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

November 2020

1. New Applications

a. 18/CAG/0188 - Road Traffic Injury – Analytics for Integrated Data (RTI-AID)

Name	Capacity
Dr Patrick Coyle	CAG Vice-Chair
Professor Lorna Fraser	CAG Member
Mr Tony Kane	CAG Member
Ms Caroline Watchurst	HRA Confidentiality Advisor

Context

Purpose of application

This application from Imperial College London set out the purpose of medical research which aimed to investigate the patterns of physical trauma caused amongst individuals suffering road traffic accidents in order to identify risk factors for injury severity. The project will use Greater London as a representative population of the UK. The project will link datasets from the London police, transport and health systems in order to create a database which follows individuals involved in road traffic accidents from the point of impact to indefinite care in order to facilitate analysis of patterns of risk and injury behaviour.

The study will link information from the following sources:

- STATS19 accident data – police accident reporting form (out of scope for CAG),
- Trauma Audit Research Network (TARN) – which operates with support under the Regulations under reference ECC 7-05(g)/2011,
- London Ambulance Service (LAS) – no confidential patient information (out of scope for CAG)
- Hospital Episode Statistics (HES).

To limit access to confidential patient information, data will be disclosed from TARN direct to NHS Digital, which will act as trusted party for the project, facilitating linkage with the HES dataset, prior to disclosing a pseudonymised dataset to the applicants at Imperial College London to be utilised for analysis. This is with the exception of data items from LAS, who will send to NHS Digital via Imperial College London, as the dataset does not contain any confidential patient information, and STATS19 accident data which will also be sent to NHS Digital via Imperial College London.

The project will also link the data from these established data sources with novel datasets including Transport for London Public API, Waze traffic app, news feeds, Twitter posts. This supplementary information is available within the public domain and is out of scope for CAG consideration.

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

Confidential patient information requested

Cohort

All individuals who were involved in a road traffic collision and road traffic collision in the Greater London area between 2013 and 2017 featured in the datasets prescribed (STATS 19, LAS, HES, TARN). It is estimated that there will be 5,000 patients within the cohort.

The following items of confidential patient information have been requested for the purposes as specified below:

- Name – sample validation and linkage,
- NHS Number – sample validation and linkage,
- Hospital ID No – sample validation and linkage,
- Date of birth – sample validation and linkage,
- Date of death – sample validation, linkage and analysis,
- Postcode – sample validation and linkage,
- Sex – analysis,
- Ethnicity – linkage and analysis.

Confidentiality Advisory Group advice

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

Despite the two year hiatus between the provisional outcome letter and the response to provisional the CAG were content to consider the response without the need for a new application, and the applicant provided sufficient justification for this delay.

1. **Provide further information around the analysis which would be undertaken on the linked database to explain how this would be used to improve public health.**

   The applicant responded that the current linkage of HES and STATS19 data already underpins conclusions on injury outcomes from road collisions in England by the Department for Transport, and described improvements in this methodology. This is therefore expected to provide an adequate linkage for the project aims. It was also pointed out that comment can also be made on which types of records have been linked vs those not linked, which would aid interpretation.

   The proposed study would help in understanding how poor outcomes occur and therefore enable the design of more effective preventative measures and post-crash care interventions. It was explained that public health could be improved in a variety of ways, including patient/public education through interactive web tools on risk, feedback on findings to Transport for London (TfL) and Department for Transport (DfT) to create awareness campaigns or roadside changes, and the potential for optimising

interventions and clinical processes including triage, distributing patients and allocating resources across the London major trauma network. The CAG were content with this response.

2. **Outcomes from the review by the Research Ethics Committee should be provided for consideration.**

   REC favourable opinion provided to CAG in a letter dated 11 November 2020.

3. **Clarify what information would be released by the London Ambulance Service to NHS Digital and confirm how this falls within the scope of the definition of confidential patient information.**

   The applicant confirmed the data items sent from LAS to NHS digital, and has explained that the data contains no identifiers nor health information and will not be analysed with any other data that permits re-identification. As such these data are not defined as confidential patient information, and this element of the study will not require support under regulation 5. Furthermore, the applicants have now changed the study design to allow this flow of data to go from LAS to Imperial BDAU, who will then send on the NHS digital. These data items are: Date of call out, Time of call out, Location of call out, Assumed Age, Assumed Gender, response time, and destination. The CAG agreed with this response.

4. **Provide a definitive list of items of confidential patient information which would be released by each organisation to NHS Digital for the purposes of linkage. Discrepancies between the application form and the dataflow chart should be addressed.**

   The applicant provided a detailed updated list of data items, including an updated flow chart. There are no longer discrepancies and the CAG were satisfied with the information provided.

5. **Confirm whether date of death or fact of death alone is required for the study analysis. If date of death is required in true format, a scientific justification should be provided to support this.**

   The applicant explained that full date of death is required for analysis rather than fact of death because it is pivotal to look at both clinical evolution and efficacy of intervention in the context of trauma. Major injury is a time-critical disease which has a known

relationship between degree of injury and rapidity of death. This was explained further in the provisional response to CAG and the justification was accepted.

6. **Confirm the specific start and end dates for the inclusion timeframe for the study (DD/MM/YY format).**

The applicant provided the dates as for inclusion as 1st January 2009 to 31st December 2019. (01/01/2009 – 31/12/2019). The CAG were content with this.

7. **Clarify whether the TARN network will be releasing information on adult patients only or adult and child.**

The applicant confirmed that TARN will be releasing information on all road traffic injury cases within the study time period, including children, as well as adults. They comment that this is particularly important as traffic injury remains a leading cause of death amongst the paediatric cohort both in the United Kingdom, and globally. Further justification has been provided in the response to conditions and this has been accepted by CAG.

8. **Provide further information around the linkage process with the novel datasets (i.e. Twitter) – clarification is required around who and where this linkage would be carried out and at what stage in the project timeframe in relation to the wider linkages.**

The applicant explained that the novel database will be built by the study team at Imperial College London, and will contain a set of anonymous entities which have extracted features (road user types, location, time, severity features) without identifiers. These will be used to create clusters of signal that could relate to a collision. Clusters will then be validated against STATS19 and LAS data which is sent directly to the BDAU and later to the linked pseudonymised dataset that is created and sent by NHS Digital. Rather than performing record level-linking, the study team will be instead scoring the accuracy of these clusters in identifying collision features, however only anonymous or pseudonymous data will be used for this with no possibility of re-identification. The novel database will be constructed whilst NHS Digital are undertaking the linkage. The CAG were satisfied with this response.

9. **Explain what information would be retained following the study, with specific reference to two datasets referenced at Q54 of the application (raw data/raw pseudonymised data).**

The applicants provided the following information:

1. Raw data for linkage (STATS19, LAS, HES, TARN) will be retained by NHS Digital for 12 months to ensure linkage is successful and in order to be able to act on any dissent to inclusion in the study.

2. Data received by Imperial from third parties, including the pseudonymised data received from NHS Digital, STATS19 and LAS will be destroyed following the end of the data sharing agreement (18 months). This will cover the study period during which the analysis will be conducted, findings written up and all planned reports and articles are submitted for publication. It is anticipated that this study period will be one year from receipt and as per BDAU policy, any data within the BDAU SE that are associated with this project will be destroyed 6 months after the project has completed (unless an extension is granted by the data provider).

3. Aggregated research outputs including the purpose built novel dataset and all appropriate documentation will be retained for minimum of 10 years after the completion of the study, in the College Archive and in line with the College's research data management policy:

The Members were content with this response.

10. The Trauma and Research Network should be approached around the potential of operating a project-specific dissenting mechanism for the study. Outcomes of the discussion should be provided – if is determined that this is not feasible, a strong rationale should be provided to support this. If this will be taken forward, copies of any supplementary patient-facing information would be required, together with an overview of how the dissenting mechanism would be operated.

The applicant has detailed in their response the actions taken regarding this. It is not possible for TARN to operate a project-specific mechanism, and the rationale has been provided. The CAG commented that it is difficult to see how the applicants could practicably have done any more work surrounding this, and PPI has been performed surrounding this. The CAG therefore accepted this response.

Confidentiality Advisory Group advice conclusion

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

Specific conditions of support

1. Ways to widen the dissemination of the research findings should be explored to ensure the benefits of the project are maximised and the appropriate agencies are aware of the outcomes. Feedback should be provided at the time of annual review of progress made with the dissemination plan.

2. Favourable opinion from REC:
   Confirmed 11 November 2020

3. Continual achievement of 'Standards Met' in relation to the relevant DSPT submission (or any future security assurance changes) for the duration of support. Evidence to be provided (through NHS Digital confirmation they have reviewed and confirmed the DSPT submission as standards met' for the duration of support, and at time of each annual review.
   Confirmed - NHS Digital 2019/20 DSPT equivalent to 'standards met' (by check of DSPT tracker 2 November 2020)

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

Name	Capacity
Dr Martin Andrew	CAG Member
Ms Sophie Brannan	CAG Member
Dr Murat Soncul	CAG Alternative Vice-Chair
Ms Caroline Watchurst	HRA Confidentiality Advisor

Context

Purpose of application

This application from the University of Cambridge set out the purpose of medical research which seeks to determine the role of inherited genetic variation in cancer risk and clinical outcomes.

The SEARCH study has been running since 1996 and was set up to investigate how normal, common genetic variation affects cancer risk. Support under Section 251 has not been required previously, however the study team are now seeking to change the recruitment process. In this application, support is being sought for the National Cancer Registration and Analysis Service (NCRAS) to identify patients suitable for the study. NCRAS disclosed the patient list to NHS Digital, who then removed patients who were deceased, had moved away from the UK or who had registered a dissent. The revised list was then disclosed to the NHS Digital Personal Demographics Service (PDS), who attached patients' addresses and the name and address of patients' GP. This list was then sent to the SEARCH study co-ordinator to facilitate the invitation process.

The SEARCH study co-ordinator then contacted the GPs of eligible patients, asking them to invite patients to take in the study. The GPs were then provided with the study information leaflet, a letter of introduction from the study team and a reply slip for the patients to return to the SEARCH team if they wished to take part. Patients participation in the project then proceeded on a consented basis. Patients were not approached if the G.P. indicated that the patient was under the age of 18 or unfit to participate for any reason.

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

Confidential patient information requested

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

Cohort	Male and female patients aged between 18 and 70 years. It is anticipated that 40,400 patients will be recruited to the SEARCH Breast study.

Data sources	1. The National Cancer Registration and Analysis Service held by Public Health England (PHE) 2. Patient Demographics Service - NHS Digital
Identifiers required for linkage purposes	1. Name 2. NHS Number 3. GP registration 4. Date of birth 5. Date of death 6. Postcode 7. GP name and address
Identifiers required for analysis purposes	No identifiers are retained for analysis purposes
Additional information	

Confidentiality Advisory Group advice

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

1. **Confirm the size of the cohort to be included in this application.**

   The applicant has confirmed the size of the cohort for this application to be an additional 6,000 recruits over the next five years, if possible. Justification has been provided for this number and the CAG were content with this response

2. **The patient leaflet needs to be amended to include information on how patients can dissent from inclusion in NCRAS, as well as this specific application.**

The applicant explained that alongside the SEARCH information leaflet, every mailing to potential SEARCH recruits includes a printed copy of the NCRAS information leaflet supplied by PHE, which was provided for CAG. This gives information to participants on how to dissent from NCRAS. The Members reviewed the leaflet provided and were content with this response.

