Health Research Authority

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

September 2021

1. New Applications

a. 21/CAG/0071 (resub 20/CAG/0146) - Congenital Hypothyroidism with Gland in Situ: establishing risk factors and outcomes using population-based data linkage methods

Name	Capacity
Dr Martin Andrew	CAG member
Dr William Bernal	CAG alternative vice-chair
Ms Sophie Brannan	CAG member
Mr David Evans	CAG member
Professor Jennifer Kurinczuk	CAG member
Dr Harvey Marcovitch	CAG member
Mr Andrew Melville	CAG member
Ms Diana Robbins	CAG member
Mr Umar Sabat	CAG member

Dr Murat Soncul	CAG alternative vice-chair
Ms Caroline Watchurst	HRA Confidentiality Advisor
Dr Paul Mills	HRA Confidentiality Advice Service Manager

Context

Purpose of application

This application from UCL Great Ormond Street Institute of Child Health sets out the purpose of medical research that aims to determine why more babies are being diagnosed with congenital hypothyroidism with gland in situ (CH-GIS), and what health and development is like for children living with this condition. Applicants propose to link routine clinical and education data, and compare between children with CH-GIS, children with other forms of congenital hypothyroidism (CH), and unaffected children. Once linkage is complete, only pseudonymised data will be stored and analysed.

All children in the UK are offered screening for rare conditions at five days of age, one of which is CH, which without early detection and treatment can result in severe learning disability. Since the introduction of newborn screening 40 years ago, there has been an increase in the proportion of babies born with CH, particularly a type called CH-GIS. It is not clear why CH-GIS is becoming more common, or how it affects health, development and learning as children grow up. Study results will help inform parents and children about the health and education consequences of congenital CH-GIS, and clinicians about which treatment regimen is best for children's health and development. The results will also advise public health professionals about CH-GIS, and how it can be prevented.

The applicants are proposing two study designs within this application. A cohort study to investigate a change in the birth prevalence of CH and CH-GIS, which will link data for all children screened for a number of inborn conditions at the GOSH newborn screening laboratory between 1 January 2000 and 31 December 2020 (approximately 2.2 million children) (the GOSH NBS database) to the GOSH clinical database of diagnostic and treatment information for all children who screen positive for CH (the GOSH CH database). The applicants also plan to link the mothers to their children to indicate which babies are siblings in order to examine familial clustering of newborn TSH screening results. This dataset will be linked by NHS Digital to the Office for National Statistics (ONS) birth and deaths registration data.

The second study design is a case-control design which will link approximately 1800 children diagnosed with CH-GIS (from the GOSH CH database), will be linked by NHS Digital to Hospital Episode Statistics (HES), National Child Measurement Programme (NCMP), NHS Business Services Authority (NHSBSA) community dispensing data, and the National Pupil Database (NPD). Applicants will compare children's height and weight distribution as well as patterns of medicine dispensing in children with CH or CH-GIS compared to all children using aggregate data from NCMP and the NHSBSA dispensing database. Applicants will request these aggregate datasets from NHS Digital, for which support is not required. 15 controls per case will be selected from the HES part of the pseudonymous ECHILD database, matched on sex, month and year of birth and local authority, for which support is not required.

HES and NPD data are already linked for the ECHILD study and a pseudonymised version is held in the UCL Data Safe Haven (DSH), which applicants will be able to access with the pseudonymous HES-NPD linkage key provided by NHS Digital. NHS Digital will also provide the applicant with linked ONS data (to the whole NBS cohort), which will have all identifying information removed apart from the date of death, and the NBS identifier. NHS Digital will provide the applicant will a pseudonymous linked CH dataset, linked to NCMP and NHSBSA data.

GOSH link the datasets received from NHS Digital back to the NBS and CH linked dataset, modify the postcode to LSOA, and send the dataset to UCL Data Safe Haven for analysis. This flow also requires support as the date of birth and date of death will be contained in this file. UCL staff extract HES records (from the HES part of the linked-NPD-HES data) for children in CH database using the pseudonymised HES-NPD linkage key provided.

All the datasets will be pseudonymised for analysis. This will involve date of birth and date of death being modified to be less disclosive, and this will be performed within the UCL DSH by the named researcher. Full date of birth and full date of death will then be deleted.

The linked health data will be held in UCL's Data Safe Haven. Selected pseudonymous clinical variables from the linked health data will be securely transferred to the ONS SRS. The cohort will then be linked to the NPD part of the linked HES-NPD ECHILD data. The education outcomes will be analysed in the ONS SRS, according to DfE regulations.

The linkages are also below;

1. GOSH link two internal databases (NBS & CH) which will contain NBS cohort identifier
2. GOSH send identifiers, plus NBS cohort identifier to NHSD
3. NHSD link NBS data to ONS births and deaths registration data

4. NHSD link CH data only to NCMP data and NHSBSA data, and provide a HES-NPD ECHILD linkage key
5. Linked data sent back to GOSH, support required due to date of death, and GSH link to NBS-CH linked database using NBS cohort identifier
6. GOSH send linked dataset containing clinical information and date of birth and date of death, alongside NBS Cohort ID to UCL safehaven
7. UCL safehaven undertakes linkage from CH dataset to HES part of the linked NPD-HES data, using HES-NPD ECHILD linkage key.
8. Identifiers removed from dataset and deleted once in UCL DSH
9. Selected variables sent from UCL DSH to ONS SRS for analysis, and dataset linked to NPD part of the linked NPD-HES ECHILD data, using HES-NPD ECHILD linkage key.
10. Analysis undertaken in both ONS-SRS and UCL-DSH

