Health Research Authority

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

December 2021

1. New Applications

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

Name	Capacity
Dr Tony Calland MBE	CAG Chair
Dr Sandra Duggan	CAG member
Dr Liliane Field	CAG member
Mr. Myer Glickman OBE	CAG member
Mr Tony Kane	CAG member
Professor Jennifer Kurinczuk	CAG member
Dr Harvey Marcovitch	CAG member
Mr Andrew Melville	CAG member
Professor Sara Randall	CAG member

Mr Marc Taylor	CAG member
Ms Katy Cassidy	HRA Confidentiality Advisor
Ms Natasha Dunkley	HRA Head of Confidentiality Advice Service
Ms Emma Marshall	HRA Confidentiality Specialist
Dr Paul Mills	HRA Confidentiality Advice Service Manager
Mr Michael Pate	HRA Confidentiality Advisor
Ms Caroline Watchurst	HRA Confidentiality Advisor

Context

Purpose of application

This application from the University of Bristol set out the purpose of medical research to describe the incidence of acute lower-respiratory tract infection (aLRTI) in adults who present to primary care, and to estimate the proportion caused by vaccine preventable infections, including Streptococcus pneumoniae, Respiratory Syncytial Virus (RSV) and SARS-CoV-2.

Currently, accurate incidence rates of acute lower-respiratory tract disease (aLRTD) and its disease subsets, such as pneumonia and aLTRI in individuals presenting to primary care are unknown. The applicants seek to measure the true burden of acute respiratory disease due to these pathogens. The applicants will also undertake quality of life measurements to assess the cost-effectiveness of recommending vaccinations. This study will run alongside a sister study, Avon-CAP (Avon Community Acquired Pneumonia study), which is investigating incidence rates of adults hospitalised with community-acquired lower respiratory tract infection in Bristol. This new application will investigate the incidence rates of adults who present to primary care with chest infections. GP practices in Bristol have been selected in order to capture information for patients with different backgrounds, ethnicities and circumstances.

The study is comprised of two parts. A surveillance study will be undertaken in which routinely collected clinical data will be extracted from participating GP practices for patients who meet the eligibility criteria, and a sampling study, in which patients will be asked to complete an enrolment survey and symptom diaries, and provide naso-pharyngeal/oropharyngeal, saliva and urine samples. Participants will be consented into both parts of the study where possible, and the applicants anticipate that most study activities will be undertaken by the direct care team or with patient consent. If a health professional diagnoses an adult patient with an aLRTD, a prompt will appear advising that the patient is eligible for the study. The health professional will be prompted to outline the study, and seek consent for the patient to be sent a text message about the study. The research team will also follow-up with a phone call to explain more about the study. 's251' support is not required for this process.

Additionally, some patients will be offered an initial screening appointment with a research nurse or research practitioner, however they will have consented to this appointment offered by the direct care team in additional to usual clinical care, and 's251' support is not required for this method of identification.

A research nurse or research practitioner, who is not part of the direct care team, will additionally access patient records to screen patients for eligibility and approach for consent, in order to ensure all eligible patients are approached. 's251 support is required for this element'. An out of hours provider, Brisdoc, does not have capacity to screen for eligibility, and therefore the research staff at GP practices will also screen clinical out of hours letters each day at the GP practices, in order to identify eligible patients who were seen by Brisdoc.

Any patient who has passed away, or who the research team is unable to contact by phone, will not be offered the chance to consent, as it has not been possible. These patients will be included in the surveillance study using 's251'. These patients are not defined as non-responders, as they will not have been supplied information in the post regarding being asked for consent.

Data for the surveillance study will be processed and transferred to the University of Bristol central database on a monthly basis. Identifiable data fields will be removed from the database and transferred to a separate database with restricted access. Senior research staff will use this database to undertake any necessary analysis or processing, for example identifying individuals occurring more than once in the database. Pseudonymised data will then be transferred to a central University of Bristol database, which will therefore combine the pseudonymised data from each participating NHS Trust (AVON CAP). This pseudonymised data will be processed and analysed.

A recommendation for class 1, 2, 3, 4, 5 and 6 support was requested to cover access to the relevant unconsented activities as described in the application.

Confidential patient information requested

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

Cohort	Adults presenting to participating GP practices in Bristol (including out of hours provider Brisdoc) with acute lower respiratory tract disease, including pneumonia, lower respiratory tract infection and heart failure Maximum of 4000 patients, however 's251' support will not extend to those instances where the direct care team have screened and approached the patient.
Data sources	1. Electronic records, including out of hours discharge letters from participating GP practices, a. Courtside Surgery b. Tyntesfield Medical Group c. Concord Medical Centre d. Wellspring Surgery e. Montpellier Health Centre f. Pioneer Medical Group
Identifiers required for identifying eligibility, and approaching for consent purposes	1. Name 2. NHS number 3. GP registration 4. Date of birth 5. Date of death 6. Postcode – sector level 7. Phone number
Identifiers required for analysis purposes	1. pseudo ID 2. date of birth – modified for analysis (by University) 3. Date of death – modified for analysis (in NHS IT domain prior to University) 4. gender 5. Ethnicity 6. Sector level postcode – modified to deprivation score

	Therefore pseudonymous for analysis
Additional information	Confidential patient information will be retained in a surveillance database at University of Bristol, held separately from the pseudonymised database for analysis, linked to the pseudo ID. This includes NHS number, sector level postcode, and date of birth. Therefore 's251' support required for this element. Confidential patient information regarding the surveillance study will be sent monthly to University of Bristol from research nurses at participating GP practices

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 evidence of NHS Digital review of the 20/21 DSPT for NHS Bristol, North Somerset & South Gloucestershire CCG.**

The applicant provided NHS Digital email confirmation that this has now been reviewed.

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. Please provide clarification regarding what being 'logged and counted' means regarding patients who opted out. Is any confidential patient information recorded without consent, outside of the direct care team? Please provide a response within one month from the date of this letter.

2. Please provide a list of data items disclosed to Pfizer, within one month from the date of this letter.

3. Please provide updated posters, as per the guidance above, including the addition of 'GP', the Pfizer logo if appropriate, make the opt out option more prominent, and include the legal basis under common law to access the data. Please provide within one month from the date of this letter.

4. Favourable opinion from a Research Ethics Committee. **Confirmed 01 December 2021**

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

   The NHS Digital **20/21** DSPT review for **University of Bristol - Bristol Medical School (EE133799-BRMS)** was confirmed as '**Standards Met'** on the NHS Digital DSPT Tracker (checked 15 December 2021).

   The NHS Digital **20/21** DSPT review for **NHS Bristol, North Somerset & South Gloucestershire CCG** (to cover the 6 participating GPs) was confirmed as '**Standards Met'** by email to the CAG inbox (on 21 December 2021).

b. 21/CAG/0123 - RE-BLEED: A digital platform for identifying bleeding patients – a feasibility study

Name	**Capacity**
Ms Clare Sanderson	CAG Alternate Vice-Chair
Ms Sophie Brannan	CAG member
Mr Umar Sabat	CAG member
Mr David Evans	CAG member
Professor Jenny Kurinczuk	CAG member
Ms Kathleen Cassidy	Confidentiality Advisor

Context

Purpose of application

This application from the University of Oxford set out the purpose of medical research that seeks to test whether a digital platform can efficiently identify patients who have suffered a bleeding event, so that identified patients can be approached for consent to participate in trials of new treatments and blood tests.

Bleeding affects up to 40% of all trauma patients, up to 30% of all surgery patients, and is one of the commonest causes of death for women giving birth. The presentation and features of bleeding vary between patients. In some cases, bleeding is easily recognised but, in other cases, bleeding is harder to diagnose. Bleeding must be stopped promptly in order to prevent severe illness or death. Many studies have shown differences in how patients who bleed are treated. Some treatments are also more effective on some patients than others. Understanding how practice and patient characteristics affect outcome can aid in the design and testing of potential improvements in care. Patients in hospital have regular tests that measure levels of the different types of cells and clotting in their blood. For example, a drop in red blood cells can indicate that patients have suffered bleeding. More advanced blood tests are available that can provide more detailed information on why patients are bleeding and what treatments might be most effective, although these tests are not routinely performed in hospital.