3. **Clarify whether any patient level data samples will be transferred to the US.**

The applicant has confirmed that no samples will be transferred to the US. All the SEARCH samples will be genotyped in Cambridge, and all data is anonymized before research use. The CAG accepted this response.

Confidentiality Advisory Group advice conclusion

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

Specific conditions of support

1. Favourable opinion from a Research Ethics Committee. **(Confirmed 28 January 2019).**

2. Confirmation from the IGT Team at the Health and Social Care Information Centre of suitable security arrangements via Information Governance Toolkit (IGT) submission

   Confirmed:

   The **2018/19** NHS Digital DSPT review for - **University of Cambridge (School of Clinical Medicine) (**8F331) was confirmed as 'Standards Met' on the NHS Digital DSPT Tracker (checked 12 October 2020). (DSPT 2019/20 published but not yet reviewed).

   The **2019/20** DSPT equivalent for **NHS Digital** was confirmed as standards met on the NHS Digital DSPT Tracker (checked 12 October 2020).

   The NHS Digital **2018/19** DSPT review for **National Cancer Registration and Analytical Services (Public Health England) (X25)** was confirmed as '**Qualified Assurance – Trust has not achieved 95% staff undertaking data security awareness training'** on the NHS Digital DSPT Tracker (checked 12 October 2020). Please note the updated specific condition of support below. (DSPT 2019/20 not yet published)

All staff at **National Cancer Registration and Analytical Services (Public Health England) (X25)** that are involved in processing information under this application reference should have successfully completed local data security awareness training before processing any information under support.

c. 19/CAG/0188 - A population based study of genetic predisposition and gene-environment interactions in prostate cancer in East Anglia, Trent and West Midlands: SEARCH Prostate

Name	Capacity
Dr Tony Calland MBE	CAG Chair
Dr Lorna Fraser	CAG Member
Mr Anthony Kane	CAG Member
Ms Caroline Watchurst	HRA Confidentiality Advisor

Context

Purpose of application

This application from the University of Cambridge set out the purpose of medical research that seeks to obtain epidemiological information and biological material on a population-based series of prostate cancer cases, for the purpose of Identifying novel cancer susceptibility genes

The SEARCH study began in 1996. Participants were identified by the local cancer registry, the Eastern Cancer Registration and Information Centre (ECRIC). Participants were asked to provide a blood sample, from which the research team extracted DNA for genetic analyses, to complete a comprehensive questionnaire on their lifestyle and family history of cancer and gave consent for the research team to access their medical records and to retrieve pathology material. The applicants ceased recruiting new participants to the prostate arm of SEARCH in March 2013, due to funding. The anonymised data already collected is still used for research. The applicants are now seeking support to link this data to National Cancer Registration and Analysis Service (NCRAS) data held by Public Health England in order to update the data. NCRAS also provided regular updates on vital status from routine death notification data.

The original consent form for the application contained a clause giving consent for this access. Due to recent developments, and in accordance with guidance from the Medical Research Council and the HRA on the preparation of participant information, the participant information sheets and consent forms for arms of SEARCH where new participants are still being recruited had been updated to fully explain the access to patient records and data linkages required, including specifying that patient's electronic patient records would be accessed. The applicants had determined that it would be impracticable to recontact and consent the existing participants in the SEARCH prostate study, and were therefore seeking support under Section 251 to continue to receive confidential patient information from the Public Health England (PHE) Cancer Registry.

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	4,700 patients diagnosed with prostate cancer, who had already consented to take part in SEARCH prostate.
Data sources	1. National Cancer Registration and Analysis Service, held by NHS Digital
Identifiers required for linkage purposes	1. Name 2. NHS Number 3. Date of birth 4. Cancer Registration identifier
Identifiers required for analysis purposes	No identifiers will be retained for analysis purposes

Confidentiality Advisory Group advice

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

1. **A specific date for the review of the retention of confidential patient information needs to be provided.**

The applicant has responded with *'The retention of confidential patient information will be reviewed 3 months prior to the current time for covid linkage follow up; 30 June 2025'.* This is in relation to an amendment to all arms of the SEARCH study. The CAG were content with this response and were happy to now 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

1. Further patient and public involvement is to be carried out with feedback to be provided at the time of first annual review. This activity should explore different methods of notifying patients that the study is being undertaken and ways of facilitating study specific dissent.

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

3. Confirmation from the IGT Team at the Health and Social Care Information Centre of suitable security arrangements via Information Governance Toolkit (IGT) submission

   Confirmed:

   The **2018/19** NHS Digital DSPT review for - **University of Cambridge (School of Clinical Medicine) (**8F331) was confirmed as 'Standards Met' on the NHS Digital DSPT Tracker (checked 12 October 2020). (DSPT 2019/20 published but not yet reviewed).

The NHS Digital **2018/19** DSPT review for **National Cancer Registration and Analytical Services (Public Health England) (X25)** was confirmed as '**Qualified Assurance – Trust has not achieved 95% staff undertaking data security awareness training'** on the NHS Digital DSPT Tracker (checked 12 October 2020). Please note the updated specific condition of support below. (DSPT 2019/20 not yet published)

All staff at **National Cancer Registration and Analytical Services (Public Health England) (X25)** that are involved in processing information under this application reference should have successfully completed local data security awareness training before processing any information under support.

d. 20/CAG/0080 - Investigating whether elevated C-reactive protein is associated with probable depression in paediatric Chronic Fatigue Syndrome/Myalgic Encephalomyelitis (CFS/ME)

Name	Capacity
Dr Lorna Fraser	CAG Member
Ms Clare Sanderson	CAG Alternative Vice-Chair
Dr Martin Andrew	CAG Member
Professor Jennifer Kurinczuk	CAG Member
Mr Tony Kane	CAG Member
Mr Andrew Melville	CAG Member
Dr Tony Calland MBE	CAG Chair
Ms Kathleen Cassidy	HRA Confidentiality Advisor

Context

Purpose of application

This application from the University of Bristol set out the purpose of medical research which aims to evaluate whether raised C-reactive protein (CRP) is associated with probable depression, as measured on the Revised Childhood Anxiety and Depression Scale.

Paediatric chronic fatigue syndrome/myalgic encephalomyelitis (CFS/ME) is relatively common (prevalence 0.1–2%), with significant morbidity for children and their families. Co-morbid mental health disorders are common in children and young people with CFS/ME. Up to approximately 30% of children diagnosed with CFS/ME have co-morbid depression. In these children, depression is not thought to be the primary cause of the fatigue or disability. Whilst we assume the depression is secondary to the disability, loss of function and subsequent loss of social life/school and friendships, it is possible that the depression describes a phenotype of CFS/ME. Several pro-inflammatory markers have been associated with depression, most notably CRP. Adult population-based studies have demonstrated an association between elevated CRP and both increased risk of depression and increased severity of depression. This study aims to understand more about the association of high CRP and probable depression; it thereby addresses an unmet need by attempting to better understand, diagnose and treat co-morbid depression in children and adolescents with CFS/ME. Establishing whether neuroinflammation could contribute to the manifestation of depression in young people with CFS/ME may help us to both phenotype the different forms of CFS/ME and also give insights into the aetiology of depression in this population.

The research team have previously undertaken two studies (FITNET-NHS and DDS/Wellbeing) in a cohort of children with CFS/ME. The Wellbeing study was completed about a year ago, whilst FITNET-NHS is still ongoing. Whilst a consented activity, the research team now wish to link the data from these studies with CRP data, held by Royal United Hospital Bath NHS Trust. The research team have discussed this with their sponsor (and data controller for the data), who believe that the original consent take was not adequate (specific enough) to provide a legal basis for the proposed activities in this retrospective part of the present study.

From the original study datasets, the applicants will create two new databases (one for each previous study) which will hold name, date of birth, respective study identifier (Participant Id/Research Id) and this study's Participant Code. Each will then be populated with questionnaire data from the original study and then pseudonymised (removing names, dates of birth and study identifiers leaving just the clinical data and the participant codes in each database). These two pseudonymised databases will then be merged into one pseudonymised dataset (minus the questionnaire data) that is then transferred to Royal United Hospital Bath NHS Trust. The Trust is then able to reidentify participants from the study keys that they already hold and populate the database with the CRP data. The returned pseudonymised CRP data is then merged with the questionnaire data to create the final dataset for the study for analysis.

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

Confidential patient information requested

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

Cohort	Participants in the Wellbeing study who have completed RCADS questionnaires (approximately 90). Participants in the FITNET-NHS study that have CRP blood results available in the Royal United Hospital Bath NHS Trust medical records at the RUH site and will be included in the current study (approximately 170).
Data sources	1. University of Bristol 2. Royal United Hospital Bath NHS Trust
Identifiers required for linkage purposes	1. Name 2. Date of Birth 3. Study ID
Identifiers required for analysis purposes	1. None

Confidentiality Advisory Group advice

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

1. **Clarify how the further data linkages required for the CADENCE study will be carried out for patients in the Wellbeing cohort, if the data for these patients has already been anonymised. If the data for patients in the Wellbeing cohort has**

not yet been anonymised, the legal basis for continuing to hold the confidential patient information needs to be clarified.

The applicants advised that the data for the Wellbeing study is stored in two separate locations. The identifiable patient information is stored in a password-protected secured folder on a UoB –hosted server. The clinical questionnaire data is held in a password-protected SPSS file, in a secure location held on a different server. The two sources of data are only linked by a patient identification code, which is unique to a particular participant and disguises any attributable information (as per standard practice).

This process was explained in the Wellbeing study Participant Information Sheet, which stated that the data "will be securely stored for 5 years"; "will be analysed in anonymous form"; and "your name or any other information that might identify you will be anonymised and kept confidential". This represents anonymisation, or perhaps more strictly pseudonymisation but this a term that might confuse potential participants prior to recruitment.

The Wellbeing study still retains confidential patient information, with implied permission granted for this. Their Participant Information Sheet stated that confidentiality will be maintained “except in the circumstances where information is provided that may place you or others at risk”. For this reason, confidential information was held securely, separated from any clinical data. Participants were made aware of it.

The proposed process of data linkage does involve briefly de-anonymising the Wellbeing/FITNET-NHS data sets – for the minimum time possible before re-pseudonymising it behind the CADENCE study identifier. It is for this that Section 251 support is sought.

The CAG noted the information provided and raised no further queries.

2. **Confirm that the previous attempts made to contact patients had not been to seek consent for the specific activity proposed in this application.**

The applicant clarified that previous attempts to contact patients have been made during other studies conducted by the research team, but not as part of the CADENCE study.

The cohorts are directly equivalent and there is a very strong likelihood of the same response (or lack thereof) from this patient group, who suffer from severe disabling fatigue.

Furthermore, under GDPR Wellbeing can only use contact information in line with the purposes for which they stated they would use it. This does not include re-contacting participants to take place in more studies.

The CAG noted the information provided and raised no further queries.

3. **Clarify if recruitment to the Wellbeing and FITNES-NHS studies could be extended so that the required number of patients can be recruited prospectively. If recruitment cannot be extended, please provide justification for this.**

Recruitment for the Wellbeing Study was completed in February 2019. The study involved detailed clinical interviewing by skilled clinicians and funding only covered the targeted number of participants. These have provided the team with sufficient power to answer their research questions and the study will not be re-opened to meet CADENCE study objectives.

