their GP or specialist. ‘s251’ support was in place to cover a further 10 year follow up on patients from the East London newborn cohort. This included clinicians updating outcomes in respect of patients who are still under the care of the Royal London Hospital (the original outcome letter states this is out of scope of the support request), and requesting information from clinicians for those patients who have moved to other hospitals for their treatment (support to cover the processing of the information from other Trusts was provided) and attempts to locate patients who are lost to follow-up through contacting GP surgeries. (support was also provided for this). The cohort was all patients added to the East London newborn cohort with sickle cell disease, found during the universal newborn screening, from its establishment in 1983. The established cohort is 396 patients, plus any additional patients who were added from 2007 onwards, who were also be followed up.

The amendment sought support to change the data flows for the study, and remove ‘s251’ support required for follow up data to be collected from any external source. This amendment therefore reduces the risk of data transfer, since in the original study applicants had been requesting data from other NHS sites. Applicants are now not seeking data from any other NHS service, only from Barts Health NHS Trust, which is their own site. However, the applicant confirmed that ‘s251’ support was still required for the retention of the confidential patient information collected about any patients from external Trusts.

The amendment also sought support to expand the cohort. The population will no longer be restricted to those identified with newborn screening and followed from birth, and instead the database will contain the entire population of patients with sickle cell disease followed in the clinical services at Barts Health NHS Trust and registered on the Sickle Cell Disease Clinical database for more than 6 months. The population will therefore increase from 404 to about 1220 subjects, with age ranging 0 to 70 years or more. The duration of follow up for each subject will be from registration in the service up until 30 June 2025, and this will be internally only within Barts Health NHS Trust. The justification for this is that applicants have identified that the original cohort is not sufficiently mature to make conclusions about incidence, prevalence and risk factors for significant long term complications of sickle cell disease (SCD) (including renal disease, cardiopulmonary disease and liver disease) which become more common after the third decade of life. The full cohort of Barts Health patients includes a large number who are currently in the age range 40-60, and therefore by extending the analysis to these patients, applicants will be able to make important observations about

long term morbidity. The rates and risks for chronic complications of SCD are largely unknown at present, and this clinical database remains a unique clinical resource in the NHS, as applicants have been entering data prospectively and retrospectively over the past 20 years. The applicants have updated the patient notification.

Despite the initial outcome letters stating that no 's251' support was required for the collection of outcome data within the applicants Trust, presumably due to this process being undertaken by direct care team only, the applicant has confirmed that 's251' support is required for the ongoing processing of the additional cohort, and follow up, as some of the individuals accessing confidential patient information within the clinical database may not be defined as direct care team, and therefore the continuation of the database requires 's251' support.

**Confidentiality Advisory Group advice**

The amendment requested was considered by Chairs' Action. The Vice-Chair noted that this amendment is to allow the applicants to study all the patients attending and followed up in the Barts NHS Trust with Sickle Cell Disease since 1983, rather than just a specific cohort identified by neonatal screening. It will also stop further collection of data on patients who had transferred to other clinics or were lost to follow up, although retaining data already collected on those individuals. This will increase the number of patients being studied, but reduce the security risks of transferring confidential patient information to and from other institutions. 'Section 251' support is still required to retain the data collected elsewhere. The more significant number of patients from Barts NHS Trust being included means confidential patient information will be handled by staff not considered part of the care team. The Vice-Chair was happy to recommend support for this amendment, as this will add greater power to the study and improve the likelihood of conclusions that will be useful in improving patient care.

**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 **2021/22** DSPT review for **Barts Health NHS Trust** was confirmed as '**Standards Met'** on the NHS Digital DSPT Tracker (checked 20 December 2022).

2. Confirmation of a favourable opinion from a Research Ethics Committee. **Confirmed non substantial 23 August 2022**

## 22/CAG/0117 – NICOR Commissioning through Evaluation Registries/Audits: Percutaneous Mitral Valve Repair, Left Atrial Appendage Occlusion and Patent Foramen Ovale Closure in Adults

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

### Context

### Amendment request

These three Commissioning through Evaluation (CtE) registries are currently already completed, and the patient data linked with NHS Digital HES APC data and ONS Mortality data. Following data analysis and reporting, NHS England requested that the linked data be retained until 2025 in case there were any public safety concerns about the treatments which warranted data reanalysis. This 's251' support was planned to be expired once any confidential patient information is removed from these datasets.

