Health Research Authority

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

October 2020

1. New Applications

a. 20/CAG/0088 - Antihypertensive Treatment in Elderly Multimorbid Patients: a pilot study

Name	Capacity
Dr Tony Calland MBE	CAG Chair
Mr Tony Kane	CAG Member
Professor Jennifer Kurinczuk	CAG Member
Ms Katy Cassidy	HRA Confidentiality Advisor

Context

Purpose of application

This application from the University of Oxford set out the purpose of medical research that seeks to address a gap in understanding of the treatment effects of blood pressure lowering treatment in older patients with many underlying health conditions, and in particular when their blood pressure is not very high.

The beneficial effects of blood pressure (BP) lowering treatment are well understood. However, the importance of BP lowering treatment in certain patient groups remains uncertain. One such group includes older patients with many underlying health problems, in particular when their blood pressure is not very high. Little research has been conducted with this group, due to the difficulty of recruiting sufficiently large numbers of older and co-morbid patients into clinical trials. The applicants are seeking to recruit 200 patients aged 65 years and over, and who have a least 3 long-term health conditions or are taking at least 5 medications in addition to being taken to manage blood pressure, into a pilot study. Participants will be randomised to receive up to 2 additional or 2 fewer classes of BP lowering medication over the course of the study with their treatment assess every 4 weeks with the aim of testing whether the intervention can lead to important changes in blood pressure. The findings from the study will be used to establish the feasibility of a larger home-based study to assess the effect of treatment changes on patient-important outcomes.

The applicants are seeking support for the disclosure of confidential patient information from NHS Digital to the research team at the University of Oxford. The study team will provide NHS Digital with a search query to select individuals aged 65 years or more with three or more chronic conditions diagnosed within a 5-year time window prior to the latest assessment date. The selection of chronic conditions of interest will be based on 3-character ICD codes and individuals with a recorded diagnosis of heart failure will be excluded. The search query will be provided on a number of occasions, each time restricted to individuals who live within different regions in the Thames Valley area and are alive at the time of data sharing with the research team. Patients will then be contacted by post by the research team and their involvement will then proceed on a consented basis.

Patients who are registered with online pharmacy, Pharmacy 2U, and who reside in the Thames Valley area, will also be included. This recruitment pathway was outside the scope of the s251 support sought, as patients will be contacted by Pharmacy 2U in order to seek consent for the sharing of their contact details with the study team. A website would also be made available for patients to register their interest in taking part. This was also outside the scope of support.

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	Male and female patients aged 65 years and over, and who have a least 3 long-term health conditions or are taking at least 5 medications in addition to being taken to manage blood pressure. Confidential patient information for over 10,000 patients will be disclosed from NHS Digital, from which the applicants anticipate that 200 will consent to take part.
Data sources	1. NHS Digital
Identifiers required for linkage purposes	1. Name 2. NHS number 3. Date of birth 4. Postcode – unit level 5. Address 6. Gender
Identifiers required for analysis purposes	1. Postcode – unit 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 a sub-committee of the CAG.

The invitation letter needs to be revised to include a clear explanation of how the researchers had obtained patients' contact details, including an explanation of the s251 support in place.

The applicant provided a revised participant invitation letter, which contained a clearer explanation of s251 support and how patients' contact details will be obtained. The CAG reviewed this 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 Health Research Authority, subject to compliance with the specific and standard conditions of support as set out below.

Specific conditions of support

1. Favourable opinion from a Research Ethics Committee. **Confirmed 29 September 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 **(Confirmed – University of Oxford Medical Sciences Division and NHS Digital (by check of the NHS Digital DSPT tracker on 17 July 2020) have confirmed 'Standards Met' grade on DSPT submission 2018/19).**

b. 20/CAG/0057 - PEARL s251 Sensitive Health Records Template (Incidence of psychosis and measures of psychotic experiences within the ALSPAC)

Name	Capacity
Dr Tony Calland MBE	CAG Chair
Dr Martin Andrew	CAG Member
Ms Sophie Brannan	CAG Member
Dr Patrick Coyle	CAG Vice-Chair
Dr Liliane Field	CAG Member
Mr Tony Kane	CAG Member

Professor Jennifer Kurinczuk	CAG Member
Mr Andrew Melville	CAG Member
Ms Clare Sanderson	CAG Alternative Vice-Chair
Mr Marc Taylor	CAG Member
Ms Katy Cassidy	HRA Confidentiality Advisor
Dr Paul Mills	HRA Confidentiality Advice Service Manager
Ms Laura Gordon	HRA CAG Assistant
Ms Natasha Dunkley	HRA Head of Confidentiality Advice Service

Context

Purpose of application

This application from University of Bristol set out the purpose of medical research to examine the proportion of children and adolescents with psychotic experiences (PEs) who transition to clinical disorder in adulthood, and estimate the extent to which they are identified by primary (PC)/secondary care (SC) services highlighting potential unmet need.

PEs are reported by 5-10% of the general population. Although usually transient, they are associated with increased risk of schizophrenia, but the natural progression of PEs and transition to schizophrenia in adulthood has not been examined in detail. Estimates of incidence are usually obtained from people presenting to clinical services and thus individuals who have not sought help would be missed from these estimates. Linking ALSPAC data with primary and secondary care records will allow the researchers to examine, prospectively, which early symptoms are most predictive of developing a psychotic disorder.

The applicants seek support to process confidential patient information from GP records, NHS Digital (HES data, the Mental Health Services Data Set) and data from the Avon and Wiltshire Mental Health Partnership, in line with ALSPAC's existing approval.

ALSPAC wish to:

- If the required sensitive data has already been collected through a previous project specific s251 support, repurpose the data for this purpose, in order to reduce flow of confidential information.
- For data not already collected though a previous project specific s251 support, request data from GP providers, NHS Digital and Avon and Wiltshire Mental Health Partnership using existing processes.

The data will then combined/anonymised by the ALSPAC team within UKSeRP (hosted by the University of Swansea but managed by ALSPAC staff). ALSPAC staff will then make the anonymised combined data available to the research team for this project.

A recommendation for class 1 and 4 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 people enrolled in ALSPAC, excluding those who have explicitly withdrawn from the study, declined consent to linkage to their health record, have not received ALSPAC fair processing information or have consented to data linkage.
Data sources	1. NHS Digital (HES and MHSDS data) 2. GP software providers 3. Avon and Wiltshire Mental Health Partnership NHS Trust
Identifiers required for linkage purposes	1. NHS Number 2. Date of birth 3. Date of death
Identifiers required for analysis purposes	1. Gender 2. Date of Birth will be used (by ALSPAC) to derive 'Age at Event' (expressed in days, minutes, seconds) and time intervals. This allows ALSPAC to provide information to researchers in event sequence order without disclosing Date of Birth or event date.
Additional information	Of the 15,000 ALSPAC participants, around 5500 have consented to data linkage and are not part of this request for 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 the CAG.

1. **Provide a dataflow diagram which indicates the flow of confidential patient information and pseudonymised data, indicating which identifiers are used within which flow.**

The applicant provided a revised data-flow diagram for NHS Digital data and a data-flow diagram for GP data. These were reviewed by the CAG, who raised no further queries.

2. **In the web notification, add a link to the ALSPAC opt out page.**

The applicants confirmed that a link to the ALSPAC opt-out page had been added to the web notification. The text and a link to the notification was provided. The CAG reviewed this and raised no further queries.

3. **Review and revise the language used in the patient notification to be in plain English**

The patient notification materials were updated, and members raised no further queries on this aspect.

4. **Explain in the web notification that a participant can opt out of this specific project, without opting out of ALSPAC as a whole.**

The applicants provided the text of the web notification and a link, which described that patients could opt-out of inclusion in this project specifically. The CAG reviewed this and raised no further queries.