The FITNET-NHS Study is due to complete in October 2020. It is a large multi-centre, international trial and recruitment has been running since 2016. The total participant numbers are, at last time of counting: n=314. Recruitment has already been extended by 6 months and rates of recruitment (typically single figures per month) make this option impractical to reach the sample sizes required by the CADENCE study.

The CAG noted the information provided and raised no further queries.

4. **The patient notification materials need to be submitted for review. These materials need to provide patients with a mechanism to dissent from the inclusion of their data in the CADENCE study.**

The applicant provided a study poster. This was reviewed by the CAG and found to be satisfactory.

5. **Further patient and public involvement needs to be undertaken around the specific issue of the processing of confidential patient information without consent required in order to complete the required linkages. Feedback from this needs to be provided to the CAG for review.**

The applicant provided details on the patient and public involvement undertaken with the Bristol Young Person's Advisory Group and the CFS/ME PAG. The CAG considered the response and was satisfied by the patient and public involvement carried out.

6. **Demonstrate how the specific activity is operating in compliance with each principle of the GDPR and Data Protection Act 2018, as follows:**

    a. **Lawfulness, fairness and transparency - Information is processed lawfully, fairly and in a transparent manner in relation to individuals;**

The lawful basis is Article 6 of the GDPR, the processing is necessary for the legitimate interests of the third party (and no good reasons to protect the individual's personal data exist that overrides the legitimate interest).

    b. **Specific and legitimate purposes - Information is collected for specified, explicit and legitimate purposes and not further processed in a manner that is incompatible with those purposes;**

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

    c. **Data minimisation - Information is adequate, relevant and limited to what is necessary in relation to the purposes for which they are processed;**

The applicant provided assurance that the minimum amount of confidential patient information required to meet the aims of the study would be processed.

    d. **Accuracy - Information is accurate and, where necessary, kept up to date; every reasonable step must be taken to ensure that personal data that are inaccurate, having regard to the purposes for which they are processed, are erased or rectified without delay;**

The applicants confirmed that reasonable steps would be undertaken to ensure the accuracy of the confidential patient information processed.

    e. **Storage limitation - Information is kept in a form which permits identification of data subjects for no longer than is necessary for the purposes for which the personal data are processed;**

The applicant provided assurance that the confidential patient information required to meet the aims of the study would be retained for the minimum time necessary.

f. Security - Information is processed in a manner that ensures appropriate security of the personal data, including protection against unauthorised or unlawful processing and against accidental loss, destruction or damage, using appropriate technical or organisational measures;

The applicants confirmed that reasonable steps would be undertaken to ensure the security of the confidential patient information processed.

g. The accountability principle – Demonstrate how the controller shall be responsible for and be able to demonstrate compliance with the accountability principle.

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

The CAG reviewed the responses given and raised no further queries.

Confidentiality Advisory Group advice conclusion

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

Specific conditions of support

1. Favourable opinion from a Research Ethics Committee. **Confirmed 22 October 2020.**

2. Confirmation provided from the IG Delivery Team at NHS Digital to the CAG that the relevant Data Security and Protection Toolkit (DSPT) submission(s) has achieved the 'Standards Met' threshold. See section below titled 'security assurance requirements' for further information. **Confirmed: Royal United Hospital Bath NHS Trust and the University of Bristol have confirmed 'Standards Met' grade on DSPT 2019/20 (by check of the NHS Digital DSPT tracker on 20 November 2020).**

e. 20/CAG/0099 - Promoting vision-related quality of life (QoL): first stage development of a model for intervention from the evidence of what matters most to visually impaired children and their families

Name	Capacity
Dr Lorna Fraser	CAG Member
Dr Harvey Marcovitch	CAG Member
Ms Clare Sanderson	CAG Alternative Vice-Chair
Ms Kathleen Cassidy	HRA Confidentiality Advisor
Ms Caroline Watchurst	HRA Confidentiality Advisor

Context

Purpose of application

This application from the University College London Great Ormond Street Institute of Child Health set out the purpose of medical research that seeks to identify the key 'risk' and 'protective' factors associated with self-perceived quality of life, identify the time points when specific factors exert the greatest influence and propose which factors can be used in an intervention model to improve quality of life for children and young people with visual impairment and their families.

The applicants aim to inform intervention development by identifying risk and protective factors that promote better quality of life by investigating the views and experiences of children and young people with visual impairment and their families, as well as their personal and environmental characteristics. The applicants have developed a suite of validated age-appropriate patient-reported outcome measures (PROMs), which will be used to enable children to self-report their views on the impact of their visual impairment on their everyday lives and the health care they receive. These PROMs will be used in a large-scale survey of children and young people with visual impairment and their parents, in combination with other questionnaires measuring the family environment, levels of support, social-emotional well-being, personal and psychological factors, health and clinical and socio-economic

characteristics of the child. In-depth qualitative interviews will also be undertaken with a subset of these participants.

The applicants seek support to allow a research assistant, who is not part of the clinical care team, to access confidential patient records at Great Ormond Street Hospital (GOSH) for Children NHS Foundation Trust in order to identify eligible patients. Patients will then be contacted about the study and to seek consent to participate. The applicants also noted that, should it become necessary, patients may also be identified from Moorfields Eye Hospital. An amendment to the CAG will be submitted should this be necessary.

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

Confidential patient information requested

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

Cohort	Patients aged between 8 and 18 years of age who attend Paediatric Ophthalmology services at Great Ormond Street Hospital (GOSH) who are sight impaired/severely sight impaired (defined as corrected visual acuity LogMAR > 0.50) due to any disorder and are able to assent (aged 8-15 years) or consent (aged 16-18 years), but are without significant motor, intellectual, learning/cognitive and other sensory impairments. Also the parents or primary carers of children or young people with visual impairment selected as eligible and able to consent to take part will also be invited to participate. 150 family units will be recruited.
Data sources	1. Patient records held at Great Ormond Street Hospital (GOSH) for Children NHS Foundation Trust

Identifiers required for linkage purposes	1. Name 2. NHS Number 3. Hospital ID number 4. GP Registration 5. Date of birth 6. Postcode – unit level
Identifiers required for analysis purposes	1. Date of birth 2. Postcode – unit level 3. Ethnicity 4. Visual acuity

Confidentiality Advisory Group advice

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

1. **Confirm that the study poster will be displayed 6-8 weeks before the start of screening. If not, please justify why this is not possible.**

The applicant confirmed that the poster will be displayed for 6-8 weeks before screening begins. The CAG noted this and raised no further queries.

2. **Clarify if the posters will also be made available in an accessible format.**

The applicant confirmed that the study poster will be made available in an accessible format for children and young people with visual impairment. The CAG noted this and raised no further queries.

Confidentiality Advisory Group advice conclusion

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

Specific conditions of support

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

2. Confirmation provided from the IG Delivery Team at NHS Digital to the CAG that the relevant Data Security and Protection Toolkit (DSPT) submission(s) has achieved the 'Standards Met' threshold **(Confirmed – Great Ormond Street Hospital (GOSH) for Children NHS Foundation Trust has a confirmed 'Standards Met' grade on DSPT submission 2018/19 by check of the NHS Digital DSPT Tracker on 09 September 2020).**

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

Name	Capacity
Dr Lorna Fraser	CAG Member
Ms Diana Robbins	CAG Member
Ms Clare Sanderson	CAG Alternative Vice-Chair
Ms Kathleen Cassidy	HRA Confidentiality Advisor
Ms Caroline Watchurst	HRA Confidentiality Advisor

Context

Purpose of application

This application from the Oxford University Hospitals NHS Foundation Trust set out the purpose of medical research that seeks to develop understanding and identify the clinical success factors contributing to Covid-19 negative and positive patients being detected as deteriorating and rescued within the clinical ward area.

Up to 40,000 hospital patients yearly suffer a preventable death due to staff failing to recognise patient illness or delays in medical review, leading to a delay in the escalation of care. This problem has been identified in NHS care reviews and current research is focused on the reasons why escalation of care does not always happen. Further reduction in patient death may be possible by examining the care of unwell hospital patients who are successful

managed and identifying success factors in the escalation of care. The applicants noted that the Covid-19 pandemic presented an opportunity to examine care escalation in two distinct patient groups, those who are Covid-19 positive and those who are Covid-19 negative, as the NHS has had to modify care delivery models meaning that success factors may now be evident.

The application is formed of 4 Stages:

Stage 1 – Staff observations during escalation events. 200-400 care escalation events will be observed, detailing staff interactions for Covid-19 positive and negative patients.

Stage 2 – Care record reviews. 200-400 records of Covid-19 positive and negative patients who deteriorated, improved and were not admitted to ICU.

Stage 3 – Staff interviews. The applicant will interview 30 doctors and nurses to identify escalation success factors, how these could be applied effectively and the impact of pandemic care models.

Stage 4 – Data integration phase. The study will use a 'coding buddy' who will ensure confirmability in qualitative data findings. The advice of a qualified statistician will be sought for the quantitative data analysis.

The applicants are seeking support for Stage 2 of the study, to extract and anonymise data from patients who are unable to consent or for whom an approach to seek consent is impracticable. Records for 200 – 350 patients who deteriorated to the point where an intensive care review was triggered but did not require admission to ICU. Up to 50 notes will be reviewed for patients who became unwell while on the ward, were admitted to ICU and then died. The purpose of the notes review is to develop understanding of the care of patients with Covid-19, such as the recognition and presentation of their deterioration, how current care processes support or hinder their deterioration events, their illness patterns, care delivered and management.

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

Confidential patient information requested

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

Cohort	Patients aged 18 years and over, both Covid-19 positive and negative. 830 patients in total will be included, however the records of up to 400 patients will be examined for Stage 2, for which support is sought. 2 - 400 escalation events will also be observed.
Data sources	1. Hospital electronic and paper patient records, held at Oxford University Hospital NHS Foundation Trust
Identifiers required for linkage purposes	1. Name 2. NHS number 3. Hospital ID number 4. Date of birth
Identifiers required for analysis purposes	1. Date of birth 2. Date of death 3. ward location and movement throughout the admission episode if relevant to escalation of care episode 4. Gender

Confidentiality Advisory Group advice

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

1. **Assurances need to be sought from the appropriate persons within Oxford University Hospital NHS Foundation Trust that the researcher has an existing legal basis for this processing of confidential patient information without being in breach of the Common Law Duty of Confidence, or whether support under s251 was needed to provide an alternative legal basis.**

The applicants provide a letter from the Trust, explaining the existing legal basis in place regarding the confidential patient information that the applicants may be incidentally exposed to during Stage 1 of the study.

2. **Clarify how the list of records to be accessed in Stage 2 will be obtained.**

The applicant advised that the information request would be submitted to the IT department at Oxford University Hospital NHS Foundation Trust in writing. The IT department will then run a database query within the vital signs database (SEND) to identify a list of patients meeting the study criteria who were treated in the last year. The report will contain the patients' name, date of birth, medical records number and date of admission. This report will then be transferred to the research team via a secure NHS email.

