Health Research Authority

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

July 2020

1. New Applications

a. 20/CAG/0007 - Professional work in austere healthcare in the UK- the case of physiotherapy

Name	Capacity
Dr Patrick Coyle	CAG Vice-Chair
Dr Lorna Fraser	CAG Member
Mr Myer Glickman	CAG Member
Ms Kathleen Cassidy	HRA Confidentiality Advisor

Context

Purpose of application

This application from the University of Nottingham set out the purpose of medical research that seeks to investigate how the physiotherapy healthcare profession, as a healthcare profession outside of medicine and nursing, responds to austerity measures and financial pressures in the National Health Service in the UK.

After the 2008 global financial crisis, widespread austerity measures were imposed across the public sector, including the NHS, in the UK. Research has been conducted in examining how medicine and nursing have adapted to austerity measures and financial pressures, but very little research has been done outside of these professions. The applicants had selected the physiotherapy profession to examine in this study in order to assess how different professions, which may have different resources, skills and abilities, respond to the challenges that austerity measures can provide.

This is a single centre, organisational, ethnographical study. The researcher will observe the practices within a physiotherapy department within an NHS organisation for 4-6 months. Physiotherapists will be observed in their normal working day and may also discuss their working life with the researcher. The physiotherapist may also be invited to take part in an interview, where they will be asked questions about their experience of working in the NHS during times of financial pressure. The researcher will not observe direct contact with patients, services users or relatives. Physiotherapists will be observed during team meetings, handover, interactions between members of the physiotherapy team, for example during prioritisation of caseload and allocation of workload, general presence in clinical areas and staff breaks. The observations will take place onsite at Nottingham University Hospitals NHS Trust in both inpatient and outpatient departments. This may include observations on general medical wards, specialist departments such as burns and plastics and musculoskeletal outpatients. The researcher may be exposed to confidential patient information during these observations and support under Section 251 and its Regulations is sought to cover these incidental disclosures.

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

Confidential patient information requested

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

Cohort	The participants are 50 physiotherapists, recruited from Nottingham University Hospitals NHS Trust. No patients will be recruited into the research.

Data sources	No confidential patient information will be collected
Identifiers required for linkage purposes	No items of confidential patient information are required for data linkage purposes.
Identifiers required for analysis purposes	No items of confidential patient information are required for analysis purposes.

Confidentiality Advisory Group advice

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

1. **The poster is to be revised as follows;**

    a. **A phone number is to be provided in addition to the email contact.**

    b. **The poster needs to mention the observation of staff meetings and professional conversations. The poster also needs to specifically state that information about individual patients will not be recorded**

    c. **The academic supervisor's name needs to be included.**

A revised poster was provided. This was reviewed by the CAG and no further queries were raised.

2. **Clarify that the lawful basis relied on for the processing of personal data is: Article 6(1)(e) Processing is necessary for the performance of a task carried out in the public interest or in the exercise of official authority vested in the controller.**

The applicant confirmed that the lawful basis relied on for the processing of personal data is Article 6 (1) (e) Processing is necessary for the performance of a task carried out in the public interest or in the exercise of official authority vested in the controller.

3. **Clarify that the lawful basis relied on for the processing of special category data is Article (9)(2)(j) Processing is necessary for scientific research purposes in accordance with Article 89(1).**

The applicant confirmed that the lawful basis relied on for the processing of special category data is Article (9) (2) (j) Processing is necessary for scientific research purposes in accordance with Article 89(1).

Confidentiality Advisory Group advice conclusion

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

Specific conditions of support

1. Favourable opinion from a Research Ethics Committee. **Confirmed 14 January 2020.**

2. Confirmation provided from the IG Delivery Team at NHS Digital to the CAG that the relevant Data Security and Protection Toolkit (DSPT) submission(s) has achieved the 'Standards Met' threshold. See section below titled 'security assurance requirements' for further information. **Confirmed: Nottingham University Hospitals NHS Trust - NHS Digital have confirmed qualified assurance against the organisation's 2018/19 DSPT submission on the basis that the Trust has not met the 95% standard relating to staff security awareness training.**

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

b. 20/CAG/0011 - An exploratory descriptive analysis of the 5-year survivorship of total ankle replacements compared with equivalent rates in administrative datasets with further adjusting for co-varieties

Name	Capacity
Dr Malcolm Booth	CAG Member
Mr. Myer Glickman	CAG Member
Mr Tony Kane	CAG Member
Dr Murat Soncul	CAG Alternative Vice-Chair
Ms Gillian Wells	CAG Member
Ms Kathleen Cassidy	HRA Confidentiality Advisor

Context

Purpose of application

This application from the Royal Devon and Exeter NHS Foundation Trust set out the purpose of a service evaluation to determine the 5-year survivorship of total ankle replacements.

Over 650 total ankle replacements (TAR) are recorded in the National Joint Registry each year. There have been varying results reported with these implants, and considerable research is ongoing in assessing long term outcomes of these replacements and comparing total ankle replacements with ankle arthrodesis. A previous systematic review on long term outcomes of ankle replacements found that TAR had a positive impact on patients' lives, but was unable to make strong conclusions as previous studies have been small and of poor quality.

This service evaluation aims to determine the failure rate of ankle replacements. A failure is determined as revision, arthrodesis or amputation. This will enable further information to be to be given to patients in the consenting process, and inform surgeons of the likely outcomes for these patients. It will also determine risk factors for ankle replacement failures.

The NJR will disclose confidential patient information to NHSD to facilitate linkage with HES/ONS. The linked, anonymised dataset will be returned to the applicant for analysis.

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.

Cohort	Patients who underwent ankle replacement surgery in the UK that are recorded on the NJR between 01/01/2010 and 31/12/2018. The applicants estimate that 5,500 patients will be included.
Data sources	1. National Joint Registry 2. HES/ONS data held by NHS Digital
Identifiers required for linkage purposes	1. Individual anonymised number 2. Age 3. Sex 4. Date of admission 5. Indication for primary procedure, previous infection, previous fracture, previous surgery, ankle ROM, associated procedure, side 6. ASA grade: 7. Implant data/ brand / manufacturer: 8. Revision codes 9. Below knee amputation 10. Site code for the ankle joint combined with fusion codes 11. 30 day and 1-year mortality
Identifiers required for analysis purposes	1. Individual anonymised number 2. Age 3. Sex

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. **A stronger justification for why patients cannot be re-contacted for consent to this further use of their data needs to be provided.**

The applicant explained that the National Joint Registry (NJR) contains the data of around 3 million patients spanning a period of 17 years. The NJR routinely runs data against NHS Digital data for other purposes, including NHS Digital tracing services, so postal addresses are available for the majority of patients, however there were a number of reasons why contacting those patients to consent to this study is infeasible. A large number of applicants may have died, left the UK or be otherwise untraceable. The applicants also did not have the resources to trace the number of patients involved. The applicants also noted that multiple contacts may be required within each patient. As complete a dataset as possible was required, in order to calculate the true failure rates of ankle replacements. Further information had been included on the NJR website about how the data that the patients consent for is used including 'Operation and patient information in the NJR is used to link to other healthcare information, including data held by NHS Digital and the NHS Wales Informatics Service'. The Group noted the information provided and raised no further queries.

2. **The patient information leaflet on the website needs to be amended to include information on how patients can opt-out.**

The applicant provided a link to the online patient information sheet, which had been revised to include opt-out information. The CAG noted this revised document and raised no further queries.

Confidentiality Advisory Group advice conclusion

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

Specific conditions of support

1. Further patient and public involvement and engagement needs to be carried out. Feedback from this is to be provided in the first annual review for the project.

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. **It was confirmed that the relevant DSPT submission related only to NHS Digital.**

c. 20/CAG/0055 - Can clinical and biochemical variables be used innovatively to improve risk modelling of mortality in patients undergoing emergency abdominal surgery?

Name	Capacity
Dr William Bernal	CAG Alternative Vice-Chair
Dr Malcolm Booth	CAG Member
Mr Tony Kane	CAG Member
Ms Kathleen Cassidy	HRA Confidentiality Advisor

Context

Purpose of application

This application from the Portsmouth Hospitals NHS Foundation Trust set out the purpose of medical research that seeks to investigate and test innovative ways of using clinical data and blood tests to predict the risk of death for patients who undergo emergency abdominal surgery.

Emergency abdominal surgeries are performed to treat bowel emergencies, such as a bowel blockage or perforation. This is a high-risk surgery for many patients and has a mortality rate of 10%. Risk models are routinely used within the NHS to predict a patient's risk of death prior to carrying out the laparotomy. This information can then be used by clinicians to help discuss the risks of surgery with patients and plan their care before and after surgery. The applicants plan to investigate and test ways of using clinical data and blood tests to improve the accuracy of models used to predict the risk of death for patients who undergo emergency

laparotomy. The applicants plan to use the results of this study to guide the development of a larger, multi-site study.

The applicants seek support to process confidential patient information for patients who underwent emergency laparotomy at Queen Alexandra Hospital from December 2013 onwards. Data for these patients was entered into the National Emergency Laparotomy Audit (NELA) database. The student researcher, who is not a member of the direct care team, will extract the confidential patient information from the NELA database. The NELA database for Queen Alexandra Hospital is stored on Portsmouth Hospital NHS Trust servers. The patient's NHS or Medical Records Number (MRN) will be used to extract clinical and biochemical data from electronic hospital records into datasets. Logistic regression analysis and other classification algorithms will be used to assess the predictive value of novel variables.

A recommendation for class 1, 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	Patients aged 16 years and over who have had an emergency laparotomy for an intestinal emergency at Queen Alexandra Hospital from December 2013 onwards. The applicants anticipate that 2000 patients will be included.
Data sources	1. The National Emergency Laparotomy Audit (NELA) database within Portsmouth Hospitals NHS Trust 2. Electronic patient records within Portsmouth Hospitals NHS Trust

Identifiers required for linkage purposes	1. Name 2. NHS Number 3. Date of birth 4. Date of death 5. Postcode
Identifiers required for analysis purposes	1. Date of death

Confidentiality Advisory Group advice

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

1. **Clarify whether any researchers outside of the direct care team, other than the applicant and named Trust data manager, will process confidential patient information for this application. If other researchers will access confidential patient information, please provide a justification for this and clarify their employment status within the Trust.**

The applicant confirmed that only Dr Alex Darbyshire and PHT Data Manager would have access to and process confidential patient information. The CAG noted this clarification and raised no further queries.

2. **The start and end dates for inclusion in the study need to be clarified.**

The applicant confirmed that the start date for the study is 1st of December 2013 and the end date is 31st of January 2020. The CAG noted this clarification and raised no further queries.

3. **Clarify whether any patients will be recruited prospectively. If so, justification needs to be given as to why consent cannot be sought from these patients.**

The applicant confirmed that no patients will be prospectively recruited. The CAG noted this clarification and raised no further queries.

4. **Provide clarification on whether patients' date of death would be converted to age death or days following laparotomy as a numeric value, and when this would be done.**

The applicants advised that patients' date of death would be retained in the dataset. The date could not be converted into a numeric value as it was needed to perform seasonal data analysis so that mortality can be modelled over different time frames and in reference to changes in organisation structure and also national outcomes from NELA.

The applicants explained that disguising the date of death may be problematic to perform as all other dates related to the episode will also need to be disguised, which may cause problems during analysis in that it cannot be related to other time dependent events or organisational factors. Changing dates may also cause confusion during data analysis and increase risk of errors. The CAG noted this information and raised no further queries.

5. **The poster, designed to promote the study, needs to be submitted to the CAG for review.**

The study poster was provided for review. The Group reviewed the poster and asked that it was revised to include a telephone number and email address, in order to provide a local dissent mechanism, in addition to the National Data Opt-Out. A revised poster was submitted. This was considered by the CAG, who raised no further queries.

6. **A local dissent mechanism needs to be created.**

The applicants explained that the National Data Opt-Out would be implemented. Once the NELA audit data has been extracted, the PHT data manager will validate and clean the NELA audit data against PAS (patient administration system) patients and hospital admissions. The list of cleaned and validated NHS numbers (from the NELA database) will then have the National Data Opt-Out screening applied to produce the final study cohort, prior to data extraction. The national data opt out is applied by linking with NHS Digital using a MESH Client. The CAG noted this information and raised no further queries.

7. **Further information is required to demonstrate how the following GDPR Principles will be met.**

    a. **Principle a: information processed lawfully, fairly and transparently with basis for processing special category data listed.**

The lawful basis for using this personal data is to undertake a research study to develop new risk modelling strategies to try and improve pre-operative prediction of mortality for emergency abdominal surgery. Personal data is required to identify patients who have had emergency abdominal surgery to be included in the study. The processing of this data is fair and should not affect individuals concerned.

b. Principle b: information collected for specified, explicit and legitimate purposes

The study is using personal data for a specified and legitimate reason. Without the personal data from the NELA database we would be unable to identify patients for the study, and thus unable to complete it. The use of personal data in this study should not affect the individuals concerned. Reasonable measures to inform the relevant population of the study and its use of data have been taken, in form of poster to be displayed in relevant parts of the hospital, and also on the research department's website.

c. The controller shall be responsible for the handling of personal data in accordance with the principles ('accountability principle)

The applicant and PHT data manager are both employees of PHT and subject to their Information Governance and Data Protection procedures (attached). The educational supervisors from UoP are both employees of UoP and subject to their Data Protection Policies (attached). The Data Protection policies for both institutions are fully compliant with GDPR principles and all individuals are accountable to their respective institutions policy. A data protection impact assessment will be completed once the study has full REC/CAG approval and thus able to proceed. An Information Sharing Agreement between PHT and UoP will then be formalised; a draft template is attached. The CAG noted the above information and raised no further queries.

Confidentiality Advisory Group advice conclusion

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

Specific conditions of support

1. Favourable opinion from a Research Ethics Committee. **Confirmed 30 April 2020.**

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

• Confirmed – Portsmouth Hospitals NHS Trust has a confirmed 'Standards Met' grade on DSPT submission 2018/19 by a check of the NHS Digital tracker on 20 May 2020.

d. 20/CAG/0021 - Breast Reconstruction: InvestigatinG long-term clinical and cost-effectiveness in tHe National MasTectomyand BrEast Reconstruction Audit cohort

Name	Capacity
Dr Patrick Coyle	CAG Vice-Chair
Mr David Evans	CAG Member
Dr Katie Harron	CAG Member
Ms Kathleen Cassidy	HRA Confidentiality Advisor

Context

Purpose of application

This application from the University of Bristol set out the purpose of medical research that seeks to compare long-term clinical and cost-effectiveness of implant based and autologous breast reconstruction to help patients, health professionals and commissioners make more informed decisions about reconstructive breast surgery.

The majority of the 55,000 women diagnosed with breast cancer each year will be long-term cancer survivors but up to 40% will still require a mastectomy. Breast reconstruction is routinely taken in order to improve quality of life for patients. Decision-making for breast reconstruction is complex. Reconstruction can be performed using implants or the patient's own tissue from the back, abdomen or buttocks either at the time of mastectomy or at a later date, often after necessary cancer treatments have been completed. Each technique has different short-term risks and benefits, such as the duration of recovery, number and position

of scars and surgical complications. Patients and surgeons need to balance these factors against the long-term outcomes of different procedures to make fully informed decisions about surgery. There is currently a shortage of evidence for patients and surgeons on which method of breast reconstruction after a mastectomy may be the best for patients in the long term. There is some evidence on the risks and benefits for each method of reconstruction during the next few years after the operation, but there is little evidence yet to say how patients will fare in the years further into the future.

The applicants will seek views from women who have undergone a mastectomy with and without breast reconstruction 10 years ago. Patients who underwent a mastectomy for breast cancer or a delayed breast reconstruction following a previous breast cancer diagnosis in an NHS setting between 1 January 2008 and 31 March 2009 will be identified within HES and data for this cohort extracted up until 31 March 2019. An up to date list of contact details for surviving patients will then be provided from National Cancer Registration and Analysis Service (NCRAS) via PHE. The research team at the University of Bristol will then contact the patients to invite them to complete questionnaires about their experience. Their involvement will then proceed on a consented basis.

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	Patients who underwent a mastectomy for breast cancer or a delayed breast reconstruction following a previous breast cancer diagnosis in an NHS setting between 1 January 2008 and 31 March 2009. The applicants expect that 16212 patients will be included.
Data sources	1. HES and NCRAS data held by Public Health England

Identifiers required for linkage purposes	1. Name 2. NHS number 3. Postcode – unit level
Identifiers required for analysis purposes	3. Date of birth 4. Region of NHS care provider 5. Ethnicity

Confidentiality Advisory Group advice

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

1. **The patient facing information documents need to be amended to explain that support under s251 is required to access HES data, should the patient not respond to the information leaflet opportunity to object.**

An amended patient information leaflet, invitation letter and website text were provided, revised in line with the above request. These were reviewed by the CAG and the changes made were accepted.