5. **Clarify and update the project start date in the web notification.**

The applicant clarified that the start date for the project was listed as December 2018 as ALSPAC collected data was being used in the analyses. In September 2019, data was linked

to electronic health records for patients who had consented. The applicants noted that it was common in these types of projects for data to be provided to the researchers in stages and linked data may not be included until some time after the project start date, with the consenting sample being made available first if support under s251 is required. The CAG noted this clarification and raised no further queries.

6. **Change the web notification to make clear that it is preferred for participants to opt out prior to the start date, but they can opt out at any time.**

The applicant advised that participants were able to change their mind at any point, however consent updates were not fed into the live in-use dataset.

The CAG noted that it appears that any person who opts out now will not be able to have their wishes abided by and this was put to the applicants. The applicants confirmed that participants had between December 2018 and September 2019 to opt out through the notification process, but additionally agreed to refresh the opt out for this linkage upon support from CAG.

Members noted this response and exceptionally agreed to support on this basis. The applicants are reminded it is not usual practice to undertake the notification and opt out procedure prior to an application to CAG, and any future applications should be made before the notification and opt out process begins.

7. **Define what the term community records mean, with respect to where data is collected from.**

The applicant advised that "community records" is defined in the ALSPAC section of the University of Bristol website. The records used are "1. Health records (from your GP, hospital visits and community care) about mental health conditions, treatments and care. 2. Department for Education and local authority records on children who had a statement of special educational needs." The CAG noted this clarification and raised no further queries.

8. **Clarify whether, in advance of the National Data Opt-Out applying, whether the GP Type 1 opt out will be applied.**

The applicant explained that if the Type 1 Opt-Out was applied, then data cannot leave the practice, as this is classed as sharing information for non-care purposes, which this flag stops. Type 1 Opt-Out will be applied to the extract of GP records, as the GP system providers can see it, but the applicants will not see flows of this to implement it later. NHS Digital were aware

of this and the applicants were attempting to establish a mechanism to resolve this. The CAG noted this information and raised no further queries.

9. **Confirm that the applicants are not collecting free text data.**

The applicant clarified that no free-text data will be accessed or collected. The CAG noted this clarification 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 February 2011**

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. **The NHS Digital DSPT review for University of Bristol, The Phoenix Partnership and the EMIS Group was confirmed as 'Standards Met' on the NHS DSPT Tracker (checked 10 May 2020).**

c. 20/CAG/0087 - Research database for Cambridgeshire & Peterborough NHS FT (CPFT)

Name	Capacity
Dr Tony Calland MBE	CAG Chair
Dr Martin Andrew	CAG Member
Dr Malcolm Booth	CAG Member

Dr Patrick Coyle	CAG Vice-Chair
Dr Liliane Field	CAG Member
Mr Tony Kane	CAG Member
Ms Diana Robbins	CAG Member
Ms Clare Sanderson	CAG Alternative Vice-Chair
Mr Marc Taylor	CAG Member
Ms Natasha Dunkley	HRA Head of Confidentiality Advice Service
Dr Paul Mills	HRA Confidentiality Advice Service Manager
Ms Caroline Watchurst	HRA Confidentiality Advisor

Context

Purpose of application

This application from Cambridgeshire and Peterborough NHS Foundation Trust (CPFT) sets out the purpose of medical research which aims to link data from a research database with nationally held datasets to enhance the database. The CPFT Research Database has been established since 2012 acting under a consented model to (a) use CPFT data for research purposes and (b) use CPFT data to identify and approach patients for direct research.

However, given the current research database only contains data from CPFT, there are limitations in the usefulness of the database. As such, the applicants request support to extend the database by linking data held by NHS Digital (HES and ONS mortality data) and the Department of Education (National Pupil Database). For each, identifiable data will be sent to NHS Digital and Department of Education. Each body will link to the data they hold, remove identifiers and return the data using the CPFT database pseudonym, at which point the data will be linked with existing CPFT data. Note that the applicants are also linking with PHE (NCRAS) data, but this does not involve the transfer of patient identifiable information and support is not requested for this aspect.

The research database will be used for epidemiological research purposes. Those wishing to apply for access will be required to have a contractual relationship with CPFT and will need to apply to the CPFT Research Database Oversight Committee (with representation including

patients/carers, clinicians, and R&D/information governance staff). Once access is granted, researchers will not have access to any identifiable information, and will need to access the data through the CPFT network (and are not sent the data).

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	All patients with a record at Cambridgeshire and Peterborough NHS Foundation Trust, except those that have opted out.
Data sources	1. Cambridgeshire and Peterborough NHS Foundation Trust 2. NHS Digital 3. Department of Education
Identifiers required for linkage purposes	1. NHS number 2. Name 3. Date of birth 4. Postcode
Identifiers required for analysis purposes	
Additional information	Whilst the data is pseudonymised and may be reidentified by Cambridgeshire and Peterborough NHS Foundation Trust, as data controller, researchers will not have the key to reidentify patients date of birth/death changed to month and year of birth/death and postcodes are truncated to the district level and Office of National Statistics (ONS) Lower Level Super Output Area (LSOA) codes.

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. **Review and provide an updated patient information leaflet, which provides clear opt out information, including a contact telephone number and email address.**

The patient information leaflet was updated to provide clear opt out information. The CAG was content with these updates.

2. **Review and provide an updated poster, which includes clear opt out information, including a contact telephone number and email address.**

The poster was updated to provide clear opt out information. The CAG were content with these updates.

3. **Consider the use of a simplified leaflet in addition to other patient notification materials which details the work of the research database and includes clear opt out information, including a contact telephone number and email address.**

The applicant considered this request and, with the input of patient groups considered a new leaflet was not necessary, instead using the poster text in a leaflet format.

The CAG raised no issues with this proposal.

4. **Review the content of the website information to ensure it is up to date, and incudes the linkages of confidential patient information with other sources, without consent.**

The applicant stated that they were in the process of refreshing the website text following the CAG and REC processes.

Members were content with this response, though requested to see the updated text within one month of the date of this letter.

5. **Confirm that the committee which oversees approval of research requests includes lay representation.**

It was confirmed that the committee currently has three lay members, which the CAG was content with.

6. **Confirm that any research request to access the database must include a medical purpose.**

The applicants confirmed that the any research request to access the database will include a medical purpose, to which the CAG raised no issues.

7. **Consider the use of automated algorithms to extract coded information from free text information for transfer.**

The applicants confirmed that natural language processing is used to convert free text into structured data. The applicants also confirmed their willingness to commit to no free text data to be included within linked data sets, linking only structured CPFT data (be that structured data from the original data set, or structured data created by NLP tools from free text).

The CAG noted this response and were happy to support on the basis that no free text data will be included in linked datasets.

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 updated website text within one month of the date of this letter.

2. Favourable opinion from REC **Received 06 August 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. **The NHS Digital DSPT reviews for Cambridgeshire and Peterborough NHS Foundation Trust, NHS Digital and Department for Education were confirmed as ‘Standards Met’ on the NHS DSPT Tracker (checked 03 August 2020)**

d. 20/CAG/0068 - South London and Maudsley NHS Foundation Trust CRIS data linkage with the National Pupil Database

Name	**Capacity**
Dr Tony Calland MBE	CAG Chair
Dr William Bernal	CAG Alternative Vice-Chair
Ms Sophie Brannan	CAG Member
Dr Lorna Fraser	CAG Member
Professor Jennifer Kurinczuk	CAG Member
Dr Harvey Marcovitch	CAG Member
Ms Diana Robbins	CAG Member
Ms Clare Sanderson	CAG Alternative Vice-Chair
Ms Gillian Wells	CAG Member
Ms Katy Cassidy	HRA Confidentiality Advisor
Ms Caroline Watchurst	HRA Confidentiality Advisor
Dr Paul Mills	HRA Senior Confidentiality Advisor
Ms Natasha Dunkley	HRA Head of Confidentiality Advice Service

Context

Purpose of application

This application from King's College London (with the controller for the activity confirmed to be South London and Maudsley NHS Foundation Trust) set out the purpose of medical research which aims to create a linked education and mental health dataset for research purposes.

