Health Research Authority

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

February 2022

1. New Applications

a. 21/CAG/0180 - National COVID-19 Chest Imaging Database (NCCID)

Name	Capacity
Dr Tony Calland MBE	CAG Chair
Dr Sandra Duggan (written comments)	CAG member
Dr Liliane Field	CAG member
Mr. Myer Glickman OBE	CAG member
Mr Tony Kane	CAG member
Professor Jennifer Kurinczuk	CAG member
Dr Harvey Marcovitch	CAG member
Mr Andrew Melville	CAG member
Professor Sara Randall	CAG member
Mr Marc Taylor	CAG member

Context

Purpose of application

This application from NHS England (with the joint controllers for the activity confirmed to be NHS England and the Department of Health and Social Care) set out the purpose of medical research which aims to create a research database to be used to improve the identification and triage of Covid-19 patients.

The applicants have created the National COVID-19 Chest Imaging Database (NCCID) in response to the Covid-19 crisis. The database will be used to enable the validation and development of automated analysis technologies and to promote research projects in response to the Covid-19 pandemic. Data collection is happening across the country and the applicants are seeking to consolidate these individual data collection activities into a single national database, in order to avoid duplication of effort.

The main data collection involved is the collection of chest x-rays and CT scans and a small amount of relevant clinical information from NHS trusts throughout the UK which is transferred centrally to Royal Surrey County Hospital NHS Foundation Trust. Data is then linked with other datasets and transferred to the NCCID cloud storage for subsequent access by researchers.

Support is requested to allow staff at participating NHS trusts, who are not members of the direct care team, to access confidential patient information in order to identify participants and carry out the pseudonymisation process, before the pseudonymised data is transferred to the Royal Surrey NHS Foundation Trust for inclusion in the NCCID.

Support is required for participating NHS Trusts to transfer the encrypted NHS number with clinical data and images to the Royal Surrey Hospital. The image data and clinical data flow separately. The image data will contain the encrypted NHS number that the Royal Surrey Hospital has the ability to reidentify to apply the national data opt out and for linking with the NHS England Segmentation Database.

Support is required for NHS number to flow from the Royal Surrey Hospital to the NHS England Segmentation Database, in order to gain ethnicity data (for those where this is not recorded in data from Trusts). NHSE have to reidentify the NHS number in order to gain the ethnicity data to return back.

When setting up Trusts with the software to conduct the pseudonymisation process, Surrey have to test to make sure it is working. For many Trusts, this involves the Trust providing phantom data (i.e. no real data) to Surrey to test. However, some Trusts do not have this so, in this case, Trusts provide Surrey with hospital number of a sample of patients in order to test the system. This is expected to continue past the expiry of the COPI Notice, so support for this is required, where necessary.

The Royal Surrey will send ISARIC and PHOSP-COVID hashed NHS numbers which those study teams will match with their own hashed NHS numbers. Support will not be needed for this, as the NHS numbers are not identifiable.

Although mentioned in the protocol, Faculty are no longer involved in the study and are thus not a data processor.

There is data processing in Scotland which falls outside of scope, with PBPP approval already in place.

A recommendation for class 1, 2, 3 ,4 and 6 support was requested to cover access to the relevant unconsented activities as described in the application.

Confidential patient information requested

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

Cohort	All patients aged between 12 and 109 years of age who present with suspected Covid-19 and who have had an RT-PCR swab.
Data sources	1. NHS Trusts 2. Royal Surrey Hospital SMART portal
Identifiers required for linkage purposes	<u>NHS trusts</u> 1. NHS number 2. Hospital number

	SMART Portal 1. NHS number Royal Surrey Hospital 1. NHS number
Identifiers required for analysis purposes	1. Date of death
Additional information	N/A

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. To confirm the number of patient records to be used to test the software, where no phantom data is available, as well as justification on why neither phantom records could be created by the site, or consent could be given by the individuals.

The applicant confirmed that in the instances where the research team set up a site and the site is unable to provide a pseudo or phantom patient entry for testing, then the site is asked to provide us with a single patient identifier. This identifier is entered into the automated collection system to undertake the test. This is always an identifier (normally hospital number) which corresponds to a patient with a set of pre-existing retrospective images in the hospital PACS system. The test thereafter is automated.

Where phantom records cannot be created by the site, this is down to a lack of technical ability from the teams onsite.

With respect to taking consent from individuals where numbers are likely to be small, the research team have avoided this approach given the large number of sites, the fact that the test is utilising a single patient and is fairly automated and there are no other consent processes elsewhere in the project. The overhead of implementing a consent process and documentation/training of local staff at a large number of sites for a single patient was considered counterproductive.

The CAG were happy with these explanations.

2. To provide a revised privacy notice which

a) clearly describes the flows of identifiable data.

b) allows people the opportunity to opt out, both nationally and locally.

c) uses Patient and Public Involvement to aid in its revision.

The Privacy Notice was amended and provided to the CAG in response.

The CAG felt that the Privacy Notice was long and complicated, but that it was acceptable. As a recommendation only, a contact email address should be included in the privacy notice to signpost people for more information.

3. To create a poster to include the options for opting out of the study, including a local option, and details of where they would be placed

The research team will design electronic posters which will detail the study and include the details on how a patient is able to opt-out at their local hospital. These posters could be downloaded and printed by the participating sites and displayed in the relative waiting areas, such as the Radiology waiting area and reception rooms.

The research team did not create a poster which included options for opting out of the study for the first round of patient and public workshops they have conducted. However, during this first round of workshops, they dedicated a whole slide to the National Opt out process, which they discussed with patients.

In our recent engagement with Trusts and relevant organisations, the research team had designed a leaflet which had been circulated along with proposed dates for the workshops. However, due to the poor uptake, the workshops have been postponed.

The CAG accepted the poster.

4. To ensure that participating Trusts have a local opt-out mechanism in place at the time of COPI Notice expiry, which should include a record of those who have expressed a wish to have their data opted-out.