2. **Patients are to be given a month after receiving the patient information to respond to the applicants in order to register dissent.**

An amended protocol, patient information leaflet, invitation letter and website text were provided, revised in line with the above request. These were reviewed by the CAG and the changes made were accepted.

3. **The applicants' email address, telephone number and postal address were included in the website text in the paragraph describing dissent.**

The amended website text was provided, revised in line with the above request. This was reviewed by the CAG and the changes made were accepted.

Confidentiality Advisory Group advice conclusion

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

Specific conditions of support

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

2. Confirmation provided from the IG Delivery Team at NHS Digital to the CAG that the relevant Data Security and Protection Toolkit (DSPT) submission(s) has achieved the 'Standards Met' threshold. See section below titled 'security assurance requirements' for further information. **(Confirmed: University of Bristol – Bristol Medical School (by NHS Digital email dated 17 December 2019), Public Health England (by NHS Digital email dated 02 September 2019) and NHS Digital (by NHS Digital email dated 10 June 2019) have confirmed 'Standards Met' grade on DSPT 2018/19).**

e. 19/CAG/0192 - IgG4-related Orbital Disease (IgG4-ROD): A Surveillance Study

Name	Capacity
Ms Clare Sanderson	CAG Alternative Vice-Chair
Dr Simon Kolstoe	CAG Member
Mr Tony Kane	CAG Member
Ms Kathleen Cassidy	HRA Confidentiality Advisor

Context

Purpose of application

This application from University Hospitals Bristol NHS Foundation Trust set out the purpose of medical research which aims to establish the incidence, case mix management of probable or definite orbital IgG4-related disease. The study will follow the established British

Ophthalmologist Surveillance Unit (BOSU) methodology, using the monthly reporting card amongst UK ophthalmologists.

The BOSU methodology is established and has received support in principle from the CAG. Ophthalmologists will indicate that they have seen a new of probable or definite orbital IgG4-related disease case through the BOSU. The BOSU collects no patient identifying information but will notify the study investigator of all ophthalmologists who report new cases. The researcher will then contact the reporting ophthalmologist directly and will be sent a questionnaire requesting information to determine the incidence, but also secondary aims of histological subtype, the treatment given, prognosis and the effect on vision. The primary questionnaire will be completed at the point of notification with follow-up at 12 months.

The aim of the project is to identify factors that might lead to an increased risk of severe, or relapsing disease, and whether there are any links between the orbital and systemic forms of the disease, in order to inform risk assessment and management of patients in the future. The applicants anticipate that the study would also help to raise awareness of a relatively newly recognised disorder, which may previously have been labelled as 'idiopathic orbital inflammatory disease' so that this subset of patients can be appropriately identified and managed.

A recommendation for class 1, 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	Any patient presenting to a participating ophthalmologist with probable or definite IgG4-related orbital disease. It is anticipated that this will include 60-75 patients in the 12-month reporting period.
Data sources	1. Patient medical records, Hospital Eye Units in England and Wales

Identifiers required for linkage purposes	1. Hospital ID 2. Month and year of birth
Identifiers required for analysis purposes	1. Sex 2. Ethnicity

Confidentiality Advisory Group advice

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

1. **Provide a copy of the patient-facing information sheet.**

The patient-facing information sheet was submitted. This was reviewed by the Sub-Committee who raised no further queries.

2. **Revise the follow-up questionnaire to replace patient date of birth with month and year of birth.**

A revised follow-up questionnaire was provided. This was reviewed by the Sub-Committee who raised no further queries.

Confidentiality Advisory Group advice conclusion

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

Specific conditions of support

1. Favourable opinion from a Research Ethics Committee. **Confirmed 26 September 2019**

2. Confirmation provided from the IG Delivery Team at NHS Digital to the CAG that the relevant Data Security and Protection Toolkit (DSPT) submission(s) has achieved the 'Standards Met' threshold. See section below titled 'security assurance requirements' for further information. **(Confirmed: University Hospitals Bristol NHS Foundation Trust (by NHS Digital email dated 06 July 2020) has confirmed 'Standards Met' grade on DSPT 2018/19).**

f. 20/CAG/0072 - How effective and cost-effective is water fluoridation for adults? A 10-year retrospective cohort study

Name	Capacity
Dr Martin Andrew	CAG Member
Ms Sophie Brannan	CAG Member
Dr Patrick Coyle	CAG Vice-Chair
Mr Myer Glickman	CAG Member
Ms Kathleen Cassidy	HRA Confidentiality Advisor

Context

Purpose of application

This application from the University of Manchester set out the purpose of medical research that seeks to determine whether water fluoridation for adults is affects the invasive dental treatments received by adults attending NHS dental practices, and whether water fluoridation is cost-effective.

Tooth decay is common and is costly both to the NHS and patients. The NHS currently spends £3.4 billion on NHS dental services, and patients pay another £653 million in patient charges. The majority of these costs are spent on the treatment of tooth decay and its consequences. Fluoride has been added to some public water supplies since the 1940's and has been added to toothpastes since the 1970's. In America and Australia, fluoride is added to almost all public water supplies, while 10% of water supplies in England contain fluoride. It is the decision of

Local Councils whether fluoride should be added to the water supply and currently little modern research has been carried out that supports the benefit of water fluoridation.

The applicants are seeking support to process confidential patient information collected in NHS dental practice records in order to understand the impact of water fluoridation on adults. The number and type of dental treatments provided to approximately 6 million people living in fluoridated or non- fluoridated areas over a ten-year period will be compared. Anonymised, patient-level dental data will be provided from the NHS Business Services Authority to the research team at the University of Manchester. Patients in fluoridated or non- fluoridated areas will be 'matched' so that patients can be compared to other patients who as similar as possible.

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.

Cohort	Six million patients who attended a dental practice within England at least twice between 2010 and 2020. Patients will have been aged 12 years and over at the start of the time period. The applicants anticipate that twenty million patient records will be included in the transfer to anonymised patient records from NHS BSA to the University of Manchester. The six million patients required will be selected from this, according to which individuals best meet the matching requirements. The applicants will request a full ten years of retrospective data. Specific dates could not be provided, as the extract would be ten years from the date that NHS BSA accessed the system and extracted the dataset.

Data sources	1. Information on dental care held by NHS Business Services Authority
Identifiers required for linkage purposes	1. Name 2. NHS Number 3. Date of birth 4. Postcode 5. Composite ID used by NHS BSA, composed using patient surname, first initial, gender and date of birth
Identifiers required for analysis purposes	1. Postcode – sub-sector level 2. Lower Super Output Area of postcode 3. Gender 4. Ethnicity 5. NHS dental charges exemption category

Confidentiality Advisory Group advice

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

1. **Provide clarification on whether any patient data would be retained for longer than the 10 years patients had consented to.**

The applicant advised that the patient declaration on the NHS BSA FP17 form, which was the source of the data the applicants were requesting, stated that, “Your personal data will be deleted within 10 years of receipt into our systems”. Patient identifiable data will not be retained for longer than the original 10 years, as it will be anonymised as soon as possible during the BSA process of cohort identification and data linkage. The CAG noted this information and raised no further queries.

2. **Further information on why it is necessary to release data on 20 million patients from NHS BSA to the research team;**

    a. **Clarify if NHS BSA can apply the study criteria or propensity matching, and release data on only the 6 million patients required.**

The applicants advised that they would not know how the fluoridated and non-fluoridated groups may differ in terms of characteristics that may be linked to the outcome of interest until

they had examined the data. Identifying the factors linked to the outcome of interest and exploring which ones need to be taken account of in the analysis was a core part of the study. Some imbalances may be managed through matching using propensity scores, but others may be managed through other statistical techniques such as regression adjustment. The applicants did yet know enough to ask NHS BSA to undertake this work on their behalf. The CAG noted this information and raised no further queries.

b. Advise why aggregated data from NHS BSA is not sufficient.

The applicants advised that aggregate data would provide the numbers of dental procedures carried out in small geographic areas, or perhaps in groups of people defined by certain characteristics. The applicants sought to investigate the impact of exposure to water fluoridation on individuals, in order to establish if it's effects might be different depending on different individual characteristics. Individual level data was required in order to identify which factors were most important. If NHS BSA was asked to provide aggregate data they would only be able to provide summaries for each category separately. The CAG noted this information and raised no further queries.

3. Provide further justification on why patients who were children when they received treatment need to be included.

The applicants explained that there was a shortage of recent evidence on the dental health effects of water fluoridation at any age. The Dental Public Health team at Manchester are also running CATFISH, an ongoing 7-year prospective cohort study that is following children up until the age of 12, in fluoridated and non-fluoridated areas of Cumbria. The CATFISH study is aiming to produce data on the cost-effectiveness of water fluoridation for these children, up to the age of 12. Older children were not included due to the difficulty in engaging this age group in dental survey examinations during the later school years, when they are getting ready for exams. The applicants had therefore chosen to include 12-year-olds and older in the LOTUS study to explore the cost-effectiveness of water fluoridation for the whole population. The CAG noted this information and raised no further queries.

4. Consider whether any further steps can be taken to promote the study and provide feedback on the further steps to be taken.

The applicants advised that they could approach other dental patient and public facing organisations to request that a summary of the study and the link to the privacy notice was included on their websites. The Group agreed that this should be done.

Confidentiality Advisory Group advice conclusion

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

Specific conditions of support

1. Favourable opinion from a Research Ethics Committee. **Confirmed 27 May 2020.**

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

g. 20/CAG/0027 - Congenital Heart Audit: Measuring Progress In Outcomes Nationally

Name	Capacity
Dr Martin Andrew	CAG Member
Dr Patrick Coyle	CAG Vice-Chair
Mr David Evans	CAG Member
Dr Lorna Fraser	CAG Member
Ms Clare Sanderson	CAG Alternative Vice-Chair
Dr Paul Mills	HRA Senior Confidentiality Advisor

Context

Purpose of application

This application from University College London set out the purpose of medical research which aims to develop tools for routinely measuring congenital heart disease outcomes that are considered meaningful and appropriate by stakeholders and can inform the delivery and commissioning of services for patients.

Congenital heart disease requires lifelong clinical input and significant healthcare utilisation. In 2015, NHS England called for better reporting of quality of services, beyond the current focus on 30-day survival following paediatric cardiac surgery. This project will draw on a number of data sources to:

- Define the scope of adult procedures for national reporting, identify what outcomes to measure;
- Explore potential risk factors, and develop a fair way of reporting surgical outcomes;
- Investigate longer-term outcomes tracking people with representative diagnoses through a combined dataset, describing their long-term survival, and the number of operations within and outside the anticipated treatment plan;
- Develop prototype software tools to calculate and display longer-term and adult outcomes providing meaningful information to patients and commissioners of CHD services.

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

Confidential patient information requested

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

Cohort	Approximately 130,000 children and adults with congenital heart disease. From birth, no upper age limit. England only.
Data sources	1. The LAUNCHES dataset [18/CAG/0180] 2. National Adult Cardiac Surgery Audit (NACSA) [17/CAG/0071] – pseudonymised, linked to the LAUNCHES dataset. 3. National Congenital Anomaly and Rare Disease Registration Service (NCARDRS) [CAG 10-02(d)/2015] – pseudonymised, not linked

	4. Clinical audit data from Barts Health NHS Trust – pseudonymised, not linked
Identifiers required for linkage purposes	1. Name 2. NHS number 3. Hospital ID no. 4. Date of birth 5. Postcode
Identifiers required for analysis purposes	1. Hospital Name 2. Place of occurrence of death (categorical: one of home/hospice/hospital/care home) 3. Gender 4. Ethnicity 5. Month and year of birth (not day). 6. Age at procedures, hospital admissions etc (to four decimal places). Age to 4 decimal places is needed to sequence events that happen on the same day (e.g. two procedures on the same day).
Additional information	The application set out an online forum hosted by three charities - Somerville Foundation (TSF), Children's Heart Federation (CHF) and Little Hearts Matter (LHM); this is not within the scope of the proposed support.

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. **The data flow diagram is to be updated to clearly set out what data is anonymous, pseudonymised, and identifiable, and which parts of the data flows will be subject to section 251 support.**

An updated flow diagram was provided that detailed which data flows will be subject to support. The sub-committee were content with the diagram, noting it is a complex data flow.

2. **The privacy notice is to include a project-specific point of contact for opt out enquiries to help any patients who are uncertain about what they want to opt out from.**

An updated privacy notice was provided, with the opt out provided on the full notice. The sub-committee were content with the responses.

3. **The privacy notice and opt out information is to be made available on the University College London website, and the websites of the charities involved in the online focus groups. This information is to be displayed before the linkage takes place.**

The applicants confirmed that the privacy notice and opt out information will be made available on the University College London website, and the websites of the charities involved in the online focus groups before linkage takes place. The sub-committee were content with the response.

4. **Further patient and public involvement, specifically regarding the use of confidential patient information without consent for this project, must be completed before section 251 support can be recommended. The patient and public should be asked for their views on the use of the data without consent and any negative views reported back to CAG**

The applicants contacted the study's PPI subgroup in the first instance. They also contacted the charities involved in the online forums who are happy to post questions on their websites seeking patient and public views on this issue. However, the charities raised concerns that this was not a good time to seek feedback given that many patients/families were very preoccupied with concerns about COVID-19 and because the charities were very overwhelmed with additional workload as well as having to consider furloughing staff. As such, the applicants proposes delaying posting the questions until the Covid19 situation eases.

The sub-committee were content with these responses.

5. **The privacy notice is to be presented in a layered format, so that the initial information is high level, but provides links to more detailed information for those who are interested.**

The applicants submitted a leaflet providing short description of the work of the project, which links to the full privacy notice, thereby providing information in a layered format. The sub-committee were content with this response.

6. **The privacy notice is to reflect that confidential patient information is being accessed and used for this project under section 251 support.**

The full privacy notice provides information that confidential patient information is being accessed under section 251 support. The sub-committee 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

1. Favourable opinion from REC **Confirmed 14/02/2020.**

2. Continual achievement of 'Standards Met' in relation to the relevant DSPT submission (or any future security assurance changes) for the duration of support. Evidence to be provided (through NHS Digital confirmation they have reviewed and confirmed the DSPT submission as standards met' for the duration of support, and at time of each annual review. **Confirmed: University College London (by NHS Digital email 02 July 2019), University of Leeds (by NHS Digital email 28 August 2019), ICNARC (by NHS Digitial email 29 May 2019), NHS Digital (by NHS Digital email 10 June 2019) and Public Health England (by NHS Digital email 02 September 2019) have confirmed 'Standards Met' grade on DSPT 2018/19.**

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

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

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

Name	Capacity
Dr Tony Calland MBE	CAG Chair
Dr Martin Andrew	CAG Member
Dr Liliane Field	CAG Member
Dr Paul Mills	HRA Senior Confidentiality Advisor

Context

Purpose of application

This application from the Cambridge University Hospitals NHS Foundation Trust set out the purpose of medical research that seeks to determine the incidence of Chronic Recurrent Multifocal Osteomyelitis (CRMO) within the UK.

CRMO, also known as chronic non-bacterial osteomyelitis (CNO), is a rare auto-inflammatory condition affecting the bones. It occurs primarily in children and teenagers, although cases in adults have been reported. Its clinical presentation is characterised by bone pan and swelling, in the absence of infection or tumour. Milder cases require treatment with nonsteroidal anti-inflammatory drugs (NSAIDS) for disease control, while more serious cases more require treatment with multiple medications, including treatments that suppress the immune system. CRMO was first identified over 40 years ago, but it is now known how common it is. The applicants seek to gather information about the prevalence of CRMO.

The study will be conducted using British Paediatric Surveillance Unit (BPSU) methodology. Each month the BPSU will send an eReporting card to all consultant paediatricians across the UK and Republic of Ireland. The card will list the conditions currently being studies, including

CRMO. If a clinician has seen a child affected by CRMO they tick the corresponding box on the card and return it to BPSU. BPSU then notify the applicants and provide the contact details of the reporting clinician. The applicants then contact the clinician with a confidential case report form requesting further information, including the child's demographic details, presentation, investigations and initial management. Reporting paediatricians will be contacted again 12 months later to collect follow up information on treatment received and outcome. Some patients with CRMO are referred to and managed by paediatric orthopaedic surgeons, without input from paediatricians, therefore the applicants will also run a parallel surveillance study through the British Society for Children's Orthopaedic Surgery (BSCOS), surveying all paediatric orthopaedic surgeons. The same case report and follow-up forms from the BPSU survey will be used for initial case identification and follow-up.