3. **A public-facing poster and leaflet need to be provided for review. These need to include a description of the dissent mechanism and contact details, including telephone and email contacts, for the study team.**

A poster, and leaflet have been developed and submitted for review. Members noted that the poster stated that 'no patient identifiable data will be collected' and that this didn't accurately reflect the activity undertaken as, while no confidential patient information would be extracted, confidential patient information would be accessed. The poster, information leaflet and webpage material referred to "CAG permission" and "CAG allows." This doesn't accurately reflect the CAG's role. Members asked that this was refused along the lines of, "The CAG recommended support for the proposed activity to the Decision Maker within the HRA." Members asked that the documents were revised. Revised documents were provided, which were reviewed and accepted.

4. **The wording to be used on the Trust websites needs to be provided for review.**

The website text was provided for review. The applicant advised that the wording used in this document will be the framework for the study webpage.

5. **Further attempts were to be made to undertake patient and public involvement around the use of confidential patient information to investigate Covid-19. The CAG suggested that the applicants utilise the resources available through Oxford University Hospital NHS Foundation Trust and NIHR.**

The applicant advised that a programme of patient and public involvement activity had been conducted in preparation for the submission of the study for NIHR funding. Patient and public involvement would be carried out in three phases, pre, intra and post study, and the applicant provided details on the activity that had already taken place as well as future plans.

Members could not identify where it had been clearly stated that patient and public involvement has been conducted around the acceptability of the use of confidential patient information in relation to this specific COVID-related research. The CAG asked for confirmation that this was discussed at future patient and public events and feedback when you submit the annual review. The applicant confirmed that further patient and public involvement would be carried out and feedback at the first annual review

6. **Clarify whether the date of birth and date of death for patients will be retained or whether these dates will be converted into less identifiable formats, such as month and year of birth and age at death.**

The applicant confirmed that patients' name and date of birth would be retained for the minimum length of time necessary. The applicants would also follow the CAG suggestion of converting the date of birth to a less identifiable format.

Confidentiality Advisory Group advice conclusion

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

Specific conditions of support

1. Further patient and public involvement will need to be conducted around the acceptability of the use of confidential patient information in relation to this specific COVID-related research and feedback provided at the first annual review.

2. Favourable opinion from a Research Ethics Committee. **Confirmed 12 October 2020.**

3. Confirmation provided from the IG Delivery Team at NHS Digital to the CAG that the relevant Data Security and Protection Toolkit (DSPT) submission(s) has achieved the 'Standards Met' threshold **(Confirmed – Oxford University Hospital NHS Foundation Trust has a confirmed 'Standards Met' grade on DSPT submission 2018/19 by NHS Digital email dated 17 September 2019).**

g. 20/CAG/0111 - Under 16 Cancer Patient Experience Survey 2020-2023

Name	Capacity
Ms Clare Sanderson	CAG Alternative Vice-Chair
Ms Diana Robbins	CAG Member
Dr Lorna Fraser	CAG Member
Mr Myer Glickman	CAG Member
Dr Malcolm Booth	CAG Member
Ms Kathleen Cassidy	HRA Confidentiality Advisor

Context

Purpose of application

This application from NHS England and NHS Improvement and Picker Institute Europe (Picker) set out the purpose of a patient survey to collect patient experience data for patients aged under 16 years of age with a diagnosis of cancer.

The National Cancer Patient Experience Survey (CPES), commissioned and managed by NHS England and NHS Improvement, is one of the ways that patient experience data for cancer patients in England is captured. The results of these surveys are used to help commissioners, providers and national policy makers to identify priority areas of improvement for services. However, as recognised in the Achieving World Class Cancer Outcomes: A Strategy for England 2015-2020, January 2015, NHS Independent Cancer Taskforce, the CPES is not appropriate for use with children with cancer. This Strategy recommended that NHS England and NHS Improvement "should develop a methodology to collect data on patient experience for under 16s". This commitment to improvement was recently restated in the NHS

Long Term Plan, January 2019, NHS England. This application supports NHS England and NHS Improvement to fulfil the Cancer Strategy recommendation and Long-Term Plan objectives. NHS England and NHS Improvement has commissioned Picker Europe Ltd.to develop and carry out the Under 16 Cancer Patient Experience Survey over the period 2020-2023.

The applicants are seeking support to collect and use confidential patient information for patients under 16 years of age diagnosed with cancer and other tumours in order to conduct the Under 16 Cancer Patient Experience Survey between 2020 and 2023. Confidential patient information will be disclosed from NHS Principal Treatment Centres (PTCs), delivering children's cancer care and treatment in England, to Picker Europe Ltd. Picker will also liaise with PTCs so that patient questionnaires are sent to recipients on the letter-headed paper for the appropriate trust. The survey materials will be addressed to parents of children who have received care. The first wave of data collection is due to take place in the autumn of 2020 and repeated on an annual basis thereafter. Support is sought for the first three years of the survey.

Once Picker receives the patient information from the PTCs, most of the checking and mailing processes are automated (in-house) with access limited to approved individuals in accordance with their Information Security Management System.

Other details are needed to verify survey responses, check eligibility to take part or to provide data that patients could not be expected to supply. These details (e.g. age and coding of cancer diagnosis ICD10 codes) will be used to check the accuracy of the sample data, and to compare different groups' experiences of acute cancer care at the reporting stage, where numbers allow.

As hospitals do not routinely collect email and/or mobile phone numbers for patients, for the first 1-2 survey waves, the applicants intend to approach patients by post using a paper-based survey, with the option for respondents to complete the survey online, should they prefer. However, in response to advances in digital communications, for future waves the applicants intend to explore a mixed-method approach in instances where email and/or mobile phone numbers are available, e.g. an initial approach by email, or survey reminders sent by SMS. Support is therefore requested for email and/or telephone number to be collected to further explore the digital potential for the survey. The patient name and address will be needed to send out postal surveys to recipients, and the email address and mobile phone number of the parent(s)/carer(s) (where available) will be needed to explore whether a mixed-mode approach could be used in future waves of data collection.

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

Confidential patient information requested

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

Cohort	All children aged under 16 at the time of their care, with a confirmed primary diagnosis of cancer or a non-malignant brain, other central nervous system or intracranial tumour, who are aware of their diagnosis and have received NHS care and/or treatment for their cancer or tumour within a recent twelve-month period. This will include: • Admitted patients who did not stay overnight (e.g. emergency admissions and planned day cases) • Admitted patients who did stay overnight • An ICD-10 code of C00 – C97, D32 - D33, D35.2 - D35.4, D42 - D43, D44.3 - D44.5, D48, D76.1. The applicants estimate that this will include between 1,000 and 10,000 patients per year.
Data sources	1. NHS Principal Treatment Centres (PTCs)
Identifiers required for linkage purposes	1. Patient name 2. Address 3. Sex 4. Ethnic group 5. Date of birth 6. ICD10 code 7. Discharge date 8. Specialty code 9. NHS number 10. Site code 11. Trust code 12. Patient classification 13. Parent email address and mobile phone number will be collected, where available.

Identifiers required for analysis purposes	No identifiers are required for analysis purposes

Confidentiality Advisory Group advice

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

1. **Further clarification on the cohort is required:**

    a. **Provide a more precise number of anticipated patients.**

The applicants advised that a precise figure could not be provided until the first wave of sampling had concluded. There was evidence that almost 1,500 patients under the age of 15 were newly diagnosed with cancer in England between 1st January and 31st December 2017. The numbers in the sample may vary as the sample will include patients with some non-malignant tumours, all cancer patients who have been recently discharged from hospitals, not that just who have a recent diagnosis, and will include patients who are 16 years and younger. The applicants noted that they could provide a more accurate number at a later date.

    b. **Provide further clarification on when the 12-month period will be.**

The applicant noted that the exact time frame depended on when approvals were in place from NHS England and NHS Improvement to contact trusts to assemble a team to draw the sample. The applicant anticipate that this will be in place by December 2020 and that sampling would begin in January 2020. Trusts would be asked to include patients who were discharged from hospital between January 1, 2020 and December 31, 2020. Wave 2 of data collection would then include patients discharged from hospital between January 1, 2021 and December 31, 2021. Wave 3 would include patients discharged from hospital between January 1, 2022 and December 31, 2022. However, the sampling period will need to be shifted to a more recent 12-month period if there are delays in NHS England and NHS Improvement approvals to contact trusts about the survey. The applicants noted that they could confirm the start date at a later date.

c. The inclusion criteria need to include a criterion that patients and their parents/carers are aware that the patients have a diagnosis of cancer.

Updated sampling instructions were provided and further details about how the sampling strategy would ensure patients were aware of their diagnosis were given in the response to point 3.

The CAG noted the above responses and raised no further queries.

2. Advise whether the email addresses and telephone numbers of patients needs to be collected, or whether a flag could be created to indicate whether the telephone number and/or email address was available. If the telephone numbers and email addresses will be collected, then justification for this needs to be provided.

The applicant advised that the project team had previously considered collection of a flag to indicate whether this data was available. However, this flag would only indicate if the data was available and would not provide an indication of how accurate it might be. To fully examine the feasibility of using a mixed-methodology approach in the future, the applicants explained that they would like to collect email addresses and phone numbers so that their format could be assessed for validity. This data would be used for exploratory purposes, and the applicants were receptive to having trusts submit email addresses and phone numbers separately from the core sample data, so that they are never linked to the patient record. This has been amended within the revised sampling instructions.

The CAG noted this information and raised no further queries.

3. Advise how it will be ensured that patients, or their parents/carers, who may not be aware that their diagnosis was of cancer would not find out their diagnosis via this survey.

Trusts will be required to liaise with a member of their clinical team, such as a lead cancer nurse, who must check that all patients have a confirmed diagnosis and that their admission was for care relating to cancer or a tumour. Trusts will have to sign a declaration form confirming that this check has been made before they can submit their patient sample. This validation check is considered to be the best way to ensure that patients and their parents/carers are aware of their diagnosis and is the approach used on the National Cancer Patient Experience Survey for those aged 16 and over.

The applicants noted that, despite these detailed manual checks by a member of the clinical cancer team, there may be some patients who were previously informed of their diagnosis but may have misunderstood this. Should this occur, potential respondents are provided with a Freephone helpline they can contact if they have any questions or concerns about the survey. The applicants anticipated that calls are likely to be rare, however the Freephone helpline provider will be briefed on the possibility of receiving such calls, and advisors trained on how to handle such calls sensitively. In such instances, parents/carers will be connected to the relevant trust as soon as possible so that confirmation of diagnosis can be provided, and clinical support given as necessary.

The applicants noted that the Under 16 Cancer Patient Experience Survey also included children who do not have a cancer diagnosis but do have a non-malignant tumour of the brain, other central nervous system or an intracranial tumour. This is explained within the covering letter of the questionnaire and the questionnaire states “These questions are about the care you received for your cancer or tumour.”

The CAG noted this information and raised no further queries.

4. **Clarify how many reminders the patients will be sent after the survey was initially sent.**

Patients can indicate their dissent in participating in the survey through a number of pathways. First, patients who view a dissent poster can use the contact information provided on the poster to inform their trust that they do not want to participate in the survey. Data team members drawing the sample are required to remove these patients from the sample list before it is submitted to Picker. Alternatively, once in receipt of a survey, patients can also return it blank to indicate that they do not want to participate. They would be excluded from any reminder mailings. Patients may also contact the Freephone helpline or email the study team to indicate their dissent and to be removed from any reminder mailings. The patient letter also contains contain details for NHS England and NHS Improvement should they wish to contact the survey commissioner directly.