The research team will implement a local-opt out process as follows:

a) An update will be made to the NCCID web portal (this is the portal through which sites submit clinical data) to include an opt-out process.

b) Participating sites will be provided with clear instructions on how to enter a patient into the opt-out section of the portal.

c) A patient will be able to request a staff member at a collection to add them to the opt out for NCCID. A staff member will follow the guide we have provided

a. Log onto NCCID portal (using pre-existing credentials)

b. Enter NHS of patient into the opt-out area

c. NHS number is hashed automatically before submission and stored in the opt-out register

d) All data and images that are submitted to NCCID will be automatically checked against the opt-out register and rejected if matched.

e) All pre-existing data will be scanned and if matched, a deletion protocol will be initiated:

a. Corresponding clinical data and images in the NCCID cloud storage will be removed

b. Audits and logs will be purged

c. When third parties sync with the data buckets, the corresponding data will automatically be removed from the third-party copy of NCCID.

The CAG accepted this opt-out process.

5. To provide details of any PPI which has been conducted which specifically addresses the use of identifiable data without consent.

The NHS AI Lab had planned to run another round of PPI workshops (based on the uptake) in January and February of this year to specifically discuss the use of identifiable data without consent. Invitations were sent out at the end of last year to hospital trusts who have donated data to the NCCID and we made a specific effort to try and engage with those who did not participate in the previous workshops. The invites specifically cited the workshop's focus on discussing the acceptability of using pseudonymised patient data without consent.

Due to current pressures facing the NHS, these workshops have had no uptake, with one trust responding that it would be impractical to run these workshops currently. We have thus decided to postpone these workshops to March 2022, when pressures on the system will hopefully be less acute.

The CAG appreciated the reasons for postponing PPI and accepted the explanation.

6. To provide justification for the continued collection of data once the database is established and the COPI Notice has expired.

COVID-19 (SARS-CoV-2) is a disease that we expect we will be living with for some time. The ability to continue research and development of digital technologies to support our ongoing response to this disease requires us to continue providing access to curated and clinical data. To clarify, the database already exists (implemented in April 2020) and is currently being used by research teams.

The CAG accepted this response.

7. To provide justification as to why the full date of death is required and why it cannot be converted into an unidentifiable format, such as 'number of days since admission'.

The research team feel that the date of death can be modified to reset the weekday to 01 (e.g., if the original is 07/11/2021 it would be set to 01/11/2021). This would have little effect on the research questions being asked of the dataset.

The CAG accepted this.

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 was only provided for the setting up of the database, and that any separate research conducted using the data from the database should be a new application.

2. Support under Regulation 5 Health Service (Control of Patient Information) Regulations 2002 will come into effect automatically following expiry of the COPI notice.

3. The National Data Opt Out will apply to processing of Confidential Patient Information under Regulation 5 at the Royal Surrey Hospital only – a local opt-out mechanism will be used at all other sites.

4. Favourable opinion from REC **Received 17 April 2020.**

5. Continual achievement of 'Standards Met' in relation to the relevant DSPT submission (or any future security assurance changes) for the duration of support. Evidence to be provided (through NHS Digital confirmation they have reviewed and confirmed the DSPT submission as standards met' for the duration of support, and at time of each annual review. **The applicant must ensure that NHS Digital confirmation of 'standards met' for organisations processing confidential patient information (NHS Trusts and the Royal Surrey Hospital) is in place once support under Regulation 5 is active.** See below for further details.

b. 21/CAG/0132 - Evaluating the health inequality effects of the Best Practice Tariff for hip fracture

Name	Capacity
Dr Patrick Coyle	CAG vice-chair
Dr Katie Harron	CAG member
Professor Jennifer Kurinczuk	CAG member
Ms Caroline Watchurst	HRA Confidentiality Advisor

Context

Purpose of application

This application from the University of York (UoY) set out the purpose of medical research that seeks to explore whether the introduction of the best practice tariff (BPT) for fragility hip fracture in 2010 and subsequent changes to its components in 2017 led

to changes in health inequalities across the population of England. This is a retrospective, observational study, which proposes to link clinical information which is already collected as part of the National Hip Fracture Audit database (NHFD) with Hospital Episode Statistics (HES) data and Office for National Statistics (ONS) Mortality data, using NHS Digital as a trusted third party to create the bridging file. 's251' support is required to undertake linkage between the datasets.

A hip fracture is a serious injury that carries a risk of death and long-term pain. It is possible that the introduction of the hip fracture BPT might lead to improvements in care delivery that benefit predominantly those with higher socioeconomic status, thereby widening inequalities. Applicants will compare how care changed in Wales over time to how care changed in England over time to tell us what difference BPTs made to each socioeconomic group of people. Applicants will then be able to describe the impact of BPTs on quality and length of life across the whole population.

In order to undertake this linkage, Crown Informatics, who process the NHFD data on behalf of Royal College of Physicians (RCP), will transfer confidential patient information to NHS Digital, (as the data controller for HES and ONS mortality data) to generate a bridging file containing NHFD ID and HES ID which is then disclosed to the applicants at UoY. Crown informatics will also disclose a clinical dataset containing NHFD ID to the applicant at UoY. The Centre for Health Economics at UoY already holds linked HES+ONS data that are used for a number of research projects, which contains HES ID, and also contains full date of death. NHFD and HES+ONS data will be linked by a member of the research team, using the bridging file, after which, the bridging file and the HES ID / NHFD ID in the resulting dataset will be deleted. Dates of events will be used to calculate time interval in days between events, so that the final analysis dataset will not include any dates. This will be effectively anonymous for analysis.

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

Confidential patient information requested

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

Cohort	Approximately 600,000 hip fracture patients in England and Wales during the period 01 April 2008 to 31 March 2020 All individuals included in the National Hip Fracture Database will be included.
Data sources	3. Crown Informatics (on behalf of the Royal College of Physicians, commissioned by HQIP); National hip fracture audit database. 4. NHS Digital – controller for Hospital Episode Statistics (HES) data and Office for National Statistics (ONS) mortality datasets, however the Centre for Health Economics at University of York already holds HES+ONS data, and outcomes will be sourced from this dataset (provided to UoY under DARS-NIC-84254-J2G1Q).
Identifiers required for linkage purposes	Disclosed from NHFD to NHS Digital: 1. NHS number 2. Date of Birth 3. Postcode 4. Sex 5. NHFD ID Bridging file disclosed from NHS Digital to University of York: 1. NHFD ID 2. HES ID (not possible for applicants to re-identify patients)

Identifiers required for analysis purposes	2. LSOA (provided by Crown informatics) 3. Sex 4. Date of death – modified to survival time from admission (in days). Effectively anonymous to applicants
Additional information	HES & ONS outcome data will be extracted for all included patients up until up to 31st March 2020.

