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

April 2021

1. New Applications

a. 20/CAG/0141 - Conversation analytic (CA) study of prognostic decision-making within palliative multi-disciplinary team (MDT) meetings

Name	Capacity
Dr Tony Calland MBE	CAG Chair
Dr Martin Andrew	CAG member
Ms Sophie Brannan	CAG member
Dr Patrick Coyle	CAG vice-chair
Mr David Evans	CAG member
Ms Diana Robbins	CAG member
Mr Marc Taylor	CAG member
Ms Caroline Watchurst	HRA Confidentiality Advisor
Dr Paul Mills	HRA Confidentiality Advice Service Manager

Context

Purpose of application

This application from University College London, Division of Psychiatry, Marie Curie Palliative Care Research Department sets out the purpose of medical research that aims to explore how health care professionals with different backgrounds make decisions regarding prognosis for terminally ill patients during MDT meetings in a hospice. The analyses will use Conversation analytic (CA) methodology to give an insight in to how MDT prognostic decisions are initiated, structured, potentially challenged and negotiated, and finally closed. This application is a qualitative study of recorded interactions between healthcare professionals in MDT meetings in the Marie Curie Hospice, Hampstead, as part of a PhD project.

Studies show that there is value for patients and families in accurate prognostic information. Clinicians' predictions about length of survival are inaccurate and over-optimistic, and no clear guidance exists on how clinicians can be taught to perform this task better. Nonetheless, clinical predictions of survival remain the most common method of arriving at a prognostic estimate. This inaccuracy and inconsistency is maintained when the timeframe of the prognosis is reduced to days. One potential method to improve prognostication has been to look at decisions made by an MDT, however the manner in which different estimates are combined to arrive at an MDT estimate is not well understood.

Applicants plan to collect video recordings of 20-30 hospice-based MDT meetings. The collaborating hospice has two wards that each holds a weekly MDT meeting, during which staff members with different professional backgrounds discuss palliative patients' care planning. Before MDT meetings, a researcher will set up equipment (cameras, microphones) in the meeting room, and immediately before the meeting begins, the equipment will be turned on. The researcher will stay outside the meeting room, to avoid interfering in the processes of the meeting. All staff and visitors taking part in the MDT will have been approached by the researcher with an information sheet and asked to provide signed informed consent. If the staff member declines consent, their data will be excluded from analysis. A note on the door will also inform staff and visitors that the meeting is being recorded.

Data will be collected using encrypted recorders. Recordings will be uploaded electronically to a UCL encrypted laptop at the hospice site as soon as possible after the meeting, and then then deleted from the recorders. If the recordings are not immediately uploaded, they will be safely stored in a locked cabinet with restricted access at the hospice for a maximum of 72 hours. The laptop will be physically transferred back to UCL, where all patient identifiable information will be deleted or anonymised from the video recordings before transferring to the UCL s:drive for storage, and deletion from the laptop.

The researcher will make detailed transcriptions of the recordings, and information that might lead to identification of the patients being discussed or of the participants in the meetings will be anonymized and pseudonymised. This will be done by (1) using pseudonyms instead of participants' and patients' names, location etc. in transcripts etc. and by (2) beeping out"/audibly masking the identifiable information in the video recording. A list of pseudonyms

will not be maintained so patients will not be able to be re-identified. No patient-identifiers will be retained because this information is not required for the study purposes. The method of CA closely investigates the sequential organisation and the interactional functions of naturally occurring talk as well as non-verbal behaviour. Therefore, the applicants plan to use the transcription system CLAN (Computerized Language Analysis) to enable them to link the transcripts to media.

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	For CAG purposes support is only given regarding patients at the Hospice, not for staff members or official visitors. The cohort is: patients treated Marie Curie Hospice, Hampstead who are being discussed during MDT meetings, whose information may be incidentally disclosed.
Data sources	1. Video recordings of MDT meetings at Marie Curie Hospice, Hampstead
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
Additional information	Video recordings will be anonymised by • Using pseudonyms instead of participants' and patients' names, location etc. in written transcripts. Applicant has confirmed that a list of patient names and their identifiers will not be kept. • Audibly masking the identifiable information in the video recording by 'beeping out'

Confidentiality Advisory Group advice

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

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. Please confirm if it is possible for the recording to be turned off at the start of each patient discussion so that full name is not recorded? If this is not possible, please provide a full justification.

The applicant has detailed in their responses why this is not possible, as this would distort the naturally occurring flow of conversation, which is the intention of the study to record. Interrupting the MDT meetings in this way could use additional time, which hospice staff do not have to spare, and may therefore negatively impact patient care by reducing the time spend discussing patients in meetings. The CAG accepted this justification.

2. Please provide an estimate of number of patients discussed in each MDT meeting.

There will be a maximum of 15 patients discussed in each MDT meeting. The CAG accepted this response.

3. Please make it clear on the poster that 'this recording is for research purposes only, and not for media use', and provide an updated poster to the CAG.

The updated poster has been provided and the Committee were satisfied with this.

4. Please ensure that it is made clear on the poster that a relative could also opt out on behalf of a patient if they lacked capacity, and provide an updated poster to the CAG.

The updated poster has been provided and the Committee were satisfied with this.

5. Please describe the practical steps that would be taken if a patient opted out.

The applicant described that if a patient opted out, the patient's discussion during the meeting will be deleted after the recording has been obtained and will not be included in the analysis. The CAG were content with this process.

6. Please undertake further PPI, to ensure the views of patients are provided regarding whether the use of their confidential patient information without their consent would be acceptable to them, should they be a patient in the hospice.

The applicant has undertaken a further Patient and Public involvement exercise as requested, with a wider group of patients and carers. Three out of four people consulted supported the use of confidential patient information without consent, and were convinced by the justifications provided by the applicant. One patient representative found it confusing that consent would not be obtained and did not accept the justifications provided. However the applicant further explained the nature of the study and worked with the patient representatives to discuss other aspects of the study. Considering that one patient representative was not in full support of the proposed use of confidential patient information without consent, the CAG have provided a

condition of support to undertake further patient and public involvement over the course of the next year, and provide an update to CAG at annual review.

Confidentiality Advisory Group advice conclusion

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

Specific conditions of support

The following sets out the specific conditions of support.

1. Wider patient and public involvement and engagement activity should be carried out to test the acceptability of the project and its methodology with a wider group. Feedback about the activity undertaken and the views expressed is required at the time of first annual review. If the views provided were negative, the CAG would take this into account when considering whether support can continue or whether further work is required.

2. Favourable opinion from a Research Ethics Committee. **Confirmed 4 December 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 – The **2019/20** NHS Digital DSPT review for **UCL School of Life and Medical Sciences (EE133902-SLMS)** was confirmed as 'Standards Met' on the NHS Digital DSPT Tracker (checked 06 November 2020).

The **2019/20** NHS Digital DSPT review for **Marie Curie London (8GK24**) was confirmed as 'Standards Met' on the NHS Digital DSPT Tracker (checked 06 April 2021).

b. 21/CAG/0025 - Retrospective Review of the Use of Simplex High Viscosity Bone Cement for Joint Arthroplasty. Short title: Simplex Cement

Name	Capacity
Dr Rachel Knowles	CAG Member
Professor Jennifer Kurinczuk	CAG Member
Dr Murat Soncul	CAG Alternative Vice-Chair

Ms Caroline Watchurst	HRA Confidentiality Advisor

Context

Purpose of application

This application from Royal Devon & Exeter NHS Foundation Trust set out the purpose of medical research which aims to evaluate the success rate of cemented Triathlon Total Knee Replacement surgery with fixation of components implanted using Simplex high viscosity bone cement (Simplex HV). Success is defined as absence of revision due to aseptic loosening in cemented Triathlon Total Knee components implanted with Simplex HV, at two years post initial surgery. This application is only for a retrospective, consecutive series, evaluation of medical records of patients who have undergone total knee replacement (TKR) at Royal Devon & Exeter NHS Foundation Trust. The study is sponsored by Stryker, and the anonymised dataset will be sent to Stryker for analysis, however this flow of data, and any other participating sites are not in scope for this application.

Nearly 100,000 primary TKR surgeries are performed per year in the UK. There has been concern that high viscosity (HV) cement could cause early loosening of the components in some patients. However, HV cement has advantages over low viscosity cement, including allowing more time to work with the cement during the handling and setting phases of surgery, which has potential to allow for greater operational/surgical efficiency. There is therefore a need to demonstrate the safety of HV cement used in TKR, as measured by the absence of loosening at two years after surgery.

As a part of routine care, Royal Devon & Exeter NHS Foundation Trust already keeps a clinical database of patients who have undergone TKR. The Chief Investigator (CI), who is part of the direct care team, will identify potential study cases from this database, therefore this element does not require support. The CI will then inform medical student researchers of eligible patients by disclosing confidential patient information. The subsequent extraction of the data for those meeting the inclusion criteria will be undertaken by medical student researchers; this element requires support under Regulation 5, as data extraction will be performed by members of staff who are not part of the direct care team, by searching the patient administration system, paper and electronic medical records and radiology systems. Name, date of birth, and hospital number will be used to ensure the information extracted is for the correct patient. The researchers will complete the paper case report forms, which are then pseudonymised by the CI with patient code (randomly allocated starting AA etc – this is not related to the patients initials), centre number and subject number. These paper based forms are then disclosed to Stryker by entering into an electronic database, and then Stryker send to their statistician in the US for analysis. This disclosure can be considered anonymous and does not require support. A log linking the study number, and patient code attributed to each patient to their confidential patient information will be kept by the CI only until 6-12 months after the results are published

(estimated date February 2023). The CI is a member of the direct care team, and therefore support not required for this.

A recommendation for class 1, 4, 5 & 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	100 Patients aged 18-100 years who have undergone total knee replacement as the treatment for end stage osteoarthritis of the knee in 2014-15. All will have had had anti-biotic loaded HV cement
Data sources	The hospital patient administration, paper and electronic medical records and radiology systems at Royal Devon & Exeter NHS Foundation Trust. Data collected as part of routine care
Identifiers required for the purposes of data extraction	1. Name 2. Date of Birth 3. Hospital number
Identifiers required for analysis purposes	1. Patient code (randomly allocated AA etc as described in application) 2. Centre number 3. Subject number 4. Age 5. Gender 6. Diagnosis (This can be considered anonymous as Stryker will not be able to re-identify)
Additional information	The CI retains the key between the patient code, centre #, subject # and the identifiers, until after publication of results,

	in case the study team find unexpected and unreported adverse events.

Confidentiality Advisory Group advice

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

1. Please provide alternatives to email contact, such as postal address and phone number as a mechanism for patients to object, and provide an updated patient notification within one month from the date of this letter.

On 2 March 2021 the applicant provided an updated patient notification (v2) addressing the changes suggested by the CAG. The members considered the notification, and suggested some further alterations to the applicant. The applicant provided the updated notification (v3) on 16 March 2021, which were accepted by the Sub-Committee, who were now content to recommend support.