The applicants will develop and test a real-time hospital-wide digital system to identify patients in hospital who have suffered from bleeding and whether this system could be used in future to identify patients suitable to take part into trials of new tests or treatments. Both retrospective and prospectively collected data will be used to identify patients in hospital with acquired bleeding. Retrospective data collected from patients admitted to one hospital over a ten-year period will be used to develop the algorithm. The algorithm will be refined using prospective data collected over a three-month period.

Participants who experienced bleeding will be identified from electronic patient records at Oxford University Hospitals NHS Trust. For the retrospective cohort, suitable patients will be identified from electronic patient records at Oxford University Hospitals NHS Trust as being admitted to, or attending the emergency department at, Oxford University Hospitals NHS Foundation Trust between 1/3/2011 and 1/3/2021. Approximately 1,750,000 patients will be included. These records will be used to construct a research database of patients who have likely experienced bleeding. Data for those who are screened but who are not identified as having experienced bleeding during their hospital admission will be deleted. A dataset, pseudonymised by applying

the study idea, will be transferred to the University of Oxford and used to develop the algorithm.

In the final three months of the study, the algorithm will be tested with a prospective cohort. Patients currently in hospital will be identified by the real time digital platform created using the data collected in the retrospective cohort. During the period the algorithm is running, it will digitally screen all new admissions to the hospital. It will retain all the data fields that were identified in the retrospective stage and listed in the protocol for the duration of that hospital admission. This is because bleeding can occur at any point during an admission and the aim is to capture bleeding in all its clinical manifestations. If bleeding has not occurred by the point of discharge or death, the records will be deleted. Only those that are identified as bleeding will be retained.

If a patient is identified as meeting the study criteria, members of the research team will liaise with the clinical care team. A member of the clinical care team will approach the patient and introduce a member of the research team, who will explain the study and seek consent. Should the patient consent, the Trust laboratory will be notified and advised that the patients blood sample needs to be retained until the end of the study. If a patient lacks capacity to consent, then a consultee opinion will be sought in line with the Mental Capacity Act.

A recommendation for class 1, 3, 4 and 6 support was requested to cover access to the relevant unconsented activities as described in the application.

Confidential patient information requested

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

Cohort	Retrospective cohort: Adults aged 16 – 110 years of age who were admitted to, or attended the emergency department at, Oxford University Hospitals NHS Foundation Trust between 1/3/2011 and 1/3/2021. Approximately 1,750,000 patients will be included. Prospective cohort: Adults aged 16-110 years of age who were admitted to, or attended the emergency department at, Oxford University Hospitals NHS Trust between 01/10/2021 – 01/02/2022. The data for 87,500

	patients will be screened in order to gain consent from 200 patients.
Data sources	2. Electronic patient records at Oxford University Hospitals NHS Trust
Identifiers required for linkage purposes	8. Name 9. NHS Number 10. Hospital ID number 11. Date of birth 12. Date of death 13. Postcode – unit level
Identifiers required for analysis purposes	7. Gender 8. Occupation 9. 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. **Provide clarification on why so many records needs to be accessed in order to identify a relatively small number of patients and a more accurate estimate of the number of patient records that would be accessed needs to be provided.**

The applicant clarified that the 1,837,500 records quoted in the application was the upper limit of admission records that will be accessed in the both the retrospective and prospective phases of the study.

The vast majority of records will be from the 10 years of retrospective hospital data. This pre-existing pseudonymised research dataset is controlled and maintained by the Oxford University Hospitals NHS Trust (OUHNHST). The OUHNHST will apply the exclusion criteria on the applicants' behalf prior to transfer of the data to the study team for analysis. This is expected to substantially reduce the size of the retrospective cohort. The most severe form of bleeding occurs roughly 200-400 times per year across OUHNHST. Ten years of data will capture sufficient numbers of events to enable us robust testing of the algorithm.

The applicant confirmed that support was not required for the retrospective cohort as the researchers will not have access to identifiable data.

The prospective phase will run for 3-6 months and the algorithm will screen all eligible adult admissions to hospital during that period. As bleeding can occur at any point during the admission, the figure quoted of 87,500 relates to the total anticipated number of adult admissions to the OUHNHST during the maximum 6-month period the study will run for. Data from admissions that do not include a bleeding episode will not be retained, so the final study dataset will only include those that have bled. This is expected to be a small fraction of the total number of admissions. The CAG noted this and raised no further queries.

2. **A poster needs to be created for display on appropriate wards. The poster should provide brief information about the study and contain links to other the further information online.**

The applicants provided a poster, which had been revised following consultation with the PPI Group. The CAG noted this and raised no further queries.

3. **Clarify whether patient records will be checked for expressions of dissent.**

The applicants explained that screening will be performed digitally by the algorithm. The NHS Opt-Out will be applied. The CAG noted this and raised no further queries.

4. **A project-specific dissent mechanism needs to be created and details given to the CAG.**

The applicants advised that a patient dissent section had been added to the protocol. The study team references and contact details had been revised across all documents to ensure that the details provided were consistent. The CAG noted this and raised no further queries.

5. **Further patient and public involvement needs to be undertaken. Promotion of this activity should mention the processing of confidential patient information. The activity should also include review of the patient notification documents.**

The applicants explained that a further PPI meeting had been held. A presentation was given, and a discussion centred around confidentiality took place. The patient facing documents were circulated and feedback from the PPI was incorporated into the revised documents. The CAG noted this and raised no further queries.

6. **Provide clarification on which identifiers will be retained for analysis.**

The applicant confirmed that no identifiers will be retained for analysis. The CAG noted this and raised no further queries.

7. **Confirm that the expert panel will not have access to confidential patient information.**

The applicants confirmed that the expert panel would not have access to confidential patient information. That had been clarified in the protocol.

8. **The statement in the patient notification about permission from the CAG needs to be revised to "Following advice from the CAG, the Decision Maker within the Health Research Authority agreed that support should be given under Regulation 5 of the Control of Patient Information (COPI) Regulations."**

The applicant provided a revised patient notification document. 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 15 November 2021.**

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 **2020/21** DSPT review for Oxford University Hospitals NHS Foundation Trust is confirmed (by check of the NHS Digital DSPT tracker on 15 September 2021)**.**

a. 21/CAG/0128 - Investigating the role of play experiences in paediatric hospital settings

Name	Capacity
Dr William Bernal	CAG Alternate Vice-Chair
Mr David Evans	CAG member
Professor Lorna Fraser	CAG member
Ms Kathleen Cassidy	Confidentiality Advisor

Context

Purpose of application

This application from the University of Cambridge set out the purpose of medical research that seeks to investigate the play provisions available in hospital settings, and explore the experiences and opinions of staff, children and families engaging in hospital play.

Paediatric patients with chronic or severe illness may spend significant portions of their children in hospital. The European Association for Children in Hospital (EACH) Charter stipulates that children have a full opportunity for recreation and play, suitable to their age and in an environment suitable to their needs. Access to provisions for play can vary widely between hospitals. In certain circumstances various healthcare professionals, including play or child life staff, nurses, physicians, surgeons, therapists, etc, may utilise play in their delivery of care, whether for children's physical, mental, or emotional health. Paediatric patients can partake in these more structured or designed playful opportunities, but will also engage in free, spontaneous play in the hospital. Previous research has shown that free, child-directed play, is positively associated with the physical, mental and emotional health of children. The applicants note the need to better understand the play provisions that exist in paediatric settings, including experiences and opinions on the role and value of hospital play.