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

1. **Please simplify the language of the patient notification, and ensure accuracy. Please ensure this is reviewed by a patient and public involvement group, rather than one individual, and provide the updated notification to the CAG.**

The applicant provided an updated notification, which was developed with the help of patient and public involvement over two meetings. The CAG were content with the notification.

2. **Please undertake more patient and public involvement, with a larger number of patients, which is specifically focused on the use of confidential patient information without consent.**

The applicant explained they contacted Involvement@York, the PPI network at the University of York, and recruited and consulted six additional members of the public with experience of hip fracture care. Two meetings have been undertaken so far, and all six participants expressed that they thought the proposed research would provide social value, and that the use of confidential patient information without consent was appropriate. The CAG 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. Favourable opinion from a Research Ethics Committee. **Confirmed 29 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 **20/21** DSPT reviews **for Crown informatics, NHS Digital and University of York EE133913-CHE** were confirmed as '**Standards Met'** on the NHS Digital DSPT Tracker (checked 12 October 2021)

c. 22/CAG/0021 - The South London Stroke Register: Improving the lives of stroke survivors with data. (SLSR)

Name	Capacity
Dr Tony Calland MBE	CAG Chair
Mr David Evans	CAG member
Dr Harvey Marcovitch	CAG member
Ms Caroline Watchurst	HRA Confidentiality Advisor

Context

Purpose of application

This application from King's College London set out the purpose of medical research which aims to develop the South London Stroke Register (SLSR) to estimate the

incidence of stroke and its outcomes in South London (Lambeth and Southwark) to address key questions in stroke epidemiology, particularly around the health of newly classified mild stroke patients and long term stroke survivors.

The SLSR is a consented observational study which has been recruiting patients since 1995, and at present there are over 7,000 people on the register. Data from the SLSR have underpinned improvements in acute stroke care and rehabilitation in the UK, which have led to reduced stroke death and disability, better long-term health outcomes, and cost savings for the NHS. Stroke is the fourth leading cause of death in the UK and the single largest cause of complex disability in adults. Definitions of stroke are changing, and therefore updated data is required to describe survivors' needs and outcomes adequately. The updated SLSR will address the challenges posed by the changing nature of stroke leading to future improvements in stroke care and patient outcomes. Since 1995, the SLSR team have been screening and consenting patients at the Trusts, however due to evolution in Trust policy, the clinical researchers are no longer considered direct care team, and ‘s251’ support is now requested.

As a consented register, ‘s251’ support is not required for the majority of study processes. However ‘s251’ support is sought for members of the SLSR research team from King's College London, who are not considered direct care team, to screen medical records at participating Trusts in order to identify eligible participants for the purposes of seeking consent. The applicants reason that this would be too onerous for the direct care team to undertake. If a patient does not consent within 6 months, their confidential patient information is deleted. No identifiable data items will leave the Trusts without the consent of a patient or their consultee. ‘s251’ support is also required for members of the SLSR research team from King's College London, to view confidential patient information regarding eligible patients who are deceased, in order to collect a pseudonymous dataset for analysis. No identifiable data will be disclosed outside of the Trusts. The applicants reason that it is important that data can be collected about people who have died from stroke. These people are more likely to have experienced severe stroke, adverse health or socioeconomic circumstances, or in some cases possibly poor quality care.

A recommendation for class 1, 2, 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 with a confirmed first stroke (WHO ICD-11 clinical definition) since 1st October 2021 who live in the Lambeth and North Southwark areas of South London Approximately 400 patients will be recruited prospectively per year. (2000 total over 5 years) Applicants estimate approximately 4000 records would need to be viewed per year to identify 400 potential participants annually. Therefore 's251' support required for approximately 20,000 individuals records to be screened.
Data sources	5. Guy's and St Thomas' NHS Foundation Trust and 6. King's College Hospital NHS Foundation Trust Patient medical records (paper and electronic notes), and hospital ward lists, including stroke clinic lists, radiology reports, Electronic patient records (EPR)
Identifiers required for screening and inviting patients to consent	**Screening:** 6. Access to medical records [Screening for eligibility] 7. Postcode [Screening for eligibility] 8. NHS number [Screening for eligibility] 9. Hospital ID [Screening for eligibility] **Invitation:** 10. Name 11. Hospital number 12. Ward location [inpatients] 13. Telephone number [discharged patients]
Identifiers required for analysis	5. Date of Birth (modified to age in years at time of stroke)

purposes (relevant for deceased patients only, as the rest of the cohort is consented)	6. Date of death (modified to days from stroke until death) 7. Postcode (modified to area-based socioeconomic score) 8. Ethnicity recorded as ONS broad category 9. Sex Therefore this can be considered anonymous for analysis as the register staff will not have access to CPI regarding deceased patients at KCL.
Additional information	No confidential patient information will be disclosed outside of participating trusts without consent.

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 Favourable Opinion of the REC, as per standard condition of support.**

REC favourable opinion was provided on 9th February 2022.

The applicant response to the provisional condition applied was also considered by a sub-committee of the CAG.

1. **Please include on the notification poster that the screening and consent approach undertaken by people who are not direct care team, is undertaken under Regulation 5 of the Health Service (Control of Patient Information) Regulations 2002 ('section 251 support'), and provide an updated version to CAG within one month of final support provided.**

The applicant provided an updated poster, which the CAG suggested changes to. Once the final version was provided, the members were content 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. Support provided for 5 years in the first instance to match the current funding. A duration amendment will be required at this timepoint to extend the duration of 's251' support.