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

Confidential patient information requested

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

Cohort	All babies born in the North Thames region (including North London, Bedfordshire, Hertfordshire and Essex), whose newborn screening blood spot sample was tested at the Great Ormond Street Hospital (GOSH) newborn screening laboratory between 1 January 2000 and 31 December 2020 (approximately 2.2 million children) This will include approximately 1800 children with congenital hypothyroidism in the GOSH CH database. age limit: 0 - 20 Years The childrens mothers will also be included, however this will be less than 2.2 million mothers as some children will have the same mother

	Population based study: all 2.2 million Case-control study: 1800
Data sources	1. **Great Ormond Street Hospital for Children NHS Foundation Trust**: a. North Thames Newborn blood spot screening database– held at GOSH (GOSH NBS database). (**legal basis =Clinical database**) b. GOSH Congenital Hypothyroidism (CH) Database – held at GOSH (GOSH CH database). (**legal basis = Clinical database)** 2. **NHS Digital**: a. Hospital Episode Statistics (HES), Admitted Patient Care (HES-APC), Accident & Emergency/Emergency Care Dataset (HES A&E), Outpatient Data (HES-OPD): Note, HES records for both mother and baby will be linked and analysed for this study. linkage key for NPD-HES data obtained via NHS Digital, (the data controller), however the pseudonymous HES ECHILD database is retained in the UCL DSH b. Office of National Statistics Birth and Deaths registration data (ONS) (held by NHS Digital) c. National Child Measurement Programme (NCMP, held by NHS Digital; height and weight of primary school children at 4-5yr and 10-11yr) (**legal basis = nationally mandated**) d. NHS Business Service Authority (NHSBSA) community dispensing data (held by NHS Digital) 3. **Department for Education (DfE):** a. National Pupil Database (NPD), information on school performance and special educational needs) (**has alternate legal basis – not defined as confidential patient information**) – linkage key for NPD-HES data obtained via NHS Digital, DfE is the data controller for this dataset, however the pseudonymous NPD ECHILD database is retained in the ONS SRS

Identifiers required for linkage purposes	1. Name 2. NHS number (of child) 3. Mothers NHS number 4. Hospital ID 5. Date of Birth 6. Date of Death 7. Postcode (Unit level) 8. Postcode histories 9. NBS Cohort identifier
Identifiers required for analysis purposes	No identifiers which have not been modified are required for analysis: identifiers will be deleted once they are modified. 1. Date of Birth - modified to analysis variable such as week of birth. This will be done by named researcher at UCL DSH 2. Date of Death - modified to month and year of death. Follow-up time from birth in days will also be calculated. This will be done by named researcher at UCL DSH 3. Post code (unit level) - used to map to Lower Super Output Areas. This will be done by the GOSH DRE team. 'Researchers' will not have access to full postcodes. 4. Gender 5. Ethnicity 6. Parent's country of birth, 7. Parent's occupation 8. NBS Cohort identifier 9. HES-NPD linkage key
Additional information	Linked health data is stored in the UCL Data safe haven. The linked NPD data will be kept in the ONS Secure Research Service.

Confidentiality Advisory Group advice

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

1. **Please provide the REC favourable opinion of the amendment when this is available (see standard condition of support below).**

This was provided on 24th June 2021.

2. **Please provide evidence of NHS Digital review of the 19/20 DSPT for Great Ormond Street Hospital for Children NHS Foundation Trust (see standard condition of support below).**

The 20/21 DSPT review was provided to the CAG by NHS Digital on 18th August, however this was now after the switchover date. The additional security assurances were confirmed to be in place on 3rd September by email to the CAG inbox.

Confidentiality Advisory Group advice conclusion

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

Specific conditions of support

The following sets out the specific conditions of support.

1. Please provide feedback at the time of the first annual review around the planned communication activities undertaken.

2. Please provide a lay explanation of hypothyroidism at the start of the notification materials, and provide an updated version to CAG, within one month from the date of this letter.

3. Please provide feedback surrounding further patient and public involvement undertaken with healthy mothers, to ensure the acceptability of using their confidential patient information without consent, within six months from the date of this letter.

4. Favourable opinion from a Research Ethics Committee **Confirmed 24 June 2021**

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

   The NHS Digital **20/21** DSPT reviews for **University College London – School of Life and Medical Sciences (**EE133902-SLMS), **Office for National Statistics** (**ONS SRS)** (XDC), **Great Ormond Street Hospital for Children NHS Foundation Trust** (RP4) and **NHS Digital** (X26) were confirmed as 'Standards Met' on the NHS Digital DSPT Tracker (checked 07 September 2021)

b. 21/CAG/0088 - Barts Structural Interventional Registry (BSIR)

Name	**Capacity**
Professor William Bernal	CAG alternative vice-chair
Mr David Evans	CAG member
Professor Lorna Fraser	CAG member
Mr. Myer Glickman OBE	CAG member
Dr Katie Harron	CAG member
Dr Pauline Lyseight-Jones	CAG member
Dr Harvey Marcovitch	CAG member
Ms Rose Payne	CAG member
Professor Sara Randall	CAG member
Ms Diana Robbins	CAG member
Mr Umar Sabat	CAG member
Dr Murat Soncul	CAG alternative vice-chair

Dr Paul Mills	HRA Confidentiality Advice Service Manager
Ms Caroline Watchurst	HRA Confidentiality Advisor

Context

Purpose of application

This application, from Barts Health NHS Trust, aims to undertake medical research to understand the characteristics and outcomes in patients with valvular heart disease (VHD).

VHD is defined as any alteration to the normal structure and/or function of the heart valves and is often caused by a combination of cardiac and often non-cardiac factors. It is often caused by a number of diseases rather than a single one and often several valve diseases coexist in the same patient. Much research has been undertaken within strict conditions, but the real-world efficacy is not known for some sub-populations. The database will be used to test several hypothesis including but not limited to investigating characteristics of patients treated, complications of interventional and medical treatment, outcomes of patients and highlight structural and fluid-dynamics performance. This research will add substantially to the literature by providing real-world data from a leading valvular interventional centre.