Patients who have not returned a completed survey or have not indicated their dissent will be sent up to two reminder mailings, sent two to three weeks apart. The first reminder mailing would consist of a short letter. The second reminder mailing would consist of a short letter and a questionnaire. These materials were included in the documents sent to CAG in the initial application.

The CAG noted this information and raised no further queries.

5. **Further details on the patient notification and dissent process are required:**

    a. **Clarify how long the poster will be displayed for.**

The applicant explained that the dissent posters had been provided to PTCs for display from July 2019. PTCs were contacted in January 2020 to ask them to continue to display the posters and they have been encouraged to continually display the posters as the sampling timeframes will be continuous for future survey waves. Copies of the poster template will be posted to the project website. These posters contain a field in which individual PTCs provide a telephone number, email, and postal address for patients to register dissent. PTCs were made aware that the text within the posters could also be displayed digitally, such as via the trust website or using digital screens within the hospital.

    b. **Confirm that all PTCs will provide a telephone number, email and postal address on the poster, for patients to use to register dissent.**

The poster templates contain a field in which individual PTCs provide a telephone number, email, and postal address for patients to register dissent. PTCs were made aware that the text within the posters could also be displayed digitally, such as via the trust website or using digital screens within the hospital.

    c. **Provide clarification as to why the names and addresses of patients who dissent will be retained to ensure patients are not re-contacted, or whether it is possible to retain patients' NHS numbers and either their date of birth or age. It also needs to be explained in the patient notification that details on those who dissented will be retained.**

The applicant advised that no information will be collected on patients who dissent from participating in the survey via the dissent poster, as trusts will be instructed to remove these patients from their sample lists. The names and addresses of patients who dissent after they have been sent a survey or who do not respond to the survey will be securely deleted at the end of the fieldwork period. This explanation has been added within the two mailing covering letters. All other information for these patients will be retained for the purposes of examining any demographic differences between responders and non-responders/dissenters. This information will be used to inform future methodology approaches (for example whether particular activities are recommended to support engagement / survey uptake from under-represented groups of patients or parents). Any requests made under GDPR will be strictly adhered to.

d. Additional ways of promoting the survey, including via social media, are to be considered and fed back to the CAG.

The applicants explained that they would use social media to share information about the survey and keep people updated with progress, once the survey website is launched. Social media will be used to increase awareness of the survey amongst patients, parents and cancer staff. However, the applicants will not be able to directly ask people to complete a survey via social media without knowing their social media details. Although the survey could be promoted on social media by offering an open access survey link, the applicants would lose control over who responded, and it would not be able to ascertain whether they were eligible to take part and the PTC they are answering about. Parental consent was also needed for children to take part and it is, therefore, important that all correspondence goes to parents in the first instance. The applicants advised that they would investigate ways that survey results can be shared via social media and are currently investigating child-friendly engaging outputs that can be shared online.

The CAG noted the above responses and raised no further queries.

6. Clarify if the specific question of sending confidential patient information to Picker and the number of contact attempts that would be made had been raised during patient and public involvement. If so, details of the feedback received need to be provided.

During the cognitive testing phase of the project, participants were asked about their views on data sharing. All of the cognitive testing participants mentioned that they would be happy for their contact information to be passed to Picker for the purposes of being sent a questionnaire. Only two concerns were raised about contact attempts. One participant raised a concern about receiving duplicate surveys due to her child receiving care from multiple hospitals. This concern is eliminated through the de-duplication process between different PTC sample files. Another participant mentioned that bereaved parents/carers might be less inclined to answer the questionnaire. This concern should largely be addressed through DBS checks to remove deceased patients during the sampling process and before each of the survey mailings is sent.

The CAG noted this information and raised no further queries.

7. Can the check that patients are still living be done via the Patient Demographic Service using the NHS notification of death which would be available prior to the official registration.

The applicant explained that trusts are required to conduct Demographic Batch Service (DBS) checks prior to submitting their patient sample to Picker. Picker will also conduct its own DBS checks for the entire approved sample prior to each of the mailings. The DBS tracing service used by Picker runs on the Patient Demographic Service. In addition, trusts will be provided with the mailing dates so that they can conduct their own local checks ahead of each mailing if they wish.

The CAG noted this information and raised no further queries.

Confidentiality Advisory Group advice conclusion

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

Specific conditions of support

1. 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 – Picker Institute Europe has a confirmed 'Standards Met' grade on DSPT submission 2018/19 by check of the NHS Digital email dated 17 July 2019)**

h. 20/CAG/0120 - Incidence of Avoidant/Restrictive Food Intake Disorder (ARFID) in children and young people presenting to secondary care in the UK and Ireland

Name	Capacity
Dr Murat Soncul	CAG Alternative Vice-Chair
Professor Barry Evans	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 Imperial College London sets out the purpose of medical research that aims to determine the number of new cases of children and young people with Avoidance/Restrictive Food Intake Disorder (ARFID) and associated psychiatric symptoms in the UK and Republic of Ireland over one year. The study also aims to examine referral pathways, patterns of presentation, and clinical features of ARFID, including eating behaviours, medical complications and the types of medical or psychiatric presentations it is associated with. The applicants also plan to compare rates, presentation and management of ARFID with other countries, as well as generating new research questions on prognosis, long-term outcomes and treatment of ARFID.

ARFID is an umbrella term used to describe restrictive eating patterns which result in significant health problems, including weight loss, poor growth, nutritional deficits or poor emotional wellbeing. Unlike in anorexia nervosa, restrictive eating in ARFID is not associated with concerns about body image, weight or shape. To date very little is known about this disorder and its associated behaviours and outcomes in British and Irish children and adolescents.

The limited research data on ARFID means that it was excluded from the scope of the NICE (National Institute for Health and Care Excellence) guidelines on eating disorders (NG69) and therefore from commissioning guidance for children and young people with eating disorders (2015). The exclusion of ARFID from NICE guidelines has resulted in different referral pathways and availability of care depending on where in the UK patients live. The proposed research will help in improving the help that affected children and their families receive by ensuring standardised intervention, treatment paths and care.

This national active surveillance study will be established using the British Paediatric Surveillance Unit (BPSU) and Child and Adolescent Psychiatric Surveillance system (CAPSS) research methodology. Every children's doctor in the UK, through the BPSU and CAPSS, will be asked whether they have seen a child that month with ARFID. The Imperial College ARFID research team will contact reporting clinicians to ask for service specific information, information about the case reported including clinical presentation, investigations and findings, impact of the disorder and management in the form of a questionnaire. A follow up questionnaire one year later will be conducted to understand the course of the disorder, impact and further management. The research will be taking place across England, Wales, Scotland, Northern Ireland and the Republic of Ireland, however support under the Regulations only covers England and Wales.

The research team will access questionnaire data through REDCap and store as a password protected Excel sheet. The research team will not have access to the full identifiable details (such as names, etc.) of the patients that clinicians report in the surveillance, instead, they will have access to partial identifiers such as date of birth, sex and ethnicity. Each record will have a separate unique code which the research team will assign to cases. The research team will separate the identifiable data and the clinical data and use the unique code to link the two. After the 12 month follow up questionnaire has been completed date of birth will be converted to age in months for analysis. Gender, ethnicity, and sector level postcode will be retained alongside age in months for analysis, and additionally for 10 years after the study has closed. These partial identifiers will therefore also be potentially shared with other countries outside the EEA.

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	**Estimated sample size: 180** **Reporting Instructions** requested of all consultant paediatricians and child psychiatrists in the UK and Republic of Ireland on the BPSU and CAPSS mailing list**:** Please report any child seen in the last month who meets the case definition in the UK or the Republic of Ireland. However support under the Regulations is given only for those patients seen in England and Wales. **BPSU** surveillance system: children and young people aged 5-15 years **CAPSS** surveillance system: children and young people aged 5-17 years Any child or adolescent aged 5 to 17 years with persistent restriction of quantity and/or range of food intake, associated with one or both of the following: • Nutritional deficiency that requires additional clinical investigation or treatment (e.g. weight loss or poor growth, micronutrient deficiency, reliance on nutritional supplementation, anaemia) that is not fully accounted for by poverty or neglect, cultural practice or an existing medical condition or another mental disorder* • Interference with day-to-day functioning due to eating behaviour (e.g. unable to eat at school or with peers, needs to take preferred foods when out of home). Not explained by ANY of the following: • Lack of available food (e.g. from poverty, famine or neglect) • Culturally sanctioned practice (e.g. endorsed religious and cultural practice) • Other known diagnosis o e.g. Allergy to specific food group (e.g. dairy) o Gastrointestinal disorder o Constipation o Swallowing difficulties o Other eating disorder e.g. anorexia nervosa, bulimia nervosa

	○ Other medical or psychiatric disorder that fully explains food restriction (not requiring additional clinical attention) e.g. depression, anxiety, OCD, malignancy, diabetes mellitus, inflammatory bowel disease, thyroid disease *If eating disturbance occurs in the context of another condition/disorder, then in order to meet case definition for ARFID, the severity of eating disturbance should exceed that routinely associated with the particular condition/disorder - and warrant additional clinical attention.
Data sources	1. Reporting clinicians
Identifiers required for de-duplication and linkage with 1 year follow-up purposes	1. Sex 2. Date of Birth 3. Ethnicity 4. Sector level postcode
Identifiers required for analysis purposes	1. Sex 2. Ethnicity 3. Sector level postcode Age – Date of Birth will be converted to age in months, after it has been used at 12 months for de-duplication. The full DOB is not required for analysis.
Additional information	Reporting clinicians will not provide names and addresses to the study team.

Confidentiality Advisory Group advice

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

1. **The phrase *'we cannot withdraw or remove personal information from the study as this would make the research invalid'* should to be removed from the**

patient/parent information sheet, and an updated document is to be provided to CAG.

The applicant has removed the phrase requested from the patient/parent information sheet and provided an updated document to the sub-committee who were content with the response and 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

1. Data sharing with other countries to pool estimates of the frequency of occurrence, is supported on the understanding that this is limited to anonymised data only.

2. Favourable opinion from a Research Ethics Committee.
   Confirmed 7 October 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 NHS Digital **2018/19** DSPT review for **Imperial College London - School of Public Health Medical Trials and Research (EE133887-SPHTR)** was confirmed as 'Standards Met' on the NHS Digital DSPT Tracker (checked 15 October 2020). The 2019/20 DSPT is currently under review by NHS Digital.

i. 20/CAG/0121 - Strengthening the Implementation and Operationalisation of 'Open Disclosure' with Women and Families After Unexpected Harm in NHS Maternity Care: DISCERN study

Name	Capacity
Dr Murat Soncul	CAG Alternative Vice-Chair
Dr Rachel Knowles	CAG Member
Professor Barry Evans	CAG Member
Ms Caroline Watchurst	HRA Confidentiality Advisor
Dr Paul Mills	HRA Confidentiality Advice Service Manager

Context

Purpose of application

This application from King's College London sets out the purpose of medical research that aims to explore the critical factors that can improve the incidence and quality of disclosure and discussion of harm or 'Open Disclosure' (OD) in NHS maternity services, and what the actual or anticipated consequences of these improvements are likely to be for different stakeholders and in what contexts. The applicants aim to generate actionable evidence and produce tailored outputs to inform maternity providers how to strengthen OD practice and processes in NHS maternity services, to improve the quality and safety of maternity care for the benefit of women, families and clinical teams.