2. Favourable opinion from a Research Ethics Committee. **Confirmed 9 February 2022**

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 **Guy's and St Thomas' NHS Foundation Trust (RJ1) and King's College Hospital NHS Foundation Trust (RJZ)** were confirmed as '**Standards Met'** on the NHS Digital DSPT Tracker (checked 01 February 2022)

d. 21/CAG/0155 - Using patient records to identify potential participants for the fourth National Survey of Sexual Attitudes and Lifestyles (Natsal-4)

Name	Capacity
Dr Liliane Field	CAG member

Dr Rachel Knowles	CAG member
Professor Jennifer Kurinczuk	CAG member
Dr Harvey Marcovitch	CAG member
Ms Rose Payne	CAG member
Mr Umar Sabat	CAG member
Ms Clare Sanderson	CAG alternative vice-chair
Dr Murat Soncul	CAG alternative vice-chair
Ms Katy Cassidy	HRA Confidentiality Advisor
Ms Natasha Dunkley	HRA Head of Confidentiality Advice Service
Dr Paul Mills	HRA Confidentiality Advice Service Manager
Ms Caroline Watchurst	HRA Confidentiality Advisor

Context

Purpose of application

This application from the University College London set out the purpose of medical research that seeks to use confidential patient information held by NHS Digital, to create a sampling frame in order to invite English participants to consent into the fourth National Survey of Sexual Attitudes and Lifestyles (Natsal-4). Natsal is the world's largest, most detailed study of sexual behaviour, and has taken place every 10 years (1990, 2000, 2010). Previous iterations have used an address-based sample frame (Postcode Address File - PAF), and conducting eligibility screening and selection on the doorstep. However this has been found to be inefficient, especially regarding young person and ethnic minority boost samples, who experience a disproportionate burden of adverse sexual and reproductive health outcomes. The applicants plan to use name based sampling for the 'dress rehearsal and mainstage' of Natsal-4, but will also include the address based sampling into their ethics application as a back-up in case they cannot implement the names based method in time. However they do not consider this to be a practicable alternative to CAG support, due to the huge inefficiencies found in implementation, and the lack of ability to include boost samples.

Natsal-4 will provide updated nationally representative data on sexual and reproductive health. Past equivalent data has been extensively used to guide policy and practice,

including to improve sexual health education, design interventions (e.g. chlamydia screening, teenage pregnancy strategy, HPV vaccination) and deliver health services.

The Natsal research team at NatCen provide NHS Digital with a specification of the sample file requirements. This will provide the number of records required, the geographical areas to be included, and the stratification requirements (e.g. by age, ethnicity, and potentially other demographic stratifiers). NHS Digital will create a named sampling frame from Demographics and HES datasets, and provide this information to NatCen. NatCen will disclose this information on to Formara, and also to individual interviewers in order for them to consent patients as part of fieldwork. Natsal-4 aims to achieve a consented sample of 10,000 participants aged 16-59 who will be randomly selected from across Britain. Applicants plan to include young person (16-29 year olds) and ethnic minority boost samples to ensure robust subgroup analyses in these groups. Prior to the letters being sent, the applicants plan to have a notification on the study website, so people can opt out of this if they wish.

Formara send out invitation letters to patients, which also have an opt out option included on the letter. Approximately a week later, an interviewer will visit the address of the selected individual and will explain the study further. This is the same approach used in a number of other social surveys (including the Mental Health of Children and Young People 16/CAG/0016). The patient is then consented into the study, and asked to complete a computer-assisted questionnaire, provide a biological sample (urine or vaginal swabs) and consent to data linkage, and these elements are therefore out of scope for support as they are undertaken with consent as the legal basis under common law.

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	Participants aged 16-59 resident in private households in England. Up to 80,000 will be approached via letter in order to consent 10,000.

	Boost samples of young people (16-29) and ethnic minorities will also be recruited, this is included in the above figures.
Data sources	1. NHS Digital: a. Demographics b. Hospital Episode Statistics (HES)
Identifiers required for linkage purposes	14. Full name 15. Address including postcode 16. Gender 17. Date of birth 18. Ethnicity
Identifiers required for analysis purposes	2. N/A any data for analysis is retained with consent

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 an updated notification poster/leaflet, with the specified changes regarding the HRA 'giving permission', and ensure that the version provided to CAG has been edited to reflect the correct sampling method.**

The applicant has provided an updated notification, and the CAG were content with the updated versions provided.

2. **Please update the initial invitation letter with additional opt out contact details to include telephone, email and postal.**

The applicant has provided an updated invitation letter, and the CAG were content with the updated version provided.

3. **Please clarify if the length of time between initial invitation letter, and interviewer arriving on the doorstep can be extended to longer than one week? If not, please provide justification.**

Applicants now propose a minimum 10-day interval between the advance mailing and doorstep contact. The CAG were content with this.

4. **Please develop further descriptions/questions surrounding specific processing of confidential patient information without consent, naming organisations and describing data flows and items, in order to present to a patient and public involvement group. The CAG will also want to see evidence of some responses prior to recommending support.**

The applicant has provided an update on patient and public involvement undertaken, and evidence has been provided regarding support from patients and the public for this processing of confidential patient information without consent. The Sub-Committee were content with the update provided.

5. **Please provide an updated protocol which includes the study design presented to CAG.**

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

6. **It is understood that the applicant has agreed with REC to submit the Natsal-4 mainstage (which cover the elements relating to CAG application) as an amendment to IRAS reference 275649. This is awaiting favourable opinion. Please provide to CAG when available, as per standard condition of support below.**

This was confirmed 20 January 2022.

7. **Please provide evidence of NHS Digital review of 20/21 DSPTs for NatCen social research and Formara Limited, as per standard condition of support below.**

These were confirmed via email to the CAG inbox on 7 December 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. Favourable opinion from a Research Ethics Committee. **Confirmed 20 January 2022 (amendment)**

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 **20/21** DSPT review for **NHS Digital** was confirmed as '**Standards Met'** on the NHS Digital DSPT Tracker (checked 23 November 2021).

   The NHS Digital **20/21** DSPT reviews for **NatCen social research** (8HW76) and **Formara Limited** (8JK40) were confirmed as '**Standards Met'** via email to the CAG inbox (07 December 2021).

e. 21/CAG/0150 - Biliary Atresia Registry (England and Wales)

Name	Capacity
Dr Tony Calland MBE	CAG Chair

Dr Liliane Field	CAG member
Dr Rachel Knowles	CAG member
Professor Jennifer Kurinczuk	CAG member
Dr Harvey Marcovitch	CAG member
Ms Rose Payne	CAG member
Mr Umar Sabat	CAG member
Ms Clare Sanderson	CAG alternative vice-chair
Dr Murat Soncul	CAG alternative vice-chair
Ms Katy Cassidy	HRA Confidentiality Advisor
Ms Natasha Dunkley	HRA Head of Confidentiality Advice Service
Dr Paul Mills	HRA Confidentiality Advice Service Manager
Ms Caroline Watchurst	HRA Confidentiality Advisor

Context

Purpose of application

This non-research application from Kings College Hospital NHS Foundation Trust (KCH) set out the purpose of creating a registry of all infants with biliary atresia (BA) in England and Wales from Jan 1999 onwards. The purpose of the registry is to monitor the outcome of the clinical management of BA. Prior to 1999, management in the UK was decentralised. Outcome surveys had shown that only the larger centres treating more than 5 cases per year had acceptable results, so it was mandated that the care of such infants was to be centralised and managed only at three large national centres in London, Birmingham and Leeds. Since centralisation, there has been a dramatic improvement in national outcome.