Barts will send NHS Digital identifiers of the eligible cohort, in order to link to central datasets. This data, including date of death, will be returned to Barts and linked back to clinical information. Data that is subsequently required for research purposes under the terms of this support will be extracted by the clinical team, pseudonymised and provided to the research team for research purposes. Pseudonymisation will be achieved by assigning each patient with a study ID. A file will be created linking the study ID to the identifiable data. This file will be held by the CI on a Barts Health NHS server under password protection. Any data that is used for research purposes will only contain the study ID. This data will not have patient name, date of birth, postcode or NHS number. The application also explains how a data access committee will approve all uses of data required from NHS Digital, however after clarification from the REC, this application is for a specific study only, rather than a research database, and as such, any further uses of this data will require a further application.

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	Any patient >16 years old with VHD referred to Barts Health NHS Trust from 01/01/2015 until present (Retrospective patients only included)
Data sources	1. Barts Health NHS Trust clinical data; (PACS, CRS, patient notes) 2. NHS digital; a. The office for national statistics (ONS) Mortality dataset b. Health episodes statistics (HES) c. Electronic Prescription Service d. Patient Related Outcome Measures (PROMS)
Identifiers required for linkage purposes	1. Name 2. Date of birth 3. Postcode 4. NHS number 5. Study ID
Identifiers required for analysis purposes	1. Study ID 2. Age 3. Date of admission 4. Date of intervention 5. Date of discharge 6. Date of death (this will be modified for analysis) 7. Gender
Additional information	Annual extracts will be undertaken, but only for the retrospective patients.

Confidentiality Advisory Group advice

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

1. **Please confirm that this activity cannot be undertaken by using any datasets held by NICOR, and therefore justify the public interest in this activity.**

The applicant provided a response which explains the application focuses on areas of valvular heart disease (VHD) that have not been addressed by previous studies and the main clinical trials. The NICOR database, whilst large and contains valuable datapoints, does not fulfil the current gaps in the literature for VHD. This is further explained in the response letter, and the CAG were content with the response.

2. **Please confirm the specific research question or questions which this activity is proposing to answer.**

The applicant provided some specific research questions including **'***Identify predictors of mortality, hospitalisation and deterioration in quality of life in medically managed patients', 'patients with multiple valvular pathologies',* and *'Identify predictors of mortality and hospitalisation in patients with mitraclip edge-to-edge repair'.* More detail is provided in the response letter to the CAG, and the members were content with this response.

3. **Please provide further justification for consent not being practicable, in the context of originally proposing it would be feasible.**

The applicant has confirmed there has been a misunderstanding. In the CAG form, section 15-3; 'What changes have you made to your study as a result of your service user involvement?' the applicant responded: '*Following the results of the survey, we have removed the requirement for patient consent for access to their clinical data from the study protocol.*' However the applicant has now explained that they did not believe consenting patients was feasible prior to the survey. A more appropriate explanation would be that the results of the survey supported the proposal to obtain data from NHS digital without prior consent from patients. From the conception of this study the applicants knew that obtaining consent would not be feasible. The Sub-Committee were content with this response.

4. **Please consider if full date of death can be modified for analysis, and deleted, to remove the need for continued support under Regulation 5.**

The applicant explained that date of death can be modified before providing it to any research team members (outside of the direct care team) for analysis. However full date of death will still be retained by the applicants as without the full date of death, they will be unable to accurately assess the safety and efficacy of various treatments at various time points, especially as some procedures are associated with mortality within hours to days. Ongoing support will therefore be required for retention of date of death. The CAG were content with this response.

5. **Please confirm where 'quality of life data' and 'medication data' is proposed to be collected from, to evidence that the data required to undertake the study is actually available to use in order to answer the proposed research question.**

Medication data is obtained via NHS digital from the Electronic Prescription Service. Quality of life outcomes data can be obtained from NHS Digital through Patient Related Outcome Measures (PROMS). PROMS data is collected for patients, post-intervention or surgery, so applicants will acquire this data for patients who have undergone a valve replacement. The Committee were content with this response although noted that the data sources were in addition to HES and ONS mortality data originally requested The support letter has been updated accordingly.

6. **Please confirm if the cohort is for retrospective patients only, from 1 January 2015, until the date support is provided.**

The applicant confirmed this and the CAG were content with this response.

7. **Study specific patient notification should be developed and provided to the CAG.**

The applicants have provided a poster that will be put up in all clinical areas that patients with VHD will be encountered. This describes the rationale, objectives and methodology of the research. It also provides patients with a contact so that they can get more information or opt-out of research if they wish to. The Committee was broadly content with the content of the poster, but considered that it should contain more information about the research questions being addressed and the datasets that will be accessed. They did not wish to delay the research activity from starting, however a condition has been applied for annual review.

8. **A study specific opt out option should be developed.**

As explained above, the applicant has developed posters, and these posters will be placed in the valve wards, clinics and imaging departments to enable people to opt out if they wish. The CAG were content with this response.

9. **Please undertake study specific patient and public involvement surrounding the specific activity requested in this application, focussing on the use of confidential patient information without consent**.

The applicants have provided the survey and corresponding results from a new study-specific patient and public involvement survey. Overall the survey confirms that patients are agreeable for the applicants to use their clinical data and obtain data from NHS digital without their prior consent. The Members were content with this response.

Confidentiality Advisory Group advice conclusion

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

Specific conditions of support

The following sets out the specific conditions of support.

1. An updated patient notification poster should be provided at the time of first annual review, which contains more information about the research questions being addressed and the datasets that will be accessed.