In 2016 the South London and Maudsley (SLaM) NHS Trust created a linked education and mental health research database of nearly 30,000 patients (s251 support provided). However, the current database only contains information regarding young people in the SLaM region up to and including 2013. Given a variety of factors, this resource is significantly more outdated than would initially be expected. The applicants now wish to update this database to create dataset which covers all school-aged children and young people (between 4 and 19 years) who reside in the SLaM and local catchment area in order to undertake further research.

SLaM will identify the cohort and provide (a) a pseudonymised dataset (data for the cohort identified only by a pseudonym) to Office for National Statistics (ONS) and (b) identifiable information (including the allocated pseudonym) to the Department for Education (DfE). DfE will use the identifiable information to access corresponding pupil data on the National Pupil Database (NPD). DfE will transfer the cohort dataset (identified only by the allocated pseudonym) to the ONS, who will link the SLaM and DfE data into one dataset. Any researchers wishing to access this dataset will have to gain permission from the oversight committees of SLaM, DfE and ONS.

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	All children and young persons between 4-19 years who have accessed SLaM services between 1 January 2008 and 31 August 2019.
Data sources	1. Medical records in the SLaM CRIS database 2. National Pupil Database held by DfE
Identifiers required for linkage purposes	1. Name 2. Date of birth 3. Address 4. Sex 5. Postcode
Identifiers required for analysis purposes	1. Year of birth 2. Postcode (at district level) 3. Gender 4. Ethnicity
Additional information	Because of the changes related to DfE data hosting policies, the applicants require a complete refresh of the linkage as the DfE from 1 January 2008, not from the end of the previous data collection.

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 information letter needs to be amended to contain assurance that patients' treatment would not be affected if they dissented from inclusion in the project.**

The applicant provided an updated CRIS CAMHS leaflet, which describes the that education data is linked to CRIS. The sentence, "You have the right to opt out of your data being included in CRIS. This will not impact the care you receive in any way" has been added to the contact us section on the back page. The CAG reviewed this document and raised no further queries.

2. **Confirm that the project run by Cambridge and Peterborough NHS Foundation Trust is separate to this application.**

The applicant confirmed that this was correct. 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**

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.

    - **South London and Maudsley NHS Foundation Trust and the Office for National Statistics have a confirmed 'Standards Met' grade on DSPT submission 2018/19 by checking the NHS Digital DSPT Tracker on 21 May 2020.**

    - **Security assurances for the Department for Education has a confirmed 'Standards Met' grade on DSPT submission 2018/19 by check of the DSPT Tracker on 11 June 2020.**

e. 20/CAG/0081 - Predicting vascular complications in diabetes

Name	Capacity
Dr Tony Calland MBE	CAG Chair
Dr Martin Andrew	CAG Member
Professor Barry Evans	CAG Member

Dr Lorna Fraser	CAG Member
Mr Tony Kane	CAG Member
Professor Jennifer Kurinczuk	CAG Member
Mr Andrew Melville	CAG Member
Ms Clare Sanderson	CAG Alternative Vice-Chair
Mr Marc Taylor	CAG Member
Ms Katy Cassidy	HRA Confidentiality Advisor
Ms Natasha Dunkley	HRA Head of Confidentiality Advice Service
Dr Paul Mills	HRA Senior Confidentiality Advisor
Ms Caroline Watchurst	HRA Confidentiality Advisor
Mr Ben Caswell	Observer

Context

Purpose of application

This application from Barts Health NHS set out the purpose of medical research to determine whether artificial intelligence (AI) can identify and predict the progression of diabetes foot disease.

Diabetes is an important public health problem. It currently affects almost 3.7 million people in the UK, with 12.3 million at increased risk of type 2 diabetes. Vascular complications include diabetic foot disease, which, in the three-year period 2013-2016 was responsible for 121,067 hospital admissions and 1,688,699 days spent in hospital in England by 73,388 patients, 31% of whom had more than one admission. Over the same time period, 7119 major amputation procedures were performed, an age and ethnicity standardised rate of 8.1 major amputations per 10,000 population-years. This project has been created to contribute towards improving the health of the public by using natural language processing (NLP) and machine learning methods, applied to text rich hospital records and to develop predictive tools with which to identify those at high risk of an active diabetic foot problem and/or amputation at an earlier stage than currently possible. The applicants aim to enable newer interventions to prevent or delay disease progression to be tested and management of diabetes to be optimised.

The research team will extract the structured and free text records from case patients (diabetics who developed foot disease) and controls (diabetics who did not develop foot disease) at Barts Health NHS Trust into a study database, held within Barts Health NHS Trust. The free text data will be run through a natural language processing program to turn the free text into structured codes (Snomed codes). The research team will then compare the codes extracted from free text data against the structured data within the patient medical records to determine the effectiveness of the program in predicting onset of diabetic foot disease.

A recommendation for class 1, 2, 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	Matched groups of equal size of patients at Bart's Health NHS Trust that have either diabetes foot disease or diabetes that have not developed diabetes foot disease. Patients are over 18 years old and must have had at least one encounter with Bart's Health NHS Trust since 2014 which produced free-text data. The applicants anticipate that approximately 5000 patients will be included.
Data sources	1. Bart's Health NHS Trust
Identifiers required for linkage purposes	1. Hospital ID
Identifiers required for analysis purposes	1. Date of death 2. Gender 3. Occupation 4. Ethnicity 5. Postcode

Additional information	All free text information from patient records would be temporarily processed for this research. Once retrieved the free text data will be run through natural language processing to turn it into structured data codes. Free text data will be deleted following this process.

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 data from GP practices will be obtained.**

The applicants advised that the date of death will be extracted from the NHS Personal Demographic Service using the Trust's connection via their Electronic Health Record system. No data will be requested from primary care or general practice and the applicants no longer planned to use the Discovery data service to obtain GP data. The CAG noted this information and raised no further queries.

2. **Confirm that patients in the diabetes cohort will be identified from coded data only and not via access to free text.**

The applicants advised that they would only use SNOMED or ICD10 encoded data, stored in the Barts Health data warehouse, to create the diabetes cohort. Both Type 1 and Type 2 diabetes patients will be added to the overall diabetes cohort. The CAG noted this information and raised no further queries.

3. **Clarify whether any sensitive data items would be contained in the extracts from free text and, if so, whether these details would be removed from the free text extract. If any sensitive data items would be retained, provide justification for the retention of these details.**

The applicant noted that it was possible that a range of more or less sensitive data phrases will have been recorded by health professionals in the free text. Much of this data, including mental health information, is relevant to the study, as there is published data that shows correlation of impaired diabetes outcomes with deteriorating mental health scores. The free text will be converted by the Natural Language Processing Tool and the data de-identified, so that sensitive data items cannot be linked back to individual patients. The original text, once

encoded, will not be retained in the research data system, although the free text will continue to be available in the electronic health records to the direct care team. The CAG noted this information and raised no further queries.

4. **Clarify whether both patients' postcode and Lower Layer Super Output Area needed to be retained for analysis.**

The applicant explained that patients' recorded postcodes will be held in the demographic section of the patient administration system. This will be used to link to the Lower Layer Super Output Area and will them be removed. The postcode will not be retained. The CAG noted this information and raised no further queries.

5. **Patient and public involvement and engagement needs to be carried out around the specific issue of access to confidential patient information without consent, and feedback from this provided to the CAG.**

The applicant advised that a patient and public involvement strategy had been created and provided details on the planned activity. The CAG noted this information and raised no further queries.