This registry has been in existence since 1999 when the Department of Health mandated that a record be kept of all infants in England and Wales with BA. However, it has been operating without a legal basis under common law, and this application is therefore to provide a legal basis under common law to retain the database which has

been created retrospectively, and to provide a legal basis for the data collection prospectively. NHS England are supportive of this registry being controlled by KCH moving forwards, under ‘s251’, as there does not appear to be any current NHS Directions mandating the data collection.

Biliary atresia is a rare, potentially life-threatening, condition of newborns characterised by persisting jaundice and the development of liver fibrosis and cirrhosis. It requires early identification and prompt surgical management to try and forestall liver failure. The registry is required to continue to provide regular, consistent and transparent monitoring of the outcomes of all infants with BA, in order to continue to improve outcomes of infants and children with this disease.

Data is collected by the direct care team in individual centres, and name is removed. At the end of each year, confidential patient information including hospital ID number, date of birth, gender and NHS number, alongside a pseudo-Identifier and clinical information about each new patient treated in the centre for BA is transferred via a password-protected spreadsheet using NHS emails, to the central database (in KCH), together with a yearly record of outcome of all infants previously registered. These annual updates of patient management and outcome for previously registered children are then linked to baseline measures via the hospital ID. Data are stored on password-protected hospital server at KCH and only accessible by Mark Davenport, and a nominated deputy.

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 infants diagnosed with biliary atresia and managed in one of the three national centres, from January 1999 onwards

	Approximately 850 infants, and more prospectively.
Data sources	Medical records at the three national centres; • Kings College Hospital, London • Birmingham Women's and Children's Hospital • Leeds Children's Hospital
Identifiers required for linkage purposes (for annual follow up)	1. Hospital ID
Identifiers retained in registry	1. Hospital ID – to allow linkage 2. NHS number – as suggested by CAG in 21/CAG/0019 (to ensure future linkage is possible if required) 3. Date of Birth – to allow linkage and for analysis 4. Maternal Postcode – for analysis 5. Gender – to allow linkage and for analysis 6. Ethnicity – for analysis 7. Date of surgical (Kasai) intervention – for analysis 8. Clearance of jaundice – Primary outcome measure 9. Associated anomalies – for analysis 10. Type of BA – for analysis 11. Need for and date of transplant – for analysis 12. Date of death – for analysis
Identifiers required for analysis purposes	1. Maternal postcode (at time of childs birth) 2. Ethnicity, 3. Associated congenital anomalies, 4. Type of biliary atresia, 5. Date of surgical (Kasai) intervention 6. Date of liver transplant 7. Date of death 8. Date of birth 9. Gender
Additional information	An update of patient management and outcomes for all previously registered children is also sent annually to KCH.

	These annual outcomes will cease once a child turns 16, but their previously collected data will remain in the registry

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 arrange a meeting with the CAG Chair (Via CAT). This is to ensure the applicants understanding of terminology and other important elements of this application.**

The applicant arranged a meeting with the CAG Chair which was completed on 14 January 2021. The Chair thanks the applicant for his time, and the interesting discussions. The Chair is now content with the applicants understanding of terminology, and no further action is required regarding this point.

2. **Please provide further justification regarding why full postcode is required for analysis, and why this cannot be modified to a less identifiable format.**

The applicant has confirmed that full postcode is required for retention in order to undertake future linkages if required. The Chair was content with this response.

3. **Please provide updated patient notification for both parents and children turning 16, as described above. These notification materials should include;**

    a) **The data items collected**
    b) **How the data is collected (including the annual follow up data disclosure, and the data flow between Trusts),**
    c) **The legal basis of the data collection and processing.**
    d) **It should be clear that the mothers postcode will be collected and retained for analysis indefinitely.**
    e) **Correct the statements regarding the function of CAG which are required to be corrected; *'The contents and design of the Registry have been approved by the Confidentiality Advisory Group'* should be altered to state something similar to the following; 'The Secretary of State for Health and Social Care, following advice from the Confidentiality Advisory Group (CAG), has provided support for the**

Biliary Atresia Registry to process confidential patient information without consent under Regulation 5 of the Health Service (Control of Patient Information) Regulations 2002 ('section 251 support').'

f) **Clearly explain why the data is collected.**
g) **Ensure the notification for those turning 16 is age appropriate (and describe the process of how they will be notified)**
h) **Consider developing a poster for clinical areas**
i) **Ensure the above documents are discussed with a patient and public involvement group.**

The applicant has provided a poster which can be displayed on the Children's Liver Disease Foundation (CLDF) website, and clinical areas in the participating Trusts. The Chair thanked the applicant for this greatly improved patient notification poster. The Chair was broadly content with this notification, which contained a clear opt out mechanism, commenting that it was very good. Of the points above, the only remaining elements to be met are d), g), and i). These will now be included as conditions of support, which the applicant is requested to return to CAG in 3 months. The Chair concluded that this registry is low risk and of high public interest, and is content to recommend support prior to these final points regarding notification, to enable the applicant to continue the registry.

4. **Further Patient and Public Involvement and Engagement is required to be undertaken. This should better describe the activities, and not refer to the information being processed as anonymous or pseudonymous. Children should be asked for their opinions if possible. Feedback should be specifically requested on;**

a) **The acceptability of this use of confidential patient information without consent;**
b) **Their opinions on the level of confidential patient information retained;**
c) **Feedback surrounding newly developed notification materials;**

The applicant has established strong links with the Children's Liver Disease Foundation (CLDF), and over the next year, the applicant plans to seek the opinions of patients and the public through this communication route. The Chair is content to recommend support on this basis, with this point as a condition of support, to report back at annual review.

5. **Please provide further details on the structure of the steering committee, which would include lay representation.**

The applicant has confirmed that the steering committee will include the consultant representatives of the three English centres, together with the Chief Executive of CLDF (or nominee) and a parent (also nominated by CLDF). The Chair was 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 Secretary of State for Health and Social Care, subject to compliance with the specific and standard conditions of support as set out below.