This amendment sought support to re-instate the registries; Percutaneous Mitral Valve Repair, Left Atrial Appendage Occlusion and Patent Foramen Ovale Closure in Adults. This includes both the previously archived data, and beginning a new data collection prospectively.

NHS England has now commissioned these procedures to be part of standard treatment available to patients, and therefore NHS England has commissioned NICOR, hosted at NHS Arden and Greater East Midlands Commissioning Support Unit (Arden and GEM), to re-set up these three national clinical registries, so that the hospitals treating patients with these procedures can submit the data to NICOR for analysis and reporting. NHS England has asked that the data previously collected in the CtE registries for these procedures be migrated to the new registries, as these patients groups are quite rare, and it is important to retain all useful information about these treatments. Just like other NICOR registries and audits, the data will be collected and retained on an ongoing basis so it may be used for long-term trend analyses, patient safety and quality improvement, bench marking and treatment outcomes. Unlike the original CtE project, which had a specific end point, the new registries using the same dataset as the previous CtE projects will continue indefinitely without an endpoint. There is no change to the data controller (NHSE) or the processor (Arden and GEM). There are no changes to data sources, other than NHS England has asked that data for these registries is collected from all hospitals (both NHS and private) in England and Wales, which are carrying out these procedures.

The applicant has provided an updated patient notification leaflet.

**Confidentiality Advisory Group advice**

The amendment requested was considered by Chair's Action. The Chair noted he was content to recommend support for the amendment, and that it was in the public interest. However he advised that a separate NDO exemption application regarding this application must be submitted, and the applicant cannot rely on the previously submitted NDO exemption applications for other distinct CAG applications.

**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 2021/22 DSPT reviews for NHS Arden and Greater East Midland Commissioning Support Unit (Arden & GEM) & Redcentric (Harrogate) were confirmed as 'Standards Met' on the NHS DSPT Tracker (checked 21 December 2022)**

## 18/CAG/0159 – Housing, family and environmental risk factors for hospital admissions in children

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

### Context

#### Amendment request

The applicants are seeking support to extend the duration of 's251' support until 31 December 2024. This is due to delays caused by the Covid-19 pandemic.

### 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:**

   The NHS Digital 21/22 DSPT reviews for **the Office for National Statistics, University College London – School of Life and Medical Sciences & NHS Digital** were confirmed as 'Standards Met' on the NHS Digital DSPT Tracker (checked 20 December 2022)

2. Confirmation of a favourable opinion from a Research Ethics Committee. **Confirmed 16 January 2023**

## 19/CAG/0164 – Investigation of gender mortality differences in children admitted to UK Paediatric Intensive Care Units

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

**Context**

### Amendment request

This application from the University College London Great Ormond Street Institute of Child Health seeks to investigate why girls admitted to Paediatric Intensive Care Units (PICU) in England and Wales have a higher mortality rate than boys. Support is in place to allow NHS Digital to link PICAnet data to HES and ONS mortality data.

In this amendment, the applicants seek to extend the duration of support until 01 March 2025. Patients dates of birth and dates of death will be retained until this date. The dates will then be converted to month and year only, which will be held until 31 August 2026.

**Confidentiality Advisory Group advice**

The amendment requested was considered by the Confidentiality Advice Team. The Team agreed that the extension of the duration of support was in the public interest.

### Confidentiality Advisory Group advice conclusion

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

### Specific conditions of support

The following sets out the specific conditions of support.

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

   **Confirmed:** The NHS Digital 2020/21 DSPT review for University College London – School of Life and Medical Science was confirmed as 'Standards Met' on the NHS Digital DSPT Tracker (checked 06 January 2023).

2. Confirmation of a favourable opinion from a Research Ethics Committee. **Confirmed:** 13 January 2023

## 21/CAG/0058– Evaluation of Homeless Health Peer Advocacy: an analysis of secondary data

| Name | Capacity |
|---|---|
| Dr Murat Soncul | CAG alternative vice-chair |
| Ms Caroline Watchurst | HRA Confidentiality Advisor |

### Context

### Amendment request

This application from the London School of Hygiene & Tropical Medicine (LSHTM) set out the purpose of medical research that seeks to explore how the homeless health peer advocacy (HHPA) intervention affects homeless peoples' use of health services.

Regarding the intervention group, ‘s251’ support is currently in place to allow the disclosure of confidential patient information regarding 150 HHPA clients from Groundswell to NHS England (previously NHS Digital), in order to undertake linkage with PDS data to identify missing NHS numbers, and then undertake linkage to HES data, in order to provide a pseudonymised intervention dataset to UCL SLMS.