6. **A patient notification strategy and dissent mechanism needs to be created and provided to the CAG for review. The patient notification strategy needs to be implemented at least six weeks prior to the beginning of the data extraction, to allow patients sufficient time to dissent.**

The applicants provided an information poster, which would be displayed in diabetes foot clinics within the Trust. This poster was displayed in clinics from 12 August 2020. The applicant noted that patients had continued to attend these clinics during the Covid-19 pandemic. The poster was also available on the Barts Life Sciences webpages and has also been viewed through the EastLondonDiabetesFoot project Twitter link. Additional information links have also been made available through Diabetes UK, the Trust PPI group and local Diabetes Commissioning Network. The Trust surgical lead in diabetes also discussed the project with patients during clinic and is available to take any questions from patients who read the poster while in clinic.

The CAG noted that the poster did not contain the level of information they would usually expect. Members asked that the poster was revised to include email, phone and postal contacts for the study team. Further details also need to be provided on the confidential patient information that will be processed. The poster also needs to explain that patients can dissent and an assurance that dissenting will not affect their care.

7. **The start date needs to be clarified.**

The applicant advised that they planned to begin the study as soon as the appropriate support and approvals were in place. The CAG noted this information and raised no further queries.

8. **Confirm that amendments will be submitted if the database were to be made available for other research in future.**

The applicant advised that the CAG would be notified if the applicants intended to make any additional queries or undertake new approaches to analytics which were not included in the current scope of the application. 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. The poster needs to be revised as follows and the revised poster submitted to the CAG within one month of the issuing of this letter:

    a. Email, phone and postal contacts for the study team need to be provided.

    b. Further details need to be provided on the confidential patient information that will be processed.

    c. The poster needs to explain that patients can dissent and contain an assurance that dissenting will not affect patients' care.

2. Favourable opinion from a Research Ethics Committee. **Confirmed 13 April 2020.**

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

further information. **Confirmed: 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.

d. 20/CAG/0104 - POST-BOX: Consensus-building a post-partum haemorrhage kit using citizen science (Workpackage 1)

Name	Capacity
Dr Simon Kolstoe	CAG Member
Dr Harvey Marcovitch	CAG Member
Ms Clare Sanderson	CAG Alternative Vice-Chair
Ms Katy Cassidy	HRA Confidentiality Advisor
Ms Caroline Watchurst	HRA Confidentiality Advisor

Context

Purpose of application

This application from the THIS Institute at the University of Cambridge set out the purpose of medical research that seeks to inform the design and use of post-partum haemorrhage (PPH) kits used in UK maternity units.

Post-partum haemorrhage is a rare complication where a woman experiences heavy bleeding after the birth of their baby. PPH kits are kits used on maternity units which bring together the equipment needed to manage PPH effectively and rapidly. The content, form and packing of PPH kits varies widely across Trusts. The applicants intend to investigate how the design of PPH kits can be optimised in order to ensure that patients are offered the best care.

The applicants plan to visit 3-5 maternity units in England and Wales to observe practice and interview a sample of healthcare professionals who use or stock PPH kits, in order to develop understanding of current practice. Maidstone and Tunbridge Wells (MTW) NHS Trust has been identified as a participating trust. The applicants are in the process of recruiting the other sites and will submit amendments to include additional trusts as data processors. The applicants will also explore the practicalities of uploading photographs of PPH kits and their contents to the study platform to be used for following work packages, the Thiscovery platform. Patients will not be involved directly, but the applicants may be incidentally exposed to confidential patient information when carrying out the observations and interviews with staff, therefore support under s251 is sought.

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 cohort involved are NHS staff working in clinical roles in maternity units or in a procurement function. No patients will be recruited into the study.
Data sources	Interviews and observations carried out in participating Trusts. 3-5 trusts will be involved, but only one has been identified at this point: 1. Maidstone and Tunbridge Wells (MTW) NHS Trust
Identifiers required for linkage purposes	No items of confidential patient information will be collected for linkage purposes
Identifiers required for analysis purposes	No items of confidential patient information will be collected 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 needs to be displayed on doors, or elsewhere in the department, advising patients that the researchers were present, providing a brief description of the project and advising patients that the researchers can be asked to leave.**

The applicant confirmed that the poster will be displayed in the unit where the researchers will be present. Copies would also be provided to the maternity unit in the local information pack. The CAG noted this information and raised no further queries.

2. **Members also asked that a simplified information sheet was provided, containing a brief outline of the project.**

A revised information sheet was provided. The CAG reviewed this and agreed that the information sheet was largely satisfactory, but requested that the statement, “There are researchers working in the maternity unit today. If you do not want to take part please let a member of staff know. This will not affect your treatment.” should be displayed more prominently in the letter.

3. **Clarify how long it is anticipated it will take for the recordings to be transcribed and fully anonymised.**

The applicant advised that the recordings will be transcribed and anonymised within 14 days. 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 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

1. The information sheet is to be revised to display the following statement more prominently, "There are researchers working in the maternity unit today. If you do not want to take part, please let a member of staff know. This will not affect your treatment."

2. Favourable opinion from a Research Ethics Committee **Confirmed 18 June 2020.**

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

    - **Confirmed – University of Cambridge has a confirmed 'Standards Met' grade on DSPT submission 2018/19 by check of the NHS Digital DSPT tracker on 09 September 2020.**
    - **Confirmed – Maidstone and Tunbridge Wells NHS Trust has a confirmed 'Standards Met' grade on DSPT submission 2019/20 by email from NHS Digital DSPT tracker on 29 October 2020.**

2. New Amendments

a. CAG 2-03(PR4)/2014 – 1970 British Cohort Study

Name	Capacity
Dr Paul Mills	HRA Confidentiality Advice Service Manager

Context

Amendment request

The application was supported for NHS Digital to provide current address details of the 'untraced' cohort. The Centre for Longitudinal Studies provide identifiers for those lost to follow up and are returned current address details from NHS Digital for contact.

This amendment requests support for two three additional elements:

1. The addition of IPSOS Mori as an additional data processor for the study. IPSOS Mori will be provided with the current address details in order to undertake the supported activities.

2. The original application stated that NHS Digital will only be provided the details of those lost to follow up, with current address returned. This would be undertaken on an ad hoc basis. Due to changes to processes at NHS Digital this is no longer possible. This amendment therefore requests support for details of the entire cohort of the study to be provided to NHS Digital and address to be returned.

3. Notification that data storage arrangements have been updated at University College London to provide enhanced security and access controls to the data.

Confidentiality Advisory Group advice

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

It was confirmed that the National Data Opt Out will be applied to the requests to NHS Digital. The applicants also clarified that the notifications will also be updated in light of the change to requesting addresses from the entire cohort. Members noted that the updated notification had not been provided. The group were content to support with a condition that the updated notification materials are provided to the CAG within two months of the date of this letter.

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. Provide the updated patient notification materials to the CAG within two months of the date of this letter.

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. The NHS Digital DSPT review for University College London and IPSOS Mori were confirmed as 'Standards Met' on the NHS DSPT Tracker (checked 23 September 2020).**

3. Confirmation of a favourable opinion from a Research Ethics Committee. **Confirmed 14 September 2020**

b. CAG 1-03(PR2)/2014 - National Child Development Study

Name	Capacity
Dr Paul Mills	HRA Confidentiality Advice Service Manager

Context

Amendment request

The application was supported for NHS Digital to provide current address details of the 'untraced' cohort. The Centre for Longitudinal Studies provide identifiers for those lost to follow up and are returned current address details from NHS Digital for contact.

This amendment requests support for three additional elements:

1. The addition of IPSOS Mori as an additional data processor for the study. IPSOS Mori will be provided with the current address details in order to undertake the supported activities.