Open disclosure (OD) – the disclosure and discussion of harm that has happened to a patient during healthcare – has been identified as important in health services. OD is now publicly recognised as an entitlement of harmed patients and families, and research has identified multiple potential benefits. However, OD is often not routinely practiced and, when it is, it often falls short of both patient and family expectations and of professional or organisational guidelines. Research shows that the issue of Open Disclosure is often problematic in maternity care, where incidents tend to have high stakes in terms of emotional, professional, and economic costs

While the barriers to improving the incidence and quality of OD have been extensively documented, how some maternity services are managing to negotiate these barriers to improve OD policies, procedures and practices has yet to be answered. A central aspect of maternity review and investigation improvement identified by the Secretary of State is communication with families, including explanation of events of harm and assurance that lessons have been learned. There is therefore a need to understand how this difficult work can be best encouraged and supported within services.

This study is being undertaken in 3 phases. Phase 1 and 3 are outside of scope of this support. Phase 2 is in scope and applicants will undertake in-depth case studies in 3 NHS maternity services. The case studies will comprise of observations of OD work routines and effects, staff interviews, patient interviews and analysis of paperwork. The case studies will be undertaken by a series of virtual visits to staff and patients, completed over 8 months. All visits will be remote/virtual due to the Covid-19 pandemic, until or unless otherwise agreed with clinical leads, however it is possible that the applicants will occasionally be observing or meeting people face-to-face rather than virtually. All staff observations and staff and patient interviews will be undertaken where possible with written informed consent, however it is likely that most observations of individual staff will indirectly involve others (for example, in meetings, training events). Support under the regulations is required in case of accidental disclosure of confidential patient information regarding a non-consented patient during either observations or interviews with staff and consented patients. The researchers have put in a number of safeguards to protect patient confidentiality including consent where possible, avoiding meetings where patient details may be disclosed, and reminding all staff and patient participants to respect patient confidentiality during interviews and observations.

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	Support is only given regarding patients of maternity services, not for NHS staff or family members of patients. The cohort are patients treated on maternity wards who are not consented into this study, whose information may be incidentally disclosed.

Data sources	Interviews and observations carried out in 3 participating NHS Trusts: • West Sussex Trust • Guys and St Thomas NHS Foundation trust • Chelsea & Westminster Hospital NHS Foundation Trust
Identifiers required for linkage purposes	1. No items of confidential patient information will be collected for linkage purposes
Identifiers required for analysis purposes	1. No items of confidential patient information will be collected for analysis purposes

Confidentiality Advisory Group advice

This letter summarises the outstanding elements set out in the provisional support letter, and the applicant response. The applicant response was considered by the Confidentiality Advice Team (CAT).

In order to complete the processing of this application, please provide favourable opinion from the REC when available;

The applicant provided the CAT with the favourable opinion from the REC on 30 November 2020.

Confidentiality Advisory Group advice conclusion

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

Specific conditions of support

1. Favourable opinion from a Research Ethics Committee

Confirmed – REC Favourable opinion issued 23 November 2020

2. Confirmation from the IGT Team at the Health and Social Care Information Centre of suitable security arrangements via Information Governance Toolkit (IGT) submission
   Confirmed:

   The **2018/19** NHS Digital DSPT reviews for **Chelsea and Westminster Hospital NHS Foundation Trust** RQM (2019/20 not yet published), **Brighton and Sussex University and Western Sussex Hospitals Trusts** RXH (covers West Sussex trust) (2019/20 not yet published), and **Guys and St Thomas' NHS Foundation Trust** RJ1 (2019/20 submitted but not reviewed) were confirmed as 'Standards Met' on the NHS Digital DSPT Tracker (checked 12 October 2020).

2. New Amendments

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

Name	Capacity
Ms Kathleen Cassidy	HRA Confidentiality Advisor

Context

Amendment request

The applicants have existing support to allow the disclosure of specified items of confidential patient information from participating Trusts to Crown Informatics for the purpose of the national paediatric asthma clinical audit and for onward disclosure to NHS Digital and NHS Wales Informatics to facilitate linkage with wider administrative datasets in order to follow-up patient outcomes.

In this amendment, the applicants are seeking support to amend the flow of the linked outcome data, so that the data will be sent by NHS Digital and NWIS to Imperial College London directly. The data will be sent in a pseudonymised, patient-level format. Crown Informatics Ltd would therefore no longer receive the returned linked data from NHS Digital and NWIS. This change is being made as Crown Informatics Ltd have indicated that the process of receiving and anonymising the linked data prior to the data being sent to Imperial College London may be delayed in future, which will impact on the report production timeframes for Imperial College London and the Royal College of Physicians. The ultimate aim of NACAP is to improve healthcare quality and outcomes. The proposed change are intended to enable the outcome reporting process to be quicker and more consistent with other NACAP audits.

The revised data flow would be as follows:

1. Crown Informatics Ltd will securely transfer identifiable data (NHS number, date of birth and postcode and a unique audit identifier for the cohort to NHS Digital and NWIS.
2. NHS Digital will link the data to HES and ONS datasets, and NWIS will link the data to the PEDW dataset.

3. NHS Digital and NWIS will pseudonymise the linked data at source as follows:
    a. NHS number replaced with unique audit identifier
    b. Date of birth replaced with age at admission
    c. Postcode replaced with Lower Super Output Area (LSOA)
4. NHS Digital and NWIS return the pseudonymised linked data to Imperial College London for analysis. This data file will include date of death, which is now a Civil Registration Data Item and no longer considered patient identifiable as an independent data item.
5. Imperial College London will use the unique audit identifier to link the pseudonymised data files with the NACAP children and young people's secondary care dataset
6. Once this process has been completed Imperial College London will transfer the national, country and service level aggregated data to The Royal College of Physicians for production of the reports and drafting of commentary.

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 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

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 from the IGT Team at NHS Digital of suitable security arrangements via Data Security and Protection Toolkit (DSPT) submission –
   Confirmed:
   - **Crown Informatics has a confirmed 'Standards Met' grade on DSPT submission 2019/20 by NHS Digital DSPT Tracker checked 12 October 2020**
   - **Aimes Management Services has a confirmed 'Standards Met' grade on DSPT submission 2019/20 by NHS Digital DSPT Tracker checked 12 October 2020**
   - **NHS Digital has a confirmed 'Standards Met' grade on DSPT submission 2018/19**
   - **NHS Wales Informatics Service, confirmed CPIP Assurance in place.**

b. ECC 3-04(o)/2011 - NHS Abdominal Aortic Aneurysm Screening Programme (NAAASP)

Name	Capacity
Dr Paul Mills	HRA Confidentiality Advice Service Manager

Context

Amendment request

This application, from Public Health England has support to allow confidential patient information to be shared between NHS Digital and Northgate Public Services to support the Abdominal Aortic Aneurysm Screening Programme activities.

This amendment requests support to allow for additional identifiers (mobile phone number, home phone number and email address) to be shared from NHS Digital (through the Personal Demographics Service). Using these forms of contact is anticipated to improve screening uptake.

The amendment also notifies the intention to also collect language preference and the need for the use of a translator. This letter acknowledges this notification.

Confidentiality Advisory Group advice

The amendment requested was considered by the Chair of the Confidentiality Advisory Group who was content with the amendment and justification provided.

Confidentiality Advisory Group conclusion

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

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. **The NHS Digital DSPT review for Northgate Public Service was confirmed as 'Standards Met' on the NHS Digital DSPT Tracker (checked 20 October 2020).**

   The NHS Digital DSPT review for Public Health England was confirmed as 'Standards Not Fully Met (Plan Agreed)' on the NHS Digital DSPT Tracker (checked 20 October 2020). Please note the updated specific condition of support. Public Health England should achieve the security assurance action plan as agreed with NHS Digital. All staff involved in processing information under this application reference should be aware of the precise scope of support and its boundaries and have successfully completed local security awareness training before processing any information under support.

c. 19/CAG/0167 - SEARCH trial legacy study: long-term follow-up of participants using electronic health records

Name	Capacity
Ms Kathleen Cassidy	HRA Confidentiality Advisor

Context

Amendment request

The applicants have existing support for the disclosure of trial IDs from University of Oxford to NHS Digital to facilitate linkage with standard administrative datasets, in order to undertake the long-term follow-up of patients who were previously recruited to the HPS2-THRIVE Trial. Support was originally given for the applicants to conduct the study in England, with appropriate support being sought from the appropriate bodies in Scotland and Northern Ireland for patients in these nations, and the applicant advised to submit an amendment to the CAG in order to bring the Welsh patients within the scope of support, once the data flows and linkage process with NHS Wales Informatics Service was established.

The applicants are now seeking to extend the scope of the existing Section 251 support to include Welsh data and Cancer Registration data including:

(a) Data from Welsh patients held by NHS Digital (both data provided historically and potential new data requests)

(b) Linkage with HES, from the equivalent Welsh providers e.g. NHS Wales Informatics Services (PEDW).

(c) Access to NHS Digital provided Cancer Registration data for analysis purposes (as well as the validation and linkage already covered by the current agreement)

(d) Linkage to cancer registration data from Public Health Wales and the SAIL databank (held by the Welsh Cancer Intelligence and Surveillance Unit (WCISU).

Confidentiality Advisory Group advice

The amendment requested was considered by the Confidentiality Advisory Group. The Group noted that the amendment had been submitted in response to a request made by the CAG following the original review and was satisfied that the changes were in the public interest.

Confidentiality Advisory Group conclusion

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

Specific conditions of support

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

    - **Confirmed: University of Oxford - Medical Sciences Division – Nuffield Department of Primary Care Health Sciences (EE133863-MSD-NDPCHS – NHSD Tracker 01/11/2019) and NHS Digital have confirmed 'Standards Met' grade on DSPT 2018/19.**

- **CPiP Confirmation from NHS Wales Informatics Service that the appropriate security assurance is in place for the NHS Wales Informatics Services via the Caldicott Principles into Practice report (Confirmed 15 June 2020)**

- **CPiP Confirmation from NHS Wales Informatics Service that the appropriate security assurance is in place for the Welsh Cancer Intelligence and Surveillance Unit via the Caldicott Principles into Practice report (Confirmed 09 November 2020)**

2. Confirmation of a favourable opinion from a Research Ethics Committee. **Confirmation provided on 06 August 2020 that the original Favourable Opinion issued by the REC included the activity described in this amendment.**

d. ECC 2-03(c)/2012 - National Paediatric Diabetes Audit (NPDA)

Name	Capacity
Ms Kathleen Cassidy	HRA Confidentiality Advisor

Context

Amendment request

The applicants have existing support for disclosures of confidential patient information from the National Paediatric Diabetes Audit (NPDA) between 2003/04 and 2015/16 to NHS Digital.