The applicants will undertake ethnographic observations followed by semi-structed interviews with staff and patients, to explore perceptions and experiences of hospital play. A preparatory phase will be undertaken, in which the research team will meet with hospital stakeholders to determine the appropriate location and population for the study, and learn the hospital safety and safeguarding protocols. Phase 1 of the study will

consist of a 3-4 week ethnographic period, focusing on the observation of play experience and opportunities within the culture of the hospital ward. The researchers will tale detailed field notes around existing play provisions and the parameters by which play occurs. The study will be conducted on 1-2 paediatric wards. Appropriate wards will be determined in consultation with the hospital's clinical stakeholders.

In Phase 2, semi-structured interviews will be conducted with healthcare professionals to collect their experiences of engaging in and utilising play in their delivery of paediatric medical care. Interviews will also be held with young patients and their families.

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

Confidential patient information requested

Cohort	Patients aged 3 – 12 years of age who are inpatients in participating hospitals.
Data sources	1. Addenbrooke's Hospital, Cambridge University Hospitals NHS Foundation Trust The observations will take place at the above Trust, but no confidential patient information will be recorded.
Identifiers required for linkage purposes	No patient identifiers will be collected for linkage purposes.
Identifiers required for analysis purposes	No patient identifiers will be collected for analysis purposes.

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. **Provide further clarification on how instances where patients and carers disagreed over participation or observation will be handled.**

The applicants explained that they would follow the wishes of child participants wherever possible. Under no circumstances would a child be included in the study, either for observation or interview-based data collection, if they expressed that they did not want to participate.

If a child expresses interest in participating, but their caregiver disagrees or declines consent, the researcher will discuss that particular circumstance with the family's clinical care team as well as the research supervisory team, to determine whether it would be appropriate to have a follow up discussion with the caregiver. If so, a representative from the patient's clinical care team (and/or the researcher, if deemed appropriate) will reiterate the parameters and focus of the study, ways in which we protect and maintain confidentiality, and the child's interest in participating. If the caregiver still does not wish for their child to take part for any particular reason at that time, the applicants will respect the family's decision. All such instances will be handled on a case-by-case basis.

The CAG noted this information and raised no further queries.

2. **Patient and public involvement is to be carried out with children and carers specifically about researchers being present on the ward and the potential that they may over-hear sensitive information, and feedback provided to the CAG.**

The applicants provided feedback from the further patient and public involvement carried out. The CAG reviewed this information and raised no further queries.

3. **Any participant information documents revised in response to the REC need to be provided.**

The applicants provided the documents which had been revised following the REC review. The CAG noted these documents 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 24 November 2021.**

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 **2020/21** DSPT review for Addenbrooke's Hospital, Cambridge University Hospitals NHS Foundation Trust was confirmed as 'Standards Met' on the NHS Digital DSPT Tracker (21 September 2021).

2. New Amendments

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

Name	Capacity
Dr Tony Calland MBE	CAG Chair
Dr Patrick Coyle	CAG vice-chair
Ms Caroline Watchurst	HRA Confidentiality Advisor

Context

Amendment request

The applicant noted to the Confidentiality Advice Team (CAT), that the CAG non-research register entry for the Hip Fracture Audit lists the items of confidential patient information collected into the NHFD as NHS number, postcode, date of birth and date of death. The applicant stated that it appeared name was not included on the CAG register as an item of confidential patient information which they have support to collect. On reading the original application form, in section (i), name is not listed as required, whereas in a further section (m), it is listed. This was discussed with the Chair team and it was felt this could be resolved via amendment, to ensure clarity on the CAG register.

This amendment request also clarified that sex was collected. This is not a direct identifier alone, hence not being listed on the CAG register as an item of confidential patient information collected.

The amendment request also details a number of additional data items to the main dataset and the theatre dataset, however none of these additional data items and clarifications appear to be additional items of confidential patient information. The data collected includes Covid-19 status, however the amendment is to reduce the number of data items collected from 7 to 4. The clarifications requested to the Hip Fracture Audit are required in order to ensure the data capture is as accurate as possible.

Confidentiality Advisory Group advice

The amendment requested was considered by the Confidentiality Advisory Group Chair Team. The Chairs reviewed the information provided and was satisfied that the activity described was in the public interest, and that clarity surrounding support for the collection of name should be provided.

Confidentiality Advisory Group advice conclusion

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

Specific conditions of support

The following sets out the specific conditions of support.

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

The NHS Digital **20/21** DSPT reviews for **Royal College of Physicians, Crown Informatics University of Bristol - Bristol Medical School** were confirmed as 'Standards Met' on the NHS Digital DSPT Tracker (checked 1 December 2021)

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

Name	Capacity
Ms Caroline Watchurst	HRA Confidentiality Advisor

Context

Amendment request

In December 2018, the applicants were given support, via submission of an amendment, to include the National Audit of Inpatient Falls (NAIF) under the existing 's251 support' for the Hip Fracture Audit. The first phase of this new audit began in January 2019, and included a small dataset, completed by the falls team at participating trusts by retrospective case note review. The main aim of the first phase was to pilot the new audit process, which involved identifying the trust or heath board in which an inpatient fall occurred and ensuring that the falls team provided the relevant patient data. The second phase began in January 2020, and utilised a fuller dataset, collecting data on management prior to the facture-causing fall. Amendments to the dataset, in line with amendments submitted and given support for the National Hip Fracture Database (NHFD), were also made. Two amendments, making these changes, were submitted and given support in November 2019.

Updated data collection began in January 2021, after an amendment was supported on 27 November 2020 to reduce the dataset for NAIF, and to include an audit of both falls prevention activity prior to the hip or femoral fracture and the immediate post-fall care. The dataset collection questions were to be reviewed at the end of 2021 by the multidisciplinary advisory group for NAIF and a further amendment was to be submitted, if needed.

This amendment is to include 5 new questions into the dataset collected, from January 2022 , in order to increase data accuracy. The 5 new subset questions have been added to gather more detailed data on the location of falls, pre and post fall care processes. This data will continue to be a subsidiary dataset to the NHFD. This phase 3 dataset will include 34 questions in total (29 of the questions are the same

as those asked in the previously supported 2021 dataset and 5 are new subset questions). These changes will help to provide further details about falls, which will result in better data for clinicians to use to conduct quality improvement initiatives.

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

Confidentiality Advisory Group advice

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

Confidentiality Advisory Group advice conclusion

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

Specific conditions of support

The following sets out the specific conditions of support.

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

The NHS Digital **20/21** DSPT reviews for **Royal College of Physicians, Crown Informatics University of Bristol - Bristol Medical School** were confirmed as 'Standards Met' on the NHS Digital DSPT Tracker (checked 1 December 2021)

18/CAG/0146 – National Joint Registry (NJR)

Name	Capacity

Dr Tony Calland MBE	CAG Chair
Dr Patrick Coyle	CAG vice-chair
Ms Caroline Watchurst	HRA Confidentiality Advisor

Context

Amendment request

The National Joint Registry (NJR) collects data on all hip, knee, ankle, elbow and shoulder replacement operations carried out in NHS and independent sector hospitals and treatment centres in England and Wales from 1 April 2003 onwards. There is support in place to record confidential patient information in the NJR database when the consent status is 'unknown'.

Support is also in place to allow the flow of confidential patient identifiable information in relation to all patients with the relevant OPSC4 codes from NHS Digital and NHS Wales Informatics Service to Northgate Public Services in order to be able to identify procedures missing from the NJR dataset. This includes Hospital Episodes Statistics (HES), PROMs, Civil Registry (formerly ONS) and Patient Episode Database Wales (PEDW) data. Support under the Regulations is in place for all patients including those with a consent status of 'unknown' or 'no'. Linkage with the NJR database would then only be undertaken for those patients whose consent status was confirmed as 'yes' and 'unknown'.