Regarding the comparison group, ‘s251’ support is in place to allow NHS England (previously NHS Digital) to identify a comparator group of 1000 individuals, by searching the HES database against inclusion and exclusion criteria and then linking to further information in the HES database, in order to provide a pseudonymised control dataset to UCL SLMS.

This amendment sought support to amend the definitions of both the intervention group and the comparison group. The intervention group inclusion criteria is now expanded to include "significant interactions" with HHPA. “Significant interaction" is defined as any one of the following interactions:

- Being accompanied to an outpatient appointment by an HHPA
- a client is supported to attend a healthcare appointment (eg a peer books a cab for them to attend an appointment)
- a “client engagement call” (wherein a client is referred to Groundswell, and a peer makes contact through a phone call)
- a remote appointment wherein a peer is present with client as they receive call from GP or hospital

This is because applicants felt that in only including the original definition, applicants might miss or underestimate the impacts of having a peer, since peer engagements with clients are not limited to accompanying them to outpatient appointments. This will allow examination of the effect of different levels of exposure to HHPA service (from minimal support with transport to accompaniment at an outpatient appointment).

Applicants originally stated that Groundswell would extract data on 150 participants registered before March 2019. Applicants have changed this to specify a recruitment period 1st April 2018 - 31st March 2019, rather than a specific sample size. Applicants expanded the timeframe for the intervention group following a review of Groundswell’s data that show a considerable proportion of identifiers were missing and/or not routinely collected during the recruitment period. Including clients for the period March 2018 to 2019 will expand the sample submitted to NHS England (previously NHS Digital) (from

150 to approximately 240) enabling applicants to allow for missing data which is then not matched to individual NHS records.

The inclusion age range for both the intervention and the comparison group has also been expanded to now include those aged 18 years or older (rather than 25 years or older). Applicants had originally been advised by Groundswell that only those aged 25 years or older are recruited to HHPA, but having reviewed the programme database there are in fact individuals aged between 18 and 25 years who have been included, and therefore the applicants need to also include these individuals in the study to avoid bias.

An additional criteria has been included to the comparator group – applicants have added an additional criteria to the homeless phenotype, to include individuals whose postcodes (recorded in their patient records) are a known, residential homelessness hostel during the recruitment period (March 2018 to 2019). These only include hostels that have unique post codes to avoid extracting data on other individuals. The addition of homeless hostels will increase the comparability of the comparison group to HHPA clients, given that Groundswell's peer advocates actively work in hostels to identify clients. Applicants will provide postcodes of hostels in boroughs that Groundswell are not commissioned to work.

A further addition to the inclusion criteria for the comparator group is to include those who had unattended appointments, and not just those who had and attended hospital-based care. This refers to individuals who fulfil one or more of the inclusion criteria, and who had any hospital-based care, and/or had a missed appointment, during the recruitment period. Applicants have included people with an appointment recorded irrespective of attendance, because given that one of the outcomes is attendance at an outpatient appointment, applicants also need to capture those who do not attend.

**Confidentiality Advisory Group advice**

The amendment requested was considered by Chair's Action. The CAG Alternate Vice-Chair was content to recommend support for this amendment, noting that the applicant had appropriately justified why it was required.

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

### Specific conditions of support

The following sets out the specific conditions of support.

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

   The NHS Digital **21/22** DSPT equivalent review for **NHS Digital** and **Groundswell (8J114**) was confirmed as 'Standards Met' (by check of the NHS Digital DSPT tracker 12 January 2023)

2. Confirmation of a favourable opinion from a Research Ethics Committee.
   **Confirmed 15 November 2022**

## 3. Amendments – Response to Provisional Outcome

### a. 17/CAG/0184 – Epilepsy12

| Name | Capacity |
|---|---|
| Dr Tony Calland MBE | CAG Chair |
| Mr David Evans | CAG member |
| Dr Harvey Marcovitch | CAG member |
| Professor Sara Randall | CAG member |
| Ms Diana Robbins | CAG member |
| Ms Clare Sanderson | CAG alternative vice-chair |
| Ms Caroline Watchurst | HRA Confidentiality Advisor |

## Context

### Amendment request

This is a request to defer the National Data Opt-Out for 17/CAG/0184, Epilepsy12 - the National Clinical Audit of Seizures and Epilepsies for Children and Young People.

Healthcare Quality Improvement Partnership (HQIP) commissions The Royal College of Paediatrics and Child Health (RCPCH) to undertake the Epilepsy audit of children and young people, within the wider National clinical audit and patient outcomes programme (NCAPOP).