2. Favourable opinion from a Research Ethics Committee. **Confirmed 17 June 2021**

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

   The NHS Digital **20/21** DSPT review for **Barts Health NHS Trust** and **NHS Digital** were confirmed as '**Standards Met'** on the NHS Digital DSPT Tracker (checked 07 September 2021).

c. 21/CAG/0099 - Governing parental opioid use: a relational ethnography. Short title: The Relations Study_v1.0

Name	Capacity
Dr Martin Andrew	CAG member
Ms Sophie Brannan	CAG member
Dr Liliane Field	CAG member
Professor Lorna Fraser	CAG member
Mr Myer Glickman OBE	CAG member
Dr Pauline Lyseight-Jones	CAG member
Mr Dan Roulstone	CAG member
Mr Umar Sabat	CAG member
Ms Caroline Watchurst	HRA Confidentiality Advisor

Context

Purpose of application

This application from University of Stirling sets out the purpose of medical research that aims to better understand the treatment and care of parents who use drugs and their families, including from the perspective of professionals and service providers.

There are 4 workstreams in this study, and CAG support is only relevant regarding workstream 3, as other activities are being undertaken with consent. In workstream 3, researchers will attend, observe and listen to professional meetings at which patients are not present and where it is not possible to know in advance who is going to be discussed. Researchers will not record any confidential patient information and will make anonymised notes concerning 'Patient or Family X' and the type of issues being discussed. There is likely to be incidental disclosure of confidential patient information during these observations, and it is for these incidental disclosures that ‘s251’ support is required.

There is a growing consensus that in order to fully understand, and respond to, parental opioid and other drug use, research must take into account the wider context, rather than simply focus on drug use in isolation. Observation of professional meetings will help understand professional decision-making and how staff discuss and manage risk, make decisions together, work together, and plan care and services together. The in-depth information and learning from these observations will inform recommendations for changes to policy and practice in the future, or may inform the development of future interventions, which in turn, may lead to better treatment and better outcomes for parents who use drugs and their families.

Applicants will undertake observations of clinical practice in 3 NHS Trusts in London, and additionally in 3 other types of service provider and the equivalents in Scotland which are out of scope for support. The observations will include staff meetings, shadowing staff, discussing policies and guidelines, and additional observations described in the protocol, via several different methods depending on how the service functions. Patients are not the focus of the staff/service observations. Observations will be undertaken by a researcher from Kings College London, who will situate themselves within participating sites for a consecutive time period of between 3-6 months either full or part time. The observations will be completed over 21 months altogether. All staff observations and staff and patient interviews, and ethnographic observations of parents and families will be undertaken with written informed consent, however it is likely that most observations of clinical practice will indirectly involve other patients (for example, in meetings). Support under the regulations is required in case of accidental disclosure of confidential patient information regarding a non-consented patient during ethnographic observations of practitioners and services. The researchers have put in a number of safeguards to protect patient confidentiality including consent where possible, not recording any confidential patient information in the written field notes, and removing themselves from the area if requested. At all times, the researchers will wear their University staff badge on a lanyard whilst on site.

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

Confidential patient information requested

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

Cohort	For CAG purposes support is only given regarding patients of services, not for NHS staff or family members

	of patients (unless they themselves are patients of the service). The cohort is: Parents who are in treatment for opioid use who are not consented into this study, whose information may be incidentally disclosed. The applicants have estimated this to approximate 144 families, however, it is not possible to predict incidental disclosures, and this could be more or less.
Data sources	Observations carried out in 3 participating NHS Trusts: • Homerton University Hospital NHS Foundation Trust • South London and Maudsley NHS Foundation Trust • Lewisham and Greenwich NHS Trust
Identifiers required for linkage purposes	No items of confidential patient information will be collected for linkage purposes
Identifiers required for analysis purposes	No items of confidential patient information will be collected for analysis purposes

Confidentiality Advisory Group advice

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

1. **A patient information leaflet should be developed for situations where verbal consent is being asked of patients (for example in a one-to-one consultation if the researcher is observing the staff member).**

This has been developed and provided to the CAG, who were content with this response.

2. **Please explain how you plan to act in situations within workstream 3 where a patient refuses an observation of a consultation (assent request) and then these same patients may be discussed in an MDT. Please confirm whether you plan to ask these patients about their wishes regarding MDT observations, and ensure the researcher leaves the room during MDT discussions of those patients if required.**

The applicant explained that the clinician (direct care staff member) would need to establish assent/dissent and then inform the rest of the clinical team and the researcher. However, as MDTs are only one setting where patients will be discussed, it may be difficult to control researcher exposure to patient discussions in all scenarios, including multiagency meetings where workers from other services/agencies are present and discussing families (unaware of their dissent for the researcher to be party to the discussion). While attempts to prevent this occurring will be implemented, the applicants are not able to give reassurances to patients that this would not happen. Applicants will respect patient wishes where possible, and the researcher will remove themselves from situations where it is known that patients do not want the researcher to observe. The Members were content with this response.

3. **Please provide an updated poster, including the following;**
    a. **More information about the reason the researcher is observing (i.e. incidental disclosure of MDT and staff interaction, NOT patient information)**
    b. **A space for a photograph of the researcher**
    c. **A contact number and email address for the researcher**
    d. **Provide more assurance regarding anonymity and that the researchers will not be recording any confidential patient information**
    e. **Add Kings College London logo (and alter wording if required)**
    f. **Add text to state that the researcher will leave the clinical area if requested**

An updated poster has been provided, and the applicant has stated email addresses are not permitted. The CAG were satisfied that the above points were sufficiently answered in order for support to now be recommended. However the Members felt that some of the language on this poster could be more direct, and therefore are making the following strong recommendations to the applicant;

- The CAG suggested the following comment "*However, you will not be identified in any observational notes*." Could be altered to the following "*Researchers are studying how staff make decisions, so none of your personal data will be collected during the observation*"

- The CAG suggested the following comment "*The researcher will leave the meeting if you do not feel it appropriate for us to be there."* Could be altered to the following "*Please ask the researcher to leave the meeting if you do not feel it appropriate for us to be there"*

- Regarding "email addresses are not allowed", the Committee wondered if it was possible to have a central query email address for Kings/ SLaM.