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

Confidential patient information requested

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

Cohort	135 patients diagnosed with CRMO
Data sources	1. Clinicians reporting cases via British Paediatric Surveillance Unit (BPSU) 2. Clinicians reporting cases via the British Society for Children's Orthopaedic Surgery (BSCOS)
Identifiers required for linkage purposes	1. NHS number 2. Date of birth 3. Date of death 4. Postcode – sector level 5. Ethnicity
Identifiers required for analysis purposes	1. Date of birth 2. Date of death 3. Postcode – sector level 4. Gender 5. Ethnicity

Confidentiality Advisory Group advice

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

1. **Contact is to be made with the Facebook group for parents of children with the condition in order to facilitate promotion of the study.**

The applicant responded that they have already contacted the CRMO-UK facebook group in Jan 2019, and four parents from the group have volunteered to join the patient advisory group, with initial meetings held. Once the study begins, the application will make further contact with both the patient advisory group and the facebook group to facilitate promotion of the study.

The sub-committee were content with this response.

2. **Patient facing materials are to be produced for children old enough to understand information about the study.**

The applicants provided the group with child-friendly information, which was adapted from the current patient information materials. Whilst members were content to support on the basis of the provided leaflet, they suggested that there should be multiple versions of the poster, adapted appropriately to cover the spectrum of understanding across all ages of children.

3. **Confirmation is be provided that, if a patient had previously opted-out or dissented from the use of their data in research, this will be respected.**

The application confirmed that this will be respected. The sub-committee 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

1. Favourable opinion from REC **Confirmed 06 March 2020**

2. Continual achievement of 'Standards Met' in relation to the relevant DSPT submission (or any future security assurance changes) for the duration of support. Evidence to be provided (through NHS Digital confirmation they have reviewed and confirmed the DSPT submission as standards met' for the duration of support, and at time of each annual review. **(Confirmed – Cambridge University Hospitals NHS Foundation Trust has a confirmed 'Standards Met' grade on DSPT submission 2018/19 by NHS Digital email dated 08 July 2019).**

i. 20/CAG/0043 - Adult social care free text analysis

Name	Capacity
Dr Patrick Coyle	CAG Vice-Chair
Mr David Evans	CAG Member
Dr Harvey Marcovitch	CAG Member
Dr Paul Mills	HRA Senior Confidentiality Advisor

Context

Purpose of application

This application from London Borough of Islington Council set out the purpose of the management of health and social care services which aims to inform the management of health and social care services and provision of care locally.

London Borough of Islington Council and NHS Islington CCG would like to combine datasets from GP practices in Islington, hospital admissions and adult social care, with “free text” data from adult social care records (e.g. assessment forms) to inform the management of health and social care services and provision of care locally. Examples of uses includes (but not limited to) informing the design and implementation of local integrated care systems, and well as providing reasons for delayed transfers of care so service provision can be redesigned to reduce this.

Adult Social Care data containing NHS number, as well as other identifiers contained in free text information, will be transferred to NEL CSU. NEL CSU will pseudonymise the free text information. The pseudonymised dataset will be transferred to London School of Economics for structuring. Finally, GP data (held by NEL CSU) and secondary care data (held by NHS Digital) will be linked by NHS number to provide a final pseudonymised dataset for analysis.

A recommendation for class 1, 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	People aged 65 and over, using adult social care services in Islington. Those with HIV will be removed from the dataset.
Data sources	1. London Borough of Islington Council 2. NHS Digital 3. NEL CSU
Identifiers required for linkage purposes	1. NHS Number
Identifiers required for analysis purposes	1. Identifiers (e.g. names, addresses) contained within free text information provided by London Borough of Islington Council. This will be held temporarily by NEL CSU whilst they strip the information from identifiers during pseudonymisation.
Additional information	Note that there are three separate functions of NEL CSU involved in this application:

	• NEL Data Flow team: Will apply the free-text de-identification process prior to routing data through DSCRO. • NEL DSCRO team: De-identification and data linkage on standard attributes such as NHS number. • NEL Data management team: Manages infrastructure used by customers.

Confidentiality Advisory Group advice

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

1. **Provide further information on the structured dataset, how it is produced, what information is contained and whether any identifiable information is within it.**

The applicant confirmed that structured dataset will consist of fields from the adult social care system, and provided a file detailing these fields. This will be linked to GP and hospital data and all personal data will be removed once the linkage has occurred.

The sub-committee were content with this response.

2. **What identifiable items may be in the free text data?**

The applicant responded to say that the following free text data will be irreversibly redacted:

Service user name ; Names of relatives or associates of service user; Address or other contact details of service user (or relatives or other close associates of service user); Names of staff/key workers (including health professionals) involved with application, provision or monitoring of service; Carer/Support organisation or Referrer/service provider details; Sheltered accommodation details or any other address details; General e-mail and telephone contact number details; Person's NHS Number; Any money, financial or transaction details; Any other location details that are felt to be able to identify an individual or their locations (e.g. details "went round the corner to the big Sainsbury's Store on Y road").

The sub-committee were content with this response.

3. **Please comment on the accuracy of the information contained in the free text data.**

The applicant clarified that the free text notes in adult social care records are treated as official records in any legal undertakings, and therefore it is assumed that the free text records are accurate.

The sub-committee were content with this response.

4. **What information will the pseudonymised version of the free text data contain with respect to safeguarding or criminality?**

The applicant responded that, after redactions, only references to the fact that service workers have fears that that there are safeguarding issues will be present. This is similar for criminality details.

The sub-committee were content with this response.

5. **What will the dataset look like when returned?**

The applicant provided an example of the pseudonymised dataset to demonstrate. The sub-committee were content with the dataset.

6. **Consider a layered approach for privacy information, provide updated materials, or justification why a layered approach is not to be used.**

The applicant submitted revised privacy information using a layered approach. The sub-committee were content with the revised privacy information

7. **Provide patient communication materials before support can be given**

The applicant provided the proposed patient information leaflet but clarified that it is currently in draft form and subject to review by the organisational communications team.

The sub-committee were content with the content but requested that a condition of approval is that the final patient leaflets are provided to the CAG when ready.

8. **Provide further clarity on the flow of identifiable items, from source to use, how this will happen and when.**

The applicant provided a flow diagram which explains the data flows. The sub-committee were content with this response.

9. **Clarify the approximate numbers of service user records to be used in this project.**

The applicant clarified that approximately 3000 service user records will be used in this project. The sub-committee were content with this response.

10. **Clarify opt out procedures if systems other than EMIS are used.**

The applicant confirmed that all practices in Islington are using EMIS. The sub-committee were content with this response.

11. **Confirm plans on using the national data opt out.**

The applicant responded that the national data opt out will apply. The sub-committee were content with this response.

12. **Consider linking with a wide PPI group for continued patient engagement.**

The applicant clarified that they will be linking with the NCL STP Digital and Analytics Board Resident Reference Panel and the NCL Citizen Panel and Local Healthwatch organisations in each of the 5 boroughs.

The sub-committee were content with this response.

13. Confirm if any exclusions, other than those with HIV, apply.

The applicant responded that they will be excluding the standard NHS sensitive codes from the healthcare records. The sub-committee 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

1. Provide the CAG a copy of the patient information materials once it has been subject to review by the communications team.

2. Continual achievement of 'Standards Met' in relation to the relevant DSPT submission (or any future security assurance changes) for the duration of support. Evidence to be provided (through NHS Digital confirmation they have reviewed and confirmed the DSPT submission as standards met' for the duration of support, and at time of each annual review. **The NHS Digital DSPT reviews for NEL CSU, London Borough of Islington and Islington CCG were confirmed as 'Standards Met' on the NHS DSPT Tracker (checked 12 July 2020)**

j. 20/CAG/0035 - Safety INdEx of Prehospital On Scene Triage (SINEPOST): The derivation and validation of a risk prediction model to support ambulance clinical transport decisions on scene

Name	Capacity
Dr Tony Calland MBE	CAG Chair
Dr Rachel Knowles	CAG Member
Mr Andrew Melville	CAG Member
Mr Marc Taylor	CAG Member
Ms Kathleen Cassidy	HRA Confidentiality Advisor

Context

Purpose of application

This application from the University of Sheffield set out the purpose of medical research which aims to determine whether ambulance service clinical data can predict an avoidable attendance at the Emergency Department in adults using classification models.

Paramedics have specialist knowledge and skills in helping people in emergencies. The bulk of ambulance service patients who call have problems that are described as 'urgent'. These are cases where the patient may need access to healthcare and medical help, but there is only a very small chance that the problem is life threatening. The care of urgent patients is complex and trying to find the right place for their care can be hard. In 2014 in Yorkshire, up to 16.9% of patients could have avoided being taken by ambulance to the Emergency Department (ED). This group of patients had no special tests or treatments and were sent home. This means they had a minor problem that could have been managed elsewhere. When the ED is busy, ambulances have to wait a long time to handover the care of their patients. This delay stops ambulances being free to respond to the next emergency. These problems mean paramedics need to make sure the ED is the right place for their patient before they take them there. This project aims to develop a tool to help with that decision by showing the paramedic the likelihood of treatment at an ED being of benefit to the patient.

The applicants are seeking support under s251 to access the Electronic Patient Care Record at Yorkshire Ambulance Service NHS Trust and to obtain Emergency Department Care data from NHS Digital. The first stage of the study requires that data from the Yorkshire Ambulance Service NHS Trust is linked to data from a large hospital via NHS Digital, in order to provide show us the complete patient journey from their call for help through to leaving the ED. An anonymised dataset will then be provided to the applicants at the University of Sheffield. This information will be used to create a tool that identifies patients who may not need to be taken

to the ED. The public will be invited to face-to-face meetings to help the researcher produce a lay summary of this phase. In the second stage, data from the Yorkshire Ambulance Service NHS Trust will be linked to Emergency Department Care data from NHS Digital for a different hospital, to see if the test can work in different settings.

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

Confidential patient information requested

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

Cohort	467329 patients treated by Yorkshire Ambulance Service NHS Trust and by the two participating Trusts.
Data sources	1. Electronic Patient Care Record at Yorkshire Ambulance Service NHS Trust 2. Emergency Department Care data provided by NHS Digital
Identifiers required for linkage purposes	1. Name 2. NHS number 3. Date of birth 4. Date of death 5. Postcode -unit level
Identifiers required for analysis purposes	1. Postcode – sector level

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 Chair's Action.

1. **Provide the names of the two organisations whose Emergency Department Care data would be combined by NHS Digital with the Electronic Patient Care Record from Yorkshire Ambulance Service NHS Trust.**

The applicant advised that the study would use regional data from every acute trust in Yorkshire, however this will be done through NHS Digital using routinely collected data. The specific trusts data which will be included are Airedale General Hospital, Barnsley Hospital, Bradford Royal Infirmary, Calderdale Royal Hospital, Dewsbury and district Hospital, Doncaster Royal Infirmary, Harrogate district Hospital, Huddersfield Royal Infirmary, Hull Royal Infirmary, Leeds General Infirmary, Northern General Hospital, Pinderfields Hospital, Rotherham Hospital, Scarborough Hospital, St. James's University Hospital and York Hospital.

The CAG had requested that DSPTs for the two organisations were provided. However, due to the increase in the number of organisations, it was decided that individual DSPT submissions will not be required for the purpose of the application. Support is recommended on the basis that the applicant ensures the required security standards are in place at each site prior to any processing of confidential patient information with support under the Regulations.

2. **Confirm that patient and public involvement will be undertaken around developing a patient notification strategy. Please provide a summary of the feedback received about the patient notification put in place within three months of support under s251 being confirmed.**

The applicant confirmed that further public involvement will be undertaken to develop a patient notification strategy. A report on this further patient and public involvement will be submitted within 3 months of the s251 being confirmed. 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

1. Favourable opinion from a Research Ethics Committee. **Confirmed 08 November 2019.**

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 (by NHS Digital email 10 June 2019) and Yorkshire Ambulance Service NHS Trust (by NHS Digital email 07 January 2019) have confirmed 'Standards Met' grade on DSPT 2018/19).**

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

k. 19/CAG/0210 - Discovery and Analysis Of Novel Biomarkers In Urological Diseases (DIAMOND STUDY)

Name	Capacity
Dr Patrick Coyle	CAG Vice-Chair
Professor Barry Evans	CAG Member
Professor Jennifer Kurinczuk	CAG Member
Dr Harvey Marcovitch	CAG Member
Mr Andrew Melville	CAG Member
Ms Kathleen Cassidy	HRA Confidentiality Advisor

Context

Purpose of application

This application from University of Cambridge set out the purpose of medical research which aims to evaluate the utility of biomarkers to improve the screening, diagnosis, prognosis and treatment of urological cancers. The applicants wish to identify a cohort of patients which were referred to undergo an MRI scan as part of the diagnostic process for prostate cancer, in order to invite them to provide a sample to be used in the biomarker analysis. A sub-cohort of

patients who were referred for an MRI, which was found to be inconclusive, and were subsequently discharged back into the community has been identified, which are not currently included in the analysis and may be causing bias in the reported results.

The application has operated since 2003 with the applicants approaching patients at the point they are attending their outpatient appointment and have been focussing on biomarkers within patients with localised or advanced disease. In recent years, the focus for prostate cancer has changed to early detection and applicants are now looking to test biomarkers in the early stage of the disease. This has led to the change in methodology which requires an application for section 251 support. The applicants are seeking support to access medical records on site at Cambridge University Hospitals NHS Trust to identify patients who have been invited for a pre-biopsy MRI scan, so these individuals can be invited to attend the early diagnostic research clinic alongside their scheduled MRI appointment. Support is sought to access the medical records and invite eligible men to participate in the study.

A recommendation for class 1, 2, 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	All patients being referred from their GPs to the MRI department or to Outpatient Urology clinics at Cambridge University Hospitals NHS Trust for a suspected urological cancer.
Data sources	1. Electronic patient records for MRI outpatient appointments
Identifiers required for linkage purposes	1. Name 2. NHS Number 3. Hospital ID 4. Full address and postcode

Identifiers required for analysis purposes	Not applicable – all identifiers retained for analysis will be done so under patient consent.

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. **A sample size calculation needs to be provided.**

That applicant advised that this was difficult to provide as it was not yet known which markers will show value. They explained that they had estimated that a population size of at least 1187 will be required to detect a marker with at least a 10% increased chance of detecting cancer over the current methods. A target of 1500 will cover this and allow for any dropouts. The CAG noted this information and raised no further queries.

2. **Clarify whether the specific issue of the use of confidential patient information without consent had been discussed with patients and the public and provide feedback from these discussions. This needs to include information on the activity undertaken the demographics of those present and the views expressed.**

The applicants explained that this issue had been put to the patient and public involvement panel. The panel was comprised of both patients diagnosed with prostate cancer and lay members. In total there were 5 people in this group, aged 60-75, the intended demographic for this study, and they were invited to give individual opinions and then in a group setting. Individual comments from participants were provided by the applicant. The CAG noted this information and raised no further queries.

3. **The Patient Information Sheet needs to be revised as follows;**

    a. **References to 'cancer' need to be amended,**

    b. **The conditional language used needs to be revised,**

c. **The language used needs to be simplified to be clearer to a lay person.**

d. **The Information Sheet needs to clearly explain that patients attending for appointments at the weekend would not be included. Alternatively, confirmation needs to be given to the CAG that the patient leaflet will not be sent to patients whose appointments fall outside the research teams working hours.**

The applicants provided a revised Patient Information Sheet. This was reviewed by the CAG and the changes accepted.

4. **Clarify whether patients could choose whether to attend for weekday or weekend appointments, and if it is anticipated that patients attending at weekends would differ from those attending on weekdays.**

The applicant explained that there was no clinical or demographic difference between men attending at weekends or weekdays, as this availability is purely by what clinical space and capacity there is, and no other selection is used. The CAG noted this information and raised no further queries.

Confidentiality Advisory Group advice conclusion

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

Specific conditions of support

1. Favourable opinion from a Research Ethics Committee. **Confirmed 11 February 2020.**

2. Confirmation provided from the IG Delivery Team at NHS Digital to the CAG that the relevant Data Security and Protection Toolkit (DSPT) submission(s) has achieved the 'Standards Met' threshold. See section below titled 'security assurance requirements' for further information. **Confirmed - Cambridge University Hospitals NHS Trust has a confirmed Standard Met grade on DSPT 2018/19 (NHS Digital Tracker 05 November 2019).**

I. 20/CAG/0031 - Self-management and support programme for COPD (EDGE2)

Name	Capacity
Dr Tony Calland MBE	CAG Chair
Dr Rachel Knowles	CAG Member
Ms Gillian Wells	CAG Member
Dr Paul Mills	HRA Senior Confidentiality Advisor

Context

Purpose of application

This application from the University of Oxford set out the purpose of medical research that seeks to determine the feasibility of integrating hospital data with data collected by patients at home.