Specific conditions of support

The following sets out the specific conditions of support.

1. Support will be provided for 5 years in the first instance. A duration amendment will be required at this time to ensure continuing 's251' support.

2. Please provide updated patient notification for both parents and children turning 16, as described above. These notification materials should be returned to CAG within 3 months from the date of this letter, and should include;

    a) The poster should be updated to ensure it is clear that the mothers postcode will be collected and retained for analysis indefinitely.
    b) Develop a poster notification for those turning 16, ensuring it is age appropriate
    c) Ensure the above documents are discussed with a patient and public involvement group – (this is part of condition 3 and can be provided at annual review).

3. Further Patient and Public Involvement and Engagement is required to be undertaken. This should better describe the activities, and not refer to the information being processed as anonymous or pseudonymous. Children should be asked for their opinions if possible. Feedback should be provided to CAG at annual review, and is specifically requested to focus on;

    a) The acceptability of this use of confidential patient information without consent;
    b) Their opinions on the level of confidential patient information retained;
    c) Feedback surrounding newly developed notification materials;

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

   The NHS Digital **20/21** DSPT reviews for **King's College Hospital NHS Foundation Trust** and **Birmingham Women's and Children's NHS Foundation Trust** and **Leeds Teaching Hospitals NHS Trust** were confirmed as '**Standards Met'** on the NHS Digital DSPT Tracker (checked 25 November 2021).

f. 21/CAG/0149 - Legacies and Futures: Gestational Parents' Experiences with Vulnerability and Resilience as it Influences Parent and Neonatal Health

Name	**Capacity**
Dr Tony Calland MBE	CAG Chair
Professor Lorna Fraser	CAG member
Dr Sandra Duggan	CAG member
Ms Sophie Brannan	CAG member
Dr Martin Andrew	CAG member

Context

Purpose of application

This application from University College London sets out the purpose of medical research that aims to research what roles resilience and vulnerability play in the health and wellbeing of LGBTQ+ gestational parents, as compared to their cis-heterosexual peers, during their antenatal care and their neonates.

There is an assumption that those using pregnancy-related health services are cisgender and heterosexual. The patient population also includes those of different genders and sexual orientations. Structural cis-genderism and hetero-sexism in reproductive healthcare may cause stressors of stigma and discrimination, including

social and medical exclusion, during critical windows of foetal development. Stress and discrimination are linked to higher rates of miscarriage, preterm birth, macrosomia, and other undesirable birth outcomes. These stressors affect more than 525,000 lesbian, gay, bisexual, queer, and/or transgender (LGBTQ+) potential gestational parents in the UK, resulting in preventable higher risk for prenatal complications. The applicants intend to assess the impact of vulnerability as a measure of minority stress and systemic exclusion, alongside multi-level resilience factors.

Four sites, University College London Hospitals NHS Foundation Trust, Brighton and Sussex University Hospitals NHS Trust, Imperial College Healthcare NHS Trust and King's College Hospital NHS Foundation Trust, have been selected as recruitment sites, based on higher rates of LGBTQ+ residents in their catchment area. A monthly report will be run by the Principal Investigator or a supporting IT midwife at each site. This report will include active antenatal patients with a gestational age lower than 36 weeks. This list will be transferred to the Data Safe Haven at University College London, where the researcher will access the information. A selection of participants from this list will be emailed by the researchers and invited to take part in the study. LGBTQIA+ participants will be matched with cis-heterosexual parents accessing antenatal services at the same care site. Matching cases across the groups controls for potential confounders, including geographic and temporal differences that would otherwise not key to the overall analysis as individual variables. If interested, participants will follow a link in the email to a screener questionnaire that will be used to assess eligibility. If eligible, patients will be emailed with an invitation to participate in the study and sent a link to provide consent and complete the study surveys. Their participation will then proceed on a consented basis. Support is needed for the research team to receive the list of patients from the participating sites and to email eligible patients.

A recommendation for class 2, 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 18-49 years who identify as lesbian, gay, bisexual, queer and/or transgender, or cisgender and heterosexual, and who are currently pregnant and receiving antenatal care at one of the 4 study sites.

	The applicants anticipate that 800 patients will be included.
Data sources	7. Electronic and paper records held at 4 participating sites: • University College London Hospitals NHS Foundation Trust • Brighton and Sussex University Hospitals NHS Trust • Imperial College Healthcare NHS Trust • King's College Hospital NHS Foundation Trust
Identifiers required for linkage purposes	19. Name 20. Hospital ID number 21. Date of birth 22. Date of death 23. Postcode – district level
Identifiers disclosed to the Data Safe Haven at UCL for contact purposes	1. Name 2. Email address 3. Gestational due date
Identifiers required for analysis purposes	3. Date of birth 4. Date of death 5. Postcode – district level 6. Gender 7. Ethnicity 8. Sexual orientation
Additional information	The scope of support only extends to the sharing of contact details with the researchers. Once consent has been given, patients will complete online surveys and an at-home journal.

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. **Clarify how long the gap will be between the researchers receiving patient email addresses and the sending out of the invitation email.**

The applicant advised that there would be a two-week gap between the site PI's receipt of the email addresses and the sending of recruitment emails. The email addresses are likely to be used within 1-month of receipt and will be retained for a maximum of 45 weeks and will be deleted if they are not used by the patients' due date. In the instance where email addresses are marked "no further contact", these will be kept on record until the end of the data collection period in the event that another pregnancy takes place. This was clarified in the email protocol.

The CAG reviewed this response but remained concerned over the two-week delay between the receipt of email addresses from the site PI and the sending of recruitment emails to patients. A significant number of patients could have suffered a miscarriage in this time. The CAG queried whether a shorter time frame could be implemented and suggested that contact should be made within 48 hours and within a maximum of four days.

The applicant advised that there were some limitations to contacting patients within the suggested timeframe. The applicant noted that most miscarriages occur before week 16 of pregnancy and suggested that patients were contacted after week 16 and before week 36. The applicant also proposed a new average turnaround time of five working days, with a maximum of six working days and a minimum of four working days. These changes had been added to the email protocol document. The CAG accepted these changes.

2. **Clarify whether support is required for the research midwives in participating trusts to access patient records.**

The applicant confirmed that all site PIs and the research midwives would require support. This answer was accepted by the CAG.