- It was noted that the posters have a QR code to link to the website, but the website has no statements about confidentiality – it is advised that this should be expanded on the website in order for a layered notification approach to be in place.

4. **Please discuss the updated poster with drug using parents as part of Patient and Public Involvement, to establish if this would deter them from accessing the clinical care they required.**

The applicant has provided feedback from six parents regarding the poster and leaflet in an online meeting on the 9th August 2021. The purpose of the poster and leaflet were explained and the documents were discussed in a shared screen. Changes were made to the poster based on parents' suggestions for wording. Parents also suggested that information should be laid out more simply (e.g. in bullet points). Participants emphasised that verbal assent should be sought from parents at the same time that the leaflet is given to them. Participants liked the idea of the QR code on the leaflet that links to the project website. It does not appear that he presence of this poster would deter them from accessing clinical care. The CAG were content with this response.

5. **Please consider if there is likely to be any crossover between consented patients in the interview cohort (workstream 2), and those discussed in MDTs in workstream 3, and if so, please ensure these details are passed to the clinical team in workstream 3 in order for the researcher to leave the room during discussions of those patients.**

The applicant explained that all parents who are consented into workstream 2 (family ethnography) will be asked to give their permission for the research team to notify direct care team staff that they are taking part in the research. Parents who consent into the study will be asked to name the practitioners who they want to be notified. If parents provide consent for notification, a letter will be sent to the named practitioner/services. If there is a crossover with the service ethnography (workstream 3) - conducted by a different researcher - the researcher for workstream 2 will ask the parent if they

assent/dissent to the other researcher observing practice/meetings where they are discussed (incidental disclosure). If the parent expresses dissent, this will be recorded and this information will be passed to the service ethnography researcher and the service ethnography team manager so the direct care team know about the parent's decision. This will ensure that their wishes are respected as far as possible. The research team consider that consent/dissent from the parent would need to be explicit as the service ethnography researcher will not necessarily know the personal details of the parents and families in workstream 2. This will ensure the research team maintains their duty of confidentiality to research participants, respects their wishes about notification, and avoids any potential conflicts of interest in the conduct of the study. It should be noted that some parents in this study will be self-referrals and/or referred by third sector agencies and they may not wish statutory services, including the NHS, to be informed of their involvement in the research. This population of parents and families also often attend numerous services at the same time, or over time, so obtaining assent/dissent in respect of crossover between workstream 2 and 3 will need to be an ongoing process.

The CAG were content with this response.

6. **Please consider if staff posters should be developed for staff areas, to ensure staff are aware that observations are taking place and advise the CAG of the decision.**

A poster has been provided that makes clear that applicants are seeking assent from staff for the researcher to be present in any observational setting. This poster will be sent to all staff in the service via email and will be put up around the building and in offices. In addition, the researchers will make their presence known and will consistently check that staff assent to any observations. The Committee were content with this response.

7. **A description of the membership of the Learning Alliance should be provided, in order to understand how many drug using parents are involved.**

The applicant responded that the learning alliance is made up of 6 parents who are in treatment for substance use in London and Lothian, Scotland. However the CAG noted there was no detail of what proportion of the membership they represent. The website does give more detail, and the Members were content with the information that membership of the Learning Alliance – currently numbering around 50 participants — is drawn from a wide range of stakeholder communities in both England and Scotland, including parents who have lived experience of opioid dependence, other 'affected

family members', who include kinship carers, siblings, grandparents, and family friends, young people aged between 16 and 25, who include children of parents who use(d) drugs and other youth connected to families impacted by lived experience of opioid dependence, among other interested parties.

8. **Please provide evidence that NHS Digital have reviewed all relevant DSPTs, as per standard condition of support.**

Security assurances are now in place, as evidenced by the NHS Digital DSPT tracker, and the final Trust was confirmed on 7 September 2021.

Confidentiality Advisory Group advice conclusion

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

Specific conditions of support

The following sets out the specific conditions of support.

1. Support only extends to England and does not cover sites in Scotland.

2. Favourable opinion from a Research Ethics Committee. **Confirmed 30 March 2021**

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

   The NHS Digital **20/21** DSPT reviews for **South London and Maudsley NHS Foundation Trust** (RV5), **Homerton University Hospital NHS Foundation Trust** (RQX) and **Lewisham and Greenwich NHS Trust** (RJ2) were confirmed as '**Standards Met'** on the NHS Digital DSPT Tracker (checked 15 September 2021).

d. 21/CAG/0048 - Systemic Therapy in Advancing or Metastatic Prostate Cancer: Evaluation of Drug Efficacy

Name	Capacity

Dr Patrick Coyle	CAG vice-chair
Dr Sandra Duggan	CAG member
Professor Barry Evans	CAG member
Dr Liliane Field	CAG member
Professor Lorna Fraser	CAG member
Dr Katie Harron	CAG member
Mr Tony Kane	CAG member
Dr Simon Kolstoe	CAG member
Dr Pauline Lyseight-Jones	CAG member
Dr Murat Soncul	CAG alternative vice-chair
Mr Marc Taylor	CAG member
Ms Katy Cassidy	HRA Confidentiality Advisor
Ms Caroline Watchurst	HRA Confidentiality Advisor
Dr Paul Mills	HRA Confidentiality Advice Service Manager
Ms Natasha Dunkley	HRA Head of Confidentiality Advice Service

Context

Purpose of application

This application from the Institute of Cancer Research, University of London set out the purpose of medical research that seeks to improve the way in which prostate cancer is managed.

Prostate cancer is a major health problem world-wide and accounts for nearly one fifth of all newly diagnosed male cancers. In the UK, approximately 57,192 people were diagnosed with prostate cancer in 2018 and over 11,500 people died from the disease. Because of the shortage of research in prostate cancer, the National Cancer Research Institute (NCRI) has identified prostate cancer as high priority for research in the UK.