Support under the Regulations also includes the disclosure of confidential patient information from the local PAS (Patient Administration Systems) at participating Trusts and Health Boards to Northgate Public Services as processor for the NJR, in relation to all patients who have undergone a specified joint replacement, to facilitate auditing of the data submitted to the NJR. Again, linkage with the NJR database would then only be undertaken for those patients whose consent status was confirmed as 'yes' and 'unknown'

An amendment supported on 18th September 2020, provided 's251' support to reverse the direction of flow for PROMs data only.

This amendment clarified that Northgate Public Services has now been renamed NEC Software Solutions (UK) Ltd (NECSWS), which constitutes a change of name only. This amendment also sought support to reverse the direction of flow for Hospital Episodes Statistics (HES), and Civil Registry mortality data (formerly ONS), so that name, NHS number, DOB, Gender and Postcode from within the NJR database and the corresponding unique NJR identifier would flow from

NECSWS (on behalf of the NJR) to NHS Digital. NHS Digital would then link the NJR records directly to HES and civil registry data at the patient level, remove the listed identifiers and send the data linked to NJR ID back to NECSWS. This flow would include date of death, and therefore would require 's251' support. Only patients with a consent status of 'yes' or 'unknown' would have identifiers sent from NJR to NHS Digital for linkage. NJR would not receive any HES or civil registration data regarding the patients with a consent status of 'no'. 's251' support under regulation 5 is not required for those that have consented into NJR, as this data flow is undertaken with consent as the legal basis under common law.

Flows for PEDW data would remain as described in the current support.

This amendment has been requested in order to Improve monitoring of patient outcomes and patient safety and the ability of the data collected to influence clinical practice.

Confidentiality Advisory Group advice

The amendment requested was considered by the Chair team. The Chairs were content to recommend support for this amendment. The Chairs commented that the change to the direction of data flows was a less disclosive method and noted this amendment will improve the quality of data available, and increase the number of joint replacements available for analysis.

Confidentiality Advisory Group advice conclusion

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

Specific conditions of support

The following sets out the specific conditions of support.

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

The NHS Digital **2020/21** DSPT review for **NEC Software Solutions (UK) Ltd** was confirmed as 'Standards Exceeded' on the NHS DSPT Tracker (checked 03 December 2021), and the NHS Digital **2020/21** DSPT review for **NHS Digital** was confirmed as 'Standards Met' on the NHS DSPT Tracker (checked 03 December 2021).

18/CAG/0131 – Inflammatory Bowel Disease Registry

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

Context

Amendment request

The national IBD Registry has support to process confidential patient information, in relation to all patients in the UK who had been diagnosed with inflammatory bowel disease (IBD). NHS Trusts currently upload confidential patient information via a web portal system, which is collected by NHS Digital. NHS Digital currently allocates an IBD registry number, and pseudonymises the data, as a Trusted third party. Pseudonymised data is then disclosed to the IBD registry, hosted at AIMES management service. 's251 support' is not required regarding consented patients.

This amendment request is to amend the data flows to enable NHS Trusts to upload confidential patient information via a web portal system, direct to the IBD Registry data management platform, hosted at AIMES, instead of to NHS Digital. AIMES will allocate the IBD Registry ID number and pseudonymise the data, before disclosing internally to a separate environment for analysis. This is to ensure data collected under 's251 support' can flow alongside the consented data to the applicants newly developed platform, so that the whole dataflow (consented + 's251') now goes to AIMES instead of to NHS Digital.

The key between the NHS Number and the IBD Registry Identifier will be retained indefinitely by AIMES. This will ensure that no duplication of data will occur if a patient later consents to the Registry. This will be stored within AIMES and tightly

controlled using Role Based Access Controls. This will ensure that no one undertaking analysis will have the capability of linking the two.

The applicant has reasoned there are multiple benefits of the amendment, including simplified and more consistent data handling for clinical teams, providing teams with the ability to send all their data (both consented and 's251') as one upload to the new platform, as opposed to having to separate out the 's251' data and the consented data to send to different platforms. The amendment will streamline processes and enhance data security, as there will be fewer transfers. The current model is hospital site-specific. This means a patient can be consented at one site, but another site could in theory be sending data under 's251' or a separate site-specific consent. The proposed change of dataflow will ensure that there is no mismatch of permissions between hospital sites.

The applicant has advised that any linkage to HES and ONS datasets can be undertaken, however this will not be done automatically. If applicants plan to undertake this linkage in the future, an amendment will be submitted to CAG.

The applicant has requested a dual dataflow for the 's251' data between December 2021 and April 2022 which allows both the previous dataflow and the new dataflow to function within this timeframe. This will allow the applicants to transfer hospital teams across to the new platform in a managed staggered manner. Therefore this amendment is to be implemented in addition to the original support until April 2022.

The applicant advised that the patient notification materials would be updated accordingly.

Confidentiality Advisory Group advice

The amendment requested was considered by Chairs Action. The Chair was content with the changes and explanation provided, and commented that the amendment seemed to be very sensible.

Confidentiality Advisory Group advice conclusion

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

Specific conditions of support

The following sets out the specific conditions of support.

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

The NHS Digital **20/21** DSPT reviews for **Civica - (previously CIMS), AIMES management service, IBD Registry Limited and NHS Digital** were confirmed as 'Standards Met' on the NHS Digital DSPT Tracker (checked 2 December 2021)

DHCW (previously NWIS) has a valid CPiP Outturn report.

15/CAG/0158 – The Fracture Liaison Service Database

Name	Capacity
Ms Caroline Watchurst	HRA Confidentiality Advisor

Context

Amendment request

This amendment sought support for minor clarifications to the main clinical dataset collected as part of the application. These are three clarifications such as inclusion of a new treatment drug as one of the data collection options, in order to ensure the data collected is accurate. The applicant clarified that no changes will be made to the number of items of confidential patient information collected, nor will there be any data items added or deleted, only additional or edited response options. There is additionally no change to data flows or any other change to confidential patient arrangements.

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 Secretary of State for Health and Social Care.

Specific conditions of support

The following sets out the specific conditions of support.

1. Confirmation provided from the IG Delivery Team at NHS Digital to the CAG that the relevant Data Security and Protection Toolkit (DSPT) submission(s) has achieved the 'Standards Met' threshold: **Confirmed:** The NHS Digital **20/21** DSPT reviews for **The Royal College of Physicians of London, Crown Informatics, and** were confirmed as **'Standards Exceeded'**, and **University of Bristol – Bristol Medical School** was confirmed as **'Standards Met'** on the NHS Digital DSPT Tracker (checked 07 December 2021).

19/CAG/0182 – National Joint Registry – Research Database

Name	Capacity
Dr Tony Calland MBE	CAG Chair
Dr Patrick Coyle	CAG vice-chair
Ms Caroline Watchurst	HRA Confidentiality Advisor

Context

Amendment request

This application has ‘s251’ support to allow the secondary use of data collected for audit purposes by the National Joint Registry (under reference 18/CAG/0146) for research purposes.

This amendment clarified that Northgate Public Services has now been renamed NEC Software Solutions (UK) Ltd (NECSWS), which constitutes a change of name only. This amendment also sought support to reverse the direction of flow for Patient Reported Outcome Measures (PROMs), Hospital Episodes Statistics (HES), and Civil Registry mortality data (formerly ONS), so that name, NHS number, DOB, Gender and Postcode from within the NJR database and the corresponding unique NJR identifier would flow from NECSWS (on behalf of the NJR) to NHS Digital. NHS Digital would then link the NJR records directly to HES and civil registry data at the patient level, remove the listed identifiers and send the data linked to NJR ID back to NECSWS. This flow would include date of death, and therefore would require ‘s251’ support. Only patients with a consent status of ‘yes’ or ‘unknown’ would have identifiers sent from NJR to NHS Digital for linkage. NJR would not receive any HES or civil registration data regarding the patients with a consent status of ‘no’. ‘s251’ support under regulation 5 is not required for those that have consented into NJR, as this data flow is undertaken with consent as the legal basis under common law.

Flows for PEDW data would remain as described in the current support.