2. Please provide evidence of NHS Digital confirming 'Standards met' for the 19/20 DSPT review for Royal Devon & Exeter NHS Foundation Trust, see standard conditions of support below.

The applicant confirmed this via the CAG inbox on 24 March 2021.

Confidentiality Advisory Group advice conclusion

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

Specific conditions of support

The following sets out the specific conditions of support.

1. It is a condition of support that the applicant comply with the national data opt out once this is mandated for NHS Trusts.
2. Favourable opinion from a Research Ethics Committee. **Confirmed 09 February 2021**
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:

The NHS Digital **19/20** DSPT review for **Royal Devon & Exeter NHS Foundation Trust** was confirmed as 'Standards Met' (by email to the CAG inbox on 24th March 2021)

c. 21/CAG/0028 - Motor Neuron Disease Register for England, Wales and Northern Ireland

Name	Capacity
Dr Tony Calland MBE	CAG Chair
Dr Malcolm Booth	CAG Member
Ms Sophie Brannan	CAG Member
Dr Patrick Coyle	CAG Vice-Chair
Professor Lorna Fraser	CAG Member
Mr Tony Kane	CAG Member
Dr Rachel Knowles	CAG Member
Dr Simon Kolstoe	CAG Member
Dr Harvey Marcovitch	CAG Member
Dr Murat Soncul	CAG Alternative Vice-Chair
Ms Caroline Watchurst	HRA Confidentiality Advisor
Dr Paul Mills	HRA Confidentiality Advice Service Manager
Ms Natasha Dunkley	HRA Head of Confidentiality Advice Service

Context

Purpose of application

This non-research application from Kings College London (KCL), set out the purpose of creating a register that will act as a central resource of information about all people with a diagnosis of Motor Neuron Disease (MND) as confirmed by a consultant neurologist in England, Wales and Northern Ireland, to enable the calculation of incidence and prevalence of MND in England, Wales and Northern Ireland. Confidential patient information will also be linked with clinical data from national datasets. This non-research application is for the purpose of improving care planning, looking at regional differences, and enabling the applicants to provide answers associated with the NICE MND Audit. There is also a separate research application (21/CAG/0009).

Motor neuron disease (MND, ALS) is a terminal disease resulting in progressive paralysis and leading to respiratory failure around 2–5 years after symptom onset. Research shows that the

overall number of people diagnosed with MND in the UK is expected to increase significantly. Across the UK there are five regional population registers for MND. Current estimates suggest there are 5,000 people living with MND in the UK at any one time, but whether this is the true figure and how people with MND are geographically distributed is not known. Having a national MND Register for patients living in England, Wales and Northern Ireland will enable calculation of the incidence and prevalence of the disease across these three regions, improve care provision, examine regional differences in survival, and reveal clusters. A national register will also allow the correct modelling of epidemiological variables, for example, the development of a mathematical model of MND. Such models can inform future studies, drug discovery and knowledge of pathogenesis of the disease.

The MND Register for England, Wales and Northern Ireland has been established to provide the international research community with a resource to understand the epidemiology of MND in the UK, and to further knowledge of causative and disease modifying factors in the disease. It has been funded through a healthcare research grant provided by the MND Association. The MND Register received REC approval in 2015, and has been recruiting patients from England, Wales and Northern Ireland for 5 years using a consented model. Applicants have recruited 1,802 patients across 32 centres in England and Wales which includes complete data capture from six recruiting centres only, and a rate of 38% ascertainment. The current consented register is used for the described non-research purposes.

Applicants have found it difficult to meet the primary objective of obtaining the incidence and prevalence of MND across England, Wales and Northern Ireland as data has been incomplete. Applicants are therefore proposing to change to an opt-out registry to ensure complete ascertainment, and are seeking support under Regulation 5 to enable the prospective recording of all patients with MND across England and Wales. Northern Ireland Is not covered by regulation 5 support. Support is also being sought to collect data retrospectively for patients dating back to June 2015, however, the applicant has confirmed that anyone who previously declined will not be added, and their dissent will be respected.

Applicants will collect confidential patient information regarding every person with MND in England and Wales, including name in order to prevent double counting, and disclose NHS Number, Date of Birth, Gender, Full Postcode and Unique study identifier to NHS Digital and NWIS annually for the purposes of linkage with data from Hospital Episode Statistics (HES), and Office of National Statistics (ONS) mortality data (held at NHS Digital), and also to Patient Episode Database for Wales (PEDW) data held at NHS Wales Informatics Service (NWIS). The register is currently consented, however, the consent taken does not cover the proposed linkages with HES and ONS data. Therefore Regulation 5 support is requested to link identifiers from the previously consented patients to these datasets, and also to link data about every patient added to the register under Regulation 5 support, either prospectively or retrospectively. Clinical and identifiable data will be sent to the study team at KCL every 6 months from clinicians and other providers. Each participant will be assigned a unique study identifier by the direct care team, at the time of data collection and this will be used throughout the involvement of the project.

Identifiers will be held in a separate database to clinical information and this will be linked through the unique study identifier. No identifiable data will be used as part of analysis for non-research purposes. The following fields will never be shared: Full name, date of birth,

NHS number, full postcode, exact dates for example date of birth or date of death. If the year of birth is required for risk factor analysis, then this will be provided.

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

Confidential patient information requested

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

Cohort	Data will be collected from patients living in England, Wales, and Northern Ireland over the age of sixteen with a diagnosis of Motor Neuron Disease (MND) as confirmed by a consultant neurologist. This collection will be retrospective dating back to June 2015, and prospective. Note: CAG support only extends to patients in England and Wales, and will not override the dissent of anybody who previously declined.
Data sources	1. NHS Digital - HES Admitted Patient Care, Outpatients, and ONS Mortality datasets 2. NHS Wales Informatics Service, Patient Episode Database for Wales (PEDW). 3. Clinical notes of MND patients in England and Wales held at various: • NHS Providers • Independent Sector Providers • Voluntary & Third Sector Providers
Identifiers required for linkage purposes	1. NHS Number 2. DOB, 3. Gender 4. Full Postcode 5. Unique study identifier
Identifiers retained in KCL database	1. Date of Birth 2. Gender 3. Postcode 4. NHS number 5. Name (First name and surname) – to prevent double counting 6. Full date of death 7. Ethnicity 8. Date of diagnosis

	9. Unique Study identifier Patient identifiable information will be held in a separate database to clinical information and this will be linked through a unique study identifier These identifiers will be held within the database but not released; any dates required will be modified before releasing.
Identifiers required for analysis purposes	1. Date of birth (modified for release to year of birth) 2. Date of death (modified for release) 3. Gender 4. Ethnicity 5. Date of diagnosis (modified for release) 6. Unique study identifier Other clinical data as described in the application Data released for analysis can be considered anonymous
Additional information	Annual extracts from HES – identifiers are sent each time to NHS Digital/NWIS from KCL, and not retained by NHS Digital/NWIS.

Confidentiality Advisory Group advice

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

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. Please provide justification for why any identifiers would need to be retained if a participant had died, and the final linkage had been performed, within one month from the date of this letter.

A detailed response was provided on 8th March 2021 explaining that it is important to retain identifying information to keep open the possibility of future linkage of the register with other studies. The response provided examples of research studies which had beneficial impacts due to the retention of identifiers, and explained that overwhelmingly, people with ALS and their families rank research as their highest priority. The Sub-Committee accepted this justification.

2. Please clarify if name is required to be retained in the database for linkage purposes, and confirm that NHS Digital have stated that these identifiers for linkage are the minimum required, within one month from the date of this letter.

The applicants have responded on 8th March providing a justification for retaining name, which is to ensure that when data is transferred from each data collection centre and cleaned that the applicants can check for patients who are duplicates, as some patients with MND are seen at different centres across the UK for second opinions. After much discussion and re-reviewing of submitted documents the CAG Sub-Committee members accepted that name could be retained in order to prevent double counting.

However the clarification requested was not to justify the retention of name, but rather to confirm whether or not name was required for linkage purposes with datasets held by NHS Digital. The applicant confirmed in the response to provisional on 8th March that NHS Digital has not specified that these identifiers are required for linkage purposes, however the applicant had not requested this information from NHS Digital. On further clarification, the applicant confirmed by an email sent from NHS Digital on 14th April that name is not required for linkage purposes. Name will however be retained in the MND database indefinitely to prevent double counting.

3. Please confirm if the original consent was face to face only, or if some was undertaken via the post? If the latter is the case, please clarify how care providers will be able to have an up to date record of every patient who 'dissented', within one month from the date of this letter.

The response to provisional clarified that the original consenting method was face-to-face. However, during the COVID-19 pandemic, some care centres did undertake postal consent, with a phone consultation taking place to answer any questions the patient had prior to signing the consent form. Any patients who did not provide consent to the MND Register will be assumed as dissented. The members accepted this response.

4. Please confirm if the care providers who would be sending retrospective data to KCL can send the retrospective data required, and omit from the list any patients who had previously dissented, instead of the applicant receiving lists of identifiers for those who have previously dissented. Please confirm if this process is possible within one month from the date of this letter.

The applicant confirmed that this would be possible, and they will ask care providers to provide identifiable data for people seen in their clinic before the date of approval only if a consent form had been returned. The CAG Sub-Committee were content with this response.

5. As the national data opt out is respected, a statement to this effect should be added to the privacy notice, and an updated version provided to the CAG within one month from the date of this letter.

The applicants provided an updated Patient Privacy notice (v3 23 February 2021) which refers to the National Data Opt-out. The Members accepted this updated privacy notice as a response to provisional outcome, however they provided some further suggestions for the applicant.

The CAG commented that on further reading of the privacy notice, they suggested that it would be good practice to put a reference to opt-out near the beginning of the document rather than at the end. The also suggested a re-wording of the following statement; Please bear in mind if you do opt out that any data we have already collected and included in an existing dataset cannot be removed or erased. This includes anonymised data provided to researchers. However the comments regarding the privacy notice do not require a response and are not conditions of support, they are provided as suggestions only.

Confidentiality Advisory Group advice conclusion

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

Specific conditions of support

The following sets out the specific conditions of support.

1. As applicants are planning to consult with patients on an ongoing basis, any feedback regarding these ongoing conversations with patients should be provided to the CAG at the time of the first annual review.

2. Support is in place for five years from the date of the final outcome letter. Further support is to be sought after this time

3. Support is not in place for those people who previously dissented to be part of the MND register when the consented model was in place.

4. Support is only in place for England and Wales, and does not extend to Northern Ireland.

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

‘Standards Met’ threshold. See section below titled ‘security assurance requirements’ for further information.

Confirmed:

The NHS Digital 19/20 DSPT review for Kings College London (HQ) EE133874 was confirmed as ‘Standards Met’ on the NHS Digital DSPT Tracker (checked 08 February 2021)

The NHS Digital 2019/20 DSPT equivalent was confirmed as ‘Standards Met’ on the NHS Digital DSPT Tracker (checked 08 February 2021).

A CPiP has been received for NHS Wales Informatics Service (NWIS).