3. **Clarify that the data on all patients not consented by their due date will be deleted.**

The applicants confirmed that patients who have not given consent and whose email addresses were not used, would be deleted around their due date. If patients have not joined the study, but have dissented from their email being used for further contact, their information will be retained on the secure server to ensure that they are not contacted in the future, even if their due date passes or their pregnancy concludes. This need to retain the information until the end of the data collection window is to make sure that there is no further contact during their current, or future, pregnancy. This is clarified on page 2 of the email protocol under “Deletion of Email Addresses”. The CAG accepted these changes.

4. **Confirm that no patient information will be disclosed to the USA.**

The applicant confirmed that no patient information will be disclosed to the USA. The CAG noted this and raised no further queries.

5. **Patient notification materials, which explain how patients can dissent to contact prior to receiving the email invitation, need to be created and provided to the CAG.**

The applicants created a set of materials to pair with the existing notification materials. The text on the graphics had been adapted from the NHS Data Matters website. Choice of focus on the National Opt-out ensures advice will be across the person’s NHS record (i.e., a patient starting at UCLH would be able to opt-out and then transfer care without needing to opt-out again at their new care site). These materials will be shared by the sites as their capacity allows them to (i.e., if they can post a study poster, they are required to also post a poster about data access).

Members asked that the reference to the CAG in the patient notification materials was revised to explain the role of the CAG and a reference to s251. The CAG suggested the following, “The application has been reviewed by the Confidentiality Advisory Group, who recommended that the application be given support under Regulation 5 of the Control of Patient Information (COPI) Regulations. CAG are an independent group of experts and lay people who scrutinise applications to access confidential patient information for research purposes and advise the Health Research Authority.” A revised recruitment and accepted. The applicant provided an updated recruitment

email, which contained text explaining the role of the CAG and Regulation 5 support. This was accepted by the CAG.

6. **The following changes to the invitation email need to be made:**

    a. **The text of the invitation emails needs to be revised to explain how patients contact details had been obtained by the researchers.**

The email was revised to include a section explaining how patient email addresses had been obtained.

    b. **The other participating sites should also be mentioned**

The section “How do you have my email address?” includes a link to a webpage listing each site’s information and a link to their Patient Advice and Liaison Service (PALS). PALS is the local contact that would assist if there are any concerns about the study, as well as if they are looking for more information about opting-out of data use for research locally (as explained to the PPI participants).

The CAG noted that patients will be advised to contact local PALS team and requested assurance was provided that local PALS teams will be informed about the project and the opt-opt process. The applicant explained that the intention is to sign-post people to the Trust-level data use policies that discuss opting out at the Trust-level if they wish. A link to the study-level opt out form, along with a clearer description of the site-specific links, has now been added to the top of this webpage from the study site. The PALS links remain as they are part of the REC required information that is also available within the PIS, thus have been added to the study site for further ease of access along with the data use policy links. The language has tried to encourage awareness of the resources while still trying to sign-post primarily to the Study-level opt out based on the concerns in mentions in Point 3 above.

    c. **An NHS header needs to be included on the email and NHS involvement explained.**

An NHS header had been added to the email.

d. Email and telephone contacts for the researchers also need to be provided.

Email address and physical address has been included for the study contact/coordinator. There is no phone number available, since the study coordinator does not have a work phone number due to being a PhD student. The CAG noted the importance of including a telephone number, so that patients without access to the internet can still opt-out. The applicant provided postal and telephone contact details. These additions were accepted by the CAG.

e. The email needs to be reviewed by a relevant patient and public involvement group.

A revised email was provided for review. This was reviewed by 4 patient and public involvement participants. The email was revised further based on the feedback received and reviewed by 4 other patient and public involvement participants. The final version was provided to the CAG.

The CAG noted the information provided above and agreed that further changes were needed. The L+F_Draft_Sites_Webpage referred to a local opt-out and suggested that PALS can assist. However, the other notification and dissent materials provided directed patients to the National Data Opt-Out. The CAG agreed that a project specific out-out needed to be created, so that patients could opt-out of the inclusion of their data in this project specifically rather than via the National Data Opt-Out, which opts patients out of use of their data in all research. The patient notification documents, including the poster, also needed to explain that patients will receive an email and direct to information about the project specific opt-out.

The applicant revised the social media images, which will be used alongside the social media posts, to make it clearer that the best option is opting out locally. The images emphasised the study specific opt out, while still providing the signposting to learning more about the National Data Opt-Out. Image captions have also been expanded for the images have been added to the study protocol.

The CAG also asked that the text to be displayed on relevant websites was provided. The applicant advised that no information specific to the study will be added to Trust websites, as the study website will sign-post to existing, Trust-level services that are already handled by the office. The study webpage had been revised to make this clearer.

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. Provide a report on the progress of recruitment within 3 months of the Fully Supported Outcome being issued.

2. Favourable opinion from a Research Ethics Committee. **Confirmed 10 September 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 **2020/21** DSPT review for **University College London, University College London Hospitals NHS Foundation Trust, Brighton and Sussex University Hospitals NHS Trust and King's College Hospital NHS Foundation trust** are confirmed as 'Standards Met' on the NHS Digital DSPT Tracker (checked date 14 October 2021).

The NHS Digital **2020/21** DSPT review for Imperial College Healthcare NHS Trust is pending.

g. 21/CAG/0121 - Long-term risk of cancer and general health outcomes in women who underwent assisted reproductive technology in Great Britain, 1991-2010: a data linkage study

Name	Capacity
Ms Clare Sanderson	CAG Alternate Vice Chair
Dr Pauline Lyseight-Jones	CAG member
Professor Jenny Kurinczuk	CAG member
Ms Rose Payne	CAG member
Mr Myer Glickman	CAG member

Context

Purpose of application

This application from UCL Institute of Child Health set out the purpose of medical research that seeks to investigate the long-term risk of cancer and general health outcomes in women who underwent assisted reproductive technology treatment.