This amendment is in parallel to amendments submitted to the non-research application (18/CAG/0146), reversing the flow for PROMS (18th September 2020), and for HES and civil registration data (submitted 07 October 2021).

This amendment has been requested in order to improve monitoring of patient outcomes and patient safety and the ability of the data collected to influence clinical practice.

Confidentiality Advisory Group advice

The amendment request was considered by the Chair team. The Chairs were content to recommend support for this amendment. The Chairs commented that the change to the direction of data flows was a less disclosive method and noted this amendment will improve the quality of data available, and increase the number of joint replacements available for analysis.

Confidentiality Advisory Group advice conclusion

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

Specific conditions of support

The following sets out the specific conditions of support.

1. Confirmation provided from the 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 **NEC Software Solutions (UK) Ltd** was confirmed as 'Standards Exceeded' on the NHS DSPT Tracker (checked 03 December 2021), and the NHS Digital **2020/21** DSPT review for **NHS Digital** was confirmed as 'Standards Met' on the NHS DSPT Tracker (checked 03 December 2021).

2. Confirmation of a favourable opinion from a Research Ethics Committee. **Confirmed 07 December 2021**

18/CAG/0091 – Connected Bradford Linked Education and Healthcare Research Database

Name	Capacity
Ms Caroline Watchurst	HRA Confidentiality Advisor

Context

Amendment request

This study from the Bradford Teaching Hospitals NHS Foundation Trust is for a research database aiming to understand the relationship between child health issues and educational attainment levels within the Bradford and Airedale locality. Support is currently in place to collect confidential patient information alongside clinical and educational data on all individuals within the Bradford and Airedale locality who were born between 01 January 1988 and 01 September 2016, and to continually update

the database with a new cohort of children each year, for 10 years. A previous amendment supported 16 December 2019 covers the process of geospatial data linkage.

This amendment is to clarify the process required to undertake the previously supported geospatial data linkage, as applicants have identified that they will require an additional data processor, in the form of a geospatial analyst based at UCL to support the geospatial data linkage.

Both Apollo and BTHFT will send confidential patient information to the UCL geospatial data analyst, who will then undertake linkage to environmental data and de-identify individuals before sending back to the Connected Bradford programme.

This amendment is required because applicants were unable to identify a geospatial data analyst from the Born in Bradford programme or from the local authority.

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 **20/21** DSPT review for **Bradford Teaching Hospitals NHS Foundation Trust (RAE)** was confirmed as 'Standards Met' (by check of the DSPT tracker 7 December 2021)

As there are 5 or more organisations, security assurance has not been checked by the Confidentiality Advice Team (CAT) for all data processors. Support is recommended on the basis that the applicant is

responsible for seeking assurance that the appropriate security arrangements are in place. The applicant should ensure that 20/21 DSPTs for the following organisations have been reviewed as 'standards met' by NHS Digital;

- **Bradford District Care Trust (Org Code: TAD)**
- **Airedale NHS Trust (Org Code: RCF)**
- **Apollo Medical Software Solutions Ltd. (Org Code: 8HH66)**
- **Department for Education**
- **City of Bradford Metropolitan District Council (Org Code: 209)**
- **Humber Teaching NHS Foundation Trust (Org Code: RV9)**

2. Confirmation of a favourable opinion from a Research Ethics Committee. **Confirmed 02 December 2021**

18/CAG/0015 – Improving diagnosis and management in dementia with Lewy bodies using the CPFT Research Database (CRATE)

Name	Capacity
Ms Caroline Watchurst	HRA Confidentiality Advisor

Context

Amendment request

This study from the University of Cambridge on behalf on the Cambridgeshire and Peterborough NHS Foundation Trust aims to improve the diagnosis and management of care for patients with dementia with Lewy Bodies. Using the Cambridgeshire and Peterborough NHS Foundation Trust (CPFT) Research Database (CRATE) the Lewy-CRATE project will identify a cohort dementia patients with Lewy bodies (DLB) cases and non-DLB disease dementia controls to allow a detailed examination of their characteristics and outcomes. Once the patient cohort has been identified, linkage will be undertaken with HES and ONS datasets held by NHS Digital.

This amendment is to extend the duration of support until 31 March 2024, in order for the applicant to retain full date of death whilst analysis is undertaken.

Confidentiality Advisory Group advice

The amendment requested was considered by the Confidentiality Advice Team. The Team raised no queries and were content to support 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**
   Cambridgeshire & Peterborough NHS Foundation Trust has confirmed 'Standards Met' on DSPT 2018/19 (by check of DSPT Tracker 18 May 2020).

2. Confirmation of a favourable opinion from a Research Ethics Committee
   Confirmed non substantial 12 November 2021

19/CAG/0053 – Myeloproliferative neoplasms Associated SplanChnic vein Thrombosis: Mascot Registry

Name	Capacity
Ms Caroline Watchurst	HRA Confidentiality Advisor

Context

Amendment request

This application has ‘s251’ support to allow the disclosure of specified confidential patient information from participating Trusts to Dendrite Clinical Systems Ltd for the purposes of establishing a research database of patients with Myeloproliferative neoplasms Associated SplanChnic vein Thrombosis (MPN-SVT). Support is currently in place until February 2022.

This amendment seeks to extend the duration of support until March 2023. This is due to difficulties in being able to recruit staff to undertake analysis, which is related to the pandemic

Confidentiality Advisory Group advice

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

Confidentiality Advisory Group advice conclusion

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

Specific conditions of support

The following sets out the specific conditions of support.

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

   The NHS Digital **20/21** DSPT review for **Dendrite Clinical Systems Ltd.** was confirmed as ‘**Standards Met’** on the NHS Digital DSPT Tracker (checked 13 December 2021)

2. Confirmation of a favourable opinion from a Research Ethics Committee. **Confirmed 03 December 2021**

ECC 1-05(b)/2012 - ALSPAC Study Young Adults: Enrolment and Consent for record linkage

Name	Capacity

Ms Caroline Watchurst	HRA Confidentiality Advisor
Dr Tony Calland MBE	CAG Chair
Dr Murat Soncul	CAG alternative vice-chair

Context

Amendment request

Background to the Amendment

The Avon Longitudinal Study of Parents and Children (ALSPAC) is a longitudinal birth cohort consisting of approximately 14,000 patients across three generations of study participant families. The initial study was operated on a consented basis; however, an application was submitted to the CAG to follow-up enrolled patients via administrative datasets with support under the Regulations. This follow-up sub-study was entitled 'the PEARL Study' and received a recommendation of support in August 2012.

The current recommendation of support relates only to the G1: Index Children. The recommendation of support extended to the follow-up of patients via various administrative datasets held by the then NHS Information Centre, a predecessor of NHS Digital. The current recommendation of support extended to the processing of NHS number, date of birth and GP registration to facilitate the linkage process. Only pseudonymised data which included a unique reference number (ALPSAC ID) for each individual was available to the applicant.

The scope of support provided under the Regulations was scrutinised by NHS Digital as part of the review of a data sharing agreement. It was confirmed in correspondence dated February 2016 that NHS Digital did not believe the historic application and subsequent recommendation of support provided sufficient granular detail of the items of confidential patient information that would be processed or the data sets and items with which this would be linked. This historic correspondence was reaffirmed in August 2018 by a member of the Data Access Request Service (DARS) team. The outcome of the assessment was the determination by NHS Digital that a legal basis had not been established to support the data processing and linkage which was currently requested.

The initial recommendation of support which was given for the PEARL Study did not extend to the linkage with sensitive data fields, including sexual and mental health information. A condition was added to the recommendation of support that projects which requested this data would be required to submit an individual application supported by a favourable opinion from an NHS REC for review by the CAG. To date,

five separate projects have been submitted and received a recommendation of support from the CAG as follows:

- CAG 7-06(a)/2013 – Accuracy of estimates for self-harm;
- 14/CAG/1032 – Association between IQ and self-harm;
- 15/CAG/0175 – Early life causes of depression and anxiety;
- 15/CAG/0176 – Predictors, prevalence and impact of chlamydia;
- 15/CAG/0177 – Substance use and mental health.