As there are additionally 5 or more organisations who will be processing confidential patient information without consent as part of this application, the Confidentiality Advice Team (CAT) team will not check these individually. It is the responsibility of the applicant to ensure these are in place.

d. 21/CAG/0009 - Motor Neuron Disease Register for England, Wales and Northern Ireland (research)

Name	Capacity
Dr Tony Calland MBE	CAG Chair
Dr Malcolm Booth	CAG Member
Ms Sophie Brannan	CAG Member
Dr Patrick Coyle	CAG Vice-Chair
Professor Lorna Fraser	CAG Member
Mr Tony Kane	CAG Member
Dr Rachel Knowles	CAG Member
Dr Simon Kolstoe	CAG Member
Dr Harvey Marcovitch	CAG Member
Dr Murat Soncul	CAG Alternative Vice-Chair
Ms Caroline Watchurst	HRA Confidentiality Advisor
Dr Paul Mills	HRA Confidentiality Advice Service Manager

Ms Natasha Dunkley	HRA Head of Confidentiality Advice Service

Context

Purpose of application

This application from Kings College London (KCL) set out the purpose of medical research which aims to create a research database that will act as a central resource of information about all people with a diagnosis of Motor Neuron Disease (MND) as confirmed by a consultant neurologist in England, Wales and Northern Ireland, to enable the calculation of incidence and prevalence of MND in England, Wales and Northern Ireland. Confidential patient information will also be linked with clinical data from national datasets. There is also a separate non-research application (21/CAG/0028).

Motor neuron disease (MND, ALS) is a terminal disease resulting in progressive paralysis and leading to respiratory failure around 2–5 years after symptom onset. Research shows that the overall number of people diagnosed with MND in the UK is expected to increase significantly. Across the UK there are five regional population registers for MND. Current estimates suggest there are 5,000 people living with MND in the UK at any one time, but whether this is the true figure and how people with MND are geographically distributed is not known. Having a national MND Register for patients living in England, Wales and Northern Ireland will enable calculation of the incidence and prevalence of the disease across these three regions, improve care provision, examine regional differences in survival, and reveal clusters. A national register will also allow the correct modelling of epidemiological variables, for example, the development of a mathematical model of MND. Such models can inform future studies, drug discovery and knowledge of pathogenesis of the disease.

The MND Register for England, Wales and Northern Ireland has been established to provide the international research community with a resource to understand the epidemiology of MND in the UK, and to further knowledge of causative and disease modifying factors in the disease. It has been funded through a healthcare research grant provided by the MND Association. The MND Register received REC approval in 2015, and has been recruiting patients from England, Wales and Northern Ireland for 5 years using a consented model. Applicants have recruited 1,802 patients across 32 centres in England and Wales which includes complete data capture from six recruiting centres only, and a rate of 38% ascertainment.

Applicants have found it difficult to meet the primary objective of obtaining the incidence and prevalence of MND across England, Wales and Northern Ireland as data has been incomplete. Applicants are therefore proposing to change to an opt-out registry to ensure complete ascertainment, and are seeking support under Regulation 5 to enable the prospective recording of all patients with MND across England and Wales. Northern Ireland Is not covered by regulation 5 support. Support is also being sought to collect data retrospectively for patients dating back to June 2015, however, the applicant has confirmed that anyone who previously declined will not be added, and their dissent will be respected.

Applicants will collect confidential patient information regarding every person with MND in England and Wales, including name in order to prevent double counting, and disclose NHS Number, Date of Birth, Gender, Full Postcode and Unique study identifier to NHS Digital and NWIS annually for the purposes of linkage with data from Hospital Episode Statistics (HES), and Office of National Statistics (ONS) mortality data (held at NHS Digital), and also to Patient Episode Database for Wales (PEDW) data held at NHS Wales Informatics Service (NWIS). The register is currently consented, however, the consent taken does not cover the proposed linkages with HES and ONS data. Therefore Regulation 5 support is requested to link identifiers from the previously consented patients to these datasets, and also to link data about every patient added to the register under Regulation 5 support, either prospectively or retrospectively. Clinical and identifiable data will be sent to the study team at KCL every 6 months from clinicians and other providers. Each participant will be assigned a unique study identifier by the direct care team, at the time of data collection and this will be used throughout the involvement of the project.

Identifiers will be held in a separate database to clinical information and this will be linked through the unique study identifier. The Applicants describe the Data Access Committee (DAC) for the MND register as consisting of the Principal Investigators Professor A Al-Chalabi and Professor K Talbot, the Project managers, computer scientist, a representative of the MND Association, a patient representative (for example a patient with MND or a carer) and two annually elected representatives of the local registers that contribute to the database. The DAC will grant access to data to researchers according to the DAC terms of reference, which have been provided as part of the application. No identifiable data will be made available to external researchers. The following fields will never be shared: Full name, date of birth, NHS number, full postcode, exact dates for example date of birth or date of death. If the researcher requires the year of birth (for risk factor analysis) then this will be provided. Data will be sent directly to researchers securely, via a secure encrypted spreadsheet.

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

Confidential patient information requested

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

Cohort	Data will be collected from patients living in England, Wales, and Northern Ireland over the age of sixteen with a diagnosis of Motor Neuron Disease (MND) as confirmed by a consultant neurologist. This collection will be retrospective dating back to June 2015, and prospective.

	Note: CAG support only extends to patients in England and Wales, and will not override the dissent of anybody who previously declined.
Data sources	1. NHS Digital - HES Admitted Patient Care, Outpatients, and ONS Mortality datasets 2. NHS Wales Informatics Service, Patient Episode Database for Wales (PEDW). 3. Clinical notes of MND patients in England and Wales held at various: • NHS Providers • Independent Sector Providers • Voluntary & Third Sector Providers
Identifiers required for linkage purposes	1. NHS Number 2. Date of Birth, 3. Gender 4. Full Postcode 5. Unique study identifier
Identifiers retained in KCL research database	1. Date of Birth 2. Gender 3. Postcode 4. NHS number 5. Name (First name and surname) – to prevent double counting 6. Full date of death 7. Ethnicity 8. Date of diagnosis 9. Unique Study identifier Patient identifiable information will be held in a separate database to clinical information and this will be linked through a unique study identifier.

	These identifiers will be held within the research database but not released to applying researchers; any dates required will be modified before releasing.
Identifiers required for analysis purposes	1. Date of birth (modified for release to year of birth) 2. Date of death (modified for release) 3. Gender 4. Ethnicity 5. Date of diagnosis (modified for release) 6. Unique study identifier Other clinical data as described in the application Data released for analysis can be considered anonymous
Additional information	Annual extracts from HES – identifiers are sent each time to NHS Digital/NWIS from KCL, and not retained by NHS Digital/NWIS

Confidentiality Advisory Group advice

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

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. Please clarify how date of death is modified for release to researchers, within one month from the date of this letter.

The applicant provided a response on 8th March 2021, clarifying that 'time to death' would be calculated from other dates held in the dataset. If researchers require date of death, a modified version is provided, using the year of the patient's death but the day and month adjusted to first day of the first month, for example 01/01/2020. The CAG accepted this clarification.

2. Please provide justification for why any identifiers would need to be retained if a participant had died, and the final linkage had been performed, within one month from the date of this letter.

A detailed response was provided on 8th March 2021 explaining that it is important to retain identifying information to keep open the possibility of future linkage of the register with other studies. The response provided examples of research studies which had beneficial impacts due to the retention of identifiers, and explained that overwhelmingly, people with ALS and their families rank research as their highest priority. The Sub-Committee accepted this justification.

3. Please clarify if name is required to be retained in the database for linkage purposes, and confirm that NHS Digital have stated that these identifiers for linkage are the minimum required, within one month from the date of this letter.

The applicants have responded on 8th March providing a justification for retaining name, which is to ensure that when data is transferred from each data collection centre and cleaned that the applicants can check for patients who are duplicates, as some patients with MND are seen at different centres across the UK for second opinions. After much discussion and re-reviewing of submitted documents the CAG Sub-Committee members accepted that name could be retained in order to prevent double counting.

However the clarification requested was not to justify the retention of name, but rather to confirm whether or not name was required for linkage purposes with datasets held by NHS Digital. The applicant confirmed in the response to provisional on 8th March that NHS Digital has not specified that these identifiers are required for linkage purposes, however the applicant had not requested this information from NHS Digital. On further clarification, the applicant confirmed by an email sent from NHS Digital on 14th April that name is not required for linkage purposes. Name will however be retained in the MND database indefinitely to prevent double counting.

4. Please confirm if the original consent was face to face only, or if some was undertaken via the post? If the latter is the case, please clarify how care providers will be able to have an up to date record of every patient who 'dissented', within one month from the date of this letter.

The response to provisional clarified that the original consenting method was face-to-face. However, during the COVID-19 pandemic, some care centres did undertake postal consent, with a phone consultation taking place to answer any questions the patient had prior to signing the consent form. Any patients who did not provide consent to the MND Register will be assumed as dissented. The members accepted this response.

5. Please confirm if the care providers who would be sending retrospective data to KCL can send the retrospective data required, and omit from the list any patients who had previously dissented, instead of the applicant receiving lists of identifiers for those who have previously dissented. Please confirm if this process is possible within one month from the date of this letter.

The applicant confirmed that this would be possible, and they will ask care providers to provide identifiable data for people seen in their clinic before the date of approval only if a consent form had been returned. The CAG Sub-Committee were content with this response.

6. As the national data opt out is respected, a statement to this effect should be added to the privacy notice, and an updated version provided to the CAG within one month from the date of this letter.

The applicants provided an updated Patient Privacy notice (v3 23 February 2021) which refers to the National Data Opt-out. The Members accepted this updated privacy notice as a response to provisional outcome, however they provided some further suggestions for the applicant.

The CAG commented that on further reading of the privacy notice, they suggested that it would be good practice to put a reference to opt-out near the beginning of the document rather than at the end. The also suggested a re-wording of the following statement; Please bear in mind if you do opt out that any data we have already collected and included in an existing dataset cannot be removed or erased. This includes anonymised data provided to researchers. However the comments regarding the privacy notice do not require a response and are not conditions of support, they are provided as suggestions only.

7. Please confirm if a privacy impact assessment will be undertaken for any individual patient level data released to researchers to ensure privacy is maintained, within one month from the date of this letter.

The applicant responded to confirm that an overall data impact assessment (DPIA) was undertaken as part of this application and reviewed by KCL Information Compliance. Applicants will not be completing a privacy impact assessment for each individual patient level data released to researchers, however the data released to researchers will remain de-identified data, with the removal of data that will identify patients on an individual basis. The Sub-Committee accepted the explanation provided.

Confidentiality Advisory Group advice conclusion

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

Specific conditions of support

The following sets out the specific conditions of support.

1. As applicants are planning to consult with patients on an ongoing basis, any feedback regarding these ongoing conversations with patients should be provided to the CAG at the time of the first annual review.

2. Support is in place for five years from the date of this letter. Further support is to be sought after this time.

3. Support is not in place for those people who previously dissented to be part of the MND register when the consented model was in place.