Chronic Obstructive Pulmonary Disease (COPD) is the name for a number of lung conditions. Individuals with COPD find breathing increasingly difficult due to the affect that the condition has on the lungs. COPD is a long-term disease without a known cure and is likely to become the third leading cause of death worldwide by 2020. Current treatments are focused on avoiding deterioration, minimising risk factors and reducing symptoms. Approximately 1 in 4 COPD patients in the NHS are re-admitted to hospital within 3 months of a previous visit. The applicants are seeking ways that digital technologies can be used by patients to monitor their condition at home and provide regular updates to their care team, so that the care team are aware if patients condition is deteriorating at home.

Potentially eligible patients attending or admitted to Oxford University Hospitals NHS Foundation Trust due to COPD exacerbation or a pulmonary infection will be identified by the clinical research team or by the clinical care team by accessing confidential patient information. If the clinical care team identify a suitable patient they will flag this with the research team who will approach the patient with verbal and written information about the study. Patients participation will then proceed on a consented basis. Patients will be given a tablet computer running the EDGE mHealth application and asked to wear the monitoring device as often as possible to monitor their physical activity levels for two weeks after being discharged from hospital.

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	200 patients, who have been admitted to hospital with a diagnosis of COPD, will be invited to take part. 15 health professionals will also be invited, but this is outside the scope of s251 support.
Data sources	1. Electronic and paper patient records held at Oxford University Hospitals NHS Foundation Trust
Identifiers required for linkage purposes	1. Name 2. Date of birth 3. Postcode – district level
Identifiers required for analysis purposes	1. Gender 2. 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. **Study-specific information needs to be created, explaining the aims of the study and how to contact the study team to dissent, and provided to the CAG for review.**

The applicants provided a patient notification that included how patients can dissent from use of their data.

Whilst members had some initial concerns, these were discussed with the study team and resolved. The group were content with the final patient notification provided.

Confidentiality Advisory Group advice conclusion

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

Specific conditions of support

1. Favourable opinion from REC **Confirmed 27 February 2020.**

2. Continual achievement of 'Standards Met' in relation to the relevant DSPT submission (or any future security assurance changes) for the duration of support. Evidence to be provided (through NHS Digital confirmation they have reviewed and confirmed the DSPT submission as standards met' for the duration of support, and at time of each annual review. **Confirmed: Oxford University Hospitals NHS Foundation Trust has confirmed 'Standards Met' grade on DSPT 2018/19 (by NHS Digital email dated 17 September 2019).**

m. 20/CAG/0054 - Screening for Hypertension in the INpatient Environment (SHINE): A Diagnostic Accuracy Cohort Study

Name	Capacity
Dr Tony Calland MBE	CAG Chair
Ms Sophie Brannan	CAG Member
Dr Harvey Marcovitch	CAG Member
Dr Paul Mills	HRA Senior Confidentiality Advisor

Context

Purpose of application

This application from University of Oxford set out the purpose of medical research which aims to determine the optimal in-hospital blood pressure threshold above which to undertake community ambulatory blood pressure monitoring to detect hypertension.

Hypertension is the leading risk factor for death globally, with 12.8% of global deaths annually attributable to hypertension. Increased blood pressure measurements in the hospital setting are frequently dismissed, possibly due to clinicians attributing raised blood pressure to anxiety, pain or White Coat Hypertension. Clinicians usually expect that a patient's blood pressure will normalise following discharge, however limited data suggests that those with elevated blood pressure in hospitals frequently remain hypertensive in the community. Untreated hypertension is associated with a progressive increase in blood pressure that can become very difficult to treat. This means that hospital detection and timely management of hypertension offer an important intervention opportunity of address this major and global cause of illness and mortality. Recognition and documentation of elevated blood pressure readings in hospital is lacking, and referral for community follow-up of these patients to determine cases of persistent hypertension is low

The Oxford University Hospitals NHS Foundation Trust introduced the NIHR-funded System for Electronic Notification and Documentation (SEND) in 2015. SEND is a tailored software service, which links hospital bedside monitoring devices, including blood pressure monitors, with a tablet computer to accurately record vital observations of patients. This enables clinical researchers to access and analyse patient observation data at a population level, as well as an individual level. SEND has monitored observations for more than 100,000 patients so far and links patient observations to their Electronic Patient Record (EPR). This presents Oxford University Hospitals NHS Foundation Trust with an opportunity to screen all admitted patients for hypertension, with the potential of providing preventative medicine to patients.

The applicants intend to conduct a twelve-month prospective study. Eligible patients will be identified during their hospital admission by an algorithm run across the EPR. Selected patients will then be screened against the inclusion and exclusion criteria by members of the research team. Patients meeting these criteria will then be approached for consent to take part in the study. Support is sought for the screening of patient records for suitability prior to consent being obtained.

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 treated at Oxford University NHS Foundation Trust and identified as meeting the inclusion criteria and identified as potential participants by the SEND algorithm
Data sources	1. Electronic patient records held at Oxford University NHS Foundation Trust
Identifiers required for linkage purposes	1. Name 2. NHS Number 3. Hospital ID number 4. GP Registration 5. Date of death Postcode – unit level
Identifiers required for analysis purposes	1. Postcode – district level 2. Gender 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. **Provide patient notification materials to be used in the study, which should include information on how to opt out and contact details.**

The applicants provided a patient notification that included how patients can dissent from use of their data.

Whilst members had some initial concerns, these were discussed with the study team and resolved. The group were content with the final patient notification provided.

2. **Confirm what information in the patient record the research team will have access to. Is it the whole patient record? If not, what information will they have access to.**

The applicants clarified that the research team will have access to the entire electronic patient record, but are trained to be aware that that they should only access areas necessary to assess whether SHINE exclusion criteria have been met.

The group were content with the response.

3. **What happens to the data of those patients that are ineligible? Will the identifiable data collected by the algorithm be deleted immediately? Please provide further information about this process.**

The applicants clarified that identifiable data of those patients not enrolled will be destroyed. A screening log will be maintained that will include deidentified data of all patients screened (whether enrolled or not), which will contain age, sex and their average blood pressure (as calculated by the screening algorithm). This is important for understanding how the research can be translated into clinical care in the future.

Members were content with this response.

4. **Clarify whether patient representatives were asked about the acceptability of external researchers screening identifiable patient information prior to consent**

The applicants confirmed that this has been discussed explicitly with three members of the National Association for Patient Participation and a General Practice patient participation group local to Oxford University Hospitals, and all were supportive.

Members 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

1. Favourable opinion from REC **Confirmed 18 May 2020**

2. Continual achievement of 'Standards Met' in relation to the relevant DSPT submission (or any future security assurance changes) for the duration of support. Evidence to be provided (through NHS Digital confirmation they have reviewed and confirmed the DSPT submission as standards met' for the duration of support, and at time of each annual review. **Confirmed: Oxford University Hospitals NHS Foundation Trust has confirmed 'Standards Met' grade on DSPT 2018/19 (by NHS Digital email dated 17 September 2019).**

n. 20/CAG/0045 - An evaluation of a water fluoridation scheme in Cumbria: A population based comparative cohort study of systemic and topical fluoride exposure

Name	Capacity
Dr Tony Calland MBE	CAG Chair
Dr Simon Kolstoe	CAG Member
Ms Gillian Wells	CAG Member
Ms Sophie Brannan	CAG Member
Dr Harvey Marcovitch	CAG Member
Dr Katie Harron	CAG Member
Ms Kathleen Cassidy	HRA Confidentiality Advisor

Context

Purpose of application

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

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

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

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

Confidential patient information requested

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

Cohort	3200 children aged 4 -12 years and living in West Cumbria; Cornhow and Ennerdale, who were consented into the original study. Anonymised data will also be obtained for children born between September 2014 and September 2015, within the same geographic location, Cumbria East and West, as the children consented into the study.
Data sources	1. Dental Health Data held by NHS BSA 2. HES data held by NHS Digital
Identifiers required for linkage purposes	1. Name 2. NHS Number 3. Date of birth 4. Postcode
Identifiers required for analysis purposes	1. Date of birth 2. Postcode 3. Gender

Confidentiality Advisory Group advice

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

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

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

The key difference between the two cohorts is their age. Water fluoridation plants were turned on in 2013. Cohort 1 will therefore have received fluoridated water since conception, while Cohort 2 will have been 4-5 years old when they received fluoridated water. The CAG was satisfied by this clarification.

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

The applicant confirmed that those involved in the patient linkage will only be those who have originally consented but will exclude any participants who have opted out or withdrawn from the study. The CAG was satisfied by this clarification.

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

The applicant explained that consent was not feasible as many patients may have moved away and the researchers would not have up-to-date contact information available. The applicants also noted that it was previously easier to contact patients via their schools. However, a number of patients now attended different schools and the researchers would not have the same opportunities to contact patients as they did at the beginning of the study. The CAG was satisfied by this clarification.

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

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

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

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

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

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

Confidentiality Advisory Group advice conclusion

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

Specific conditions of support

1. Favourable opinion from a Research Ethics Committee. **Confirmed 20 July 2020.**

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

o. 19/CAG/0207 - Survival of people with screen-detected heart failure (ECHOES-Survive)

Name	Capacity
Dr Patrick Coyle	CAG Vice-Chair
Dr Lorna Fraser	CAG Member
Mrs Diana Robbins	CAG Member
Dr Katie Harron	CAG Member
Mr Marc Taylor	CAG Member
Ms Kathleen Cassidy	HRA Confidentiality Advisor

Context

Purpose of application

This application from the University of Oxford set out the purpose of medical research which aims to undertaken longitudinal follow-up of patients who were recruited on a fully consented basis to the historic 'Echocardiographic Heart of England Screening (ECHOES) Study'. The ECHOES study was carried out between 1995 and 1999 in 16 General Practices around the West Midlands region. The purpose of the study was to establish the prevalence of heart failure in the general population over the age of 45 and involved assessment of detailed clinical history and examination, 12 lead ECG, and echocardiography.

All patients who participated in this trial are flagged with NHS Digital to enable follow-up via civil registration data to ascertain which members of the cohort have died and when, together with the cause of death. NHS Digital reassessed the consenting materials for the study in 2018 and determined that these were no longer valid, in relation to the common law duty of confidentiality, to support the ongoing processing of patient information and disclosure of mortality data. The applicant was advised to submit an application to the CAG to seek section 251 support to legitimise the longitudinal follow-up of the patient cohort to undertake 20-year survival analysis.

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.

Cohort	6,162 patients who were recruited to the ECHOES trial between 1995 and 1999 on a fully consented basis from 16 GP practices in the West Midlands.
Data sources	1. ECHOES trial dataset, University of Oxford 2. ONS mortality data, NHS Digital
Identifiers required for linkage purposes	1. Name 2. NHS number 3. Date of birth
Identifiers required for analysis purposes	1. Date of birth and death – calculation of survival 2. Postcode – deprivation scoring 3. Cause of death 4. Sex 5. Ethnicity

Confidentiality Advisory Group advice

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

1. **Confirm whether section 251 support is also being sought to legitimise the ongoing retention of the study dataset and any further future follow-ups via NHS Digital.**

The applicant advised s251 support was sought to legitimise the ongoing retention of the study dataset and for any further follow-ups undertaken by NHS Digital in the future. The CAG noted this information and raised no further queries.

2. **Clarify whether the confidential patient information items retained for patients confirmed as deceased can be reduced to a less identifiable format. Confirm agreement to this and provide an overview of the data items which would remain.**

The applicant confirmed that the items of confidential patient information retained for deceased patients would be reduced to a less identifiable format. Date of death will be replaced with survival time in days. The Patient ID will be deleted, removing the link with the name, NHS Number, address, postcode and date of birth. The items remaining will be age, sex, IMD quintile, survival time, cause of death SF-36 quality of life score, smoking status, BMI, blood pressure, cardiovascular-related medical history, cardiovascular-related medications, echo measurements and heart failure diagnosis.

3. **Provide final drafts of the website text and GP practice poster for review.**

The final drafts were provided for review. The CAG agreed that the poster, to be displayed in GP practices, was too complex and asked that it was revised to give basic information, to inform patients that they can opt-out and direct patients to further information. The CAG also asked that the reference to 'CAG approval' in the Privacy Notice and Poster were corrected to 'Health Research Authority Approval.'

Revised documents were provided, which were reviewed by the CAG. The CAG was satisfied by the changes made.

Confidentiality Advisory Group advice conclusion

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

Specific conditions of support

1. Favourable opinion from a Research Ethics Committee. **Confirmed 23 April 2020**

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

on 22 July 2020) has a confirmed 'Standards Met' grade on DSPT 2018/19. The University of Birmingham (by check of the NHS Digital DSPT tracker on 22 July 2020) have confirmed 'Standards Met' grade on DSPT 2019/20.

p. 19/CAG/0205 - A large randomised assessment of the relative cost-effectiveness of different classes of drugs for Parkinson's disease

Name	Capacity
Dr Tony Calland MBE	CAG Chair
Dr Martin Andrew	CAG member
Mr. Myer Glickman	CAG member
Mr Tony Kane	CAG member
Dr Harvey Marcovitch	CAG member
Ms Kathleen Cassidy	HRA Confidentiality Advisor

Context

Purpose of application

This application from the University of Birmingham set out the purpose of medical research that seeks to determine the relative cost-effectiveness of different classes of drugs for both early and later Parkinson's Disease (PD).

Parkinson's disease (PD) is one of the commonest causes of disability in older people with at least 8000 new cases diagnosed each year in the UK alone. Levodopa (LD) controls symptoms for most patients but long-term use is associated with motor complications. A number of other drugs have been used, either alone or with reduced doses of LD, in an attempt to delay the onset of motor complications, or to control complications in later disease once they have developed. The PD MED trial began in 2000 as a large, simple, "real-life" trial that aimed to determine which class of drug provided the most effective control, with the fewest side-effects, for both early and later PD. Patients with early PD were randomised between dopamine agonists (DA), monoamine oxidase type B inhibitors (MAOBI) and categhol-O-methyltransferase inhibitors (COMTI) with the option to omit either the MAOBI or LD alone arm. Those whose disease was no longer controlled by their first class of drug, after dose

titration or addition of LD, were randomised between COMTI, MAOBI and DA, with the option to omit either the MAOBI or the DA arm. The main outcome measure was the patient-rated PDQ-39 quality of life scale, which assessed all aspects of the patient's life. Patients were followed-up by questionnaires given when they entered the study, and then repeated at 6 and 12 months, and then once a year for at least another 4 years. Their carer, if they had one, was also asked to answer questions to find out how looking after someone with PD had affected their life. The questionnaires were sent by post.

Information on hospital admissions and mortality was also requested from HES and ONS data, held by NHS Digital. When consenting to take part in the study, patients had been informed that this follow-up would continue until they died. The PD MED team were recently informed by NHS Digital that IGARD had deemed that the trial's consent form did not explicitly ask participants for permission for their confidential patient information to be disclosed to NHS Digital for linkage of HES and ONS data. Re-consenting participants in the trial would be difficult, therefore the applicants were seeking support under Section 251 to continue to collect follow-up data.

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.

Cohort	Patients aged 18 years and over, diagnosed with Parkinson's Disease and recruited into the PD MED trial. 2500 patients were recruited into the original trial.
Data sources	1. HES and ONS data held by NHS Digital
Identifiers required for linkage purposes	1. Name 2. NHS Number 3. Date of Birth 4. Date of Death

Identifiers required for analysis purposes	1. Date of Death

Confidentiality Advisory Group advice

The applicant's response to the provisionally supported outcome was considered by the CAG.

1. **Clarify the scope of the patient cohort to be included within the application, accounting for any known deceased patients and the various historic consent forms.**

The applicant explained that PD MED contained 2120 patients. 468 of these patients were consented using the original version of the consent form, which did not include permission for the applicants to receive third-part data. The consent form used to consent the other patients into the study included taking consent for the applicants to receive third-party data.

The applicant also noted that they were aware that 1461 patients had died.

The Sub-Committee noted the information provided and was satisfied that their queries had been answered.

2. **Provide confirmation that no data linkages have been undertaken without an appropriate legal basis in place.**

The applicant provided confirmation that no data linkages had taken place without an appropriate legal basis being in place.

The Sub-Committee was satisfied with the information provided.

3. **The remit of the CAG extends to England and Wales only – provide confirmation that appropriate legal basis are in place to process confidential patient information generated outside of England and Wales.**

The applicant confirmed that they were seeking appropriate support to access confidential patient information generated outside of England and Wales.

The Sub-Committee was satisfied with the information provided.