In this amendment, the applicants sought support to extend support in order to disclose the 2016/17, 2017/18, 2018/19 and 2019/20 NPDA datasets for Welsh patients to NHS Digital. This data will be held by NHS Digital and onboarded to NHS Digital's Data Access Request Services (DARS) within the linked NPDA/NDA dataset used to produce the transition audit. The dataset will be made accessible via DARS in order to maximise the availability of this data for wider service evaluation, subject to the usual DARS data access protocols and approvals.

NHS Digital have also been contracted to produce a report on young people with Type 2 diabetes in 2021. This will include an analysis of the total number of young people aged up to 25 years living with this condition in England and Wales. Linkage to the 2018/19 and 2019/20 NPDA datasets is required to complete this work, in order to support case ascertainment and to identify miscoded diagnoses within the NDA dataset.

Confidentiality Advisory Group advice

The amendment request was considered by the Confidentiality Advisory Group. Members noted that they had previously agreed to the basis of the Audit and had no objection to the planned linkage of the paediatric and adult audits.

The CAG noted that the patient notification materials required revision to provide an up-to-date explanation of the activity undertaken. Members also noted that it was difficult to find the privacy notice on the website of the NPDA and that it was unclear whether a similar notice was available for the National Diabetes Audit. It was also suggested in some places that patients were unable to opt-out of inclusion in the audit and the CAG noted that this was not in line with the support they had previously given.

The CAG agreed to recommend support for this amendment, with a condition that a new application was submitted within three months of the issuing of this letter. A number of amendments had been submitted over the years and the new application would need to ensure that the current scope of the audit was adequately explained. The support in place will lapse if a new application is not received within this time frame.

Confidentiality Advisory Group conclusion

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

Specific conditions of support

1. A new application is to be submitted within three months of the issuing of this outcome letter.

2. Confirmation provided from the IG Delivery Team at NHS Digital to the CAG that the relevant Data Security and Protection Toolkit (DSPT) submission(s) has achieved the 'Standards Met' threshold **(Confirmed – the Royal College of Paediatrics and Child Health has a confirmed 'Standards Met' grade on DSPT submission 2019/20 by check of the NHS Digital DSPT tracker on 10 November 2020).**

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

Name	Capacity
Ms Caroline Watchurst	HRA Confidentiality Advisor

Context

Amendment request

This study from University College London investigates the impact of environment and socio-economic factors on hospital admissions in children. The project uses an established birth cohort of infants born in England between 2005 and 2014. This is linked by the Office of National Statistics (ONS) to 2011 Census Data and small area level data on air pollution and building characteristics in order to create a dataset to facilitate analysis.

The applicants have existing support to process confidential patient information related to a birth cohort, previously collated under applications PIAG 2-10(g)/2005 and CAG 9-08(b)2014, through the ONS Secure Research Service (SRS). Since applicants have accessed the dataset, it has come to their attention that the research team have access to the full postcodes at delivery/birth for mothers and children. Applicants expected only to have access to lower super output areas (LSOAs), but can only access the full postcode.

This amendment is seeking support to link the postcodes to LSOAs, before ONS restricting researcher access to full postcode. ONS SRS team have been approached regarding this and will ensure the researchers are able to link to LSOA. This will be performed at ONS SRS, and no identifiable information will leave ONS SRS. Additionally no further flows of identifiable data will be necessary. Researchers require access to LSOA in order to assign area-level deprivation scores to the mothers and babies, and examine how paediatric hospital admission rates vary by local areas across England.

The applicants have amended the text on the study website to ensure the changes are clear to the public.

The applicant has also notified us of a new study protocol, with the only change being that two of the named collaborators are no longer working on the project.

Confidentiality Advice Team advice

The amendment requested was considered by the Confidentiality Advice Team. The Team agreed with the justifications provided.

Confidentiality Advice Team conclusion

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

Specific conditions of support

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

   Confirmed: the Office for National Statistics has confirmed 'Standards Met' grade on DSPT submission 2019/20 (by check of the NHS Digital DSPT tracker on 07 October 2020) **and NHS Digital has confirmed the equivalent of 'Standards Met' grade on DSPT submission 2018/19** (by check of the NHS Digital DSPT tracker on 07 October 2020)**.**

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

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

Name	Capacity
Ms Caroline Watchurst	HRA Confidentiality Advisor

Context

Amendment request

This research study from the University of Cambridge investigates the role of inherited genetic variation in breast cancer risk and clinical outcomes. The study already has support to allow the disclosure of confidential patient information from the study team at University of Cambridge to Public Health England (PHE), for linkage of the breast SEARCH database to National Cancer Registration and Analysis Service (NCRAS) data. Hospital Episode Statistics (HES) and Electronic Health Record (EHR) data are included as part of NCRAS data held by PHE. This is for patients who have consented in the past for the study, but were not able to consent specifically for the linkages as the methodology was not known about at the time of consent.

This amendment request is to additionally link the data that is already sent to PHE to National SARS-CoV2 testing data. This is in order to identify currently unknown predisposing factors affecting the response of cancer survivors to SARS-CoV-2, and which might influence long term morbidity and mortality. The applicant plans to follow up for a minimum of 5 years, until the end of September 2025, in the first instance. PHE has approved this in principal, however this is dependant upon CAG support.

The SEARCH study website will be updated with details of the proposed linkage in order to notify the patients involved. The CAG considered this adequate for the colorectal and Multi arms of the study, with a condition to make the website text more clear. This condition has therefore also been applied to this amendment regarding the breast arm of the SEARCH study.

Confidentiality Advice Team advice

The amendment requested was considered by the Confidentiality Advice Team due to the subject of the amendment being considered by a precedent set subcommittee (CAG ref **20/CAG/0125** and **20/CAG/0126**). The CAT were supportive of this amendment request, and

applied the same condition of support regarding the updated web text which is required to be provided.

Confidentiality Advice Team conclusion

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

Specific conditions of support

1. Applicants are required to provide to the CAG Sub-committee updated information to go on the website, which makes it clear what information is being linked, why, and how to raise objections, within one month from the date of this letter.

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

   Confirmed:

   The **2018/19** NHS Digital DSPT review for - **University of Cambridge (School of Clinical Medicine) (**8F331) was confirmed as 'Standards Met' on the NHS Digital DSPT Tracker (checked 12 October 2020). (DSPT 2019/20 published but not yet reviewed).

   The NHS Digital **2018/19** DSPT review for **National Cancer Registration and Analytical Services (Public Health England) (X25)** was confirmed as '**Qualified Assurance – Trust has not achieved 95% staff undertaking data security awareness training'** on the NHS Digital DSPT Tracker (checked 12 October 2020). Please note the updated specific condition of support below. (DSPT 2019/20 not yet published)

   All staff at **National Cancer Registration and Analytical Services (Public Health England) (X25)** that are involved in processing information under this application reference should have successfully completed local data security awareness training before processing any information under support.

3. Confirmation of a favourable opinion from a Research Ethics Committee.
   Confirmed 27 July 2020

g. 19/CAG/0097 - A population based study of genetic predisposition to ovarian cancer: SEARCH Ovarian

Name	Capacity
Ms Caroline Watchurst	HRA Confidentiality Advisor

Context

Amendment request

This research study from the University of Cambridge investigates the role of inherited genetic variation in ovarian cancer risk and clinical outcomes. The study already has support to allow the disclosure of confidential patient information from the study team at University of Cambridge to Public Health England (PHE), for linkage of the ovarian SEARCH database to National Cancer Registration and Analysis Service (NCRAS) data. Hospital Episode Statistics (HES) and Electronic Health Record (EHR) data are included as part of NCRAS data held by PHE. This is for patients who have consented in the past for the study, but were not able to consent specifically for the linkages as the methodology was not known about at the time of consent.

This amendment request is to additionally link the data that is already sent to PHE to National SARS-CoV2 testing data. This is in order to identify currently unknown predisposing factors affecting the response of cancer survivors to SARS-CoV-2, and which might influence long term morbidity and mortality. The applicant plans to follow up for a minimum of 5 years, until the end of September 2025, in the first instance. PHE has approved this in principal, however this is dependant upon CAG support.

The SEARCH study website will be updated with details of the proposed linkage in order to notify the patients involved. The CAG considered this adequate for the colorectal and Multi arms of the study, with a condition to make the website text more clear. This condition has therefore also been applied to this amendment regarding the ovarian arm of the SEARCH study.

Confidentiality Advice Team advice

The amendment requested was considered by the Confidentiality Advice Team due to the subject of the amendment being considered by a precedent set subcommittee (CAG ref **20/CAG/0125** and **20/CAG/0126**). The CAT were supportive of this amendment request, and

applied the same condition of support regarding the updated web text which is required to be provided.

Confidentiality Advice Team conclusion

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

Specific conditions of support

1. Applicants are required to provide to the CAG Sub-committee updated information to go on the website, which makes it clear what information is being linked, why, and how to raise objections, within one month from the date of this letter.

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

   Confirmed:

   The **2018/19** NHS Digital DSPT review for - **University of Cambridge (School of Clinical Medicine) (**8F331) was confirmed as 'Standards Met' on the NHS Digital DSPT Tracker (checked 12 October 2020). (DSPT 2019/20 published but not yet reviewed).

   The NHS Digital **2018/19** DSPT review for **National Cancer Registration and Analytical Services (Public Health England) (X25)** was confirmed as '**Qualified Assurance – Trust has not achieved 95% staff undertaking data security awareness training'** on the NHS Digital DSPT Tracker (checked 12 October 2020). Please note the updated specific condition of support below. (DSPT 2019/20 not yet published)

   All staff at **National Cancer Registration and Analytical Services (Public Health England) (X25)** that are involved in processing information under this application reference should have successfully completed local data security awareness training before processing any information under support.

3. Confirmation of a favourable opinion from a Research Ethics Committee.
   Confirmed 18 August 2020

h. 17/CAG/0098 - Population based study of genetic predisposition to endometrial cancer: SEARCH Endometrial

Name	Capacity
Ms Caroline Watchurst	HRA Confidentiality Advisor

Context

Amendment request

This research study from the University of Cambridge investigates the role of inherited genetic variation in endometrial cancer risk and clinical outcomes. The study already has support to allow the disclosure of confidential patient information from the study team at University of Cambridge to Public Health England (PHE), for linkage of the endometrial SEARCH database to National Cancer Registration and Analysis Service (NCRAS) data. Hospital Episode Statistics (HES) and Electronic Health Record (EHR) data are included as part of NCRAS data held by PHE. This is for patients who have consented in the past for the study, but were not able to consent specifically for the linkages as the methodology was not known about at the time of consent.

This amendment request is to additionally link the data that is already sent to PHE to National SARS-CoV2 testing data. This is in order to identify currently unknown predisposing factors affecting the response of cancer survivors to SARS-CoV-2, and which might influence long term morbidity and mortality. The applicant plans to follow up for a minimum of 5 years, until the end of September 2025, in the first instance. PHE has approved this in principal, however this is dependant upon CAG support.

The SEARCH study website will be updated with details of the proposed linkage in order to notify the patients involved. The CAG considered this adequate for the colorectal and Multi arms of the study, with a condition to make the website text more clear. This condition has therefore also been applied to this amendment regarding the endometrial arm of the SEARCH study.

Confidentiality Advice Team advice

The amendment requested was considered by the Confidentiality Advice Team due to the subject of the amendment being considered by a precedent set subcommittee (CAG ref

20/CAG/0125 and **20/CAG/0126**). The CAT were supportive of this amendment request, and applied the same condition of support regarding the updated web text which is required to be provided.