4. Support is only in place for England and Wales, and does not extend to Northern Ireland.

5. Favourable opinion from a Research Ethics Committee. **Confirmed 25 November 2020**

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

   The NHS Digital 19/20 DSPT review for Kings College London (HQ) EE133874 was confirmed as 'Standards Met' on the NHS Digital DSPT Tracker (checked 08 February 2021).

   The NHS Digital 2019/20 DSPT equivalent was confirmed as 'Standards Met' on the NHS Digital DSPT Tracker (checked 08 February 2021).

   A CPiP has been received for NHS Wales Informatics Service (NWIS).

   As there are additionally 5 or more organisations who will be processing confidential patient information without consent as part of this application, the Confidentiality Advice Team (CAT) team will not check these individually. It is the responsibility of the applicant to ensure these are in place.

e. 21/CAG/0036 - Identification of Specific Low-Uptake Population Segments in Breast Cancer Screening

Name	Capacity
Dr Katie Harron	CAG member
Mr Andrew Melville	CAG member
Ms Clare Sanderson	CAG alternative vice-chair
Ms Caroline Watchurst	HRA Confidentiality Advisor

Context

Purpose of application

This application from Imperial College London set out the purpose of medical research that aims to confirm the extent to which socio-demographic and co-morbidity factors predict breast screening adherence. It also aims to establish whether combinations of these factors are more strongly associated than single demographics. The applicant therefore aims to characterise a non-compliant phenotype, and this will later inform targeted measures to increase breast cancer screening adherence. This is a retrospective analysis of two linked datasets; the NHS Breast Screening Programme (NHSBSP) and Hospital Episode Statistics (HES). Linkage will be performed by NHS Digital as a trusted third party, and applicants will only have access to a dataset which is effectively anonymised.

Breast cancer is the most common cancer amongst women in the UK, and incidence rates are increasing. The NHSBSP was introduced in 1988, and it has been estimated that breast screening saves 1300 lives annually. Despite this, the number of people taking up the invitation to screen is falling, and uptake has dramatically declined over the past 5 years in some regions. Such trends can be a public health concern, and as such significant work has been undertaken to counteract this decline. Demographic and cognitive factors have been associated with poorer uptake of screening, however much of this previous research does not acknowledge geographical variability. Understanding the common and disparate characteristics of the non-compliant populations in differing regions where uptake is poor, would potentially allow for the development of more effective interventions. The applicants aim to more accurately characterise which patients do not undertake screening, and better inform a tailored intervention to increase screening compliance amongst low uptake subgroups.

Public Health England (PHE) will identify, from the NHSBSP database, a dataset containing all people who were invited to attend breast screening in England between 31st March 2012 to 1st April 2020. The dataset will contain NHS number, date of birth, postcode alongside type of invitation and whether or not the person attended. PHE will then securely transfer the dataset to NHS Digital, who will be responsible for linking with socio-demographic and medical information from the Hospital Episode Statistics (HES) database. NHS Digital will modify date of birth to age, modify postcode to LSOA, and then remove NHS number, date of birth and postcode. No other identifiers remain in the dataset. A pseudonym in the form of encrypted HESID is added for transfer to the applicant, however this flow of data can be considered anonymous and does not require support. NHS Digital transfer the data to the applicant at the

Imperial College London Big Data and Analytical Unit (BDAU). NHS Digital will retain the key that links the encrypted HESID to identifiers for 3-6 months after the linkage is performed, and then this will be deleted.

A recommendation for class 1, 2, 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	Females aged between 49y and 8months to 70 years and 11 months who were invited for breast screening in England between 31st March 2012 to 1st April 2020 The cohort includes both people who did not attend and people who did attend, and the applicants estimate this to be approximately 5.6million people.
Data sources	1. PHE; National Breast Screening Programme (NHSBSP) 2. NHS Digital; Hospital Episode Statistics (HES)
Identifiers required for linkage purposes	1. NHS number 2. Date of birth 3. Postcode
Identifiers required for analysis purposes	1. Gender 2. Ethnicity 3. Age 4. LSOA 5. Comorbidities (can be considered anonymous to the researchers)
Additional information	NHS number, date of birth, and postcode are removed by NHS Digital before sending to researchers at Imperial college

	London, and a pseudonym in the form of encrypted HESID is added. The key between the HESID and identifiers are retained by NHS Digital for a short time period and then deleted.

Confidentiality Advisory Group advice

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

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. Please provide favourable opinion from the REC when available, see below as part of the standard conditions of support.

The applicant provided the REC favourable opinion (given on 12th April) to the CAG inbox on 13th April. The Members were content with this response.

2. Please confirm within one month from the date of this letter, that the research study will be mentioned on the IGHI twitter account and consider developing a social media strategy for patient notification for this study.

The applicants have agreed a social media strategy, including twitter posts from the official account of the IGHI and website blog posts. This is detailed in the correspondence provided. The CAG Sub-committee were content with this response.

3. Please develop a study specific opt out, or provide a justification as to why this cannot be developed, within one month from the date of this letter.

The applicant has developed a study specific opt out with NHS Digital, and provided communications to support this. Those who wish to opt-out specifically will be able to highlight this to the research team (who will then pass on this information to PHE) or directly to the PHE screening team. The cohort supplied to NHS Digital will have those individuals removed. Should an individual subsequently wish to have their data not included, NHS Digital have agreed that modified cohorts can be supplied from PHE to NHS Digital, in which individuals who have subsequently opted-out will be highlighted. NHS Digital will then remove those individuals' data from the cohort for processing. Once processing is complete, however, study-specific opt-out as described in the above manner cannot be entertained. This is because as part of the processing activity personal identifiers are being removed so individual records cannot be determined.

The Sub-Committee were content with this development of a study specific opt-out, however they commented that they would like to see the text relating to a study specific opt out, to

make sure the process is realistic and meaningful. The applicant provided further documentation containing the opt out wording – the website text including opt out (shorter notification) and the longer privacy notice/information sheet also with opt out information. The CAG were content with these documents and were now happy to recommend support.

Confidentiality Advisory Group advice conclusion

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

Specific conditions of support

The following sets out the specific conditions of support.

1. Favourable opinion from a Research Ethics Committee. Confirmed 12 April 2021

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

   Confirmed:

   The NHS Digital 2019/20 DSPT review for Public Health England (PHE) and the equivalent for NHS Digital were confirmed as 'Standards Met' on the NHS Digital DSPT Tracker (checked 11 March 2021).

   A DSPT for Imperial College London (Big Data Analytical Unit (BDAU) is not required as no confidential patient information is processed at this organisation for the purposes of this study.

f. 19/CAG/0215 - Fractional Flow Reserve versus Angiographically Guided Management to Optimise Outcomes in Unstable Coronary Syndromes: a developmental clinical study of management guided by coronary angiography combined with fractional flow reserve (FFR) measurement versus management guided by coronary angiography alone(standard care) in patients with non-ST elevation MI.

Name	Capacity

Dr Katie Harron	CAG Member
Professor Jennifer Kurinczuk	CAG Member
Ms Clare Sanderson	CAG Alternative Vice-Chair

Context

Purpose of application

This application from the University of Glasgow set out the purpose of medical research that seeks to obtain information on how coronary fractional flow reserve (FFR) data relate to clinical decisions based on visual assessment of the coronary angiogram in order to guide the design of a future clinical trial of FFR-guided decisions in non-ST elevated myocardial infarction (NSTEMI).

NSTEMI is the commonest type of acute myocardial infarction (MI) / acute coronary syndrome and MI is a leading cause of premature ill health and death in the community. The morbidity and mortality rate in patients with NSTEMI is high and 5-10% of patients had die or experience a recurrent NSTEMI within 12 months of the original NSTEMI. Coronary fractional flow reserve is the pressure drop across a narrowed coronary artery. FFR is measured using a coronary ‘pressure wire’, similar to that used in coronary angiography and angioplasty. The pressure wire is commonly used in angina patients but not in patients who have had a recent heart attack, due to a lack of evidence of its effectiveness in this patient group. The applicants sought to gather information on whether use of the pressure wire in patients who have had a recent heart attack can alter and improve treatment decisions made in the catheter lab

A pilot study ran between October 2011 to May 2014, to collect information about the potential usefulness of the pressure wire and inform whether a larger scale trial was feasible. A two-centre study was run and recruited 350 patients who received coronary angiography and angioplasty following a heart attack. The pressure wire was used in all patients, however the FFR value would be disclosed in half of the patients (FFR group) but not in the 'usual care' group. Doctors in the FFR group were given an FFR result which they may or may not choose to guide decision-making. Clinical decisions were made in the normal way in the 'usual care' patients. Patients were recruited into the pilot study on a consented basis and followed-up for at least 6 months. Enrolment completed in 2013. NHS Digital have reviewed the patient information and consent materials used at the time and determined that it was not explicitly stated that data would be held and analysed at the University of Glasgow. Section 251 support was therefore sought for the continued holding of this data and linkage to HES data held by NHS Digital.

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

Confidential patient information requested

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

Cohort	167 patients aged 18 and over who had experienced a myocardial infarction and were recruited into the pilot study.
Data sources	1. Study data collected for the pilot study and held at the University of Glasgow 2. HES and ONS data held by NHS Digital
Identifiers required for linkage purposes	1. Name 2. NHS number 3. Date of birth 4. Postcode – unit level 5. FAMOUS study I
Identifiers required for analysis purposes	1. Date of birth 2. Date of death 3. Gender 4. FAMOUS study ID

Confidentiality Advisory Group advice

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

1. The text to be used on the study website at the University of Glasgow is to be provided for review. This text needs to include information on how patients can withdraw their consent to the ongoing processing of their data and clarity on what will happen to their data if they do.

The privacy notice was provided for review. The CAG reviewed this information and raised no further queries.

2. Clarify when all confidential patient information collected for the study will be pseudonymised.
The applicants confirmed that the clinical trial data are stored in a pseudonymised form. The identifiable information is only used for linkage purposes. This has been the case throughout the trial. The CAG reviewed this information and raised no further queries.

3. Confirm when the 20-year period of data retention period is counted from and when the study data will be destroyed.
The applicants advised that the clinical trial data would be stored for 20 years from the end of the trial date. The CAG reviewed this information and raised no further queries.

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

Specific conditions of support
The following sets out the specific conditions of support.

1. Favourable opinion from a Research Ethics Committee. **10 August 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. Pending for University of Glasgow.

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

   Confirmed – NHS Digital confirmed that ISO 27001 is acceptable security assurance for the Robertson Centre for Biostatistics at the University of Glasgow.

g. 20/CAG/0130 - Yorkshire and Humber Care Record (YHCR) Population Health Management (PHM) for non-research purposes.