Purpose of Amendment

The amendment submission set out three proposed changes to the application. This outcome letter relates only to the following two requests:

1. To clarify the scope of the existing support which is in place under the Regulations, with regard to access to registry and personal demographic records held by NHS Digital. The request seeks to either confirm that the existing support extends to the linkage described or alternatively to request an extension to cover the items described in the amendment form. This included: birth register information, birth certificate information, marriage certificate information, death registration, cancer registration and detail from the NHS Personal Demographics Service.

2. To seek support to retain sensitive information which was collected under the five individually referenced applications, in order to repurpose this data for additional research purposes.

Confidentiality Advisory Group advice

The amendment requested was considered by the Confidentiality Advisory Group. The full discussion can be found in the provisional outcome letter. The applicant was asked to provide the following further information, before support could be provided.

1. **Confirm the status of the two linked applications: CAG 7-06(a)/2013 and 14/CAG/1032 and clarify whether the sensitive data items collated under these two references would be retained for ongoing research purposes.**

   The applicant responded to this on 3rd November 2021. Despite this being years after the provisional outcome was issued, the Chairs were content to review. The applicant explained that The ALSPAC data linkage team provides extracted datasets specific to each project to both CAG 7-06(a)/2013 and 14/CAG/1032. CAG annual reviews for both these projects are up to date. The applicant confirmed that these two datasets provided for these two projects will not be retained for ongoing

research purposes, but rather will be archived as permitted by the UK GDPR in cases of research, and will only be accessed if the projects are challenged or questioned. The chairs were content with this response.

As part of this response to provisional outcome it was clarified with the applicant that 's251' support is in place to retain derived variables for future use, which do not contain any confidential patient information. The Chairs were clear that retention of these variables is supported, however, new applications would be required if the applicant wishes to utilise the data for a different purpose.

2. **Confirmation of the REC's favourable ethical opinion for the amendment.**

The applicant provided this on 3rd November 2021. The CAT queried if the content of the REC amendment was that relevant to this CAG amendment, as the date of the REC letter was dated prior to the CAG outcome, which appeared to not have viewed the REC opinion. The applicant confirmed it was the relevant REC opinion.

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. Support relates to the index children (G1) of the original ALSPAC cohort only.

2. Support extends to the linkage and access to confidential patient information held within the registry datasets and personal demographics information cited in the amendment application. Support does not extend to those items/data sources that are not clearly confidential patient information. It is the responsibility of the applicant, together with NHS Digital, to determine which of the specific data items requested would fall within the legal definition set out in the NHS Act 2006. An alternative legal basis would need to be established for information which does not fall within the legal definition set out in the NHS Act 2006.

3. Support is extended to the retention of sensitive information collated under the wider application references to enable this information to be repurposed for wider research aims. Individual applications should be submitted to seek support under the Regulations for the use of this data for a wider research purpose.

4. Confirmation provided from the IG Delivery Team at NHS Digital to the CAG that the relevant Data Security and Protection Toolkit (DSPT) submission(s) has achieved the 'Standards Met' threshold: **Confirmed:** The NHS Digital **20/21** DSPT reviews for **University of Bristol**, **and University Hospitals Bristol and Weston NHS Foundation Trust** were confirmed as 'Standards Met' on the NHS Digital DSPT Tracker (checked 14 December 2021)

   The NHS Digital 20/21 DSPT review for North Bristol NHS Trust was confirmed as 'Qualified assurance – Trust has not achieved 95% staff undertaking security awareness training' on the NHS Digital DSPT Tracker (checked 14 December 2021**). Please note the updated specific condition of support. All staff at North Bristol NHS Trust that are involved in processing information under this application reference should have successfully completed local security awareness training before processing any information under support**.

5. Confirmation of a favourable opinion from a Research Ethics Committee. **Confirmed 31 August 2018**

16/CAG/0049 - National cohort study of late effects of Hodgkin lymphoma treatment

Name	Capacity
Kathleen Cassidy	HRA Confidentiality Advisor

Context

Amendment request

The applicants are seeking to change the data controller for the application from the Institute of Cancer Research (ICR) to the Royal Marsden Hospital NHS Foundation Trust. This change has been made due to the retirement of the previous Chief Investigator, Professor Anthony Swerdlow, who has been replaced by Professor David Cunningham, who is based at the Royal Marsden.

The confidential patient information collected will be transferred to the Royal Marsden from the ICR. Active recruitment to the trial has ceased, however should any follow-

up activity be undertaken, then data would flow to the Royal Marsden NHS Foundation Trust. The changes in the relevant infrastructure, security, governance, legal and other necessary requirements have been detailed in a revised application form. The applicant confirmed that no other changes to the purpose, data sources, data items and data flows have been made.

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 2020/21 DSPT review for Royal Marsden Hospital NHS Foundation Trust was confirmed as 'Standards Met' on the NHS Digital DSPT Tracker (checked 02 November 2021).

2. Confirmation of a favourable opinion from a Research Ethics Committee. **Confirmed: 27 October 2021.**

21/CAG/0017 – Outcomes of Patients who survived Treatment on an Intensive Care unit for COVID-19 in England and Wales: a retrospective cohort study: OPTIC-19

Name	Capacity

Ms Caroline Watchurst	HRA Confidentiality Advisor

Context

Amendment request

The applicants have existing support to allow the disclosure of confidential patient information from the Intensive Care National Audit and Research Centre (ICNARC) to NHS Digital, NWIS (now known as Digital Health and Care Wales), NICOR at Barts Health NHS Trust, SSNAP at King's College London and the UKRR at the Renal Association, for the purposes of time limited linkage with clinical datasets in order for pseudonymised linked datasets to be disclosed to the applicants at the University of Oxford, and for the return of full date of death from NHS Digital and NWIS to the University of Oxford.

In this amendment, the applicants are seeking support to extend the duration of 's251' support until 21 July 2022, in line with a recent funding extension.

Confidentiality Advisory Group advice

The amendment requested was considered by the Confidentiality Advice Team. The CAT 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: As there are more than 5 organisations processing confidential patient data these will not be individually checked by the CAT team, and it is the responsibility of the applicant to ensure the DSPTs for the following organisations have been assessed as 'standards met' by NHS Digital;**

- **University of Oxford**
- **ICNARC 8HN44**
- **NHS Digital**

- **NICOR (Barts Health NHS Trust)**
- **SSNAP King's College London - Sentinel Stroke National Audit Programme EE133874-SSNAP**
- **UKRR (The Renal association) 8HQ50**

- **A CPiP assessment is in place for DHCW (previously NWIS).**

2. Confirmation of a favourable opinion from a Research Ethics Committee.
   REC **Confirmed non-substantial 7 December 2021**

19/CAG/0220 – Linked de-identified research database for congenital anomaly outcomes

Name	Capacity
Ms Caroline Watchurst	HRA Confidentiality Advisor

Context

Amendment request

This study has support to allow the disclosure of confidential patient information from localised regional registers and Public Health England to St George's University of London and subsequent disclosures to NHS Digital.

This amendment sought support to extend the duration support required until 01 June 2023, as the applicant has experienced a number of delays outside of their control, including the pandemic. The applicant also confirmed that processing of confidential patient information without consent was now restricted to the applying organisation and NHS Digital, as the data processing undertaken by Public Health England and Department for Education has already been completed.

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 **20/21** DSPT review for **NHS Digital and St George's Medical School** were confirmed as '**Standards Met'** on the NHS Digital DSPT Tracker (checked 13 December 2021)

2. Confirmation of a favourable opinion from a Research Ethics Committee. **Confirmed 06 December 2021**

21/CAG/0054 – A cluster randomised controlled trial to assess the effectiveness and cost-effectiveness of the 'Your Care Needs You' intervention to improve safety and experience of care transitions.