2. The original application stated that NHS Digital will only be provided the details of those lost to follow up, with current address returned. This would be undertaken on an ad hoc basis. Due to changes to processes at NHS Digital this is no longer possible. This amendment therefore requests support for details of the entire cohort of the study to be provided to NHS Digital and address to be returned.

3. Notification that data storage arrangements have been updated at University College London to provide enhanced security and access controls to the data.

Confidentiality Advisory Group advice

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

It was confirmed that the National Data Opt Out will be applied to the requests to NHS Digital. The applicants also clarified that the notifications will also be updated in light of the change to requesting addresses from the entire cohort. Members noted that the updated notification had not been provided. The group were content to support with a condition that the updated notification materials are provided to the CAG within two months of the date of this letter.

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. Provide the updated patient notification materials to the CAG within two months of the date of this letter.

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. IPSOS Mori have had security assurances confirmed by NHS Digital, through check of the DSPT tracker (23 September 2020).**

3. Confirmation of a favourable opinion from a Research Ethics Committee. **Confirmed 22 September 2020**.

c. 14/CAG/1006 – Millennium Cohort Study

Name	Capacity
Dr Paul Mills	HRA Confidentiality Advice Service Manager

Context

Amendment request

This amendment requests support for three additional elements:

1. The addition of NatCen and Kantar Public as additional data processors for the study. NatCen and Kantar Public will be provided with the current address details in order to undertake the supported activities.

2. The original application stated that NHS Digital will only be provided the details of those lost to follow up, with current address returned. This would be undertaken on an ad hoc basis. Due to changes to processes at NHS Digital this is no longer possible. This amendment therefore requests support for details of the entire cohort of the study to be provided to NHS Digital and address to be returned.

3. Notification that data storage arrangements have been updated at University College London to provide enhanced security and access controls to the data.

Confidentiality Advisory Group advice

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

It was confirmed that the National Data Opt Out will be applied to the requests to NHS Digital. The applicants also clarified that the notifications will also be updated in light of the change to requesting addresses from the entire cohort. Members noted that the updated notification had not been provided. The group were content to support with a condition that the updated notification materials are provided to the CAG within two months of the date of this letter.

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. Provide the updated patient notification materials to the CAG within two months of the date of this letter.

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. NatCen and Kantar Public have had security assurances confirmed by NHS Digital, through check of the DSPT tracker (23 September 2020).**

3. Confirmation of a favourable opinion from a Research Ethics Committee. **Confirmed 21 September 2020.**

d. 16/CAG/0066 - Hospital Alerting Via Electronic Noticeboard (HAVEN)

Name	Capacity
Ms Caroline Watchurst	HRA Confidentiality Advisor

Context

Amendment request

This study from Oxford University Hospitals NHS Foundation Trust aims to produce a hospital-wide IT system that enables a continuous risk assessment in all hospital patients, and predicts those at risk of deterioration. Support is currently in place to cover the disclosure of confidential patient information from Oxford University NHS Foundation Trust to the HAVEN research team.

This amendment sought support for the addition of a new data processor. Applicants requested to add Lancashire Teaching Hospitals NHS Trust as a participating site, and require support under the Regulations to cover the disclosure of confidential patient information from Lancashire Teaching Hospitals NHS Trust to the HAVEN research team. This addition is to demonstrate that HAVEN is generalisable outside of Oxfordshire.

Confidentiality Advice Team advice

The amendment requested was considered by the Confidentiality Advice Team. The CAT was supportive of the addition of a new data processor.

Confidentiality Advice Team conclusion

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

Specific conditions of support

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

   The NHS Digital **2019/20** DSPT review for **Lancashire Teaching Hospitals NHS Foundation Trust (RXN)** was confirmed as **'Standards Met'** (confirmed by NHS Digital email received 21 October 2020)

   The NHS Digital 2018/19 DSPT review for **Oxford University Hospitals NHS Foundation Trust (RTH)** was confirmed as **'Standards Not Fully Met (Plan Agreed)'** on the NHS Digital DSPT Tracker (checked 11 August 2020). Please note the updated specific condition of support below.

   Oxford University Hospitals NHS Foundation Trust (RTH) should achieve the security assurance action plan as agreed with NHS Digital. All staff involved in processing information under this application reference should be aware of the precise scope of support and its boundaries and have successfully completed local security awareness training before processing any information under support.

2. Confirmation of a favourable opinion from a Research Ethics Committee
   Confirmed: 10 February 2020

e. 15/CAG/0163 - Risk modelling for quality improvement in the critically ill: making best use of routinely available data

Name	Capacity
Ms Caroline Watchurst	HRA Confidentiality Advisor

Context

Amendment request

This study from the Intensive Care National Audit & Research Centre (ICNARC) has conducted research to understand the risk factors for, and the consequences of critical illness. The applicant currently has support for various data linkages, which have already been carried out. However support is still required under the Regulations until the point that the data has been pseudonymised.

This amendment sought an extension to support up to 31 July 2021. This is to ensure the applicants still have support until the point at which they are able to pseudonymise the dataset.

Confidentiality Advice Team advice

The amendment requested was considered by the Confidentiality Advice Team. The CAT team understand the reasons for requesting a duration amendment and raised no queries with the amendment.

Confidentiality Advice Team conclusion

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

Specific conditions of support

1. Confirmation provided from the IG Delivery Team at NHS Digital to the CAG that the relevant Data Security and Protection Toolkit (DSPT) submission(s) has achieved the 'Standards Met' threshold
   Confirmed - The NHS Digital 2018/19 DSPT review for **Intensive Care National Audit & Research Centre (ICNARC**) was confirmed as 'Standards Met' on the NHS DSPT Tracker (checked 18 August 2020)

2. Confirmation of a favourable opinion from a Research Ethics Committee.
   Confirmed non substantial by REC email 19 October 2020

f. 19/CAG/0023 - Naevoid Melanoma: Prognosis between two subtypes

Name	Capacity
Ms Caroline Watchurst	HRA Confidentiality Advisor

Context

Amendment request

This study from the Royal Surrey County Hospital aims to investigate whether there is a prognostic difference between two sub-types of naevoid melanoma. The applicants have current support to allow access to confidential patient information by the study coordinator held in medical records at the Royal Surrey County Hospital to enable follow-up of patients and to extract an anonymised clinical dataset for analysis.

The amendment request is seeking support for the applicant to disclose confidential patient information consisting of study ID, NHS number, date of birth, surname and forename, to NHS digital, in order to facilitate linkage with ONS mortality data held by NHS Digital. NHS Digital will send back to the applicant the cause of death, and age of death. The applicant already has support in place for date of death for analysis if calculated to age, however new support is required for the requested linkage with NHS Digital.

This amendment has been requested in order to minimise work for clinicians who may be searching for patient follow-up information when the individual may not be alive. The applicant will send letters only to clinicians of patients who are still alive, after they have received the mortality data.

An updated protocol v3.1 has been provided to show these changes, and an updated flow diagram v3 has been provided additionally to the protocol.

Confidentiality Advisory Group advice

The amendment requested was considered by the Confidentiality Advisory Group. The Group were supportive of this amendment request and understood the justification provided.

Confidentiality Advisory Group conclusion

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

Specific conditions of support

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

   Confirmed: NHS Digital have equivalent security assurances for **2018/19**.

   The **2018/19** NHS Digital DSPT review for **Royal Surrey County Hospital NHS Trust** was confirmed as '**Qualified Assurance – Trust has not achieved 95% staff undertaking data security awareness training'** on the NHS Digital DSPT Tracker (checked 08 September 2020). Please note the updated specific condition of support below.

   All staff at **Royal Surrey County Hospital NHS Trust** that are involved in processing information under this application reference should have successfully completed local security awareness training before processing any information under support.