Name	Capacity
Dr Patrick Coyle	CAG Vice-Chair

Dr Lorna Fraser	CAG Member
Dr Rachel Knowles	CAG Member
Professor Jennifer Kurinczuk	CAG Member
Dr Harvey Marcovitch	CAG Member
Mr Andrew Melville	CAG Member
Dr Murat Soncul	CAG Alternative Vice-Chair
Mr Marc Taylor	CAG Member

Context

Purpose of application

This application from Humber Teaching NHS Foundation Trust set out the purpose of creating a Population Health Management Solution, which will allow organisations in the Yorkshire and Humber Region to request and receive data for non-research purposes, as part of the Local Health and Care Record Exemplar (LHCRE) Programme.

Population Health Management is a technique for local health and care partnerships to use data to design new models of proactive care and deliver improvements in direct care resulting in a positive impact upon health and wellbeing of patients. This will take advantage of digital technologies and data analytics that can be used to prevent avoidable delays in diagnosis, unnecessary repeat tests and reduce clinical uncertainty that can slow down the speed at which people are able to begin to receive the treatment and care they need. The main aims of this work are to

- Improve the physical and mental health outcomes and wellbeing of people, whilst reducing health inequalities within and across the Yorkshire and Humber region.
- Reduce of re-occurrence of ill-health, including addressing wider determinants of health, and requires working with communities and partner agencies.
- Address the wider determinants of health to early intervention, primary, secondary and tertiary disease prevention.

Support is requested for the transfer of confidential patient information from participating organisations in the Yorkshire and Humber region to Humber Teaching Hospitals NHS Foundation Trust. The NHS number of patients will then be collated and sent to the NHS Digital's National De Identify / Re-Identify service, who will return a pseudonym. This will be applied to the data to render it pseudonymous prior to the person requesting access to view the data for analysis on the Humber Teaching Hospitals NHS Foundation Trust system.

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

Confidential patient information requested

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

Cohort	All patients and service users irrespective of age or characteristics from organisations in the Yorkshire and Humber area who have not opted out via the national data opt-out. The applicants anticipate that 5.5 million service users will be included once fully deployed
Data sources	1. Humber Teaching Hospitals NHS Foundation Trust 2. Rotherham, Doncaster and South Humber NHS Foundation Trust 3. Doncaster and Bassetlaw Teaching Hospitals NHS Foundation Trust
Identifiers required for linkage purposes	1. NHS number 2. Postcode
Identifiers required for analysis purposes	1. LSOA or postcode to be able to do geographical analysis and link to deprivation but will not identify individual households.
Additional information	No medical images nor free text information will be included in the clinical data provided.

Confidentiality Advisory Group advice

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

1. Provide absolute clarity on the identifiable data flows within this application, and between which legal entities these flows will be.

The applicant provided a revised data flow diagram. The CAG reviewed this document and raised no further queries.

2. Confirm that participating organisations are not transferring all data within their systems at once, only data required for each specific project will be transferred.

The applicants confirmed that only data required for each specific project will be transferred and that under no circumstances will participating organisations transfer all data within their systems. The CAG considered this information and raised no further queries.

3. Confirm that there is no exit strategy for the project as a whole (support will be ongoing) but that there is a clear exit strategy for each project as data will be deleted once the project has finished (or after 12 months of inactivity).

The applicants confirmed that there is no exit strategy for the project as a whole and that support would be ongoing, however there is a clear exit strategy for each project as data will be deleted once the project has finished or after 12 months of inactivity. The CAG considered this information and raised no further queries.

4. Confirm whether the patient and public involvement events discussed the flow of confidential patient information (i.e. clinical data identified by NHS number) without consent. If this was not discussed further patient and public involvement will be required to ensure discussion about this central specific issue, before support can be given.

The applicants confirmed that patient and members of the public have discussed the flow of confidential patient information without consent. The Yorkshire and Humber Care Record has produced a report that demonstrates engagement with members of public to explore the acceptability and to co-design explanations of how data flows in the Yorkshire and Humber Care Record (YHCR) and Population Health Management (PHM) platform.

The research took place to ensure that the public accept that their data must flow from NHS and social care systems in order for the PHM platform to operate, and that the public understand at what point their data is de-identified, how they can be re-identified, and how they can opt out.

Key Points from the Explaining Data Flow in the Yorkshire and Humber Care Record Report were provided in the applicants' response. The CAG considered this information and raised no further queries.

5. Provide further information on the plans for ongoing patient and public involvement throughout the lifetime of this project.

The applicant confirmed that regular engagement with patient groups and the public will be ongoing to ensure that their views form part of evolution of the initiative. They had conducted three extensive engagement exercises across the region. The applicants will also run public facing meetings over the coming months to allow individuals to learn more about the initiative and ask questions. The CAG asked that the patient notification materials were reviewed as part of the continuing patient and public involvement and that any changes or updates were reported at annual reviews.

6. Ensure that a project specific opt out is provided as part of this application and describe the mechanism that will be used to achieve this requirement.

The Information Poster, Leaflets and Fair Processing Notices will advise patients that they can opt out of the initiative. Patients can choose to opt out of having their de-identified data available for analysis by making a call the Information Governance Team. Information will also be available online the YHCR website and relevant social media channels. The CAG considered this information and asked that the numbers of patients who opted-out were reported at annual reviews.

7. Update the patient notification materials to make these more understandable for the general public. It is suggested that this is considered by a patient and public involvement group to aid with this. The updated patient notification materials should include information on how to opt out (using both the local and national opt out mechanism).

The applicants confirmed that patient notification materials have been updated to make these more understandable for the general public and that these include information on how to opt out, using both the local and national opt out mechanism. The language was co-produced with the public during the two engagement exercises. The CAG considered this information and accepted the documents provided. The CAG asked that the patient notification materials were reviewed as part of the continuing patient and public involvement and that any changes or updates were reported at annual reviews.

8. If there are any further organisations specific patient notification materials being used, please provide these to the group for consideration.

The applicants advised that they do not believe that any patient notification materials provided by further organisations will be used. The CAG considered 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 Secretary of State for Health and Social Care, subject to compliance with the specific and standard conditions of support as set out below.

Specific conditions of support

The following sets out the specific conditions of support.

1. Support is provided for the medical purpose of the non-research activity of the management of health and social care only and does not extend to medical research.

2. In the annual review submissions:

    - The patient notification materials are to be reviewed as part of the continuing patient and public involvement and any changes or updates are to be reported at annual reviews.

- The numbers of patients who opt-out are to be reported at annual reviews.

3. This support applies only to Humber Teaching Hospitals NHS Foundation Trust, Rotherham, Doncaster and South Humber NHS Foundation Trust and Doncaster and Bassetlaw Teaching Hospitals NHS Foundation Trust in the first instance. Where further organisations are in a position to undertake this work an amendment should be submitted to extend this support to these organisations.

4. Confirmation provided from the IG Delivery Team at NHS Digital to the CAG that the relevant Data Security and Protection Toolkit (DSPT) submission(s) has achieved the 'Standards Met' threshold. See section below titled 'security assurance requirements' for further information. The NHS Digital DSPT submission for Humber Teaching NHS Foundation Trust (18/19), Rotherham, Doncaster and South Humber NHS Foundation Trust (19/20) and Doncaster and Bassetlaw Teaching Hospitals NHS Foundation Trust (18/19) was confirmed as 'Standards Met' by NHS Digital (by check of DSPT tracker on 18 October 2020).

g. 21/CAG/0022 - The use of telephone based digital triage in urgent care provision and the associated patient service use and health outcomes: A routine data analysis study before and during the Covid-19 pandemic

Name	Capacity
Dr Simon Kolstoe	CAG Member
Mr Andrew Melville	CAG Member
Ms Clare Sanderson	CAG Alternative Vice-Chair
Ms Katy Cassidy	HRA Confidentiality Advisor

Context

Purpose of application

This application from the University of Warwick set out the purpose of medical research that seeks to determine how telephone based digital triage in the provision of urgent care affects patient use of care services and health outcomes.

Digital triage offers the potential to improve the consistency of care, patient safety and efficient use of the health system. Whilst telephone based digital triage is widely used in urgent care, evidence of its impact on patient health outcomes and health care service use is very limited and mixed. The main knowledge gaps relate to the accuracy, patient compliance, service use and health outcomes following telephone based digital triage. This project will analyse large

datasets, together with appropriate sample size calculations, to generate new information and knowledge in terms of these outcomes, to address this gap.

The project will use two datasets; triage data, provided by telephone triage services, and patient outcome data, provided by NHS Digital, which will include HES Admitted Patient Care (HES APC) and the Emergency Care Data Set (ECDS). Advanced Health and Care Ltd will provide the Data Access Request Service (DARS) at NHS Digital with patients' NHS number and date of birth, as well as the patients' study ID, to facilitate linkage to the HES APC and ECDS datasets. NHS Digital will undertake the linkage and de-identify the data, before sending the dataset to the research team at the University of Warwick for analysis. The data linkage will be undertaken on a one-off basis.

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	100,000 patients who attended A&E following telephone triage between 01 April 2019 and 30 September 2020.
Data sources	1. HES Admitted Patient Care (HES APC) and the Emergency Care Data Set (ECDS), provided by NHS Digital 2. Triage data provided by Advanced Health and Care Ltd
Identifiers required for linkage purposes	1. NHS Number 2. Date of birth
Identifiers required for analysis purposes	1. Gender 2. Ethnicity

Confidentiality Advisory Group advice

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

1. **A specific opt-out mechanism needs to be created and details on how patients can opt-out included on the information sheets, website information and on social media. The revised patient notification need to be provided to the CAG for review.**

The applicant provided a summary of the opt out mechanism. Updated information for the University of Warwick website and the triage service providers was also given. This included details on how patients can opt-out. The applicant highlighted that the postal address had been removed from this information, due to the current home working situation and limited access to the University of Warwick office. An email address and telephone number was provided for patients to register dissent. The CAG reviewed this information and raised no further queries.

Confidentiality Advisory Group advice conclusion

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

Specific conditions of support

The following sets out the specific conditions of support.

1. Favourable opinion from a Research Ethics Committee. Confirmed 01 March 2021.

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

   The NHS Digital 2019/20 DSPT review for NHS Digital was confirmed as 'Standards Met' on the NHS Digital DSPT Tracker 09 February 2021.

   The NHS Digital 2019/20 DSPT review for Advanced Computer Software Group Ltd was confirmed as 'Standards Met' on the NHS Digital DSPT Tracker 09 April 2021.

h. 21/CAG/0026 - High intensity treatment at the end of life in children with cancer: retrospective, national, data linkage study

Name	Capacity
Professor Jennifer Kurinczuk	CAG member
Dr Murat Soncul	CAG alternative vice-chair
Mr Marc Taylor	CAG member
Ms Katy Cassidy	HRA Confidentiality Advisor

Context

Purpose of application

This application from the University of York set out the purpose of medical research that seeks to determine whether the use of high intensity treatment at the end of life for children, teenagers and young adults with cancer, varies depending on the model of end of life care available.

Approximately 4,500 babies, children and teenagers in England and Wales require end of life care each year. The provision of this care varies across the country and little is currently known about how this variation impacts on children and their families. This project in comprised of three studies. The first study is a survey, conducted with relevant cancer services and other wards to provide specialist care to children, to identify the different models of providing care to patients aged 0-18 within England and Wales. The second study will involve interviews with bereaved parents about their experience of their child's end of life care. These two studies are outside the scope of support sought.