Prostate cancers depend upon the male hormone testosterone for their growth. Lowering testosterone levels, such as by removing all or the functioning part of both testes, or by having hormone therapy, slows the growth of prostate cancers. Hormone therapy is given in the long−term as standard treatment to patients whose prostate cancer has spread outside the prostate gland. Although hormone therapy is usually successful at stopping the cancer growing for a period of time, it is does not cure the cancer and most tumours will usually begin to grow again within 18−24 months. The increasing and widespread use of hormone therapy in prostate cancer management has led to growing awareness of the adverse effects of this treatment. An alternative approach for improving long-term outcomes in patients is therefore to reduce some of these side-effects. Many of these side-effects can affect quality-of-life as well, as result in significant and potentially life-threatening consequences, particularly with prolonged treatment and in patients with pre-existing medical conditions. The applicants created the STAMPEDE trial to examine the use of metformin as a treatment, as this may prevent some of the effects of long-term hormone therapy. Transdermal oestradiol patches would also be looked at as an alternative form of hormone therapy, which may be as effective or more effective than some other forms of hormone therapy in treating prostate cancer, but with fewer side-effects.

The trial was created as a multi-centre, randomised controlled trial for patients with locally advanced or metastatic prostate cancer who are initiating long-term hormone therapy. The trial uses a multi-arm multi-stage (MAMS) platform design to efficiently test a number of treatment options. The trial opened to recruitment and 2005. Initially, the effects of adding a bisphosphonate (zoledronic acid), a cytotoxic chemotherapeutic agent (docetaxel) and a cyclooxygenase (Cox-2) inhibitor (celecoxib), as single agents or combinations (arms A-F) were assessed. These were referred to as the “original comparisons”. These comparisons are now closed to recruitment and STAMPEDE is no longer collecting any further follow-up data from hospital sites. However, for the secondary aims of the trial, the applicants will obtain demographics, Civil Registration (deaths), cancer registrations, and HES data from NHS Digital. These will be used to determine the effects of trial treatments on quality-of-life, health economics, adverse effects and skeletal-related events as well as long-term overall survival, and to do associated methodological work on estimating cancer progression and the utility of routinely collected health data.

The majority of trial participants explicitly consented to the proposed data linkage. A small number explicitly dissented. The applicants have identified that there are 1585 participants, recruited between October 2005 and January 2013, for whom it is not known whether they consented to the linkages. IGARD had also agreed that the consent given at the time did not extend to these proposed data linkages. The applicants are therefore seeking support to undertake the linkages to datasets held by NHS Digital for the patients for whom consent is unknown.

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	1585 participants in the STAMPEDE trial, who were recruited into the trial prior between 17 October 2005 and 01 February 2013, when consent for the linkages to routine data was not mandatory.
Data sources	3. Demographics, Civil Registration (deaths), cancer registrations, and HES data held by NHS Digital for patients in England 4. The Civil Death Registration Dataset at NHS Digital for Welsh patients 5. STAMPEDE trial data, held by University College London in the Data Safe Haven
Identifiers required for linkage purposes	6. NHS Number 7. Date of birth 8. Postcode
Identifiers required for analysis purposes	10. Date of death

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

1. **Please provide favourable opinion form the REC regarding the amendment related to this CAG application when available.**

The REC provided an opinion 28 July 2021. This was provided to the CAG on 18th August 2021.

Confidentiality Advisory Group advice
The Sub-Committee also reviewed the responses to conditions;

1. **Further patient and public involvement needs to be carried out with a larger group, as described above. This discussion should cover different ways of promoting the study, in order to inform the study cohort of this use of their data. Please provide a report to the CAG within three months from the date of this letter.**

The applicant provided a summary of outcomes to CAG on 18 August 2021 after a focus group was held on 29 July 2021. These discussions focused on how to provide back the results of studies. As such, the CAG

Whilst the CAG noted that the applicant had undertaken further patient and public involvement with a larger group, it appeared to be focused on how to disseminate results to the participants after the study had completed. However the focus the CAG requested from the patient and public involvement was how to disseminate the planned patient notification to the relevant audience. The Sub-Committee therefore requested further feedback from patient and public involvement regarding whether the group had discussed how best to appropriately disseminate the notification documents prior to linkage being undertaken, and also wondered if the specific issue of further linkage of this historic patient data without consent was considered at the recent event.

The applicant undertook a planned second event on 09 September 2021, and provided the summary to the CAG on 22 September 2021. This second focus group discussed all the relevant issues, and the CAG were content with this response and to recommend support.

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

Specific conditions of support

The following sets out the specific conditions of support.

1. Favourable opinion from a Research Ethics Committee. **Confirmed 28 July 2021**

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

   The NHS Digital **2020/21** DSPT reviews for **University College London – School of Life and Medical Sciences and NHS Digital** were confirmed as '**Standards Met'** on the NHS Digital DSPT Tracker (checked 28 September 2021)

2. New Amendments

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

Name	Capacity
Dr Patrick Coyle	CAG vice-chair
Ms Clare Sanderson	CAG alternative vice-chair
Dr Tony Calland MBE	CAG Chair
Dr Murat Soncul	CAG alternative vice-chair
Professor William Bernal	CAG alternative vice-chair
Ms Caroline Watchurst	HRA Confidentiality Advisor

Context

Amendment request

This study from the Leeds Teaching Hospitals NHS Trust aims to test targeted Low Dose Computed Tomography (LDCT) scans screening in community settings concentrating on deprived areas of Leeds. The intention is to randomise 55-80 year old smokers or ex-smokers to intervention or usual care groups prior to approach. The intervention group will be invited to assessment for a Lung Health Check (including LDCT screening for high-risk people) framed as a pilot health service.