Confidentiality Advice Team conclusion

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

Specific conditions of support

1. Applicants are required to provide to the CAG Sub-committee updated information to go on the website, which makes it clear what information is being linked, why, and how to raise objections, within one month from the date of this letter.

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

   Confirmed:

   The **2018/19** NHS Digital DSPT review for - **University of Cambridge (School of Clinical Medicine) (**8F331) was confirmed as 'Standards Met' on the NHS Digital DSPT Tracker (checked 12 October 2020). (DSPT 2019/20 published but not yet reviewed).

   The NHS Digital **2018/19** DSPT review for **National Cancer Registration and Analytical Services (Public Health England) (X25)** was confirmed as '**Qualified Assurance – Trust has not achieved 95% staff undertaking data security awareness training'** on the NHS Digital DSPT Tracker (checked 12 October 2020. Please note the updated specific condition of support below. (DSPT 2019/20 not yet published)

   All staff at **National Cancer Registration and Analytical Services (Public Health England) (X25)** that are involved in processing information under this application reference should have successfully completed local data security awareness training before processing any information under support.

3. Confirmation of a favourable opinion from a Research Ethics Committee.
   Confirmed 18 August 2020

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

Name	Capacity
Ms Caroline Watchurst	HRA Confidentiality Advisor

Context

Amendment request

This research study from the University of Cambridge investigates the role of inherited genetic variation in prostate cancer risk and clinical outcomes. The study already has support to allow the disclosure of confidential patient information from the study team at University of Cambridge to Public Health England (PHE), for linkage of the prostate SEARCH database to National Cancer Registration and Analysis Service (NCRAS) data. Hospital Episode Statistics (HES) and Electronic Health Record (EHR) data are included as part of NCRAS data held by PHE. This is for patients who have consented in the past for the study, but were not able to consent specifically for the linkages as the methodology was not known about at the time of consent.

This amendment request is to additionally link the data that is already sent to PHE to National SARS-CoV2 testing data. This is in order to identify currently unknown predisposing factors affecting the response of cancer survivors to SARS-CoV-2, and which might influence long term morbidity and mortality. The applicant plans to follow up for a minimum of 5 years, until the end of September 2025, in the first instance. PHE has approved this in principal, however this is dependant upon CAG support.

The SEARCH study website will be updated with details of the proposed linkage in order to notify the patients involved. The CAG considered this adequate for the colorectal and Multi arms of the study, with a condition to make the website text more clear. This condition has therefore also been applied to this amendment regarding the prostate arm of the SEARCH study.

Confidentiality Advice Team advice

The amendment requested was considered by the Confidentiality Advice Team due to the subject of the amendment being considered by a precedent set subcommittee (CAG ref

20/CAG/0125 and **20/CAG/0126**). The CAT were supportive of this amendment request, and applied the same condition of support regarding the updated web text which is required to be provided.

Confidentiality Advice Team conclusion

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

Specific conditions of support

1. Applicants are required to provide to the CAG Sub-committee updated information to go on the website, which makes it clear what information is being linked, why, and how to raise objections, within one month from the date of this letter.

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

   Confirmed:

   The **2018/19** NHS Digital DSPT review for - **University of Cambridge (School of Clinical Medicine) (**8F331) was confirmed as 'Standards Met' on the NHS Digital DSPT Tracker (checked 12 October 2020). (DSPT 2019/20 published but not yet reviewed).

   The NHS Digital **2018/19** DSPT review for **National Cancer Registration and Analytical Services (Public Health England) (X25)** was confirmed as '**Qualified Assurance – Trust has not achieved 95% staff undertaking data security awareness training'** on the NHS Digital DSPT Tracker (checked 12 October 2020. Please note the updated specific condition of support below. (DSPT 2019/20 not yet published)

   All staff at **National Cancer Registration and Analytical Services (Public Health England) (X25)** that are involved in processing information under this application reference should have successfully completed local data security awareness training before processing any information under support.

3. Confirmation of a favourable opinion from a Research Ethics Committee.
   Confirmed 18 August 2020

j. CAG 8-03(PR11)/2013 (previously ECC 3-04(s)/2011) – Hip Fracture Audit

Name	Capacity
Ms Kathleen Cassidy	HRA Confidentiality Advisor

Context

Amendment request

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

Updated data collection will begin in January 2021. In this amendment, the applicants seek support to reduce the dataset for NAIF, and to include an audit of both falls prevention activity prior to the hip or femoral fracture and the immediate post-fall care. This data will continue to be a subsidiary dataset to the NHFD. The phase 2 dataset will include 29 questions in total, 3 new questions and 26 carried forward from the 2020 dataset. To reduce the burden of data, the dataset has been condensed, with 14 of the questions asked in 2020 removed.

The number of such fractures that occur in inpatient settings is relatively low, and the proposed changes have been made in order to collect more detailed information on femoral fractures. Participating sites will be encouraged to use their own patient level data to undertake case reviews and learning events. A pilot data collection template has been created for sites to use to record their learning from patient falls which result in hip fractures (the Learning from Inpatient Femoral Fracture (IFF) Pilot). The dataset collection questions will be reviewed at the end of 2021 by the multidisciplinary advisory group for NAIF and a further amendment will be submitted, if needed.

Confidentiality Advisory Group advice

The amendment requested was considered by the Confidentiality Advisory Group. The CAG reviewed the information provided and was satisfied that the activity described was in the public interest.

Confidentiality Advisory Group conclusion

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

Specific conditions of support

1. Confirmation of suitable security arrangements via Data Security and Protection Toolkit submission. **(Confirmed: The Royal College of Physicians of London, the University of Oxford – Nuffield Department of Orthopaedics, Rheumatology and Musculoskeletal Sciences, Big Health Data Group and Crown Informatics Ltd, have confirmed 'Standards Met' grade on DSPT 2019/20, by check of the NHS Digital DSPT tracker on 09 November 2020).**

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

Name	Capacity
Ms Caroline Watchurst	HRA Confidentiality Advisor

Context

Amendment request

The applicants have existing support to allow research nurses on site at participating trusts to access confidential patient information held in the medical records of deceased patients in order to extract a linked-pseudonymised dataset for analysis. 33 trusts were included in the original application.

In this amendment, the applicants sought support to include South Tees Hospital NHS Trust and 2 hospitals at University Hospitals of Derby and Burton NHS Foundation Trust (Royal Hospital Derby and Queen's Hospital) as additional data processors. It was necessary to include the additional sites so that the applicants can reach their recruitment target.

Confidentiality Advice Team advice

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

Confidentiality Advice Team conclusion

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

Specific conditions of support

1. Confirmation provided from the IG Delivery Team at NHS Digital to the CAG that the relevant Data Security and Protection Toolkit (DSPT) submission(s) has achieved the 'Standards Met' threshold: **Confirmed:**
    - **Leeds Teaching Hospitals NHS Foundation Trust** (by check of the DSPT tracker on 11/11/2020**) has confirmed 'Standards Met' grade on DSPT submission 2018/19. The 19/20 DSPT is currently being reviewed by NHS Digital.**
    - **South Tees Hospital NHS Trust** (RTR) (by check of the DSPT tracker on 11/11/2020**) has confirmed 'Standards Met' grade on DSPT submission 2018/19. The 19/20 DSPT is currently being reviewed by NHS Digital.**

- **University Hospitals of Derby and Burton NHS Foundation Trust** (RTG) (by check of the DSPT tracker on 11/11/2020**) has confirmed 'Standards Met' grade on DSPT submission 2018/19. The 19/20 DSPT does not appear to be submitted or reviewed.**
- **Original additional 33 NHS trusts not checked due to the number of sites which will be processing with support under the Regulations. Support is recommended on the basis that the applicant ensures the required security standards are in place at each site prior to any processing of confidential patient information with section 251 support**

2. Confirmation of a favourable opinion from a Research Ethics Committee
   Confirmed non substantial 2 September 2020 and 26 October 2020 by email

3. Annual Review Approvals

CAG Reference	Application Title
17/CAG/0156	Rectal Cancer Oncological Complete Response Database (OnCoRe)
15/CAG/0143	National Prostate Cancer Audit (NPCA) Patient Reported Outcome Measures (PROMs) and Patient Reported Experience Measures (PREMs)
ECC 5-07(b)/2009	Prescription-Event Monitoring
15/CAG/0158	Fracture Liaison Service Database
16/CAG/0015	Evaluating variation in special educational needs provision for children with Down syndrome and associations with emergency use of hospital care.
16/CAG/0043	British Association of Dermatologists Biologic Interventions Register (BADBIR)
18/CAG/0146	National Joint Registry
18/CAG/0175	Do Invasive Dental Procedures Cause Prosthetic Joint Infections (PJI)? - The PJI Study
CR4/2014	Asbestos Workers Survey
15/CAG/0148	Improving Care in the NHS
CAG 8-03(PR9)/2013	National Prostate Cancer Audit
18/CAG/0171	Epidemiological studies of the Porton Down veterans
CAG 5-07(d)/2013	National Emergency Laparotomy Audit
19/CAG/0115	Suspected Stroke Clinical and radiological data base (SSCRaD)
19/CAG/0102	2019 NHS Adult Inpatient Survey – Mixed Methods Standalone Pilot
16/CAG/0153	The UK Renal Registry
ECC 7-04(j)/2010	Long term risks of paediatric fluoroscopic cardiology
CAG 8-03(PR11)/2013	Hip Fracture Audit
17/CAG/0023	National Bariatric Surgery Registry (NBSR)

PIAG 4-08(b)/2003	National Confidential Enquiry into Patient Outcome and Deaths (NCEPOD)
19/CAG/0146	The TIGHT-K STUDY. Dysrhythmias on the cardiac intensive care unit - does maintenance of high-normal serum potassium levels matter?
19/CAG/0206	2020 Community Mental Health Survey
ECC 7-05(c)/2011	A prospective UK Population-based study of incidence, biology, treatment and outcomes of Non-Hodgkin Lymphoma in Young Adults
18/CAG/0180	LAUNCHES QI: Linking AUdit and National datasets in Congenital HEart Services for Quality Improvement
19/CAG/0180	CQC 2019/20 Children and Young People's Patient Experience Survey – Mixed Method Standalone Pilot
15/CAG/0139	Life course pathways to ageing in the MRC National Survey of Health and Development
18/CAG/0153	The POOL study: Establishing the safety of waterbirth for mothers and babies: A cohort study with nested qualitative component
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
19/CAG/0166	HPS2-THRIVE trial legacy study: long-term follow-up of participants using electronic health records
19/CAG/0167	SEARCH trial legacy study: long-term follow-up of participants using electronic health records
14/CAG/1032	Association between IQ and self harm
15/CAG/0175	Early life causes of depression and anxiety
15/CAG/0176	Predictors, prevalence and impact of chlamydia
15/CAG/0177	Substance use and mental health
CAG 7-06(a)/2013	Accuracy of estimates for self harm
ECC 7-05(g)/2011	The Trauma and Audit Research Network (TARN)
ECC 8-02(FT5)/2010	SABRE Study: Ethnic Differences in Cardiometabolic Risk
15/CAG/0177	Substance use and mental health

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

Signed – Chair	Date
Signed – Confidentiality Advice Team	Date