The third study will investigate the impacts of the different models of end of life care on children and their families. The findings from study 2 will help the applicants to decide which outcomes to measure, but they are likely to include quality of care at the end of life, place of death, whether care is planned and the treatments given at the end of life. Information will be collected from the medical records of approximately 4000 children treated in cancer services. Information from around 800 bereaved parents, whose child received care in neonatal or paediatric units, will also be collected.

The applicants are seeking support for the transfer of confidential patient information from PICANet and ICNARC to Public Health England. Public Health England will link the individual level data with cancer registry, death certificate data, treatment information and hospital episodes data. Public Health England will then transfer a pseudonymised dataset to the research team at the University of York.

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

Confidential patient information requested

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

Cohort	Any child, teenager of young adult (0-24 years) with a diagnoses of cancer who died between 01/01/2012 and 31/12/2020 in England and Wales.

	4000 patients will be included.
Data sources	1. PICANet (held by the University of Leeds) 2. ICNARC 3. National Cancer and Registration System (NCRAS), ONS death certificate data, treatment information and hospital episodes datasets held by Public Health England
Identifiers required for linkage purposes	1. Name 2. NHS number 3. Date of birth 4. Date of death 5. Postcode – unit level
Identifiers required for analysis purposes	1. Lower super output area 2. Gender 3. Ethnicity

Confidentiality Advisory Group advice

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

1. **The patient notification materials need to be revised as follows:**
    a. **The language in the Lay Summary needs to be simpler and more direct.**
    b. **The notification webpage needs to direct patients to information on how to dissent.**
    c. **A description of Public Health England, including a link to their website, needs to be included in the Lay Summary.**
    d. **The applicants are to consider including links to the ICNARC and PICANet websites in the Lay Summary.**

A revised Lay Summary and website notification were provided. These were reviewed and approved by the CAG.

2. **Further details need to be provided on how patients can navigate to the right section of the CCLG pages on the University of York website to access the information on how to opt-out.**

The applicant advised that instructions on how to navigate to the correct section had been added to the text of the lay summary on the MHRC website. The applicants would also link to the CCLG website from the MHRC website. The CAG noted this information and raised no further queries.

3. **The applicant raised a further query in their response. When completing the data application forms for PHE it has become apparent that in order to accurately identify treatments received in the final 14 or 28 days before death we will need to retain FULL day/month/year of date of death for analyses. The protocol reviewed by CAG stated that only month and year of death would be retained.**

The CAG noted and accepted this change.

Confidentiality Advisory Group advice conclusion

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

Specific conditions of support

The following sets out the specific conditions of support.

1. Favourable opinion from a Research Ethics Committee. Confirmed 18 January 2021

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

Confirmed: The NHS Digital 2019/20 DSPT reviews for ICNARC (by check of the NHS Digital DSPT Tracker on 23 February 2021), Public Health England (by check of the NHS Digital DSPT Tracker on 23 February 2021), University of Leeds – SEED (by check of the NHS Digital DSPT Tracker on 14 April 2021) and the University of York (Department of Health Sciences) (by check of the NHS Digital DSPT Tracker on 14 April 2021) were confirmed as 'Standards Met'.

2. New Amendments

a. 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
Dr Tony Calland MBE	CAG Chair
Dr Patrick Coyle	CAG vice-chair

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, ONS mortality data, Cancer registration data and demographics data in relation to PD MED clinical trial participants. Identifiable data is submitted to NHS Digital in order to link data to trial participants. It was understood that data was pseudonymised before being disclosed back to the applicant.

This amendment is to seek support for the PD Med team at University of Birmingham to receive confidential patient information from NHS Digital within the dataset. The application was presented to IGARD on 21 January 2021, where it was concluded that the Cancer Registration and Civil Registration (Deaths) data that NHS Digital will be providing could be considered identifiable, and requires CAG support. The applicant will be receiving Cancer Registry Data, date of birth, and date, place and cause of death, and 'establishment type where death occurred' among other data items.

Confidentiality Advisory Group advice

The amendment requested was considered by Chair and Vice-Chair's Action. The Chairs considered that as the applicant holds identifiable information in their current dataset, the flow returning from NHS Digital that includes Cancer Registration and Civil Registration (Deaths) data, and also includes the date of birth, the applicant should be provided with Regulation 5 support for this disclosure, as the data items contained in the dataset are

potentially identifiable when combined with information already held by the applicant, and in addition date of birth is also requested which is a direct identifier. This is in line with IGARD discussions, as evidenced by the minutes provided.

The Chairs would like to make it clear that the Cancer Registry data routinely received in some circumstances can include place and cause of death, and other specified data items which CAG would not consider to be identifiable. However in this application support is provided for the flow of data (rather than specific data items) due to date of birth being part of the data requested, and also due to the fact that the applicants do already hold other identifiable information, which in turn means the data provided from NHS Digital can be linked to this and re-identified, and therefore requires support in this case.

Confidentiality Advisory Group advice conclusion

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

Specific conditions of support

The following sets out the specific conditions of support.

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

The NHS Digital **2019/20** DSPT review for **NHS Digital and University of Birmingham** were confirmed as 'Standards Met' on the NHS DSPT Tracker (checked 17 March 2021).

2. Confirmation of a favourable opinion from a Research Ethics Committee. Confirmed 6 April 2021

b. 16/CAG/0118 – A Study of the Natural History of Renal Disease in TSC2/PKD1 Contiguous Gene Deletion Syndrome.

Name	Capacity
Ms Caroline Watchurst	HRA Confidentiality Advisor

Context

Amendment request

The applicant aims to determine the natural history of renal disease by a follow up study of patients with TSC2/PKD1 contiguous gene deletion syndrome. Support is currently in place in relation to deceased persons only, and allows processing of name, date of birth, date of death and NHS number, in order to identify and access medical notes at the respective health boards where the patient was registered.

The applicant is seeking support in this amendment to extend the duration of CAG support until 31 August 2021. This is due to delays caused by Covid-19 pandemic. The total recruitment target has also been increased from 255 to 300 patients. This is due to some patients recruited so far not having a complete data set as part of routine care. The amendment is therefore required to allow the collection of sufficient data for the planned statistical analysis, allowing for the incomplete investigation of some patients in the routine clinical setting. The applicant has confirmed that it is expected the majority of participants will be consented living participants, and therefore not fall under CAG remit, but it is possible that a very small proportion of the additional participants may be deceased. Applicants will avoid recruiting deceased people into the study where at all possible. Support is therefore required for the potential recruitment of further deceased patients to make up a total recruitment number of 300 patients.

Confidentiality Advisory Group advice

The amendment requested was considered by the Confidentiality Advice Team, who understood the justifications for this amendment and raised no queries.

Confidentiality Advisory Group advice conclusion

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

Specific conditions of support

The following sets out the specific conditions of support.

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

Confirmed: The NHS Digital 19/20 DSPT review for **the University of Cardiff** was confirmed as 'Standards Met' by email to the CAG inbox on 13 April 2021

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

Confirmed 30 July 2019 (cohort increase); **Confirmed non substantial 28 August 2020 (duration)**

c. 19/CAG/0173 – Critical illness related cardiac arrest (CIRCA): an investigation of the incidence and outcome of cardiac arrest within Intensive Care Units in the United Kingdom.

Name	Capacity
Ms Caroline Watchurst	HRA Confidentiality Advisor

Context

Amendment request

Support is currently in place to allow disclosure of confidential patient information from participating intensive care units to Intensive Care National Audit and Research Centre (ICNARC) to facilitate linkage with the National Cardiac Arrest Audit and onward disclosure to NHS Digital to facilitate linkage with HES and ONS datasets, for the research purpose of gaining a wider understanding on prevalence and outcomes of patients who experience cardiac arrest whilst in an intensive care unit.

This amendment is to extend the duration of support required until 4 October 2022. The study has been delayed by the Covid-19 pandemic.

The website will be updated with new study timelines.

Confidentiality Advisory Group advice

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

Confidentiality Advisory Group advice conclusion

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

Specific conditions of support

The following sets out the specific conditions of support.

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

- **Intensive Care National Audit and Research Centre (ICNARC) has a confirmed 'Standards Met' grade on DSPT 2019/20 – (**Confirmed by check of DSPT tracker 22 January 2021).
- **NHS Digital has a confirmed 'Standards Met' on the DSPT equivalent for 2019/20 – (**Confirmed by check of DSPT tracker 22 January 2021).
- **Due to the number of participating sites where confidential patient information will be accessed, individual DSPT submissions are not required for the purpose of the application. Support is recommended on the basis that the applicant ensures the required security standards are in place at each site prior to any processing of confidential patient information with support under the Regulations.**

2. Confirmation of a favourable opinion from a Research Ethics Committee. Confirmed 15 March 2021 (Applicant provided to CAG inbox 13 April 2021)

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

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

Context

Amendment request

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

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

In the original application, following the successful linkage of the various data sources included in the study, all items of confidential patient information would be destroyed to enable an exit from the requirement for support under the Regulations.

This amendment sought support to retain the identifiable dataset indefinitely, in order to enable further linkages in the future. The applicant has confirmed that a further amendment would be submitted, once the long term outcome analyses have been defined, to obtain support for linkages to the required data sources. The applicant has received 37 responses from patients and the public and 100% of the parents who responded confirmed this would be acceptable to them.

The applicant has also provided within this amendment submission an updated protocol and other supporting documentation including patient facing documentation which does not constitute a change in support. These are accepted as notification only, including protocol clarifications concerning data items, as these are not identifiable.

Confidentiality Advisory Group advice

The amendment requested was considered by the Chair's Action. The Chair considered the amendment request to retain the identifiers indefinitely to enable future linkages, however, the Chair recommended that support was provided for five years only, after which time the applicant should submit a new amendment to extend the support. This is because data governance is changing fast, and there may be very different regulations in place in five years. Despite the support being time limited, it was the Chair's view that there should not be any difficulty in extending the retention time further in 2026 in principle, however, this would be in light of any changes to the regulations in the interim.

Confidentiality Advisory Group advice conclusion

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

Specific conditions of support

The following sets out the specific conditions of support.

1. Support for the retention of confidential patient information in order to undertake future linkages, is supported for a time limited period of five years from the date of this letter, and an amendment should be submitted at this time to extend the support further.

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 19/20 DSPT review for the University of Nottingham and the DSPT equivalent for NHS Digital were confirmed as 'Standards Met' on the NHS Digital DSPT Tracker (checked 17 March 2021)

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

Confirmed Favourable opinion 1 April 2021

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

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

Context

Amendment request

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

This amendment request is to ensure the applicant is able to maintain an up to date Connected Bradford Linked Health and Education Research Database (HERD Database). The amendment sought support to add new school entrants from the age of four years old to the HERD database that are identified from routinely recorded information in their primary care records. This cohort currently include all individuals within the Bradford and Airedale locality who were born between 01 January 1988 and 01 September 2016, and the amendment requests to continually update the database with a new cohort of children each year, for 10 years.