Epilepsy12 has been supported since 2017 with consistent submission of annual reviews since that time. The Royal College of Paediatrics and Child Health delivered the audit between 2009 and 2014, however, the previous rounds of the audit had been delivered without the requirement for support under the Regulations.

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

### Confidentiality Advisory Group advice

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

1. **Further information is required to evidence that application of the National Data Opt-Out would have an adverse effect on patient safety. This should include more detail on the examples provided in the meeting, and further examples.**

The applicant responded by confirming that Epilepsy12 supports patient safety in the NHS by monitoring the performance of paediatric epilepsy services against the national guidelines, and helping Trusts assure the safety and standards of their services. Excluding data from patients who have opted out via the NDO could compromise the mechanisms and safeguards that protect the safe care of these patients and that of non-NDO patients. As the only quality focused dataset collecting information on paediatric epilepsy services, Epilepsy12 provides a platform for knowledge sharing, promotes local and regional quality improvement and reports data to NHS England and the CQC. These functions are dependent on complete high-quality data collected by the audit on patient care and service provision. Excluding data from NDO patients reduces the quality and quantity of data available for services to monitor and improve the care they provide.

Examples provided include benchmarking performance against other services and national standards. By not being able to process the data of NDO patients, the ability of the audit to identify potential problems and prevent them occurring again in the future will be compromised. Epilepsy12 reports how many children and young people (CYP) are seen by the appropriate professionals, and whether services are employing enough paediatricians with expertise and epilepsy specialist nurses to provide quality care to patients. If NDO patient data has to be excluded when calculating these results, applicants cannot accurately determine if Trusts have sufficient provision of epilepsy services and whether all patients with epilepsy are receiving equal levels of support and provision. There is therefore an increased risk of patients being treated by a service that doesn't have the necessary data to accurately ascertain whether it is maintaining the quality of paediatric epilepsy services that it provides, for example one where key professionals are not providing care in line with NICE guidance and quality standards, which would adversely impact patient safety.

Applicants reason that if the NDO was applied, Trusts would not be able to facilitate continuous improvement based on the learning from previous experiences. Epilepsy12 data collection aligns to NICE guidance and quality standards. Epilepsy12 Audit data highlights when patient care falls below these standards, for example when patients are not receiving crucial investigations such as an MRI when indicated. Clinical teams can use this information to put things right for the individual child, identify the oversight, investigate why it occurred and work to ensure the same does not occur for future patients. Adverse events and themes such as this may not be identified if the NDO were to be applied to Epilepsy12, particularly when considering the small numbers in certain groups such as those who require an MRI. This risks the safety of individual and collective patients, as services could miss opportunities to improve care for an individual child and also not have the appropriate information to identify areas for improvement and learn from previous experiences to assure safety and standards in future.

Applicants also reasoned that the safety of NDO patients who are not entered onto the data capture platform is at risk, as the Epilepsy12 data platform acts as a clinical tool to ensure children and young people receive recommended care. The configuration of the data platform allows clinicians to monitor and focus on the core elements of epilepsy care and can check if patients are receiving these components compared to the national standards when entering audit data. For example, a clinician may realise that patient X meets the criteria for needing an MRI but has not had an MRI yet, when completing their Epilepsy12 record. Prospective data entry allows this error to be identified and then rectified within the first 12 months of care, enabling the clinical team to ensure that the patient receives the appropriate investigations and maintain their safety. This also

holds clinical teams accountable for the care they provide as the tool highlights gaps in the provision of care for individual patients as well as the collective service. If an NDO patient is never entered onto the Epilepsy12 platform, it may not be identified that they are missing out on vital elements of care and their safety may therefore be affected. Therefore the applicant reasons that there is a strong patient safety element with regards to NDO patients, who would fail to benefit from the additional safeguarding checks the data platform provides, and risk not receiving safe and quality care for their epilepsy.

The CAG reviewed these responses, and requested further evidence that patient safety would be affected, using any different or more specific arguments/justifications in addition.