4. **Confirm when the last patient was recruited into the PD MED clinical trial and if they were still completing study questionnaires**

The last patient was recruited into PD MED for early disease on 22 December 2009 and on 15 December 2009 for the later disease. The patient in the later disease group had since died, but the patient in the early disease group was still completing questionnaires.

The Sub-Committee was satisfied with the information provided.

5. **If study questionnaires are still being completed, consider whether these patients could be approached for consent to the data linkage process. If this is not considered feasible, provide a strong justification to support this.**

The applicant advised that it was not feasible to re-contact patients who were still completing questionnaires due to the time constraints on the study. The trial ended in December 2019 and the employment contracts of the trial team come to an end in 2020.

The applicant explained that the patients still completing the questionnaires had been recruited later in the trial and had been consented using the consent form that explained the use of third-party data, however IGARD did not agree that consent was sufficient. The applicant also wished to avoid placing an additional burden on patients as their consent would need to be sought quickly. A significant number of patients were also deceased.

The Sub-Committee noted the information provided and was satisfied that their queries had been answered.

6. **A patient notification strategy needs to be devised. Notification about the study should be displayed on the study and Trust websites. Provide copies of the text to be displayed for review. Contact should also be made with support groups and charities for patients with Parkinson's Disease, to inform them that the study is ongoing.**

The applicant advised that the trial was not ongoing and had closed on 31 December 2019.

The text to be used in the patient notification was provided for review. The Sub-Committee reviewed this text and was satisfied with the contents.

7. **The patient notification materials need to make it clear that patients can withdraw from the use of their data, how they can request that their data is withdrawn and any limits placed on withdrawal and.**

The patient notification text explained how patients could withdraw their data from the study. The Sub-Committee reviewed this text and was satisfied with the contents.

8. **Further details on the patient and public involvement carried out is needed;**

    a. **Provide clarification on how many people had been involved in the patient and public involvement already carried out.**

6 people were involved in the patient and public involvement and engagement exercise carried out in regards to re-consent. The patients were contacted in June 2012.

    b. **Provide clarification on whether the patient and public involvement group had discussed the issue of continuing to process the data of the patients whose consent was no longer deemed sufficient.**

The issue of re-consenting the original 468 patients whose consent form did not contain information on the data linkage to NHS Digital was discussed with the patient and public involvement group. The group agreed that it was not appropriate to re-approach patients and that the original consent form implied that the data would be used in this way.

The applicant noted that the decision from IGARD had not been discussed with the patient and public involvement group

The Sub-Committee noted the information provided above and was satisfied that their queries had been answered.

9. **Further clarification on the exit strategy and how long confidential patient information will be retained needs to be provided;**

    a. **Clarify if items of confidential patient information will be deleted within 6-8 months of November 2019. If not, please clarify when items of confidential patient information held at the University of Birmingham will be deleted.**

The applicant advised that HES data was linked to the PD MED trial data. The linked data would include baseline characteristics, diagnoses, clinical data, including medication, adverse events, dates of hospitalisation, dementia and death, patient reported outcomes including quality of life and resource use. The data will be linked using trial number alone. The pseudonymised data will be stored at the University of Glasgow for at least 25 years and will not be used for any other purpose than that described in the application.

The University of Birmingham will stored the HES data received from NHS Digital on a separate hard drive, which is not linked to the server and will be stored within a locked safe. The applicant anticipates that the HES data will be deleted around August 2020. The analysed, combined, pseudonymised results will be stored for 25 years, as per MHRA guidance for Clinical Trials.

    b. **Clarify how many times the data linkages undertaken via NHS Digital will be performed and how long this process is expected to take.**

The applicant advised that the data linkage with HES would be performed once. The linkage will be performed as soon as possible, once the appropriate support and approvals are in place. The applicants aim to have the database completed by April 2020.

The Sub-Committee noted the information provided above and was satisfied that their queries had been answered.

10. **Please advise how the following GDPR principles will be met;**

    a. **Specify the lawful basis for processing personal data, and the lawful basis for processing special category data.**

The applicant advised that the lawful basis relied on for the processing of personal data is GDPR Article 6(1)(e) - processing is necessary for the performance of a task carried out in the public interest.

The lawful basis relied on for the processing of special category data is Article 9(2)(i) - processing is necessary for reasons of public interest in the area of public health.

b. Demonstrate how information will be collected for specified, explicit and legitimate purposes and not further processed in a manner that is incompatible with those purposes,

The applicant provided assurance that the confidential patient information collected would be used to meet the aims of the study only.

c. Explain how the controller shall be responsible for, and be able to demonstrate compliance with, the accountability principle.

The applicant provided assurance that the data controller would comply with the accountability principle.

The CAG noted the above and raised no further queries.

Confidentiality Advisory Group advice conclusion

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

Specific conditions of support

1. Favourable opinion from a Research Ethics Committee. **Confirmed 02 December 2019.**

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.

a. **Confirmed – NHS Digital has a confirmed 'Standards Met' grade on DSPT submission 2018/19 by NHS Digital email dated 23 May 2019.**

b. **Confirmed – the University of Birmingham has a confirmed 'Standards Met' grade on DSPT submission 2019/20 by NHS Digital email dated 15 July 2020.**

3. Continual achievement of 'Standards Met' in relation to the relevant DSPT submission (or any future security assurance changes) for the duration of support. Evidence to be provided (through NHS Digital confirmation they have reviewed and confirmed the DSPT submission as standards met' for the duration of support, and at time of each annual review.

q. 19/CAG/0182 - National Joint Registry – Research Database

Name	Capacity
Dr Martin Andrew	CAG Member
Dr Patrick Coyle	CAG Vice-Chair
Dr Simon Kolstoe	CAG Member
Ms Gillian Wells	CAG Member
Ms Kathleen Cassidy	HRA Confidentiality Advisor

Context

Purpose of application

This application from the Healthcare Quality Improvement Partnership set out the purpose of medical research through the secondary use of information collated for audit purpose by the National Joint Registry, under reference 18/CAG/0146, for research purposes.

The CAG's remit only extends to the secondary use of data for research purposes for those patients, within England and Wales, whose consent status is not known within the National Joint Registry. This currently extends to approximately 6% of records within the NJR. Those patients who have consented to the use of their information within the National Joint Registry have provided consent in relation to research purposes. The latest consent rate states 92.3% of patients have provided consent to their inclusion. Those patients who have declined consent would not be included in the research database.

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

Confidential patient information requested

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

Cohort	Patients who are included on the National Joint Registry following a 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 on the basis of section 251 support via application 18/CAG/0146.
Data sources	1. National Joint Registry dataset
Identifiers required for linkage purposes	1. Name 2. NHS Number 3. Date of birth 4. Postcode (unit level)
Identifiers required for analysis purposes	1. Gender 2. Age 3. Ethnicity
Additional information	The application set out a consented arm; this is not within the scope of the proposed support.

Confidentiality Advisory Group advice

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

1. **Provide assurance that, should a patient subsequently withdraw consent for their inclusion in the NJR and/or research database, they would be provided with an opportunity to decide what data, if any is retained for use.**

The applicant explained that, if a patient withdrew consent, all identifiable information for that patient will be removed from the record and the de-identified clinical data, which will no longer contain confidential patient information, will be retained for the NJR, but not made available via the research database. The applicant noted that the identifiable fields were not of use to the applicants in isolation, as the full dataset was needed, and there was no research use for the de-identified records, they do not offer an opportunity for patients to make more granular choices about withdrawal of consent. The CAG noted this information and raised no further queries.

Confidentiality Advisory Group advice conclusion

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

Specific conditions of support

1. Provide a revised data flow chart at the time of annual review which sets out the data flows for research purposes only.

2. Figures should be reported back within future annual reviews around the number of patients which are included within the research database under the provisions of the Mental Capacity Act 2005, together with the number included on the basis of unknown consent.

3. Favourable opinion from a Research Ethics Committee. **Confirmed 12 November 2019.**

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. See section below titled 'security assurance requirements' for further information. **Confirmed – Northgate, processor for the NJR and research database, has a confirmed 'Standards Met' grade on DSPT submission 2018/19 by NHS Digital DSPT Tracker checked 24 July 2020.**

r. 20/CAG/0012 - A Retrospective Cohort Study of Treatment Outcomes Among Adult Patients with Refractory or Relapsed Follicular Lymphoma

Name	Capacity
Dr Tony Calland MBE	CAG Chair
Dr Malcolm Booth	CAG Member
Dr Patrick Coyle	CAG Vice-Chair
Mr Tony Kane	CAG Member
Ms Kathleen Cassidy	HRA Confidentiality Advisor
Ms Natasha Dunkley	HRA Head of Confidentiality Advice Service
Dr Paul Mills	HRA Senior Confidentiality Advisor

Context

Purpose of application

This application from King's College Hospital NHS Foundation Trust set out the purpose of medical research which aims to estimate the Complete Response Rate (CRR) in adult patients with Relapsed/Refractory (R/R) Follicular Lymphoma (FL) treated with standard therapies.

Non-Hodgkin's Lymphoma (NHL) is a type of blood cancer that originates in the lymphatic system. There are various sub types of NHL, one of which includes Follicular Lymphoma (FL). Approximately 20% of all NHL and 60% of indolent NHL cases are Follicular Lymphoma (FL). FL is a disease considered treatable, but not curable with current therapeutic options. Patients with FL who relapse (when the disease comes back after treatment) or who are refractory (when the disease does not respond to treatment) to chemotherapy and other non-chemotherapy treatments are rare, and their prognosis is poor. Whilst recently approved drugs show evidence of efficacy, their use is limited by severe side effects. There is therefore a high unmet need for newer treatments with novel mechanisms of action to offer potentially curative options for these patients. Tisagenlecleucel is a cellular immunotherapy that uses autologous blood cells that have been genetically modified. Preliminary data indicates a good response in FL patients. The applicants plan to conduct a retrospective study in order to provide a

historical cohort for a planned clinical trial. It is not feasible to include a placebo-controlled arm in the trial, hence this design has been chosen.

The applicants will conduct a retrospective medical record review of a patient cohort with Follicular Lymphoma. Suitable patients will be identified using a controller data extraction from the participating Trust's electronic medical records, using a technique called 'Cogstack.' Cogstack will identify suitable patients and provide a proportion of the clinical data required. The applicants will then review each potential patient. Patients deemed unsuitable at this point will be deleted from the report. The applicants will complete an eligibility worksheet for suitable patients. A unique study ID will be assigned and non-identifiable data will be entered into the Electronic Data Capture System. The patients' unique study ID, name and hospital number will be entered into a password-protected document. Once all data queries have been resolved by the research site, the pseudo-link document will also be destroyed and there will be no identifiable data retained by sites at the end of the study.

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.

Cohort	Data will be collected from patients from multiple oncology centres with Relapsed/Refractory (R/R) Follicular Lymphoma (FL) treated between 1998 and 2019
Data sources	1. Electronic and paper patient records held at King's College Hospital NHS Foundation Trust and Guy's and St Thomas' Hospital
Identifiers required for linkage purposes	1. Name 2. NHS Number 3. Hospital ID Number 4. GP Registration 5. Date of birth 6. Date of death 7. Postcode

Identifiers required for analysis purposes	1. Gender 2. Year of birth 3. Month and year of death

Confidentiality Advisory Group advice

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

1. **Provide clarity on the role of Novartis in this research study.**

The applicant explained that the technical and operational leader for the study at Novartis had collaborated with the applicants when designing the study, developing the study protocol, and drafting the data collection form, which was subsequently converted by RTI Health Solutions into an electronic data capture system used by sites to enter the study data. The study materials were also collaboratively developed and the applicants took part in several rounds of formal scientific review with the Novartis Protocol Review Committee (PRC), which is comprised of the other Novartis scientists listed as collaborators in the IRAS application. All analyses for the study will be conducted by the applicant, and reviewed by the technical and operational leader for the study at Novartis and other Novartis scientists, and the site-level investigators. Any planned publications will also be collaboratively developed by these parties.

The CAG noted this information and raised no further queries.

2. **Describe the possible future uses of the data generated from this research study.**

The application confirmed that data collected for this application would be used as a comparator for other clinical studies. The CAG noted this answer and raised no further queries.

3. **Provide a patient notification to be used for this study, as well as details where the patient notification will be place. The notification should include clear details on how patients can opt out.**

The applicant provided the ReCORD-FL clinical poster and Opt-Out Form, used to inform potential participants of the study taking place at the Trust. The poster and Opt-out form will be placed in the Clinical Outpatient Area where relevant patients are attending for their appointments and are most likely to notice these. They will also be made available for patients who join existing lymphoma support groups. The CAG noted this information and raised no further queries.

4. **Undertake further Patient and Public Involvement and Engagement with a group relevant to this study, which should include discussion on the use of confidential patient information without consent.**

The applicant advised that efforts to conduct patient and public involvement and engagement had been hampered by the Covid-19 pandemic, however they had approached patients for feedback. The comments provided were attached. The CAG noted this information and raised no further queries.

5. **Confirm that any confidential patient information relating to patients not accepted into the study is destroyed at the earliest possible moment or anonymised if required for control purposes**

The applicant confirmed that any confidential patient information not accepted into study will be destroyed or data anonymized. The CAG noted this information and raised no further queries.

Confidentiality Advisory Group advice conclusion

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

Specific conditions of support

1. Favourable opinion from a Research Ethics Committee. **Confirmed 04 February 2020**

2. Confirmation provided from the IG Delivery Team at NHS Digital to the CAG that the relevant Data Security and Protection Toolkit (DSPT) submission(s) has achieved the 'Standards Met' threshold. See section below titled 'security assurance requirements' for further information. **Confirmed: The NHS Digital DSPT review for King's College Hospital NHS Foundation Trust (checked 17/03/2020) and Guy's and St Thomas'**

Hospital NHS Foundation Trust (check (13/05/2020) were confirmed as 'Standards Met' on the NHS DSPT Tracker

s. 20/CAG/0030 – Optimal management of lymphoedema: do attitudes towards body weight and experiences of practitioners and patients affect patient engagement and guideline adherence?

Name	Capacity
Dr Tony Calland MBE	CAG Chair
Dr Liliane Field	CAG Member
Dr Rachel Knowles	CAG Member
Dr Paul Mills	HRA Senior Confidentiality Advisor

Context

Purpose of application

This application from the University of Glasgow set out the purpose of medical research that seeks to develop understanding of the barriers and enablers of including body weight within the lymphoedema assessment and management plan.

Lymphoedema is a chronic, incurable condition which can seriously impact upon quality of life. It results from an impaired lymphatic system and can lead to swelling, pain, mobility problems, increased risk of infections and skin texture changes. Lymphoedema prevalence is rising in the developed world due to an ageing population and growing rates of obesity, chronic illness and cancer. Whilst there are a number of strategies which can be employed to manage lymphoedema, there is no known cure. Obesity has been identified as a risk factor and, as a result, lymphoedema management guidelines recommend that those presenting with lymphoedema who are overweight or obese are encouraged and supported to work towards achieving a healthy weight. However, no evidence has been published to ascertain whether body weight is a considered part of the lymphoedema assessment and management process, and the barriers and supports that can affect this aspect of care from a patient or practitioners' perspective. The applicants seek to address this gap by conducting a study, where interviews and questionnaires will be completed by practitioners treating lymphoedema and through an online questionnaire and interviews with patients treated for lymphoedema within the UK.

The study is comprised of three phases, involving multiple data collection processes. Consent from patients will be sought for each phase, apart from a retrospective revie of lymphoedema records that will be conducted within two Welsh Health Boards, the Hywel Dda Health Board and Swansea Bay University Health Board. A member of the direct care team will select the records of up to 30 suitable patients at each board. The research staff will then access the confidential patient information on site in order to extract an anonymised dataset.

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

Confidential patient information requested

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

Cohort	60 patients diagnosed with lymphoedema at Hywel Dda Health Board and Swansea Bay University Health Board
Data sources	1. Hywel Dda Health Board 2. Swansea Bay University Health Board
Identifiers required for linkage purposes	No identifiers are required for linkage purposes
Identifiers required for analysis purposes	No identifiers are required for analysis purposes

Confidentiality Advisory Group advice

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

1. **Stronger justification for not seeking consent from patients whose data will be accessed needs to be provided.**

The applicants cited the additional burden on the clinical teams to identify, approach and consent patients for purposes of their records to be reviewed. The work has been aligned to accepted practices for national audits.

The group were content with the response

2. **A patient notification and dissent strategy needs to be created and details provided to the CAG.**

A poster was provided that will be displayed in appropriate public areas of the lymphoedema service. The poster details the research, as well as a providing contact information for patients to opt out.

Members were content with the provided poster.