The applicant has support to use the electronic frailty index (eFI) value as an exclusion criteria, and use the eFI for future analysis. An amendment supported on 1 July 2020 provided support to use the eFI value in additional ways to further explore the link between frailty/comorbidity and screening outcomes, including using the read codes to calculate the eFI value in a standardised way for all trial participants. This amendment sought support to extract, store and analyse the electronic frailty index (eFI) v2 codes in the same way as the eFI codes, as there is now an updated version of this tool.

This amendment also sought support to re-contact by telephone some high risk patients who previously did not undergo an LDCT scan to see if they now wish to proceed with

ongoing screening. Approximately 1,000 people who underwent the telephone lung cancer risk assessment and were found to be at high risk did not subsequently attend the mobile units. Applicants have confirmed they would not re-contact the following groups;

1) People who had requested no further contact from the Lung Health Check team
2) People in whom screening was previously considered not appropriate for medical reasons (dementia, frailty, significant comorbidity making screening inappropriate)
3) People who were deemed unable to consent to the study
4) People who were unable to proceed with screening (e.g. unable to lie flat for the scan)

Confidentiality Advisory Group advice
The amendment requested was considered by the CAG Chair team. The Chair team agreed that the Covid pandemic would have prevented many people from going out, especially to any health facility. One additional contact was deemed to be reasonable considering the circumstances. The Chair team therefore recommended support for one additional contact. The use of the eFI2 was agreed to be reasonable and add value to the study.

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

Specific conditions of support

The following sets out the specific conditions of support.

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

   Leeds Teaching Hospitals NHS Trust has a confirmed 'Standards Met' grade on DSPT 2020/21 (by email to the CAG inbox 03 September 2021)

   University of Leeds – IRC and CFH Docmail LTD have confirmed 'Standards Met' on DSPT 2020/21 (by check of DSPT tracker 26 August 2021)

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

19/CAG/0162 – Accuracy, impact and cost-effectiveness of prehospital clinical early warning scores for adults with suspected sepsis

Name	Capacity
Ms Caroline Watchurst	HRA Confidentiality Advisor
Ms Kathleen Cassidy	HRA Confidentiality Advisor

Context

Amendment request

The applicants have existing support to allow research paramedics access to confidential patient information on site at participating ambulance Trusts to enable the eligible patient cohort to be identified, the onward disclosure to NHS Digital and access to confidential patient information at participating Trusts by research nurses.

In this amendment, the applicants are seeking to extend the retrospective data collection period from the current period of April 2018 – March 2019, to include all of 2019. The revised data collection period will then be 01 April 2018 – 31 December 2019. This change is being made to allow the study to have access to the most up-to-date and complete data which is not influenced by the effects of COVID-19. The applicants hope that this will hopefully provide an improved public benefit of accurate early detection of sepsis.

The applicants are also seeking to add Doncaster & Bassetlaw Hospitals NHS Trust, The Rotherham NHS Foundation Trust and South Warwickshire NHS Foundation Trust as data processors.

Confidentiality Advisory Group advice

The amendment requested was considered by the Confidentiality Advice Team.

Confidentiality Advisory Group advice conclusion

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

Specific conditions of support

The following sets out the specific conditions of support.

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

Confirmed: The NHS Digital 2020/21 DSPT review for University of Sheffield - School of Health and Related Research, South Warwickshire NHS Foundation Trust, Doncaster & Bassetlaw Hospitals NHS Trust and The Rotherham NHS Foundation Trust were confirmed as 'Standards Met' on the NHS Digital DSPT Tracker (checked 09 September 2021).

2. Confirmation of a favourable opinion from a Research Ethics Committee.
   Confirmed – Non-Substantial REC amendment, REC review not required.

18/CAG/0153 – The POOL study: Establishing the safety of waterbirth for mothers and babies: A cohort study with nested qualitative component.

Name	Capacity
Ms Caroline Watchurst	HRA Confidentiality Advisor

Context

Amendment request

This study aims to evaluate whether the use of birthing pools during labour and water births leads to an increased risk in poor maternal and infant outcomes.

The study has 's251' support to enable data to flow from hospital maternity records at 26 sites, to National Neonatal Research Database (NNRD), regarding approximately 600,000 maternity records between January 2015 and November 2020.

This amendment sought support to extend the duration of the data collection until June 2022, and to extend the duration of support until March 2023 in order to complete analysis. The applicant does not wish to collect an additional number of patients, and this duration extension is merely to meet the original required sample size, in order to answer the primary research question. The extension request is due to slow set up times and the Covid-19 pandemic.

Confidentiality Advisory Group advice

The amendment requested was considered by the Confidentiality Advice Team (CAT). This CAT raised no queries regarding this amendment.

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

Specific conditions of support

The following sets out the specific conditions of support.

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

   The NHS Digital **20/21** DSPT reviews for **Wellbeing Software Group Limited incorporating Healthcare Software Solutions, EuroKing, e-Healthcare Innovations (8HF02)** and **Chelsea and Westminster NHS Foundation Trust**

   were confirmed as '**Standards Met'** on the NHS Digital DSPT Tracker (checked 15 September 2021)

2. Confirmation of a favourable opinion from a Research Ethics Committee. **Confirmed non substantial by email 16 August 2021**

17/CAG/0011 – Genetic mechanisms in polyposis of the bowel

Name	Capacity
Ms Caroline Watchurst	HRA Confidentiality Advisor

Context

Amendment request

The applicants had initially applied for support under Section 251 and its Regulations to include a cohort of up to 20 deceased patients, alongside a cohort of consented participants, which is outside the scope of this support. The applicants are seeking support to extend the end date of the study until 31 August 2022 to allow more time to meet the recruitment target of 375 participants (including further deceased patients), because recruitment to the study was temporarily suspended due to Covid-19, which slowed recruitment.

The applicants have confirmed that there is no increase in the number of deceased patients to be included in this study.