2. Confirmation of a favourable opinion from a Research Ethics Committee.
   Confirmed non substantial by email 1 October 2020

g. CAG 1-03(PR3)/2014 - Next Steps (previously known as Longitudinal Study of Young People in England)

Name	Capacity
Dr Paul Mills	HRA Confidentiality Advice Service Manager

Context

Amendment request

The application was supported for NHS Digital to provide current address details of the 'untraced' cohort. The Centre for Longitudinal Studies provide identifiers for those lost to follow up and are returned current address details from NHS Digital for contact.

This amendment requests support for three additional elements:

1. The addition of NatCen, Kantar Public and Ipsos MORI as additional data processors for the study. These data processors will be provided with the current address details in order to undertake the supported activities.

2. The original application stated that NHS Digital will only be provided the details of those lost to follow up, with current address returned. This would be undertaken on an ad hoc basis. Due to changes to processes at NHS Digital this is no longer possible. This amendment therefore requests support for details of the entire cohort of the study to be provided to NHS Digital and address to be returned.

3. Notification that data storage arrangements have been updated at University College London to provide enhanced security and access controls to the data.

Confidentiality Advisory Group advice

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

It was confirmed that the National Data Opt Out will be applied to the requests to NHS Digital. The applicants also clarified that the notifications will also be updated in light of the change to requesting addresses from the entire cohort. Members noted that the updated notification had not been provided. The group were content to support with a condition that the updated notification materials are provided to the CAG within two months of the date of this letter.

Confidentiality Advisory Group conclusion

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

Specific conditions of support

1. Provide the updated patient notification materials to the CAG within two months of the date of this letter.

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. NatCen, Kantar Public and**

IPSOS Mori have had security assurances confirmed by NHS Digital, through check of the DSPT tracker (23 September 2020).

3. Confirmation of a favourable opinion from a Research Ethics Committee. **Confirmed 14 September 2020**.

h. CR4/2014 – Asbestos Workers Survey

Name	Capacity
Ms Caroline Watchurst	HRA Confidentiality Advisor

Context

Amendment request

This study from the Health & Safety Laboratory monitors the long-term health of asbestos workers and helps to determine whether the 1969 Asbestos Regulations were effective in reducing the risk of asbestos-related ill-health. This study had previously accessed data under the NHS Central Register (ECC 2-04(c)/2010) application.

Support is currently in place to cover access to mortality and cancer data from the NHS Central Register, maintained by NHS Digital (previously the Health and Social Care Information Centre - HSCIC), and to confidential patient information including name, address, date of birth and NHS number. A cohort of approximately 100,000 patients as of 2006 had been flagged at NHS Digital (previously the HSCIC). The cohort size was projected to continue to grow by approximately 2,000 per year, but participants from 2006 onwards had provided consent and are therefore not included within support given under the Regulations.

The study currently receives mortality and cancer information from NHS Digital for events in England and Wales. In the past, events in Scotland were received from National Records of Scotland (NRS) through NHS Digital, but this is no longer possible. The study team therefore needs to obtain the information directly from NRS.

This amendment requests a change in the data flow; When a study participant moves from England/Wales to Scotland, NHS digital provides the NHS number to the study team. The

study team will send NRS the NHS number. This would aid NRS in flagging the participant on their systems. Similarly, applicants propose to send NHS Digital the NHS number provided by NRS when a participant moves from Scotland to England/Wales. The disclosure of NHS number to NRS has been discussed with NHS Digital who advised that both the CAG and the Scottish Public Benefit and Privacy Panel for Health and Social Care (PBPP) would need to be approached.

The reason for this amendment request is to enable the follow-up of participants' when a participant moves between England/Wales and Scotland, and to ensure the quality of study findings. Due to the age of the cohort, which started in the 1970s, and hence the age of the address details the applicant holds for participants, it is unlikely that NHS Digital or NRS would be able to flag participants based on the identifiable information the study team can provide. It would greatly increase the likelihood of successfully flagging the participant in Scotland if applicants could share the NHS number provided by NHS Digital with NRS, and vice versa for the patients moving away from Scotland, if applicants could share the NHS number provided by NRS to NHS Digital.

It is expected that this amendment will last for the duration of the study, which has no set end date. The applicants have provided some text for the study webpage to reflect the additional data flow, which will be updated after support is in place.

This amendment request additionally is to update the study documentation, including information Leaflet, consent Form and questionnaire, to ensure compliance with GDPR. Survey participants (included prior to 2006) may return for another asbestos medical examination and at this time they will be asked to read the updated information leaflet and to sign the updated consent form. On signing the consent form, the participant will be moved from part A of the Asbestos Workers Survey that requires support under the Regulations to part B of the Asbestos Workers Survey that does not require this support. If they do not wish to take part in the survey they will be unflagged from the relevant NHS Central Register.

Confidentiality Advisory Group advice

The amendment requested was considered by the Confidentiality Advisory Group, who considered the justification for this amendment to be reasonable.

Confidentiality Advisory Group conclusion

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

Specific conditions of support

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

   The NHS Digital **2018/19** DSPT review for **Health and Safety Executive Laboratory** was confirmed as '**Qualified Assurance – Trust has not achieved 95% staff undertaking data security awareness training'** on the NHS Digital DSPT Tracker (checked 29 September 2020). Please note the updated specific condition of support below.

   All staff at **Health and Safety Executive Laboratory** that are involved in processing information under this application reference should have successfully completed local data security awareness training before processing any information under support.

2. Confirmation of a favourable opinion from a Research Ethics Committee. **Confirmed 20 July 2020**

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

Name	Capacity
Ms Kathleen Cassidy	HRA Confidentiality Advisor

Context

Amendment request

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

In this amendment, the applicants sought support to remove Group B, which includes individuals who are not at a high risk of developing smoking related cancers. In this amendment, the target accrual was increased from 25,000 to 50,000 and the age range expanded to 50-77. Now that Group B is to be removed, the target accrual will reduce to 25,000 and the age range return to 55-77. The decision not to proceed with the inclusion of Group B has been made by the study funder before any data extraction was undertaken for patients in this group and before any patients were invited or recruited to the study. The decision to remove Group B was made as patients in Group A were at a higher risk of developing cancer and a relatively small group of those in Group B were expected to require low-dose computed tomography (LDCT) screening.

Confidentiality Advisory Group advice

The amendment requested was considered by the Confidentiality Advisory Group. The CAG agreed that the amendment request was in the public interest. Members noted that the SUMMIT trial was not included on the list of trials on the UCL Clinical Trials Centre website. The details given on the study website, GRAIL website and ClinicalTrials.gov are inconsistent across the different websites. The CAG asked that the information on the websites was revised for clarity and consistency, and that the SUMMIT trial was included on the website for the UCL Clinical Trials Centre.

Confidentiality Advisory Group conclusion

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

Specific conditions of support

1. The details about SUMMIT given on the study website, GRAIL website and ClinicalTrials.gov need to be revised for clarity and consistency, and confirmation provided to the CAG that this has been done.

2. The SUMMIT trial is to be included on the list of clinical trials given on the UCL Clinical Trials Centre website. Confirmation is to be provided to the CAG that this has been done, or justification as to why this cannot be done given.

3. Confirmation provided from the IG Delivery Team at NHS Digital to the CAG that the relevant Data Security and Protection Toolkit (DSPT) submission(s) has achieved the 'Standards Met' threshold. **Confirmed University College London - School of Life and Medical Sciences and Amazon Web Services have a confirmed 'Standards Met' grade on DSPT submission 2018/19 by check of the NHS Digital DSPT tracker on 24 September 2020.**

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

j. 16/CAG/0053 - Prolonged Effects of ART: A Record Linkage study (PEARL)

Name	Capacity
Ms Caroline Watchurst	HRA Confidentiality Advisor

Context

Amendment request

This study from University of Oxford aims to create a linked dataset combining data on fertility treatment from the Human Fertilisation and Embryology Authority (HFEA) and primary care and hospitalisation data from the Clinical Practice Research Datalink (CPRD), and to use the linked dataset to assess the effect of Assisted reproductive technologies (ART) on the health of women and their children after successful fertility treatment. The funding for this study was due to end on 29 November 2020.