Name	Capacity
Ms Caroline Watchurst	HRA Confidentiality Advisor

Context

Amendment request

This application has 's251' support to allow Trust employed Research Nurses at participating Trusts (who are not part of the direct care team) to use NHS number and date of birth to access medical records to check the actual discharge destinations of patients without their consent, in order to examine the impact of the 'Your Care Needs You' (YCNY) intervention on unplanned hospital readmissions for patients aged 75 years and over who are discharged to their own homes.

This amendment sought support to include Leeds Teaching Hospitals NHS Trust and South Tees Hospitals NHS Foundation Trust as participating sites. This is to enable the applicants to meet their recruitment target, of 40 wards and 5440 patients. They have

had difficulty recruiting 40 wards from the initial trusts included in the application, due to the 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 **20/21** DSPT reviews for **Leeds Teaching Hospitals NHS Trust and South Tees Hospitals NHS Foundation Trust** were confirmed as 'Standards Met' on the NHS Digital DSPT Tracker (checked 14 December 2021)

   Security assurances are additionally required for the 11 sites in the original application where the data extraction take place. Support will be based on confirmation that the DSPT at the site will be complied with. However, as this is more than 5 organisations, these will not be individually checked by the Confidentiality Advice Team, and it is the responsibility of the applicant to ensure that appropriate security assurances are in place.

2. Confirmation of a favourable opinion from a Research Ethics Committee.
   Confirmed non-substantial 11 November 2021

CAG 7-07(a)/2013 - Application for transfer of data from the HSCIC to commissioning organisation accredited safe heavens: inclusion of invoice validation as a purpose within CAG 2-03 (a)/2013

CAG 7-07(b)/2013 - Invoice validation within Clinical Commissioning Groups (CCGs) Controlled Environment for Finance (CEfF)

CAG 7-07(c)/2013 - Invoice validation within NHS England within the Commissioning Support Units Controlled Environment (for Finance) (CEfF) on behalf of Clinical Commissioning Groups

Name	Capacity
Ms Caroline Watchurst	HRA Confidentiality Advisor
Dr Paul Mills	HRA Confidentiality Advice Service Manager
Ms Natasha Dunkley	HRA Head of Confidentiality Advice Service
Dr Tony Calland MBE	CAG Chair

Context

Amendment request

In this amendment, the applicants requested to add the date of birth as an identifiable data item. The applicants stated that this is due to the close down of the National Health and Information Service (NHAIS) Batch Tracing system which previously enabled organisations to run activity reports against NHAIS in order to ensure that the correct patient details were matched in the data required for validating invoices. The new process provided by NHS Digital to support invoice validation uses the Personal Demographics Service, which needs more than the NHS number to trace on

Confidentiality Advisory Group advice

The amendment requested was considered by the Chair and Confidentiality Advice Team. The amendment set out the extra data item is required due to the closure of NHAIS and that by adding date of birth will allow the continuation of processing to

ensure that organisations receive the correct funding for the NHS services they provide and are contracted for. Invoice validation allows prompt payments to healthcare providers to be made and fulfils the commissioners' duties for fiscal probity and scrutiny.

The CAG advised that the importance of continuing support would provide a clear public benefit in terms of the management of health and care services.

Annual review

It was noted that an annual review was provided in September 2021. Please note that this letter also confirms that the annual review is satisfactory and that the register of supported applications will be updated to confirm this.

Security assurances – outstanding action

It is the policy position of the Department of Health and Social Care (DHSC) in England that all approved activities seeking support to process confidential patient information without consent must evidence satisfactory security assurances through completion and satisfactory review by NHS Digital of the relevant Data Security and Protection Toolkit (DSPT). In England, security is considered satisfactory once NHS Digital confirm (via internal tracker or direct email) that the relevant entity has achieved 'standards met' or 'standards met – improvement plan in place'. This process applies to all supported activities.

Following review of the information submitted in the amendment, at time of submission, and following recent review of NHS Digital's internal tracker, there are a significant number of entities that have not achieved the appropriate level of security assurances necessary to process confidential patient information under support. It is important to recognise that those entities that do not meet the standard security assurance level are not covered by the legal support as the conditions of support are not being met.

The CAG understands the importance of the activity proceeding, however noted that it is important for public confidence that those operating under support maintain an appropriate level of security assurance in line with all other supported application activities. An appendix is set out in this letter that lists those entities that currently do not have satisfactory security assurances in place, as intended to be covered by support. The applicant is advised to closely review and mobilise the relevant information governance teams to complete the submissions to enable NHS Digital to complete their review and provide confirmation to CAG.

CAG advised that, on an exceptional basis, a clear update report should be provided in 3 months from date of this letter, that demonstrates clear progression of the relevant entities to achieve the required security standard. The expectation would be that the vast majority will have submitted all relevant information to enable NHS

Digital to complete their DSPT reviews and confirm these as satisfactory. For any that remain a clear plan with timescales to manage their transition to the security standards would be necessary. It should be noted that a potential recommendation following the report will be that those that have not met the standards will be updated as not being included within support. The CAG therefore strongly encouraged NHS England to work with these entities to achieve this and avoid any future restriction of support. If there are any questions over this aspect, please do not hesitate to get in contact with the Confidentiality Advice Team.

Confidentiality Advisory Group advice conclusion

In line with the considerations above, the CAT agreed that the minimum criteria under the Regulations appeared to have been met for this amendment, and therefore advised recommending support to the Secretary of State for Health and Social Care to extend the duration for a further 24 months. However, this was subject to the applicants providing a detailed report on the security status of outstanding DSPT confirmations in line with the details of the Appendix.

Specific conditions of support

The following sets out the specific conditions of support.

1. Report to be provided in 3 months providing clear update status on entities that have not yet achieved satisfactory security assurances, with expectation the majority will have achieved the standards.

ECC 8-05(d)/2011 - BRIGHT LIGHT: Do specialist services for teenagers and young adults (TYA) with cancer add value?

Name	Capacity
Ms Caroline Watchurst	HRA Confidentiality Advisor
Ms Natasha Dunkley	HRA Head of Confidentiality Advice Service

Context

Amendment request

This amendment requests to extend the duration of support until 31st December 2022. This applies to the analysis of the BRIGHLIGHT study data at UCL/UCLH. This amendment request also seeks support to allow the disclosure of an anonymous dataset to Leeds Teaching Hospitals NHS Foundation Trust in order to include the data in the analysis of additional data as part of the STARS study. Data are being transferred to Leeds Teaching Hospitals NHS Foundation Trust where they will be processed by members of the STARS team, with oversight from Professor Dan Stark, Chief Investigator for the ESRC grant, and BRIGHTLIGHT co-applicant. Inclusion of the BRIGHLIGHT data into the STARS study provides a new opportunity to maximise the use of existing data, minimise research waste, maximise the use of the NIHR funding awarded to BRIGHTLIGHT and of the current ESRC-funded project, with the ultimate aim to improve outcomes for young people. This will be analysed until December 2023. An amendment is required, as despite the shared dataset being completely anonymous, the data was collected using 's251' support, and the onwards sharing was not described in the original application.

Confidentiality Advisory Group advice

The amendment requested was considered by the CAT, who raised no queries regarding the request. This amendment was initially discussed with the Head of the Confidentiality Advice Service, and the applicant provided correspondence from these communications, which provided agreement to manage these changes with an 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**

    - **University College London Hospitals NHS Foundation Trust and University College London – SLMS** have confirmed **'Standards Met' on DSPT 2020/21 (by check of DSPT Tracker 06 December 2021).**

2. Confirmation of a favourable opinion from a Research Ethics Committee
   Confirmed 16 December 2021

16/CAG/0049 - National cohort study of late effects of Hodgkin lymphoma treatment

Name	Capacity
Ms Kathleen Cassidy	Confidentiality Advisor

Context

Amendment request

The applicants are seeking to change the data controller for the application from the Institute of Cancer Research (ICR) to the Royal Marsden Hospital NHS Foundation Trust. This change has been made due to the retirement of the previous Chief Investigator, Professor Anthony Swerdlow, who has been replaced by Professor David Cunningham, who is based at the Royal Marsden.