The applicant responded to further justify why application of the NDO would be damaging to patient safety. The applicant reasoned that the patient safety of individuals who are not included due to applying an NDO would be adversely affected. This is because, where an individual's clinical management is not reviewed using the Epilepsy12 tool, key elements of care provided would not be visible to the clinical team. Given Epilepsy12 is increasingly capturing data and reporting performance prospectively, this additional check/safety net would not be applied to those children. This may be around any of the key elements of care planning for example;

- water safety
- Sudden unexpected Death in Epilepsy (SUDEP) and other risks
- involving key professionals for example paediatricians with expertise, an epilepsy specialist nurse or referral to paediatric neurology
- omission of key investigations, for example MRI and 12 lead ECG
- valproate teratogenic risks
- or securing a school individual health care plan

The audit already reveals how frequently these key elements of care are still missed, and is aiming to prompt earlier opportunities regarding those elements of care prospectively. For example, a child may be spotted through the audit who has not had basic water safety information highlighted. This prompt may then lead to this element of care being considered at subsequent follow up, as it has been omitted from the elements traditionally discussed early on in the diagnostic journey. The initial stage of the diagnostic journey can sometimes be irregular, for example where the first parts of the patient journey are an acute or an intensive care admission and epilepsy related aspects of care may be omitted given that other elements of care may be prioritised or non-specialist professionals initially involved. Therefore if the NDO was applied, this

would directly adversely affect the safety of these children, as they may not be offered key elements of clinical treatment.

The applicants also reasoned that if the NDO was applied, patient safety would be adversely affected in marginalised groups, thereby extending health inequalities. This is because the audit is increasingly following a methodology and reporting that will investigate variation around characteristics of ethnicity, sex, socio-economic deprivation, learning disability and autism. These comparisons may be skewed or lose statistical significance by omission of individual children from the audit. This would be particularly true if certain groups of children were more likely to opt out of inclusion.

The applicants also reasoned that if the NDO was applied, patient safety would be adversely affected for Trust, ICB and regional level populations, as reporting will highlight Trusts, ICBs and regions where there is lower performance compared to others, and follow an outlier process for Trusts. Particularly at Trust level and particularly for the performance indicators where smaller numbers are involved they are likely to be impacted by the exclusion of individuals such that opportunities to highlight issues may be missed.

The CAG thanked the applicant for these further clarifications, and agreed that the application of the NDO to this audit would create a serious safety risk to patients. This is because the audit is multifactorial, and covers accurate data collection on patients with epilepsy, including demographic and ethnicity factors, a checklist of services and advice that should be offered to qualifying patients, and a series of indicators about individual professional performance and Trust performance which are there to support high standards of care based on best practice evidence. The CAG stated that parents or patients who might have registered an NDO may be unaware that they will be excluded from this audit, and therefore may miss out on the range of services and advice that is prompted by the audit which could have safety implications for individual patients, for example water safety advice. The audit monitors both individual clinician performance and Trust performance which could become inaccurate with serious consequences of error in either direction, for example failure to recognise good performance or poor performance if the NDO is applied due to missing data.

Therefore Members were supportive of exempting the NDO regarding the non-research elements of the audit, due to the strong patient safety impact.

2. **Please provide a data flow diagram to show clearly where the NDO is currently being applied, in relation to which elements are pertinent to patient care.**

The applicants have provided a data flow diagram, merely stating the NDO is applied by Trusts before being submitted to the platform. There is no indication of the interaction this has with the timepoints patients are seeking clinical care. However this is better explained in the response paper, which explains that patients are typically registered onto the audit by EEG teams when a patient undergoes their first EEG, or patients can also be registered onto the platform directly by paediatric clinical teams. The Epilepsy12 methodology and guidance for participating Trusts indicate that a patient's NHS numbers should be screened against the NDO list by EEG or clinical teams before any of their data is entered onto the Epilepsy12 data platform. When completing first year of care forms for patients, clinical teams can still indicate an opt out at this stage if one is identified after registration. Data is then deleted from the audit. The CAG were content with this response.

3. **Please consider if it is possible for a consent option to be built in to the audit, which would override the NDO.**

The initial response to this query was misunderstood by the applicant, as their response focused on why it would not be appropriate to seek consent from every individual in Epilepsy12. The CAG accept that consent would not be feasible for the entirety of Epilepsy12, but were seeking clarification on whether consent could be used for the small subset of individuals who applied an NDO, in order to ensure they gained the correct clinical care. The CAG therefore sought further clarification on this response.

The Epilepsy12 team agreed that it would be possible to build targeted consent into the audit process, where consent for patient level data into Epilepsy12 could be sought specifically for those children and young people who have opted out via the NDO. However, given that consent may be declined or not achieved for other reasons, then the safety issues, although reduced would continue. The applicant reasoned that it would be difficult to ensure that consent is sought/achieved for all NDO patients. This pathway would also introduce bias and variation between services, as it creates confusion as to where the consenting responsibility lies. Additionally, this consent process would increase the burden experienced by clinical teams, and may lead to services withdrawing from the audit completely.