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

The applicants explained that they explored this issue with a group of expert patients in Wales and 2 additional individuals living in Scotland with Lymphoedema, and no specific issues were raised.

The group accepted 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

1. Favourable opinion from REC **Confirmed 29 September 2019.**

2. Confirmation from NHS Wales Informatics Service that the appropriate security assurance is in place for the two Health Board sites in Wales via the Caldicott Principles into Practice report. **Confirmed for Hywel Dda Health Board and Swansea Bay University Health Board by CPiP Out-turn reports received 20 July 2020.**

2. New Amendments

a. 18/CAG/0159 - Housing, family and environmental risk factors for hospital admissions in children

Name	Capacity
Ms Kathleen Cassidy	HRA Confidentiality Advisor
Dr Tony Calland MBE	CAG Chair

Context

Purpose of application

The applicants have existing support to process confidential patient information related to the birth cohort, previously collated under applications PIAG 2-10(g)/2005 and CAG 9-08(b)2014, in order to investigate the impact of environment and socio-economic factors on hospital admissions in children. The project uses data from an established birth cohort of infants born in England between 2005 and 2014. This is linked by the Office of National Statistics (ONS) to 2011 Census Data and small area level data on air pollution and building characteristics in order to create a dataset to facilitate analysis.

Amendment request

In this amendment, the applicants sought support to link the birth cohort to longitudinal environmental exposure (buildings and air pollution data) via linkage to maternal and child postcode histories in the Personal Demographic Service (PDS), held by NHS Digital. In order to facilitate this linkage, postcode level data on buildings, air pollution and distance to road data will be disclosed to NHS Digital by the applicants. ONS will disclose identifiers for the cohort, including NHS number, baby sex, date of birth, postcode at birth/delivery and a study ID, to NHS Digital, who will then link the mother & baby identifiers to PDS and extract longitudinal postcode histories and time stamps. NHS Digital will then link in the postcode level air pollution, distance to road and buildings data to the longitudinal postcode histories. Following linkage, only Study IDs, longitudinal air pollution and buildings exposure histories, and time stamps will be retained and transferred to the ONS Secure Research Service (SRS) for analysis.

The applicants also sought support to link the buildings data to mothers and babies at address level, rather than postcode level. The applicants advised that, during the course of the study, it may become possible to link the cohort to the buildings data via Unique Property Reference Numbers (UPRN, held by the Ordnance Survey), rather than by postcodes, providing a more accurate assessment of exposure. NHS Digital would then link the PDS records for the mothers and babies in the cohort to Addressbase which holds the UPRNs, and then to the buildings data (have UPRNs attached). The UPRNs would then be deleted and only study numbers, time stamps and buildings exposure data maintained and transferred to the SRS for analysis.

The applicants also sought support to include the following data items;

- Stillbirth and child mortality (up to 10 years of old), in addition to hospital admission as an outcome. Exact dates of birth and death with not be retained for analysis but used to derive week of birth and follow-up time, as described in the original application to CAG.
- Inclusion of family structure, specifically single/lone parenthood, as an exposure variable in the analyses. Variables to indicate single/lone parenthood were already available in the linked dataset and the applicants had previously planned to use these indicators to define socio-economic status and adjust for lone parenthood status in the analyses, but now also plan to look at lone parenthood as one of the primary exposure for hospital admission risk in children.
- Linkage of data for the mothers and babies in the cohort to output area data on tobacco expenditure. CACI Ltd will provide the applicants with tobacco expenditure data for all output areas in England, and the applicants will link these output area values to postcodes, using publicly available geographical mapping databases provided by ONS.

Confidentiality Advisory Group advice

The amendment requested was considered by the Confidentiality Advisory Group. The Group noted that the purpose of the amendment was to identify issues of deprivation due to place of residence and family structure and that the amendment was in the public interest.

Confidentiality Advisory Group advice conclusion

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

Specific conditions of support

The following sets out the specific conditions of support.

1. Confirmation provided from the IG Delivery Team at NHS Digital to the CAG that the relevant Data Security and Protection Toolkit (DSPT) submission(s) has achieved the 'Standards Met' threshold **(Confirmed – the Office for National Statistics (by check of the NHS Digital DSPT tracker on 22 June 2020) and NHS Digital (by check of the NHS Digital DSPT tracker on 22 June 2020) have confirmed 'Standards Met' grade on DSPT submission 2018/19.**

2. Confirmation of a favourable opinion from a Research Ethics Committee. **Confirmed 14 February 2020.**

b. PIAG 4-05(e)/2008 - UK Transplant Potential Donor Audit

Name	Capacity
Dr Paul Mills	HRA Senior Confidentiality Advisor

Context

Purpose of application

This application from NHS Blood and Transplant set out the purpose of utilising donor referral information in an identifiable format to allow audit activities to take place using the data.

Amendment request

This amendment requests support to use the Microsoft Azure platform to host the data collected as part of this audit. This does not fundamentally alter the audit process but provides an enhanced level of security and form part of NHS Blood and Transplant's ongoing activity to improve its technical solutions.

The amendment also requests support to collect NHS number and date of birth, rather than age. NHS number is requested to ensure that data can be correctly linked to hospital records as and when required. Date of birth, rather than age is requested to

be used as a second identifier if the NHS number isn't available, in case the Senior Nurse Organ donation needs to discuss a particular case and allows the audit to calculate neonates age in days.

Confidentiality Advisory Group advice

The amendment requested was considered by a Sub-Committee. Members had no concerns regarding both changes, and felt the use of the additional identifiers would provide a more robust system for linkages.

Confidentiality Advisory Group advice conclusion

In line with the considerations above, the CAG/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 – NHS Blood and Transplant has a confirmed 'Standards Met' grade on DSPT submission 2018/19 by NHS Digital (by check of DSP tracker 07 July 2020).**

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

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

Context

Purpose of application

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

Amendment request

The amendment seeks support under the Regulations to extend the recruitment window from 15 months to 2 years due to study update being slower than projected. Study recruitment started 8 March 2019 and applicants seek to extend the duration of the recruitment window until 8 March 2021.

In line with the previous amendment which gained support for extending the eligible geographical cohort to invite participants from London and the surrounding areas, the applicant has provided updated area specific newspaper adverts for Hertfordshire, Essex, and South East London, and an update to the dissent text for the SUMMIT website. The current amendment does not seek to extend the eligible geographical cohort further.

The amendment also seeks support for applicants to retain an additional data point (full postcode) to determine whether distance to travel affects uptake.

Confidentiality Advisory Group advice

The amendment requested was considered by the Chair's Action. The Chair was fully supportive of the time extension to enable the applicant to reach their recruitment target. The Chair acknowledged the importance of this project in the fight against lung cancer and the need to understand reasons for reluctant uptake. The Chair was therefore supportive of the applicant retaining the full postcode to ascertain the exact distance needed to travel for screening. However, the full postcode would need to be pseudonymised or reduced in specificity at the earliest opportunity.

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

2. Confirmation of a favourable opinion from a Research Ethics Committee
   Confirmed 21 March 2020

d. ECC 3-04(f)/2011 - SLAM IG Clinical Dataset Linking Service

Name	Capacity
Dr Paul Mills	HRA Senior Confidentiality Advisor

Context

Purpose of application

This application has support to link confidential patient information between South London and Maudsley NHS Foundation Trust (SLaM) and NHS Digital to provide a dataset with the purpose of investigating the associations between specific mental disorders in secondary mental health care and physical illness. This support was provided for use in adults only. Further support in a previous amendment extended the support to research in children for specific projects only, with data linked from the National Pupil Database.

Amendment request

This current amendment request is to use the already linked data held by SLaM CRIS to undertake a specific research project in patients with a diagnosis of dissociative disorder or somatoform disorder whose diagnosis was before 19 years of age. The objective of the current research is to examine children who attend paediatric clinics for physical symptoms but have no medical explanation for these symptoms and look the pattern of use of child mental health services to detect and treat psychological factors to reduce unnecessary medicalisation of these symptoms. A pattern of use has been seen in adults and this research will explore if there is a similar pattern of service use in children with medically unexplained symptoms and what the impact is of the SLAM child and adolescent liaison psychiatry service.

No further data linkages are required for purposes of this project.

Confidentiality Advisory Group advice

The amendment requested was considered by a Sub-Committee of the group. Members though the current proposal had a medical benefit and a public interest and were content to recommend support.

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 DSPT review for South London and Maudsley NHS Foundation Trust was confirmed as 'Standards Met' on the NHS DSPT Tracker (checked 10 July 2020)**

2. Confirmation of a favourable opinion from a Research Ethics Committee. **Confirmed 13 July 2020.**

e. 17/CAG/0083 (previously 17/CAG/0022) - Is the Current Threshold for Diagnosis of "Abnormality", including non-ST Elevation Myocardial Infarction, using Raised Highly Sensitive Troponin Appropriate for a Hospital Population? The CHARIOT Study

Name	Capacity
Dr Paul Mills	HRA Senior Confidentiality Advisor

Context

Purpose of application

The application was supported to check the high sensitive troponin (Hs Trop) levels on patients who have already had blood tests undertaken as part of their routine clinical care, with a previous amendment supported to link to NHS Digital data as part of a 1-year follow up.

Amendment request

This current amendment seeks support to allow the disclosure of confidential patient information from University Hospital Southampton to NHS Digital in order to facilitate a further two and a half year mortality status follow-up via linkage with HES and ONS data.

Confidentiality Advisory Group advice

The amendment requested was considered by a Sub-Committee of the CAG. Members were supportive of the request and were content that the justifications for it were in the public interest,

Confidentiality Advisory Group advice conclusion

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

Specific conditions of support

The following sets out the specific conditions of support.

1. Confirmation provided from the IG Delivery Team at NHS Digital to the CAG that the relevant Data Security and Protection Toolkit (DSPT) submission(s) has achieved the 'Standards Met' threshold: **Confirmed. NHS Digital and University Hospitals Southampton NHS Foundation Trust have confirmed 'Standards Met' grade on DSPT 2018/19 (by check of DSPT Tracker 03 July 2020).**

2. Confirmation of a favourable opinion from a Research Ethics Committee
   Confirmed 5 February 2020

f. 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
Dr Paul Mills	HRA Senior Confidentiality Advisor

Context

Purpose of application

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 NHS Foundation Trust mental health Clinical Record Interactive Search (CRIS), and to link with the Lambeth DataNet (LDN) GP patient record data.

Amendment request

This amendment requests to link eLIXIR data, held by SLaM CDLS, with NHS Digital HES data. SLaM CDLS will provide first name, last name, gender, date of birth, NHS number and eLIXIR ID of service users to NHS Digital. NHS Digital return the HES data to SLaM CDLS in a pseudonymised fashion, using the eLIXIR ID. By incorporating this HES data, eLIXIR will create a research resource that will link maternity, neonatal, mental health, primary care and inpatient hospital record data.

Confidentiality Advisory Group advice

The amendment requested was considered by the Confidentiality Advisory Group. Members felt that by undertaking the linkage it will extend an already effective database and provide further advantages, as outline in the submission.

Confidentiality Advisory Group advice conclusion

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

Specific conditions of support

The following sets out the specific conditions of support.

1. Confirmation provided from the IG Delivery Team at NHS Digital to the CAG that the relevant Data Security and Protection Toolkit (DSPT) submission(s) has achieved the 'Standards Met' threshold **(Confirmed – South London and Maudsley NHS Foundation Trust has a confirmed 'Standards Met' grade on DSPT submission 2018/19 by NHS Digital email dated 06 December 2019). NHS Digital has a confirmed 'Standards Met' grade on DSPT submission 2018/19 by check of the DSPT tracker (14 July 2020)**

2. Confirmation of a favourable opinion from a Research Ethics Committee **(Confirmed 02 March 2020).**

g. CAG 2-07(c)/2013 - The Pesticide Users' Health Study: Nervous system, eye, respiratory and skin disease among certified pesticide users

Name	Capacity
Dr Paul Mills	HRA Senior Confidentiality Advisor

Context

Purpose of application

This application from the Health and Safety Executive (HSE) detailed a large cohort study of pesticide users comprising of more than 60,000 individuals, and received support for a one-off extraction of HES data between 1997-98 and 2011/12 from NHS Digital, which would be linked to study data retained by the HSE.

Amendment request

This amendment request comprises three separate elements:

- The data that the applicant obtained up until 2011/12 is now out of date and are requesting support to collect further HES data from NHS Digital until the latest data that data is available for so up to date data can be collected.
- The applicants also request support to transfer the NHS number from NHS Digital to National Records of Scotland (NRS), and vice versa, with each being passed through the study team. This is so that participants are not lost if they move between countries.
- The applicants request support to amend support from a one-off data collection to being able to make further ad-hoc collections from national data when new or updated analysis is required. It also moves to there being a set end date to no set end date.

Confidentiality Advisory Group advice

The amendment requested was considered by a Sub-Committee of the CAG.

The sub-committee were content with the request to collect HES data from NHS Digital for the latest date that data is available, and members thought it was beneficial to be able to use the latest available information for the study.

Members also agreed on the benefits that sharing NHS number to ensure patients are not lost to follow up bring. The group were supportive, but asked for the outcome of the PBPP application to be shared when available as a condition of support.

Members were currently not supportive of the request to move the application from a one-off data collection with a set end date to collecting data on an ad hoc basis with no set end date. The group considered this and felt that there was insufficient information regarding steps taken to, and justification as to why, the data held cannot be deidentified/pseudonymised. Members also felt that if the HSE hold the NHS number for the participants, that the support provided requires a time limit with further scrutiny if the applicant requests to hold identifiable information for a longer time period.

Confidentiality Advisory Group advice conclusion

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

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

1. The amendment to collect further HES data from NHS Digital until the latest data that data is available for is supported, subject to compliance with the standard conditions of support.

2. The amendment to transfer the NHS number from NHS Digital to National Records of Scotland (NRS), and vice versa is conditionally supported, subject to compliance with the standard and specific conditions of approval.

3. The amendment to request support to amend support from a one-off data collection to being able to make further ad-hoc collections from national data when new or updated analysis is required. is not supported.

Specific conditions of support

The following sets out the specific conditions of support.

1. Provide the outcome of the PBPP application once available.

2. Confirmation provided from the IG Delivery Team at NHS Digital to the CAG that the relevant Data Security and Protection Toolkit (DSPT) submission(s) has achieved the 'Standards Met' threshold **(Confirmed: Health and Safety Executive Laboratory - NHS Digital have confirmed qualified assurance against the Health and Safety Executive Laboratory's 2018/19 DSPT submission on the basis that the Trust has not met the 95% standard relating to staff security awareness training.**

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

3. Confirmation of a favourable opinion from a Research Ethics Committee. **(Confirmed 10 October 2019).**

h. PIAG 1-05(e)/2006 - Frequency of follow-up for patients with low-, intermediate- and high risk colorectal adenomas

Name	Capacity
Dr Paul Mills	HRA Senior Confidentiality Advisor

Context

Amendment request

This amendment is requesting support to include three additional aims in the study protocol. The overall research objectives remain unchanged. The additional aims are:

1) Are the new 2019 surveillance guidelines able to identify those patients who benefit the most from surveillance whilst reducing the number of patients recommended surveillance?

2) Is there a better way to stratify patients for surveillance than the risk groups given in the 2002 or the 2019 surveillance guidelines?

3) What is the long-term effect of surveillance in patients with inflammatory bowel disease as a model for those at higher-risk of colorectal cancer?

The first two additional aims will be addressed by repeating the analyses already conducted based on the 2002 guideline risk stratification criteria using the new 2019 risk stratification criteria.

The third aim will be addressed using a similar statistical approach employed for the original All Adenomas study aims.

Aims 1) and 2) are added because the study was designed to examine the risk stratification criteria given in the 2002 surveillance guidelines. In 2019, the guidelines for adenoma surveillance in the UK were updated. These new guidelines use different criteria to identify those patients who are recommended for surveillance.

Additional aim 3) is required to optimise surveillance strategies for ‘at risk’ population groups, as a large proportion of colonoscopy capacity (approximately 15%) is used for surveillance, and demand on colonoscopy services has been increasing in recent years and is expected to continue to rise due to increased referrals from the Bowel Cancer Screening Programme.

Confidentiality Advisory Group advice

The amendment requested was considered by a Sub-Committee who felt the additional aims were warranted and advised support for the amendment.