The amendment also seeks support to update the healthcare and education records for the existing cohort in the HERD database. This would involve yearly updates from DfE regarding the existing dataset, and data linkage updates to the existing dataset from the other data providing organisations including Bradford District Care Trusts for both the existing cohort and new school entrants. The applicants also seek to update the primary care data for the existing cohort and all new school entrants using the existing process via Apollo, on a monthly basis, for 10 years.

This amendment seeks support for geospatial data linkage, however this has been previously covered in an amendment letter date 16 December 2019.

This amendment also seeks support to include Humber Teaching NHS Foundation Trust as an additional data processor, as Bradford Teaching Hospitals NHS Foundation Trust has entered into a Data Processing Agreement with Humber Teaching NHS Foundation Trust to

host the Connected Bradford database. Bradford Teaching Hospitals NHS Foundation Trust will continue to act as controller of the data, which will now be held in a secure environment at Humber Teaching NHS Foundation Trust. The applicant is reminded to ensure the 19/20 DSPT for Humber Teaching NHS Foundation Trust has been reviewed as 'standards met' by NHS Digital.

The protocols and leaflets have been updated to reflect the proposed changes, and these have been provided to CAG for review.

Applicants have requested this amendment as they are aware that a design involving the one off linkages already performed means that the data is not current and up to date in order to continue to identify vulnerable children, individuals and families. They seek to update the database to support their community, district, local authority and CCG to derive valuable intelligence on the healthcare needs and education needs of the local population to support them in the current pandemic and beyond.

In the longer term, applicants plan to use the HERD Database to inform the Department for Education, Bradford District Care Trust (BDCT), the Local Authority, Trusts and the CCG about the optimal way of rebuilding the District. The linked dataset will allow applicants to create high quality models that will allow the BDCT, the Local Authority, Trusts and the CCG to target its services effectively.

Confidentiality Advisory Group advice

The amendment requested was considered by Chair's Action. The Chair was content to support the amendment, but was not content with a period of ten years. He clarified the reasons for this were due to the very rapidly changing information governance environment; processes and mechanisms may well have changed in a ten year period which would render the current protocol old fashioned and out of date. Therefore the Chair was content to recommend support for a five year period, after which time the applicant should either submit a further amendment to extend the time of support requested, or a resubmission if the protocol has changed significantly.

Confidentiality Advisory Group advice conclusion

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

Specific conditions of support

The following sets out the specific conditions of support.

1. Support is extended for a period of five years only rather than the requested ten year period. An extension to the amendment or a re-submission of the application will be required at that time.

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 19/20 DSPT review for **Bradford Teaching Hospitals NHS Foundation Trust (Org Code: RAE)** was confirmed as 'Standards Met' (by email to the CAG inbox on 16 April 2021).

As there are 5 or more organisations, security assurance has not be checked by the Confidentiality Advice Team (CAT) for all data processors. Support is recommended on the basis that the applicant is responsible for seeking assurance that the appropriate security arrangements are in place. The applicant should ensure that 19/20 DSPTs for the following organisations have been reviewed as 'standards met' by NHS Digital;

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

3. Confirmation of a favourable opinion from a Research Ethics Committee.
   Confirmed 04 March 2021

f. 20/CAG/0020 – Healthcare Usage of Bariatric/Metabolic Surgery

Name	Capacity
Ms Caroline Watchurst	HRA Confidentiality Advisor

Context

Amendment request

This research from King's College London seeks to assess the overall long-term healthcare usage of bariatric and metabolic surgery. Support is currently in place to allow members of the research team, who are not members of the direct care team, to process confidential patient information held in patient records at King's College Hospital NHS Foundation Trust, and for the disclosure of confidential patient information from King's College Hospital NHS Foundation Trust to NHS Digital for data linkage to HES data.

The support letter states that the cohort is 800 patients who underwent surgery at King's College Hospital NHS Foundation Trust. This number is comprised of:

- 100 consecutive patients who underwent bariatric surgery and other types of elective surgical interventions for benign diseases at King's College Hospital NHS Foundation Trust between February 2014 and March 2015.

- 700 consecutive patients who underwent other types of elective surgeries for benign diseases at the same Hospital

This amendment is to seek support to amend the dates during which the operations took place for benign diseases to between January 2006 and December 2015, as there was an error in the original application, and the team require to go back to 2006 in some specialties to identify operations that fit the inclusion criteria. The cohort is still 800 patients who underwent surgery at King's College Hospital NHS Foundation Trust. However this number is actually comprised of:

- 100 consecutive patients who underwent bariatric surgery at King's College Hospital NHS Foundation Trust between February 2014 and March 2015.

- 700 consecutive patients who underwent other types of elective surgeries for benign diseases at the same Hospital, between January 2006 and December 2015.

This amendment also seeks support to extend the duration of support until December 2021.

Confidentiality Advisory Group advice

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

Confidentiality Advisory Group advice conclusion

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

Specific conditions of support

The following sets out the specific conditions of support.

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

   Confirmed The NHS Digital 19/20 DSPT review for King's College Hospital NHS Foundation Trust was confirmed as 'Standards Met' by email to the CAG inbox on 17 March 2021 and NHS Digital 2019/20 DSPT equivalent has achieved 'standards met'.

2. Confirmation of a favourable opinion from a Research Ethics Committee. Confirmed non substantial by email 20 April 2021

g. 20/CAG/0136 – A randomised controlled trial assessing the effectiveness and cost effectiveness of thrice weekly, extended, in-centre nocturnal haemodialysis versus standard care using a mixed methods approach: NightLife

Name	Capacity
Ms Caroline Watchurst	HRA Confidentiality Advisor

Context

Amendment request

This study from University of Leicester aims to test the clinical and cost effectiveness of thrice weekly, extended hours nocturnal dialysis compared to standard dialysis care thrice weekly during the day. Support is currently in place to allow potential incidental disclosure of confidential patient information when researchers from the University of Leicester, who are not members of the direct care team, carry out consented interviews with haemodialysis unit staff, consented interviews with patients, and observations on haemodialysis units at nine named NHS Trusts

This amendment sought support to include an additional virtual, two-step, qualitative, exploration of usual care, consisting of virtual semi-structured interviews with staff and virtual photovoice with patients. This will assist the researcher to gain an understanding of usual haemodialysis practice and the patient experience of this where observational research cannot take place due to COVID-19 restrictions, but will also continue to be a flexible option for staff members and patients going forward. As current restrictions do not allow observations or face-to-face interviews on dialysis units, the applicants have explored ways of working with staff and patients, such as using digital platforms and more flexible participatory approaches such as photovoice. The virtual interviews will largely follow the same strategy as face-to-face interviews. The applicants have provided the updated notification documents and protocol describing this change.

Confidentiality Advisory Group advice

The amendment requested was considered by the Confidentiality Advice Team. The CAT considered that the justification for undertaking this amendment was due to Covid-19 restrictions, which seems reasonable. The patients and staff members remain consented, and the alternative observation methods are also likely to be less disclosive regarding incidental disclosures, as the researchers will not be physically undertaking observations at individual Trusts.

Confidentiality Advisory Group advice conclusion

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

Specific conditions of support

The following sets out the specific conditions of support.

1. Confirmation provided from the IG Delivery Team at NHS Digital to the CAG that the relevant Data Security and Protection Toolkit (DSPT) submission(s) has achieved the 'Standards Met' threshold. See section below titled 'security assurance requirements' for further information: Security assurances are required for the 9 sites where the observations take place. Support will be based on confirmation that the DSPT at the site will be complied with and that no identifiable information will be kept onsite or removed from the site. However, as this is more than 5 organisations, these will not be individually checked by the Confidentiality Advice Team, and it is the responsibility of the applicant to ensure that appropriate security assurances are in place.

2. Confirmation of a favourable opinion from a Research Ethics Committee. Confirmed 26 April 2021

h. 19/CAG/0001 – National Asthma and COPD Audit Programme (NACAP): Paediatric Asthma Clinical Audit

Name	Capacity
Ms Caroline Watchurst	HRA Confidentiality Advisor

Context

Amendment request

This application from the Royal College of Physicians on behalf of the Healthcare Quality Improvement Partnership (HQIP), is regarding the Paediatric Asthma Clinical Audit. The audit is commissioned as part of the National Asthma and COPD Audit Programme (NACAP).

Support is currently in place to cover the collection of audit data for all admissions of children and young people to hospital with asthma attacks (ages 1-18) in England and Wales, on a continuous basis.

The applicants sought support in this amendment to remove an exclusion criteria regarding wheeze, and to amend the inclusion criteria, including ensuring certain secondary position ICD-10 codes are captured in the inclusion criteria for the Paediatric Asthma Clinical Audit in order to ensure the accurate capture of all eligible patients for the Paediatric Asthma Clinical Audit.

This amendment does not seek to change the data flows or confidential patient information collected. However, the data flow diagrams have been provided for ease of review. No additional patient identifiers beyond what has already been agreed will be collected for the Paediatric Asthma Clinical Audit.

The amendment also seeks to notify the CAG about making automated real-time reports publicly available. Currently, automated reports are available via the NACAP web tool (www.nacap.org.uk, provided by Crown Informatics Limited) which are updated every 15 minutes using the data entered by hospitals, with no input from the audit team required to generate these. Over the next two years NACAP will be working to develop this automated real time reporting capability to produce additional automated reports, and making them publicly available so that all necessary stakeholders, including patients and carers, have access to them and can work with hospitals to drive improvement and change. This element does not require additional CAG support as this is in line with the original purposes of the application, and therefore is already within the scope of the current approval. The real time reports will not contain any identifiable data.

Confidentiality Advisory Group advice

The amendment requested was considered by the Confidentiality Advice Team.

Confidentiality Advisory Group advice conclusion

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

Specific conditions of support

The following sets out the specific conditions of support.

1. Support under this application extends to the non-research audit purposes only. There is no support in place for the processing of information collected within the audit for research purposes.

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 19/20 DSPT review for Crown Informatics, NHS Digital, and Aimes Management Services were confirmed as ‘Standards Met’ on the NHS Digital DSPT Tracker (checked 22 April 2021)
   NHS Wales Informatics Service, confirmed CPIP Assurance in place

i. PIAG 4-08(b)/2003 – National Confidentiality Enquiry into Patient Outcome and Death

Name	Capacity
Dr Tony Calland	CAG Chair
Kathleen Cassidy	Confidentiality Advisor

Context

Amendment request

In line with the original application, the applicant had been commissioned by HQIP to undertake two confidential reviews of case notes every year. This amendment covered the second of the reviews due to take place in 2020, which will investigate Epilepsy.

The review has been commissioned as there is believed to be room for improvement in the quality of acute and long-term care provided to patients who have an epileptic seizure.

The applicants aim to publish the results of the review in Summer 2022.

Confidentiality Advisory Group advice

The amendment requested was considered by the Chair's Action. The Chair agreed that the amendment request was in the public interest and in line with the support in place for NCEPOD.