Confidentiality Advisory Group advice

The amendment requested was considered by the Confidentiality Advice Team. No queries were raised regarding this amendment.

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

Specific conditions of support

The following sets out the specific conditions of support.

1. Confirmation provided from the IG Delivery Team at NHS Digital to the CAG that the relevant Data Security and Protection Toolkit (DSPT) submission(s) has achieved the 'Standards Met' threshold: **Confirmed: Cardiff University confirmed 'Standards Met' on DSPT 2020/21 (by check of DSPT Tracker 23 September 2021).**

2. Confirmation of a favourable opinion from a Research Ethics Committee
   Confirmed non substantial 08 June 2021

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

Name	Capacity
Ms Caroline Watchurst	HRA Confidentiality Advisor

Context

Amendment request

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

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

Confidentiality Advisory Group advice

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

Confidentiality Advisory Group advice conclusion

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

Specific conditions of support

The following sets out the specific conditions of support.

1. Confirmation provided from the IG Delivery Team at NHS Digital to the CAG that the relevant Data Security and Protection Toolkit (DSPT) submission(s) has achieved the 'Standards Met' threshold
   Confirmed - The NHS Digital 2020/21 DSPT review for **Intensive Care National Audit & Research Centre (ICNARC**) was confirmed as 'Standards Met' by email to the CAG inbox 23 September 2021)

2. Confirmation of a favourable opinion from a Research Ethics Committee.
   Confirmed non substantial 10 September 2021

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

Name	Capacity
Ms Caroline Watchurst	HRA Confidentiality Advisor

Context

Amendment request

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

The applicant is seeking support in this amendment to extend the duration of CAG support until 31 August 2022. This is due to delays caused by Covid-19 pandemic, and is required to enable the applicant to meet their original recruitment target.

Confidentiality Advisory Group advice

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

Confidentiality Advisory Group advice conclusion

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

Specific conditions of support

The following sets out the specific conditions of support.

1. Confirmation provided from the IG Delivery Team at NHS Digital to the CAG that the relevant Data Security and Protection Toolkit (DSPT) submission(s) has achieved the 'Standards Met' threshold :
   Confirmed: The NHS Digital **20/21** DSPT review for **the University of Cardiff** was confirmed as 'Standards Met' by check of the NHS Digital DSPT Tracker (24 September 2021)

2. Confirmation of a favourable opinion from a Research Ethics Committee.
   Confirmed non substantial 18 August 2021

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

Name	Capacity
Ms Caroline Watchurst	HRA Confidentiality Advisor
Dr Patrick Coyle	CAG vice-chair

Context

Amendment request

In line with the original application, the applicant had been commissioned by HQIP to undertake two confidential reviews of case notes every year. This amendment covered the first of the reviews due to take place in 2021, which will investigate the care of patients with Crohn's disease.

The review has been commissioned as there is believed to be room for improvement in the quality of acute and long-term care provided to patients with Crohn's disease.

The applicants aim to publish the results of the review in January 2023.

Confidentiality Advisory Group advice

The amendment requested was considered by Chair's Action. The Vice-Chair agreed that the amendment request was a very important activity, very much in the public interest, that has resulted in considerable improvements in care over the years. The Vice-Chair was assured that the method will be in line with NCEPOD support. The Vice-Chair noted there is adequate patient notification described in the amendment form and commendable patient consultation described in the protocol. On the basis of usual practice, and a wish not to delay such important work, The Vice-Chair recommended support for this amendment.

However, due to the application being submitted many years ago, the Vice-Chair proposed a re-submission of the application, in order for CAG to have a more detailed review of data flows and how the anonymisation of patient records for review is carried out. This is in line with the plans of the applicant, who has already been planning to re-submit the application for CAG review.

Confidentiality Advisory Group advice conclusion

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

Specific conditions of support

The following sets out the specific conditions of support.

1. Confirmation provided from the IG Delivery Team at NHS Digital to the CAG that the relevant Data Security and Protection Toolkit (DSPT) submission(s) has achieved the 'Standards Met' threshold: **Confirmed – The NHS Digital 2020/21 DSPT review for National Confidential Enquiry into Patient Outcome and Death (NCEPOD) was confirmed as 'Standards Met' on the NHS Digital DSPT Tracker (by check of the NHS Digital DSPT Tracker on 23 September 2021).**

3. Annual Review Approvals

14/CAG/1030	AIRWAYS 2
20/CAG/0105	National Clinical Audit of Psychosis
19/CAG/0187	Multifrequency Bioimpedance in the Early Detection of Lymphoedema after Axillary Surgery
16/CAG/0079	National Clinical Audit of Breast Cancer in Older Patients (NABCOP)
ECC 3-04(o)/2011	NHS Abdominal Aortic Aneurysm Screening Programme (NAAASP)
20/CAG/0102	National Haemophilia Database (NHD)

20/CAG/0088	Antihypertensive Treatment in Elderly Multimorbid Patients: a pilot study
CAG 8-03(PR11)/2013	Hip Fracture Audit
CAG 2-03(PR2)/2014	Mental Disorder & Cancer Care: A Data Linkage Study in South London II
19/CAG/0139	The clinical and cost-effectiveness of testing for Group B Streptococcus: a cluster randomised trial with economic and acceptability evaluations (GBS3)
20/CAG/0096	Royal Free Cohort Study (RFHCS)
18/CAG/0105	The Incidence, Management and Early Outcome of Congenital Ichthyosis
19/CAG/0144	Infections in Oxfordshire: a Research Database (IORD)

Signed – Chair	Date
Minutes signed off as accurate by CAG Chair Dr Tony Calland MBE, Vice Chair Dr Patrick Coyle, and Alternate Vice Chairs Ms Clare Sanderson, Dr Will Bernal and Mr Murat Soncul	07/02/2022
Signed – Confidentiality Advice Team KM Cassidy	Date 07/02/2022