Confidentiality Advisory Group advice conclusion

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

    - **Imperial College London, Faculty of Medicine, Cancer Screening and Prevention Research Group (8HL46-FOM-CSPRG) has confirmed 'Standards Met' on DSPT 2019/20 (DSPT Tracker 01 July 2020).**
    - **NHS Digital and Public Health England have confirmed 'Standards Met' on DSPT 2018/19 (DSPT Tracker 01 July 2020).**

2. Confirmation of a favourable opinion from a Research Ethics Committee **Confirmed 4 February 2020**

i. 19/CAG/0005 - Outcomes of patients undergoing lower limb vascular procedures in the National Vascular Registry

Name	Capacity
Ms Kathleen Cassidy	HRA Confidentiality Advisor

Context

Amendment request

The applicants have existing support to allow the disclosure of specified confidential patient information from the National Vascular Registry (NVR) to NHS Digital to facilitate linkage with the HES and ONS databases. De-identified data will then be shared by NHS Digital to the

research team at North Bristol NHS Trust, to enable the researchers to undertake a service evaluation to describe the longer-term patient outcomes after lower limb vascular surgery in England.

This amendment set out a request to amend the data flow so that de-identified data will flow directly from the NVR to the University of Bristol, and then on to North Bristol NHS Trust. This is in addition to the flow of data from the NVR to NHS Digital and then to North Bristol NHS Trust. The de-identified data provided from the NVR will contain an NVR ID, which is a unique pseudonym to permit linkage. The applicants provided confirmation that HQIP, data controller of NVR, had approved the amendment.

Confidentiality Advisory Group advice

The amendment requested was considered by the Confidentiality Advice Team. The Team agreed that support this addition to the data flow did not require review by the CAG.

Confidentiality Advisory Group advice conclusion

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

Specific conditions of support

The following sets out the specific conditions of support.

1. Confirmation provided from the IG Delivery Team at NHS Digital to the CAG that the relevant Data Security and Protection Toolkit (DSPT) submission(s) has achieved the 'Standards Met' threshold **(Confirmed – NHS Digital (NHS Digital DSPT Tracker checked 08 July 2020) has a published satisfactory reviewed grade on V14.1, 2018/19**).

j. 18/CAG/0102 - HES and NICOR data linkage for cardiac failure population analysis

Name	Capacity
Dr Paul Mills	HRA Senior Confidentiality Advisor

Context

Amendment request

The applicants sought support to clarify the data flows to be used in the study, confirming that there were no changes to the actual flows.

Confidentiality Advisory Group advice

The amendment requested was considered by the Confidentiality Advisory Team, who considered the request and confirmed that there were no changes in data flows from the initial application.

Confidentiality Advisory Group advice conclusion

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

Specific conditions of support

The following sets out the specific conditions of support.

1. Confirmation of suitable security arrangements via Data Security and Protection Toolkit (DSPT) submission. **(Confirmed: NHS Digital (by NHS Digital email 10 June 2019) and King's Technology Evaluation Centre (by NHS Digital email 05 December 2019) have confirmed 'Standards Met' grade on DSPT 2018/19).**

2. Confirmation of a favourable opinion from a Research Ethics Committee – **Confirmation that review by a REC was not required was provided on 09 January 2020.**

k. 19/CAG/0054 - An evaluation of knee arthroplasty fixation in an evolving challenging population

Name	Capacity
Ms Kathleen Cassidy	HRA Confidentiality Advisor

Context

Amendment request

The applicants have existing support for the disclosure of specified items of confidential patient information from Northgate Public Services, processor for the National Joint Registry, to NHS Digital in order to facilitate linkage with HES and ONS datasets, in order to compare outcomes for patients undergoing cemented versus uncemented knee replacements in England.

In this amendment, the applicants sought support to include an additional data item, “Date of knee replacement surgery” in the data fields which Northgate Public Services send to NHS Digital for linkage purposes. This change was required as NHS Digital had changed their rules since the initial application was submitted and will only provide the applicants with HES data for the 5 years prior to the date the knee replacement surgery was undertaken. NHS Digital had informed the applicants that they were unable to determine the data of the surgery and therefore required that this data was supplied to them, in order to provide the required HES data.

Confidentiality Advisory Group advice

The amendment requested was considered by the Confidentiality Advice Team. The CAG noted that the additional item of data was required in order for NHS Digital to provide accurate data.

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: Northgate Public Services (by check of the NHS Digital DSPT tracker on 13 July 2020), University of Oxford – Nuffield Department of Orthopaedics, Rheumatology and Musculoskeletal Sciences, Big Health Data Group (by check of the NHS Digital DSPT tracker on 13 July 2020) and NHS Digital (by check of the NHS Digital DSPT tracker on 13 July 2020) have confirmed 'Standards Met' grade on DSPT 2018/19).**

2. Confirmation of a favourable opinion from a Research Ethics Committee. **Confirmed 28 February 2020.**

I. 18/CAG/0050 - The DESiGN Trial - Detection of small for gestational age fetus (SGA)

Name	Capacity
Ms Kathleen Cassidy	HRA Confidentiality Advisor

Context

Amendment request

This amendment set out a request to extend the duration of the study until 30 November 2020. This additional time is required to allow for completion of any outstanding data collection from sites in which data received was incomplete and to conduct the planned secondary analyses, which were outlined in the original protocol. The two main funders of the trial, Guy's and St Thomas' charity and Sands charity, supported this extension. Neither funder has been asked to provide additional funding as the funds to date have been conservatively managed.

Confidentiality Advisory Group advice

The amendment requested was considered by the Confidentiality Advice Team. The Team agreed that the extension 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 – Guy's and St Thomas' NHS Foundation Trust has a confirmed 'Standards Met' grade on DSPT submission 2018/19 by NHS Digital DSPT Tracker checked 24 July 2020).**

2. Confirmation of a favourable opinion from a Research Ethics Committee. **The REC confirmed on 14 July 2020 that this amendment did not require ethical approval.**

m. 18/CAG/0131 (previously CAG 6-07(d)/2013) – Inflammatory Bowel Disease Registry

Name	Capacity
Ms Caroline Watchurst	HRA Confidentiality Advisor

Context

Amendment request

This amendment seeks to extend the duration of support until 14 September 2021 to allow the applicant to continue and complete work on a new consent model, launch and rollout that is properly required for the function of the IBD Registry. This amendment is requested due to the impact on the planned consent rollout during 2020, primarily due to the impact of COVID-19. The applicant was required to divert their operational activities to support the public interest of identifying vulnerable at-risk IBD patients, and also required to reschedule all engagement work with clinical teams to a post-COVID19 timeframe.

Confidentiality Advisory Group advice

The amendment requested was considered by Chairs Action. The CAG agreed that to extend the duration of support is reasonable and understandable.

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**

    - **IBD Registry Ltd., and Chamaeleon Information Management Services (CIMS) and University of Liverpool and NHS Digital have confirmed 'Standards Met' on DSPT 2018/19 (by check of DSPT Tracker 19 June 2020).**
    - **AIMES Management Services has confirmed 'Standards Met' on DSPT 2019/20 (by check of DSPT Tracker 19 June 2020)**
    - **NWIS 2020/21 (Confirmed by CPiP letter)**

2. Condition to report to CAG at the next annual review with significant progress towards a consented model.

n. 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

Context

Amendment request

This amendment requests support for cleaned HES data to be transferred from UCL to UCLH via encrypted memory stick. This is requested because researchers analysing data at UCL have now left, so analysis needs to be continued at UCLH.

Confidentiality Advisory Group advice

The amendment requested was considered by the CAG chair, who was content with the request.

Confidentiality Advisory Group advice conclusion

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

Specific conditions of support

The following sets out the specific conditions of support.

1. Confirmation provided from the IG Delivery Team at NHS Digital to the CAG that the relevant Data Security and Protection Toolkit (DSPT) submission(s) has achieved the 'Standards Met' threshold: **Confirmed**
    - **University College London Hospitals NHS Foundation Trust and University College London - SLMS has confirmed 'Standards Met' on DSPT 2018/19 (by check of DSPT Tracker 22 June 2020).**

2. Confirmation of a favourable opinion from a Research Ethics Committee **Confirmed 7 May 2020**

o. 18/CAG/0038 - A randomised controlled trial to evaluate invitation to community-based low dose computed tomography (LDCT) screening for lung cancer versus usual care in a targeted population at risk

Name	Capacity
Ms Caroline Watchurst	HRA Confidentiality Advisor

Context

Amendment request

The original application has support for a cohort consisting of 62,980 people randomised, 31,490 in each arm.

These sample size calculations were based on best estimates given the existing literature. Interim review on study progress has indicated the eligibility rate was lower than anticipated. To ensure the study is adequately powered this amendment is requesting support to increase the sample size from 62,980 people to 90,000 people. To date, the Yorkshire Lung Screening Trial has randomised 57,551 participants. Increasing the randomisation cohort will not alter the existing timelines for the study.

The applicant has support to use the electronic frailty index (eFI) value as an exclusion criteria, and use the eFI for future analysis. There is inconsistency in the way the eFI is recorded in primary care, so the applicant requests support to use the read codes to calculate the eFI value in a standardised way for all trial participants. The eFI is constituted from 36 deficits, comprising around 2000 Read codes, however in practice each patient is

likely to have a much smaller number of codes present in their records and extracted. The flow of data will remain unchanged. The amendment seeks support to use eFI value in additional ways to further explore the link between frailty/comorbidity and screening outcomes, and the applicant does already have support to use the eFI value for future analysis.

Confidentiality Advisory Group advice

The amendment requested was considered by the CAG chair. There are no issues with this amendment request.

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**
   Leeds Teaching Hospitals NHS Trust, University of Leeds – IRC and CFH Docmail LTD have confirmed 'Standards Met' on DSPT 2018/19 (by check of DSPT Tracker 17 June 2020).

2. Confirmation of a favourable opinion from a Research Ethics Committee
   Confirmed 15 May 2020

p. 19/CAG/0221 - Association between tumour amphiregulin, epiregulin and epidermal growth factor receptor (EGFR) expression and response to anti-EGFR agents in colorectal cancer

Name	Capacity
Ms Caroline Watchurst	HRA Confidentiality Advisor

Context

Amendment request

The applicants have existing support to allow research nurses appointed solely for the purposes of the project on site at participating trusts to access confidential patient information held in the medical records of deceased patients in order to extract a linked-pseudonymised dataset for analysis.

In this amendment, the applicants sought support to include Portsmouth Hospitals NHS Trust as an additional data processor. It was necessary to include the additional site so that the applicants can reach their recruitment target.

Confidentiality Advisory Group advice

The amendment requested was considered by the Confidentiality Advice Team. The group raised no queries about the applicant requesting support to add an additional site as a data processor. However it was noted that as part of the initial application DSPT security assurances were not checked by the Confidentiality Advice Team (CAT) due to the number of sites which will be processing with support under the Regulations. Support was recommended on the basis that the applicant ensures the required security standards are in place at each site prior to any processing of confidential patient information with section 251 support. This is still an important condition of support for the applicant to ensure is in place.

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 – Leeds Teaching Hospitals NHS Foundation Trust (by check of the DSPT tracker on 16 June 2020) has confirmed 'Standards Met' grade on DSPT submission 2018/19.**
    - **Portsmouth Hospitals NHS Trust (by email from NHS Digital on 7 July 2020) has confirmed 'Standards Met' grade on DSPT submission 2019/20.**
    - **Original additional 33 NHS trusts not checked due to the number of sites which will be processing with support under the Regulations. Support is recommended on the basis that the applicant ensures the required security standards are in place at each site prior to any processing of confidential patient information with section 251 support**

2. Confirmation of a favourable opinion from a Research Ethics Committee
   Confirmed 23 January 2020

q. 17/CAG/0176 - A Risk-adjusted and Anatomically Stratified Cohort Comparison Study of Open Surgery, Endovascular Techniques and Medical Management for Juxtarenal Aortic Aneursyms: The UK Complex Aneurysm Study (UK-COMPASS)

Name	Capacity
Dr Paul Mills	HRA Senior Confidentiality Advisor

Context

Amendment request

This application from the Royal Liverpool and Broadgreen University Hospitals NHS Trust was supported to examine how the different treatments for abdominal aortic aneurysm compare in terms of clinical benefit and the utilisation of NHS resources. The study will link data between NHS Digital, imaging data from Trusts and the National Vascular Registry for both initial collection and follow up over a five-year period.

This amendment requests support to update the data fields that will be collected in each dataset, most of which are clinical data points. The applicants also request support to collect date of death (truncated to month/years) from NHS Digital HES/ONS data, as well as collect NHS number and date of birth from NHS Digital in follow up collections. These identifiable data fields are already collected, but this amendment seeks to use them for follow up data as well as at initial data collection. The applicants confirmed that there are no new data flows.

Confidentiality Advisory Group advice

The amendment requested was considered by a Sub-Committee who were content to advise support for the proposed changes.

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 Royal Liverpool and Broadgreen University Hospitals NHS Trust and NHS Digital have achieved the 'standards met' assurance through NHS Digital review (by check of DSPT tracker 15 July)**

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

r. 19/CAG/0096 - A randomised pilot study of a pharmacist-led retrospective review of prescribing by general practitioners in training (REVISiT) intervention

Name	Capacity
Dr Paul Mills	HRA Senior Confidentiality Advisor

Context

Amendment request

This application gained support under the Regulations to legitimise access to confidential patient information on site at GP practices by the Pharmacist undertaking the review of the GP trainee prescribing practices. Within the initial application and supporting documents, the applicants described that the pharmacist undertaking the review will be employed by a GP practice or Clinical Commissioning Group.

This amendment seeks to extend the support for the pharmacist undertaking the review to also include pharmacists employed by Primary Care Networks. As the NHS landscape for primary care based pharmacists is changing, pharmacists working in general practice now includes primary care pharmacists with their employment through primary care networks (PCNs). This would allow the applicants to recruit primary care pharmacists for our pharmacist-led intervention in a way that reflects ‘real-life’ practice.

The amendment also requests support for updated patient information documents (poster advert and patient information leaflet), The documents have updated the phraseology so the information reads correctly whether patients will be seeing/receiving this information physically in the practice or if they are engaging with the practice remotely, the latter being more likely as a result of Covid-19.

Confidentiality Advisory Group advice

The amendment requested was considered by a Sub-Committee, who were content to advise support for the amendment

Confidentiality Advisory Group advice conclusion

In line with the considerations above, the CAG agreed that the minimum criteria under the Regulations appeared to have been met for this amendment, and therefore advised recommending support to the 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. **Not checked due to the number of research sites involved. Support is recommended on the basis that the applicant ensures the required security standards are in place at each site prior to accessing confidential patient information with support under the Regulations**

2. Confirmation of a favourable opinion from a Research Ethics Committee. **Confirmed 31 May 2020.**

s. 19/CAG/0053 - Myeloproliferative neoplasms Associated SplanChnic vein Thrombosis: Mascot Registry

Name	Capacity
Ms Caroline Watchurst	HRA Confidentiality Advisor

Context

Amendment request

This study from the University College Hospitals London NHS Trust is establishing a research database of patients with Myeloproliferative neoplasms Associated SplanChnic vein Thrombosis (MPN-SVT). Support is currently in place for the clinical team at participating sites in England and Wales to enter confidential patient information directly into an online data platform hosted by Dendrite Clinical Systems Ltd.

In this amendment the applicant is seeking to extend support for one and a half years, until 1 February 2022. The applicant expects to complete recruitment in August 2021 and aims to complete analysis by February 2022. The extension is due to the cessation of research activity due to Covid-19. There have also been a number of changes to Principal Investigators at participating sites, and the applicant has updated the protocol accordingly as part of this amendment.

Confidentiality Advisory Group advice

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

Confidentiality Advisory Group advice conclusion

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

Specific conditions of support

The following sets out the specific conditions of support.

1. Confirmation provided from the 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 – Dendrite Clinical Systems Ltd has confirmed 'Standards Met' on DSPT 2018/19 (by check of DSPT tracker on 13 July 2020)

2. Confirmation of a favourable opinion from a Research Ethics Committee.
   Confirmed Non-Substantial 3 July 2020

t. 18/CAG/0164 - Use and impact of the pre-hospital 12-lead electrocardiogram in the primary PCI era. Mixed method study (PHECG-2)

Name	Capacity
Ms Caroline Watchurst	HRA Confidentiality Advisor

Context

Amendment request

This study from Kingston University and St George's University of London aims to assess the association of Pre-Hospital 12-lead electrocardiogram (PHECG) with patient outcomes, and research factors contributing to the decision to record (or not) a PHECG. Support is currently in place to disclose specified items of confidential patient information from Bart's Health NHS Trust (NICOR Programme) to NHS Digital to facilitate linkage with ONS mortality information and to cover access to confidential patient information by research paramedics at 2 NHS trusts in England and 1 in Wales.

The amendment seeks an extension of support until 30 September 2020 to align with the no-cost extension from the funder, to allow the research to be completed. There have been delays caused by various factors including Covid-19.

Confidentiality Advisory Group advice

The amendment requested was considered by the Confidentiality Advice Team. There were no concerns raised with this amendment.