This amendment sought to extend the duration of support to 31 May 2022. This extension is required due to a long delay in achieving the record linkage necessary for the analysis. The data controllers and processors have taken some time to come to an agreement regarding the data flows for the study, however the full linked dataset is now expected to be delivered and ready for analysis at the University of Oxford in early 2021. Without a duration amendment the applicants would be unable to complete the analysis and address the original research questions.

The extension to the study will be updated on the study website. Advertising via social media and the websites for the University of Oxford, CPRD and HFEA will direct the public to the study website.

Confidentiality Advice Team advice

The amendment requested was considered by the Confidentiality Advice Team. The Team consider the justification for the amendment to be reasonable.

Confidentiality Advice Team conclusion

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

Specific conditions of support

1. Confirmation provided from the IG Delivery Team at NHS Digital to the CAG that the relevant Data Security and Protection Toolkit (DSPT) submission(s) has achieved the 'Standards Met' threshold
   Confirmed – 2019/20 DSPT for University of Oxford – Medical Science Division – Nuffield Department of Population Health was confirmed as 'Standards Met' by NHS Digital (by check of DSPT tracker 07 October 2020)
2. Confirmation of a favourable opinion from a Research Ethics Committee.
   Confirmed non substantial 10 September 2020

k. 15/CAG/0169 - The Role and Impact of Surgical Centralisation on Renal Cancer Survival: A Multifactorial Analysis

Name	Capacity
Ms Caroline Watchurst	HRA Confidentiality Advisor

Context

Amendment request

The applicants sought support to extend the projected end date of the study by one year until 07 October 2021.

The applicants were in the final stages of the project, generating a survival model for predicting renal cancer survival, and the final stages of doctoral thesis write-up. It was anticipated that the completion of the final stages of the project would take a further year, due to the disruption caused by the Covid-19 pandemic. Confidential patient information required from HES and the National Cancer Data Repository has already been extracted and received by the applicants and the applicants sought support for continued processing of this data. The applicant confirmed that other aspects of the study remained unchanged.

Confidentiality Advice Team advice

The amendment requested was considered by the Confidentiality Advice Team. The Team accepted the rationale given for the extension.

Confidentiality Advice Team conclusion

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

Specific conditions of support

1. Confirmation provided from the IG Delivery Team at NHS Digital to the CAG that the relevant Data Security and Protection Toolkit (DSPT) submission(s) has achieved the 'Standards Met' threshold
   Confirmed: University of Cambridge (School of Clinical Medicine) has a confirmed 'Standards Met' grade on DSPT submission 2018/19 (by check of DSPT tracker 07 October 2020**).** 2019/20 DSPT has been submitted but not yet reviewed by NHS Digital.

2. Confirmation of a favourable opinion from a Research Ethics Committee.
   Confirmed non substantial in email from REC 09 October 2020

I. 19/CAG/0209 - Advanced cardiovascular risk prediction in the acute care setting

Name	Capacity
Ms Kathleen Cassidy	HRA Confidentiality Advisor

Context

Amendment request

The applicants have existing support to allow the research team at the University of Manchester to disclose confidential patient information, provided by Trusts participating in the research and using T-MACS, to NHS Digital for linkage to HES data. A pseudonymised data will then be returned to the University of Manchester.

In this amendment, the applicants are seeking support to link to the civil registration dataset, held by NHS Digital, in order to extract patients' mortality information. The outcome to be extracted from the dataset was referenced as a data item in the initial application, but it had not been made explicit that the outcome would be obtained from the civil registration dataset. A revised protocol, which had been amended to clarify that the civil registration dataset would be linked to, was provided.

Confidentiality Advisory Group advice

The amendment requested was considered by the Confidentiality Advisory Group. The CAG agreed that the amendment had been made to correct an oversight in the original submission. Members noted that the patient notification materials would need to be revised to ensure that the correct data linkages were described.

Confidentiality Advisory Group conclusion

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

Specific conditions of support

1. Provide confirmation that the patient notification materials explain the required data linkages.

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** – the University of Manchester (by NHS Digital email dated 04 October 2019), Wrightington, Wigan and Leigh NHS Foundation Trust (by NHS Digital email dated 23 January 2020), Stockport NHS Foundation Trust (by NHS Digital email dated 23 January 2020) and East Lancashire Hospitals NHS Foundation Trust (by NHS Digital email dated 24 January 2020) have confirmed 'Standards Met' grades on DSPT submission 2018/19.

   - **Confirmed** - Manchester University NHS Foundation Trust (by NHS Digital email dated 29 January 2020) 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.

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

m. 19/CAG/0109 (Previously 19/CAG/0045)– Suicide by middle-aged men

Name	Capacity
Ms Kathleen Cassidy	HRA Confidentiality Advisor

Context

Amendment request

The applicants have existing support for the disclosure of confidential patient information from the ONS mortality dataset held by NHS Digital to the University of Manchester, to enable a patient cohort to be identified and followed-up via wider health data sources. The purpose of the application is to examine the characteristics of middle-aged men who die by suicide, determine how frequently suicide is preceded by factors more often associated with suicide by men than by women, examine the role of support services and make recommendations to strengthen suicide prevention for middle-aged men. The study has been funded by the Health Quality Improvement Partnership (HQIP).

The applicants are seeking support to extend the duration of the application to 31 March 2021. Due to the Covid-19 pandemic, data collection was paused in March 2020, causing delays to the progress of the study. Data collection has now been restarted and the additional time will allow the research team sufficient time to collect the required data.

Confidentiality Advice Team advice

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

Confidentiality Advice Team conclusion

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

Specific conditions of support

1. Favourable opinion from a Research Ethics Committee. **Confirmation provided that REC review is not required.**

2. Confirmation from the IG Delivery Team at NHS Digital of suitable security arrangements via Data Security and Protection Toolkit (DSPT) submission (**Confirmed – 2018/19 DSPT for University of Manchester - National Confidential Inquiry into Suicide and Safety**

in Mental Health (8D594-ECC0020) confirmed as 'Standards Met' by NHS Digital (by check of DSPT tracker 21 October 2020)

n. 19/CAG/0197 - Vaccination timeliness in preterm infants

Name	Capacity
Ms Caroline Watchurst	HRA Confidentiality Advisor

Context

Amendment request

The applicants have existing support to allow the disclosure of confidential patient information from the Maternity Services Data Set to Information Services at Hull University Teaching Hospitals NHS Trust, and to allow further disclosure to Child Health Information Services (CHIS) and the National Neonatal Research Database for further data linkage and the return of an identifiable dataset to Information Services at Hull University Teaching Hospitals NHS Trust. The Maternity Services data set (MSDS) is provided by Northern Lincolnshire and Goole (NLAG) NHS Foundation Trust, York Teaching Hospital NHS Foundation Trust and Hull University Teaching Hospitals (HUTH) NHS Trust. The Child Health Information Service is provided by Harrogate and District NHS Foundation Trust, Humber NHS Foundation Trust, NLAG NHS Foundation Trust and North East Lincolnshire Council.

In this amendment, the applicants are seeking support to remove York Teaching Hospitals NHS Trust and Harrogate and District NHS Foundation Trust as data processors. York Teaching Hospitals NHS Trust is being excluded as it can no longer support the study during the COVID-19 crisis. Harrogate and District NHS Foundation Trust is being excluded because this was only needed to provide the immunisation data for infants identified by York Teaching Hospitals NHS Trust.