The CAG were content with this response, and agreed that this would add layers of burden to the NHS, and would add a considerable risk of system error. The CAG

considered it is easier and safer to allow the NDO exemption, without the complication of a consent mechanism. CAG is a strong supporter of using appropriate data flows to improve patient care, not to inhibit it, and therefore agree that a consent mechanism is not practicable in this case.

4. **Please provide further detail on planned communication strategy.**

CAG was originally provided with a communication strategy detailing how Epilepsy12 would inform Trusts/Health Boards, commissioners, patients and their families, and the public. This has now been updated to provide further information and was provided for review. The privacy notices will be updated, and the main communication routes of the NDO exemption are described in this document. The CAG were content with this response.

5. **Please provide evidence of discussions with patients and the public, surrounding the non-application of the National Data Opt-Out. Feedback from this activity needs to be provided to the CAG.**

The applicant confirmed that the Audits Team within the RCPCH has undertaken a number of engagement activities with children, young people, parents and carers. The Epilepsy12 project team has worked closely for a number of years with the Epilepsy12 Youth Advocates. These are a group of epilepsy experienced or interested children, young people and families who volunteer together to help shape Epilepsy12 and to lead their own aligned improvement activities with families and epilepsy services. At their most recent regular catch-up session in early November, the Epilepsy12 Youth Advocates were asked for their views on the National Data Opt Out (NDO) process. There was a consensus that Epilepsy12 data is a powerful tool used to improve services and quality of care, and should continue doing so as long as published data is anonymised and information around the audit, the NDO and how to withdraw from Epilepsy12 specifically is clearly communicated to patients and families. The CAG accepted this response.

**Confidentiality Advisory Group advice conclusion**

The CAG would like to note that the decision to overrule patient's wishes expressed through their enrolment in the NDO, is not taken lightly, and that the Group is only minded to do so in exceptional circumstances. The CAG recommendation is based on the documentation provided.

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

The following sets out the specific conditions of support.

1. This outcome confirms a change to the original conditions of support. The National Data Opt-Out is not to be applied to patients included in the activities specified in 17/CAG/0184

2. A local patient objection mechanism must continue to be used in relation to 17/CAG/0184

## 4. Annual Review Approvals

| | |
|---|---|
| 19/CAG/0190 | A prospective surveillance study of conservatively managed children with end-stage kidney disease in the United Kingdom and Republic of Ireland. |
| 21/CAG/0173 | Establishing the burden of vaccine preventable acute lower respiratory tract infections in primary care, UK: Avon-CAP GP2 |
| 17/CAG/0023 | National Bariatric Surgery Registry (NBSR) |
| 21/CAG/0154 | NHS Abdominal Aortic Aneurysm Screening Programme (NAAASP) |
| 17/CAG/0081 | UK Women's Cohort Study -HES |
| 17/CAG/0050 | Educational outcomes in children born after assisted reproductive technology; a population based linkage study |
| 16/CAG/0122 | Long-term follow-up of the Asymptomatic Carotid Surgery Trial (ACST-1) |
| ECC 8-02(FT5)/2010 | SABRE Study: Ethnic Differences in Cardiometabolic Risk |

| | |
|---|---|
| 18/CAG/0171 | Epidemiological studies of the Porton Down veterans |
| 21/CAG/0058 | Evaluation of Homeless Health Peer Advocacy: an analysis of secondary data |
| 19/CAG/0145 | Transfusion Medicine Epidemiology Review |
| 21/CAG/0113 | A comprehensive assessment of peri-prosthetic fractures associated with the CPT® stem in a large teaching hospital over 16 years |
| 19/CAG/0185 | Understanding Multidisciplinary approaches and Parental Input in perinatal mortality Review |
| 19/CAG/0127 | CRIS Linkage with the HIV and AIDS Reporting System |
| PIAG 4-06(c)/2006 | Long-term sequelae of radiation exposure from computed tomography in children and adolescents |

| Signed – Chair | Date |
| --- | --- |
| *Dr Tony Calland, MBE, CAG Chair, Dr Patrick Coyle, CAG Vice-Chair, Dr Murat Soncul & Ms Clare Sanderson, CAG Alternate Vice-Chairs* | *08 February 2023* |

| Signed – Confidentiality Advice Team | Date |
| --- | --- |
| *Ms Caroline Watchurst, HRA Confidentiality Advisor* | *01 February 2023* |