Confidentiality Advisory Group advice conclusion

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

Specific conditions of support

The following sets out the specific conditions of support.

1. Confirmation provided from the IG Delivery Team at NHS Digital to the CAG that the relevant Data Security and Protection Toolkit (DSPT) submission(s) has achieved the 'Standards Met' threshold - **Confirmed**
    - **The NHS Digital DSPT review for South Western Ambulance Services NHS Foundation Trust for 2018/19 was confirmed as 'Standards Not Fully Met (Plan Agreed)' on the NHS DSPT Tracker (checked 13 July 2020). Support is conditional upon South Western Ambulance Services NHS Foundation Trust meeting the action plan, as agreed with NHS Digital**
    - **NHS Digital, and West Midlands Ambulance Services NHS Foundation Trust have confirmed 'Standards Met' on DSPT 2018/19 (by check of DSPT tracker on 13 July 2020)**
    - **Welsh Ambulance Services NHS Trust – Caldicott Principles into Practice report received with an assessment score of 95.7% NHS Wales Informatics Service confirmed approval via email on 06/09/2019).**

2. Confirmation of a favourable opinion from a Research Ethics Committee. **Confirmed Non-Substantial 13 July 2020**

u. 18/CAG/0091 (previously 17/CAG/0178) - 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 establishing a research database aiming to understand the relationship between child health issues and educational attainment levels within the Bradford and Airedale locality.

This amendment seeks to extend the duration of support until 31 December 2021 to enable sufficient time to link the healthcare data with the Department of Education data.

This amendment also seeks support for minor updates to patient communication documentation to reflect the updated website and removal of Connected Health Cities references and logo.

Confidentiality Advisory Group advice

The amendment requested was considered by the Confidentiality Advice Team. There were no concerns raised with this amendment.

Confidentiality Advisory Group advice conclusion

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

Specific conditions of support

The following sets out the specific conditions of support.

1. Confirmation provided from the 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 following entities have 'Standards Met' assurance on DSPT 2018/19, confirmed by check of DSPT tracker on 13 July 2020:

- **Bradford Teaching Hospitals NHS Foundation Trust (Org Code: RAE),**
- **Bradford District Care Trust (Org Code: TAD),**
- **Airedale NHS Trust (Org Code: RCF),**
- **Apollo Medical Software Solutions Ltd. (Org Code: 8HH66).**

- **Department for Education has confirmed the equivalent of standards met for 2019/20 (by check of DSPT tracker 13 July 2020)**

- **City of Bradford Metropolitan District Council (Org Code: 209) has achieved Qualified Assurance on DSPT 2018/19. However the Trust has not achieved 95% of staff receiving data security awareness training. It is a condition of support that all staff within this organisation processing confidential patient information for the purposes of this study have completed data security awareness training.**

2. Confirmation of a favourable opinion from a Research Ethics Committee.
Non-Substantial amendment to REC not required for research database confirmed by REC 22 June 2020

v. 19/CAG/0196 - Evaluating prescribing safety indicators embedded in computerised clinical decision support software OptimiseRx

Name	Capacity
Ms Kathleen Cassidy	HRA Confidentiality Advisor

Context

Amendment request

The applicants have existing support to allow ResearchOne and NHS Digital to generate a SALT link key to facilitate linkage between primary care data from GP practices and HES, ONS and IMD datasets at NHS Digital. In this amendment, the applicants are seeking support to modify the data storage arrangements and to revise the outcome measures for the study.

The applicants are seeking support to expend to the range of serious harm outcomes linked with hazardous prescribing which will be examined. In the original application, the applicants had proposed to investigate gastrointestinal bleed, exacerbation of asthma, heart failure, stroke, and kidney injury, which are serious harm outcomes associated with the PINCER prescribing indicators. The applicants now intend to include seven additional serious harm outcomes to examine, where possible: myocardial infarction, acute coronary syndrome, venous thromboembolism, arrhythmia, pneumonia, fractures, and rhabdomyolysis.

OptimiseRx currently has 126 indicators for safe prescribing, obtained from the following sources: PINCER, European Medicines Agency (EMA), Medicines & Healthcare products Regulatory Agency (MHRA), Patient Safety Alert, and Royal College of GP (RCGP). The applicants had initially planned to focus on evaluating the prescribing indicators from PINCER, as this aligned with the work on PINCER undertaken in other work packages under the same programme. Following discussion with stakeholders, the applicants have determined that they should include other prescribing indicators in the

OptimiseRx evaluation. After consultation with medical and pharmaceutical experts in the study team, the applicants have now identified a total of 79 prescribing indicators from MHRA, Patient Safety Alert, RCGP, as well as PINCER, which they intend to evaluate. A list of the indicators was provided with the amendment submission.

The applicants are also seeking support to change the data storage arrangements. In their original application, the applicants had stated that all data received from ResearchOne and NHS Digital would be processed and stored within the University of Manchester's Data Safe Haven. After consulting with the University's Research IT Team, the applicants have now decided not to use the Data Safe Haven. The study data will instead by stored within the University of Manchester Research Data Storage Service. This is an access restricted data share on the University network storage infrastructure and is the recommended location for storing sensitive or critical University data.

Confidentiality Advisory Group advice

The amendment requested was considered by the Confidentiality Advisory Group. The Group agreed that the amendment was in the public interest. The Group reminded the applicants that they had been asked to re-consult the patient and public involvement group after the study had begun to assess whether the arrangements for patient notification and opt-out are working well, and a report on this feedback is to be provided when the annual review is submitted to CAG.

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 – NHS Digital has a confirmed 'Standards Met' grade on DSPT submission 2018/19 by email dated 10 June 2019.**

- **Confirmed - The Phoenix Partnership (TPP) has a confirmed 'Standards Met' grade on DSPT submission 2018/19 by email dated 09 March 2020.**

- **Confirmed - University of Manchester has a confirmed 'Standards Met' grade on DSPT submission 2018/19 by check of the NHS Digital DSPT tracker on 16 July 2020.**

2. Confirmation of a favourable opinion from a Research Ethics Committee.
   Confirmed 25 June 2020.

w. CAG 2-05(b)/2013 - Pandemic Influenza Triage in the Emergency

Name	Capacity
Ms Kathleen Cassidy	HRA Confidentiality Advisor

Context

Amendment request

Support was initially given in 2013 for the applicants to conduct a prospective observational cohort study of patients attending emergency departments with suspected pandemic influenza so as to evaluate existing triage methods, identify clinical predictors of adverse outcomes and develop new triage methods. The applicants submitted an amendment in February 2020 to activate this application in order to study patients with COVID-19. This further amendment has been submitted to make additional changes.

The protocol has been updated to include the following aims:

1. To link NHS 111 calls, identified as potentially relating to COVID-19, to participating hospital and NHS Digital data, to determine whether patients calling NHS 111 were appropriately advised or provided with an ambulance response, in terms of whether they were admitted to hospital or suffered an adverse outcome.
2. To link ambulance ePR data to hospital and NHS Digital data, to determine whether patients attended by ambulance were appropriately advised to self-care at home or transported to hospital, in terms of whether they were admitted to hospital or suffered an adverse outcome.
3. To use ambulance ePR data recording patient characteristics to determine which patient characteristics, when recorded prehospital, are useful in predicting adverse

outcome and determine the discriminant value of early warning scores, such as NEWS2, for predicting adverse outcome.
4. To explore the potential for data mining to provide new insights into the prediction of adverse outcome among patients contacting NHS 111 or ambulance services with suspected COVID-19.

The applicants also confirmed that NHS Digital and Yorkshire Ambulance Service (YAS) NHS Trust will act as data processors for the purpose of this study. An updated data flow diagram had been included to reflect this.

The following additional items of confidential patient information will be required to enable linkage between the core-PRIEST dataset, data supplied by NHS Digital and data supplied by Yorkshire Ambulance Service NHS Trust.

NHS 111 telephone service patient identifiable items (from YAS)

- NHS Number
- Postcode of residence
- Date of birth

Emergency ambulance service patient identifiable items (from YAS)

- NHS Number
- Patient name (first name and surname)
- Postcode of residence
- Postcode of incident
- Date of birth

Demographic patient identifiable items (from NHS Digital)

- NHS Number
- Postcode of residence
- Date of birth

Death registration patient identifiable items (from NHS Digital, ONS)

- Date of death

Emergency department patient identifiable items (from participating English acute hospital Trusts)

- NHS Number

- Date of birth

The applicant also clarified that they would access records relating to activity occurring within the following periods:

- NHS 111 telephone service - 01/02/2020 to 30/09/2020 (inclusive)

- Emergency ambulance service - 26/03/2020 to 30/09/2020 (inclusive)

- NHS Digital supplied data (Emergency Care Dataset / HES Admitted Patient Care / HES Critical Care / Death registrations / Demographics) - 01/02/2020 to 30/09/2020 (inclusive)

The patient identifiers would be retained for up to 18 months after all data necessary for the planned analysis are obtained, subject to data sharing agreements with data providers, to ensure that the data linkage processes can be audited. Direct identifier data items (NHS Number, name, date of birth, postcodes, date of death) will not be present in analysis datasets.

The applicants advised that data would be processed on a virtual machine, hosted on University of Sheffield servers with access limited to specific users with nominated static IP addresses. Due to home working restrictions, it is no longer possible to limit access from specific static IP addresses. However, access will be limited to specified users only and these users will require two distinct sets of credentials (username and password combinations) in order to access any identifiable data. Fully pseudonymised data may be stored on University of Sheffield (UoS) servers and accessed from UoS managed devices via a single set of (authorised) user credentials.

The applicant also provided an update on the patient and public engagement that had been carried out with two representatives from the Study Steering Committee and Yorkshire Ambulance Service patient research ambassadors. Feedback from these had been positive. The applicants are also working to establish an additional independent patient and public involvement group to advise on methods, data collection, results, and dissemination of all aspects of the PRIEST study. They were seeking members who have had COVID-19 while using emergency department and/or prehospital services.

Confidentiality Advisory Group advice

The Group agreed that there was a strong public interest in looking at the NHS 111 system and the appropriateness of the advice given. Members reminded the applicants that the database created can only be used for the purposes described in the application, quality

control of the NHS 111 and ambulance crew decision-making and to develop an algorithm to assist them.

The CAG agreed that, should any changes be made to the protocol, other than the addition of participating sites, then a new application needed to be submitted. This was to ensure that there was a clear audit trail for the project.

Members noted main concern regarding this amendment was the processing of free text data. The Group noted that processing of free text data was generally not supported by the CAG but recognised the need for this specific application. The Group noted that processing of free text data would be supported due to the particular circumstances and requirements of this application, but that this decision did not set a precedent for future applications. An effective mechanism to pseudonymise the free text needed to be created and fed back to the CAG within 3 months of the amendment being given support. If an effective mechanism could not be created, then the free text data would need to be anonymised after use. Any identifiable information extracted from the free text needed to be destroyed.

The Yorkshire Ambulance Service was mentioned, but the application also referred to 40 participating hospitals, including some in Scotland. The Group queried the scope of support required and asked that a list of participating Trusts was provided.

The CAG noted the patient and public involvement that had been carried out and agreed that further activity needed to be carried out. Members suggested that a questionnaire was created and disseminated via engagement with appropriate patient groups and charities.

The Group noted that it would be difficult to conduct effective patient notification within the patient group, who may be severely affected by coronavirus. Given the breadth of information that would be collected, members agreed that a patient notification strategy needed to be created. This needed to contain an explanation on why the amount of information collected was required.

The Group noted that patient outcomes were divided into ‘adverse outcome’ and ‘no adverse outcome’. Members queried whether the need for hide-dose anticoagulation, incidences of stroke and increase in blood viscosity were included as adverse outcomes.

Confidentiality Advisory Group advice conclusion

The CAG agreed that the minimum criteria under the Regulations appeared to have been met and that there was a public interest in projects of this nature being conducted, 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. A response to the below conditions needs to be provided within three months of the issuing of this letter:

    a. Confirmation that further amendments, or a new application, will be submitted if the database is to be used for any purposes in addition to those described in the application.

    b. An effective mechanism to pseudonymise the free text is created and fed back to the CAG. If an effective mechanism cannot not be created, then the free text data will need to be anonymised after use. Confirmation that any identifiable information extracted from the free text will be destroyed.

    c. A patient notification strategy is devised and fed back to the CAG. This needs to contain an explanation on why the amount of information collected is required.

    d. Further patient and public involvement is carried out. Members suggested that a questionnaire is created and disseminated via engagement with appropriate patient groups and charities.

    e. A list of participating Trusts, recruited to date, is provided. The addition of any further Trusts must be submitted via an amendment

    f. Should any further changes be made to the protocol, other than the addition of new participating Trusts, then a new application is submitted.

2. Confirmation of suitable security arrangements via IG Toolkit submission.
   Confirmed – University of Sheffield – School of Health and Related Research (by NHS Digital email dated 06 August 2019), Yorkshire Ambulance Service NHS Trust (by check of the NHS Digital DSPT tracker on 25 June 2020) and NHS Digital (by NHS Digital email dated 10 June 2019) have confirmed 'Standards Met' grade on DSPT submission 2018/19.

3. Confirmation of a favourable opinion from a Research Ethics Committee.
   Confirmed 29 June 2020

3. Annual Review Approvals

CAG Reference	Application Title
CAG 9-08(c)/2014	MesobanK Retrospective Sample Collection
17/CAG/0184	UK collaborative clinical audit of health care for children and young people with suspected epileptic seizures (Epilepsy12)
PIAG 1-05(e)/2006	Frequency of follow up for patients with intermediate grade adenomas
18/CAG/0131	Inflammatory Bowel Disease Registry
ECC 8-05(d)/2011	Do specialist cancer services for teenagers and young adults (TYA) add value?
ECC 4-03(g)/2012	General Health & Hospital Admissions in Children Born after ART: A Population Based Linkage Study
18/CAG/0064	National Bone and Joint Infection Registry
CR20/2014	Caerphilly ischaemic heart disease study, Speedwell study longitudinal study of ischaemic heart disease, early life origins of insulin resistance, mortality and cancer in Christs hospital school cohort
CR17/2014	Epidemiological Study of BRCA1 and BRCA2 Mutation Carriers
CR12/2014	Oxford Vegetarian Study/Study of Cancer in Vegetarians
18/CAG/0060	Prospective Investigation into Cancer and Nutrition, Oxford Cohort
CAG 1-03(PR3)/2014	Next Steps previously known as Longitudinal Study of Young People in England (LSYPE)
CAG 2-03(PR4)/2014	1970 British Cohort Study

16/CAG/0114	LUCI: Long-term follow-up of urinary tract infection (UTI) in childhood and implications; an electronic record-linked cohort study
ECC 2-03(c)/2012	National Paediatric Diabetes Audit (NPDA)
CAG 10-02(d)/2015	National Congenital Anomaly and Rare Disease Registration Service
19/CAG/0079	International Breast Cancer Intervention Study Epidemiological Cohort Study (IBIS-I)
18/CAG/0056	Retinoblastoma gene mutations and risk of second primary tumours
18/CAG/0164	Use and impact of the pre-hospital 12-lead electrocardiogram in the primary PCI era. Mixed method study (PHECG-2)
16/CAG/0063	aTTom Extended - Extended follow up of patients enrolled in the Adjuvant Tamoxifen Treatment - Offer More? (aTTom) trial
ECC 8-04(c)/2013	Out of Hospital Cardiac Arrest Outcomes (OHCAO)
17/CAG/0011	Genetic mechanisms in polyposis of the bowel
18/CAG/0195	ACST-1 follow-up study of memory and thinking function
ECC 3-04(f)/2011	Information Governance Clinical Dataset Linking Service
17/CAG/0124	National Diabetes Audit (adults) - Wales
18/CAG/0015	Improving diagnosis and management in dementia with Lewy bodies using the CPFT Research Database (CRATE)
ECC 4-02(FT2)/2012	PD MED - A large randomised assessment of the relative cost-effectiveness of different classes of drugs for Parkinson's disease
17/CAG/0126	Surveillance of Severe Microcephaly in the UK and Ireland (SSM-UKI)
16/CAG/0063	aTTom Extended - Extended follow up of patients enrolled in the Adjuvant Tamoxifen Treatment - Offer More? (aTTom) trial
19/CAG/0053	Myeloproliferative neoplasms Associated SplanChnic vein Thrombosis: Mascot registry
ECC 4-02(FT2)/2012	Application for PD MED- A Large randomised assessment of the relative cost-effectiveness of different classes of drugs for Parkinson’s disease
18/CAG/0064	National Bone and Joint Infection Registry

Signed – Chair	Date
Signed – Confidentiality Advice Team	Date