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

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 2020/21 DSPT review for Royal Marsden Hospital NHS Foundation Trust was confirmed as 'Standards Met' on the NHS Digital DSPT Tracker (checked 02 November 2021).

2. Confirmation of a favourable opinion from a Research Ethics Committee. **Confirmed: 27 October 2021.**

18/CAG/0180 - LAUNCHES QI: Linking AUdit and National datasets in Congenital HEart Services for Quality Improvement.

Name	Capacity
Ms Kathleen Cassidy	Confidentiality Advisor

Context

Amendment request

This application has existing support to link to a number of national datasets for the purpose of medical research which aims to improve services for congenital heart disease and provide a template for other lifelong conditions.

In June 2021, an amendment to extend the duration of support to 20 April 2022 was given support. The applicants are now seeking to extend the duration of support to 08 October 2023.

The applicants have been given a costed extension from the Health Foundation to allow further time to complete the planned analyses.

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 Sciences, ICNARC, University of Leeds and Barts Health NHS Trust was confirmed as 'Standards Met' on the NHS Digital DSPT Tracker (checked 13 December 2021)

2. Confirmation of a favourable opinion from a Research Ethics Committee. **REC confirmation of a non-substantial amendment received 17 December 2021.**

3. Annual Review Approvals

19/CAG/0219	Epidemiology of Pancreatic Cancer Using Longitudinal Electronic Health Record Data

ECC 5-04(b)/2010	Do hormonal treatments for assisted reproduction increase risks of cancer or mortality in women? A national cohort study.
17/CAG/0176	UK-COMPASS
18/CAG/0168	Clinical outcomes of a PPS program undertaken in a large UK cohort
19/CAG/0053	Myeloproliferative neoplasms Associated Splanchnic vein thrombosis: Mascot registry
19/CAG/0166	HPS2-THRIVE trial legacy study: long-term follow-up of participants using electronic health records
19/CAG/0167	SEARCH trial legacy study: long-term follow-up of participants using electronic health records
19/CAG/0164	Investigation of gender mortality differences in children admitted to UK Paediatric Intensive Care Units
17/CAG/0189	Surveillance of Incidence of first-time diagnosis of Early Onset Depression in children aged 3-13 years the United Kingdom and Republic of Ireland (EOD-UK & ROI)
14/CAG/1012	NIHR Critical Care Health Informatics Collaborative
18/CAG/0171	Epidemiological studies of the Porton Down veterans
CAG 5-07(f)/2013	National Vascular Registry
20/CAG/0029	Incidence of Chronic Recurrent Multifocal Osteomyelitis (CRMO) in the United Kingdom (UK) and Republic of Ireland (ROI)
19/CAG/0198	Evaluation of an aid to diagnosis for congenital dysplasia of the hip in general practice: controlled trial randomised by practice
19/CAG/0195	STRETCHED: Strategies to Manage Emergency Ambulance Telephone Callers With

	Sustained High Needs - An Evaluation Using Linked Data
17/CAG/0107	WMUK Rory Morrison Registry
14/CAG/1020	NHS Bowel Cancer Screening Programme
19/CAG/0173	Critical illness related cardiac arrest (CIRCA): an investigation of the incidence and outcome of cardiac arrest within Intensive Care Units in the United Kingdom
20/CAG/0125	A population based study of genetic predisposition and gene-environment interactions in colorectal cancer
20/CAG/0126	A population based study of genetic predisposition and gene-environment interactions in (multi) cancer
18/CAG/0142	SEARCH:A population based study of genetic predisposition to breast, OVARIAN & endometrial cancer
19/CAG/0171	SEARCH:A population based study of genetic predisposition to BREAST, ovarian & endometrial cancer
19/CAG/0172	SEARCH:A population based study of genetic predisposition to breast, ovarian & ENDOMETRIAL cancer
20/CAG/0025	SUPER (Southampton cardiac surgery Unit Performance Evaluation and Review Project)
ECC 8-02(FT5)/2010	SABRE Study: Ethnic Differences in Cardiometabolic Risk
18/CAG/0071	Avoiding Cardiac Toxicity in lung cancer patients treated with curative-intent radiotherapy to improve survival
20/CAG/0139	2021 NHS Maternity Survey – Mixed Methods
18/CAG/0156	The Distribution of Highly Sensitive Troponin in the Critically Unwell and Associated Mortality

17/CAG/0150	National Perinatal Mortality Review Tool (PMRT)
14/CAG/1025	Death Notification of participants at HSCIC
18/CAG/0038	Yorkshire Lung Screening Trial
19/CAG/0190	A prospective surveillance study of conservatively managed children with end-stage kidney disease in the United Kingdom and Republic of Ireland
18/CAG/0153	The POOL study: Establishing the safety of waterbirth for mothers and babies: A cohort study with nested qualitative component.
20/CAG/0035	SINEPOST
18/CAG/0111	Detection Dementia from Retinal Morphology: a Big Data Machine Learning based Retrospective Case-Control Study
17/CAG/0152	Barts Health NHS Trust (NICOR) UK Transcatheter Aortic Valve Implantation (TAVI) Registry
16/CAG/0124	A study to investigate the association between selective uptake of cervical cancer screening and all-cause mortality
19/CAG/0149	Mammographic Predictors of Cancer Recurrence after Breast Conservation and Adjuvant Endocrine Therapy
20/CAG/0113	Heart Protection Study Long-term Follow-up: A randomised study of the effects on mortality and morbidity of HMG CoA reductase inhibitors and of antioxidant vitamins in a wide range of people at high risk of coronary heart disease
18/CAG/0015	Improving diagnosis and management in dementia with Lewy bodies using the CPFT Research Database (CRATE)
20/CAG/0145	2020 Children and Young People's Patient Experience Survey

18/CAG/0166	National Clinical Audit for Specialist Rehabilitation following major Injury (NCASRI)
20/CAG/0122	The Prognostic Performance of the Enhanced Liver Fibrosis Test in UK Patients with Chronic Liver Disease Assessed 20 Years After Recruitment to the EUROGOLF
20/CAG/0133	Yorkshire Specialist Register of Cancer in Children and Young People
CAG 7-07(a)/2013	Invoice validation
CAG 7-07(b)/2013	Invoice validation
CAG 7-07(c)/2013	Invoice validation
PIAG 1-08(b)/2003	Breast Test Wales (BTW) and Cervical Screening Wales (CSW)
CAG 6-06(b)/2014	Congenital Anomaly Register and Information Service for Wales (CARIS) including Rare Disease Registration
CAG 6-06(c)/2014	Wales Abdominal Aortic Aneurysm Screening Programme (WAAASP) Evaluation
PIAG 6-06(c)/2008	Evaluation of the HPV Vaccination programme and its impact on the cervical screening programme
PIAG 4-06(e)/2006	New Born Hearing Screening Wales (NBHSW) Evaluation
PIAG 2-05(g)/2008	Bowel Screening Wales
CAG 6-06(a)/2014	Welsh Cancer Intelligence and Surveillance Unit (WCISU), Public Health Wales NHS Trust
19/CAG/0176	All Wales Perinatal Survey (Historic data - 1993 to 2012)
18/CAG/0202	Emergency Medical Dispatcher recognition of maternity emergencies using the International Academy Medical Priority Dispatch System: a mixed methods study

20/CAG/0149	Yorkshire & Humberside Haematology Network Register
CAG 2-07(c)2013	The Pesticide Users' Health Study
19/CAG/0226	The SAFER Trial: Screening for Atrial Fibrillation with ECG to Reduce stroke – a randomised controlled trial

Signed – Chair

Date

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

07/02/2022

Signed – Confidentiality Advice Team

Date

07/02/2022

KM Cassidy