Confidentiality Advisory Group advice conclusion

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

Specific conditions of support

The following sets out the specific conditions of support.

1. Confirmation provided from the IG Delivery Team at NHS Digital to the CAG that the relevant Data Security and Protection Toolkit (DSPT) submission(s) has achieved the 'Standards Met' threshold (Confirmed – The NHS Digital 2019/20 DSPT review for National Confidential Enquiry into Patient Outcome and Death (NCEPOD) was confirmed as 'Standards Met' on the NHS Digital DSPT Tracker (by check of the NHS Digital DSPT Tracker on 06 April 2021).

j. 18/CAG/0002 – Trajectories of diabetes related health measures (from linked lab data) and subsequent health and educational outcomes

Name	Capacity
Dr Tony Calland	CAG Chair
Kathleen Cassidy	Confidentiality Advisor

Context

Amendment request

The applicants have existing support for the disclosure of confidential patient information from both the National Diabetes Audit (Adults – England) and National Diabetes Audit (Adults – Wales) (held by NHS Digital) and the National Paediatrics Diabetes Audit (held by the Royal College of Paediatrics and Child Health) to NHS Wales Informatics Services (NWIS). Data is also released from the Higher Education Statistics Agency (HESA) dataset to NWIS; however, this is out of the CAG's remit as it is not confidential patient information.

The current approval uses SAIL as the data linkage repository. SAIL use NWIS as the data processor to create the 'linkage ID' from the confidential patient information. The applicant confirmed that the new repository is for the linkage of English data and that SAIL was used for the linkage of Welsh data in the original application to CAG.

The applicants are now seeking to include ONS Secure Research Service (SRS) as a second linkage repository for the English data. ONS-SRS will use DfE as the data processor to create the 'linkage ID' from the confidential patient information. De-identified data only will be processed by ONS-SRS, therefore support is not required for this. Support is needed for the disclosure of confidential patient information from NHS Digital to DfE.

The applicants also seek support to allow NHS Digital to disclose confidential patient information for the National Paediatric Diabetes Audit (NPDA), as well as for the National Diabetes Audit in England, to NWIS. NHS Digital would undertake this disclosure instead of the Royal College of Paediatrics and Child Health (RCPCH). However the applicants seek to retain support for the disclosure of confidential patient information from the NPDA via the RCPCH, in case of any problems with the transfer from NHS Digital.

On review by the CAG Chair, further details were requested around the retention of identifiers from the RCPCH. The Chair understood that this may be to ensure against data loss from NHS Digital, but either a time limit needed to be given or an explanation as to why the data needs to be retained for a longer period. The applicant advised that they would wish to continue to use data directly from RCPCH, as explained in their original application to the CAG. However, the proposed change in the amendment is to use an existing flow for the transitions audit under the legal arrangements for transitions audit. The data is retained by the audit for its own audit purposes and is not controlled in any way by the applicants for this study.

Confidentiality Advisory Group advice

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

Confidentiality Advisory Group advice conclusion

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

Specific conditions of support

The following sets out the specific conditions of support.

1. Confirmation provided from the IG Delivery Team at NHS Digital to the CAG that the relevant Data Security and Protection Toolkit (DSPT) submission(s) has achieved the 'Standards Met' threshold:
   Confirmed: The NHS Digital 2019/20 DSPT reviews for NHS Digital, the Royal College of Paediatrics and Child Health and the SAIL Databank and SeRP UK were confirmed as 'Standards Met' on the NHS Digital DSPT Tracker (checked 22 February 2021).
   Confirmed: the Caldicott: Principles Into Practice (CPIP) for NWIS was confirmed on 15 June 2020.

2. Confirmation of a favourable opinion from a Research Ethics Committee. The REC confirmed that an amendment was not required on 16 December 2020.

k. 20/CAG/0106 – The SUFFICE CoV-Study

Name	Capacity
Dr Tony Calland	CAG Chair
Kathleen Cassidy	Confidentiality Advisor

Context

Amendment request

The applicants have existing support to allow the applicant to access confidential patient information held in patient records at Oxford University Hospital NHS Foundation Trust in order to extract an anonymised dataset and for disclosures of confidential patient information that may be made during observations.

The applicants are now seeking to add Royal Berkshire Hospital (RNH) NHS Trust as a secondary research site. This was planned as part of the original methodology and what was outlined in the funding application to the National Institute for Health Research. The two NHS sites will generate comparative data from differing sites, adding to the value of the research.

The applicants also seek support to review the care records of patients who are scoring an Early Warning Score (EWS) of 3 or above based on their abnormal vital signs. The

applicants have completed some preliminary exploratory work based on this sampling criteria and determined that the EWS threshold needs to be lowered to ensure rescue events are adequately captured and represented within the data. The applicants therefore will change the sampling criteria to those patients who have an EWS threshold to 3 or above and will manually screen for patient rescue events to ensure the data is usable and answer the original research question. This does not change the overall methodology of the study nor does this affect patients directly. The applicants explained that the amendment would significantly increase the population which they were able to sample and review medical records. However, the overall number of patients whose medical records would be reviewed would not change, as their target was 400 records at each of the research sites.

The applicants also noted that the number of quotes relating to the number of avoidable patient deaths in the NHS each year will be revised. This will change from 40,000 deaths to 11,000 deaths in England NHS trusts each year. This will be changed on all patient information sheet, protocol and webpage wording.

Confidentiality Advisory Group advice

The amendment requested was considered by the Confidentiality Advisory Group. The CAG was satisfied that the amendment was in the public interest.

Confidentiality Advisory Group advice conclusion

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

Specific conditions of support

The following sets out the specific conditions of support.

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

   Confirmed – Oxford University Hospital NHS Foundation Trust has a confirmed ‘Standards Met’ grade on DSPT submission 2018/19 (by NHS Digital email dated 17 December 2020).
   Confirmed - Royal Berkshire NHS Foundation Trust has a confirmed ‘Standards Met’ grade on DSPT submission 2018/19 (by NHS Digital email dated 05 March 2021).

2. Confirmation of a favourable opinion from a Research Ethics Committee. REC confirmed that review is not required on 09 February 2021.

I. 19/CAG/0223 – TwinsUK: Phenotypic enrichment of the TwinsUK cohort through linkage to electronic health records and other databases.

Name	Capacity
Kathleen Cassidy	Confidentiality Advisor

Context

Amendment request

The applicants have existing support to allow the disclosure of confidential patient information from King's College London to NHS Digital, NHS Wales Informatics Service, GP Practice software providers and the Department for Education to facilitate linkage with primary and secondary care records, cancer registration, mortality data and information on educational attainment.

The applicants planned to send direct communications via post to all participants in the TwinsUK study to inform them of the proposed data linkage activities and to provide a means of dissent. The applicants explained that they were now moving to an online methodology as, due to the COVID-19 pandemic, participants have become more comfortable with completing the forms and questionnaires online. Also, at a recent meeting of the TwinsUK Volunteer Advisory Panel, members present had expressed that they would prefer to receive the fair processing materials online rather than by post.

The applicants therefore seek to revise the fair processing campaign, so that twins with email addresses who have been active with TwinsUK in the last 5 years will receive the fair processing materials by email. They will also complete the opt-out forms online, if needed. Participants will also receive a hard copy of the data linkage information leaflet when in person clinic visits resume. Twins for whom the applicants do not hold an email address or who have not actively participated in the study for 5 years will be sent the fair processing materials in the post, as described in the original application.

Participants in the TwinsUK Biobank studies will also be asked to complete a TwinsUK Biobank consent form, in which they can actively opt into the health, education and environmental records linkage (or not). The updated consent forms, and other revised patient notification materials, were submitted as a separate amendment in April 2021.

Confidentiality Advisory Group advice

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

Confidentiality Advisory Group advice conclusion

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

Specific conditions of support

The following sets out the specific conditions of support.

1. Favourable opinion from REC Confirmed on 10 March 2021.

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

3. Annual Review Approvals

19/CAG/0162	Accuracy, impact and cost-effectiveness of prehospital clinical early warning scores for adults with suspected sepsis
18/CAG/0003	FAST - Febuxostat versus Allopurinol Streamlined Trial A prospective, randomised, open-label, blinded endpoint (PROBE) clinical trial evaluating long term cardiovascular safety of febuxostat in comparison with allopurinol in patients with chronic symptomatic hyperuricaemia
ECC 1-04(b)/2010	Evaluating the age extension of the NHS Breast Screening Programme (AgeX Trial)
18/CAG/0044	Long Term follow up of the ASCO Trial into Electronic Records (LATER)
18/CAG/0182	UK Prospective Diabetes Study (UKPDS) Legacy Study: long term follow-up of participants into electronic health records
20/CAG/0028	Small Area Health Statistics Unit Research Database
PIAG 1-07(e)/2004	British Women's Heart and Health Study
ECC 2-02(a)/2011	UK Lung Cancer Screening Trial (UKLS)
19/CAG/0160	Evaluation of the NHS Breast Screening Programme - an individual-based cohort study of mortality
18/CAG/0018	PHEM (Prehospital Emergency Medicine) Feedback
ECC 6-05(e)/2012	An ongoing case-control study to evaluate the NHS Breast Screening Programme
14/CAG/1020	NHS Bowel Cancer Screening Programme
CAG 2-03(PR4)/2014	1970 British Cohort Study

CAG 1-03(PR3)/2014	Next Steps previously known as Longitudinal Study of Young People in England (LSYPE)
CAG 3-02(a)/2014	Long-term follow-up of ARTISTIC cervical screening trial cohort
ECC 5-05(j)/2012	Long term risk of cervical cancer following a HPV infection
16/CAG/0118	A Study of the Natural History of Renal Disease in TSC2/PKD1 Contiguous Gene Deletion Syndrome
17/CAG/0011	Genetic mechanisms in polyposis of the bowel
19/CAG/0079	IBIS - International Breast Cancer Intervention Study (IBIS-I)
16/CAG/0121	Epidemiology of Cancer after solid Organ Transplantation (EpCOT)
18/CAG/0185	At-Risk Registers Integrated into Primary Care to Stop Asthma crises in the UK (ARRISA-UK): A pragmatic cluster randomised trial with nested economic and process evaluations examining the effects of integrating at-risk asthma registers into primary care with internet-based training and support
CAG 7-06(a)/2013	Accuracy of estimates for self harm
ECC 3-04(a)/2012	National Audit of Cardiac Rehabilitation (NACR)
17/CAG/0025	Liver transplantation as treatment for patients with hepatocellular carcinoma; a study using existing electronic data
15/CAG/0120	National investigation into suicide in children and young people
PIAG 1-05(e)/2006	Frequency of follow-up for patients with low-, intermediate- and high-risk colorectal adenomas
18/CAG/0041	Liverpool Lung Project
19/CAG/0059	National Early Inflammatory Arthritis Audit Research Database
CAG 9-08(c)/2014	MesobanK Retrospective Sample Collection

Signed – Chair	**Date**
Agreed via correspondence	22 July 2021
Signed – Confidentiality Advice Team	Date
	22 July 2021