Confidentiality Advice Team advice

The amendment requested was considered by the Confidentiality Advice Team. The Team agreed with the rationale for this amendment.

Confidentiality Advice Team conclusion

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

Specific conditions of support

1. Confirmation of a favourable opinion from a Research Ethics Committee
   Confirmed non substantial by email from REC 22 September 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. **Due to the number of sites processing under the application scope, 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 accessing confidential patient information with support under the Regulations. This would need to be established at the following sites:**

   - **Northern Lincolnshire and Goole (NLAG) NHS Foundation Trust**
   - **Hull University Teaching Hospitals (HUTH) NHS Trust**
   - **Humber NHS Foundation Trust**
   - **North East Lincolnshire Council**
   - **Chelsea and Westminster NHS Foundation Trust**
   - **Imperial College London**

o. 18/CAG/0007 - Evaluating alternative protocols for identifying and managing patients with familial hypercholesterolaemia: cost-effectiveness analysis with qualitative study

Name	Capacity
Ms Kathleen Cassidy	HRA Confidentiality Advisor

Context

Amendment request

The applicants have existing support to allow items of confidential patient information to be disclosed from the Simon-Broome Registry, held by University College London, to NHS Digital in order to facilitate linkage with ONS mortality data.

In this amendment, the applicants are seeking to extend the duration of support for one year, from 31 March 2020 to 31 March 2021. The applicants have experienced delays in obtaining the outcome of their DARS application, partly due to the Covid-19 pandemic. The additional time will allow the applicants sufficient time to complete the required data linkages.

Confidentiality Advice Team advice

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

Confidentiality Advice Team conclusion

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

Specific conditions of support

1. Confirmation of suitable security arrangements via Data Security and Protection Toolkit submission. (**Confirmed – University College London School of Life and Medical Sciences (by NHS Digital email 13 June 2019) and NHS Digital (by NHS Digital email 10 June 2019) have confirmed 'Standards Met' grade on DSPT 2018/19).**

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

p. 19/CAG/0205 (Previously ECC 4-02(FT2)/2012)– A large randomised assessment of the relative cost-effectiveness of different classes of drugs for Parkinson's disease (PD MED)

Name	Capacity
Ms Caroline Watchurst	HRA Confidentiality Advisor

Context

Amendment request

This research from the University of Birmingham studies the long-term cost-effectiveness of 4 different classes of medication that are currently being used to treat Parkinson's disease, and is intended to provide evidence for better NICE guidance for the management of Parkinson's disease. PD MED has current support under the Regulations to link Hospital Episode Statistics (HES) data, and ONS mortality data in relation to PD MED clinical trial participants. Identifiable data is submitted to NHS Digital in order to link data to trial participants. Data is pseudonymised before being disclosed back to the applicant.

The study have already received HES data from 1999 - 2013, demographics data from August 2005 – September 2018, cancer registry data from August 2005 - September 2018, and mortality data from August 2005 - September 2018. The cancer registration and demographics data was originally covered by consent, and the linkage with HES and ONS mortality data was covered by support under the Regulations (CAG ref **ECC 4-02(FT2)/2012**). On 26 September 2019, IGARD reviewed a request for cancer registry data, and did not consider the original consent to be adequate, and so requested an amendment to support under Regulation 5. Applicants therefore submitted a new application to CAG under reference **19/CAG/0205**, however support regarding cancer registry data and demographics data was not clearly specified in the application or outcome letter, as the applicant thought that ONS data covered both mortality, demographics and cancer registry.

This amendment seeks support for the PD MED research team from University of Birmingham to send confidential patient information of PD MED trial participants to NHS Digital for additional data linkages with new demographics data from October 2018 - March 2020, cancer registry data from September 2018 to March 2020, and mortality data from September 2018 to March 2020. This amendment is advised by NHS Digital.

This amendment also seeks support to retain cancer registry and demographics data previously received from MRIS between August 2005 and September 2018, which was collected with consent as the legal basis. Additional data from HES and ONS was also received and this is retained with the current support under Regulation 5.

There is an updated privacy notice on the PD MED website which informs PD MED participants about the requested linkages. This has been provided to members for review. Applicants require the updated data from NHS Digital to complete time to event analyses accurately, which will enable the research questions to be fully answered.

This amendment also sought support to extend the duration of support under the regulations until 1 November 2022, due to delays experienced during COVID-19, and to enable applicants to finish analyses.

Confidentiality Advisory Group advice

The amendment requested was considered by the Confidentiality Advisory Group, who were content with the justifications provided for this amendment.

Confidentiality Advisory Group conclusion

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

Specific conditions of support

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

   The NHS Digital **2019/20** DSPT review for **NHS Digital and University of Birmingham** were confirmed as 'Standards Met' on the NHS DSPT Tracker (07 October 2020).

   NHS Digital have equivalent assurance for 2018/2019.

2. Confirmation of a favourable opinion from a Research Ethics Committee.

Confirmed 23 September 2020

3. Annual Review Approvals

CAG Reference	Application Title
PIAG 1-05(g)/2007	HES and STATS19 one to one matching project
CAG 7-07(a-c)/2013	Invoice validation within NHS England within the Commissioning Support Units/Clinical Commissioning Groups controlled environment (for Finance) on behalf of Clinical Commissioning Groups
17/CAG/0050	Educational outcomes in children born after assisted reproductive technology; a population based linkage study
18/CAG/0090	What changes for patients in medium secure care?
PIAG 2-10(f)/2005	Case Mix Programme
18/CAG/0168	Clinical outcomes of a PPS program undertaken in a large UK cohort
19/CAG/0110	Investigating all-cause mortality in the substance misuse treatment population
16/CAG/0079	National Clinical Audit of Breast Cancer in Older Patients (NABCOP)
17/CAG/0129	Critically ill children and young people: do national Differences in access to Emergency Paediatric Intensive Care and care during Transport affect clinical outcomes and patient experience? The DEPICT Study
17/CAG/0125	All cause mortality within 12 months following hip fracture
19/CAG/0144	Infections in Oxfordshire: a Research Database (IORD)
15/CAG/0163	Risk modelling for quality improvement in the critically ill: making best use of routinely available data
15/CAG/0169	The Role and Impact of Surgical Centralisation on Renal Cancer Survival: A Multifactorial Analysis
16/CAG/0053	Prolonged Effects of Assisted reproductive technologies on the health of women and their children: a Record Linkage study for England (PEARL)
17/CAG/0020	Clinical and Biological factors associated with relapse and length of survival following relapse in UK neuroblastomas

19/CAG/0139	The clinical and cost-effectiveness of testing for Group B Streptococcus: a cluster randomised trial with economic and acceptability evaluations
19/CAG/0033	A multi-point survey to investigate the incidence and outcome of patients who doctors or nurses feel are unlikely to leave hospital alive from intensive care and the rate of agreement between doctors and the bedside nurse
16/CAG/0066	Hospital Alerting Via Electronic Noticeboard (HAVEN)
18/CAG/0179	IMproving the practice of fetal heartrate MOnitoring with cardiotocography for safer childbirth
18/CAG/0147	National Adult Community Acquired Pneumonia Audit 2018-19
17/CAG/0150	National Perinatal Mortality Review Tool (PMRT)
CR28/2014	Study of a Birth Cohort from Hertfordshire
18/CAG/0013	Evaluating the real-world implementation of the Family Nurse Partnership in England: a data linkage study
19/CAG/0136	Acute Leukemia in Pregnancy Registry Study
17/CAG/0048	Long-term follow-up of the East London Sickle Cell Disease Neonatal Cohort
19/CAG/0118	The Orchid Research Tissue Bank - Collection of Genitourinary tissue
19/CAG/0132	Frequency of observations (FOBS)

Signed – Chair	Date

Signed – Confidentiality Advice Team	Date