Infertility, defined as the inability of a sexually active couple to achieve pregnancy within one year, is associated with significant medical, social, economic and demographic consequences and, as such, is considered a major public health problem by the World Health Organization with approximately 50 million couples experiencing it worldwide in 2010. There has been a global increase in the number of women who have undergone assisted reproductive techniques (ART). ART cycles typically require 2-4 weeks of ovarian stimulation and endometrial support with gonadotrophins and sex steroid hormones. Most women undergo multiple rounds of treatment, which results in abnormally elevated exposure to endogenous steroid hormones. This endocrine assault is a continuing source of concern for patients and the medical profession, primarily because of the potential carcinogenic effects on hormone responsive tissues, such as the breast, endometrium and ovary. Other short and long-term health outcomes observed in women who have undergone ART include ovarian hyperstimulation syndrome, multiple pregnancy, and increased pregnancy morbidity and obstetric complications, Side-effects of medications are also well known and poor mental health has also been reported. However, much of the evidence examining cancer and long-

term general health outcomes in women who have undergone ART remains largely inconsistent.

The applicants have conducted a previous study which found increased risk of in-situ breast cancer and invasive and borderline ovarian tumours in a cohort of 255,786 women who underwent ART in the UK. In this previous study, the HFEA records of women who had undergone ART in the UK between 1991 and 2009 were linked to the NHS Service Central Registers of England, Wales and Scotland as a one-off data linkage. The applicants seek to use this previously established cohort to compare hospital admission rates and general health outcomes of women who have previously undergone fertility treatment to population controls. The applicants will also investigate whether the risk of cancer has changed with the increased follow-up period.

The archived dataset from the previous study (the ART cohort) is currently held by NHS Digital. NHS Digital will identify an unexposed comparison cohort, consisting of women who conceived spontaneously, from the Personal Demographics Service dataset. Two unexposed women for each member of the ART cohort will be included, matched on month and year of birth, sex and parity. NHS Digital will link the ART and Population comparison cohorts to the NHS Digital Cancer Registration Dataset and HES. The linked datasets will then be pseudonymised. For the ART cohort, the unique ID number assigned during the previous study will be used. The Population comparison cohort will be assigned unique ID numbers. The pseudonymised datasets will then be disclosed to UCL. The datasets will be linked to pseudonymised fertility data from the previous study and held in UCL archives. The data analysis will be carried out in the UCL Data Safe Haven.

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	255,786 women who underwent fertility treatment in England and Wales between 1991 and 2009 and were included in the ART study.

	Population comparison cohort consisting of women who conceived naturally, matched for age, sex and parity, identified in a 1:2 ratio. Approximately 534,000 patients will be included as a population comparison cohort. The applicants note that the archived cohort held by NHS Digital includes patients who underwent fertility treatment in the UK between 1991 and 2009. Additionally, 5,762 women recorded as having had their first assisted reproduction cycle in the period 1st January 2010 to 31st December 2010 and as having given consent for their data to be used for research were also included in this cohort; the latter are out of scope for approval.
Data sources	8. The ART Cohort dataset, archived at NHS Digital 9. The NHS Digital Cancer Registration Dataset, held by NHS Digital 10. HES dataset, held by NHS Digital 11. The Personal Demographics Service dataset at NHS Digital
Identifiers required for linkage purposes	24. Name 25. NHS Number 26. Date of birth 27. Postcode – district level
Identifiers required for analysis purposes	9. Date of birth 10. Gender 11. Ethnicity

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

1. **Clarify whether NHS Digital will link the dataset for the unexposed comparison cohort group to the NCRAS dataset.**

The applicant explained that the unexposed comparison cohort group will be linked to the NHS Digital Cancer Registry as well as the Hospital Episode Statistics Database. This will be done in order to allow comparison of health outcomes between the ART group and the matched control population that conceived spontaneously. This information was reviewed and accepted by the CAG.

2. **Confirm that patients' date of birth will be revised to month and year and birth, and Geocode revised to Index of Multiple Deprivation in the dataset sent to University College London.**

The applicants advised that patient's date of birth will be revised to month and year of birth, and Geocode revised to IMD in the dataset sent to the research team at UCL. This requirement will be included in the DARS application to NHS Digital and will also be communicated to the data team prior to commencement of linkage. This information was reviewed and accepted by the CAG.

3. **Further details (a list of data items) need to be provided on the information held in this fertility dataset, so the CAG can have greater clarity about the nature and content of the final linked dataset which will be created.**

A list of data items included in the fertility dataset was provided. This information was reviewed and accepted by the CAG.

4. **Clarify why patients' gender is required in the analysis dataset.**

The applicants advised that patient's gender was included in the application as it will be used by NHS Digital to identify the unexposed control group from the Personal Demographics Dataset. This variable can be excluded from the final datasets shared

with the research team at UCL. This information was reviewed and accepted by the CAG.

5. **The annual review for application ECC/HFEA 5-04(b)/2010 needs to be submitted.**

The annual review reports for application ECC/HFEA 5-04(b)/2010 have now been submitted. This information was reviewed and accepted by the CAG.

6. **Patient notification, separate to the Privacy Notice, needs to be created. This needs to explain that support for the application activity is given under Regulation 5 of the Control of Patient Information (COPI) Regulations ('s251 support'). The patient notification needs to explain what will happen to patient data for both the ART cohort and the comparison cohort.**

A Patient Notification was created and submitted. The applicants advised that this will be made available on the UCL website. This information was reviewed and accepted by the CAG.

7. **The ART cohort need to be checked against the National Data Opt-Out.**

The applicants confirmed that the ART cohort will be checked against the National Data Opt-Out the data linkage is carried out. This will be specified in the DARS application and will also be conveyed to the NHS Digital data linkage team. This information was reviewed and accepted by the CAG.

8. **A dissent mechanism needs to be created for this application specifically and ways in which patients can register dissent need to be explained in the patient notification.**

A dissent mechanism was created and information about this provided in the patient notification documents.

The CAG noted that the patient notification advised patients to contact their GPs to dissent. GPs would register a Type 1 objection to the National Data Opt-Out, which would not affect the data being used for this specific project. The CAG advised that including the NHS Digital link to the National Data Opt-Out would be more appropriate. The applicants provided a revised patient notification document. This information was reviewed and accepted by the CAG.

9. **Provide clarification on how long the linkage will take place and when the confidential patient information will be deleted by NHS Digital, or if an alternative to deletion is being considered then a justification needs to be provided.**

The NHS Digital data team advised the applicant that the data linkage process would take approximately 6-8 months.

The applicants noted that the CAG had suggested retaining patient data for further linkage in the future, considering the age of the cohort, and recognised the value of exploring health outcomes in this cohort with longer follow-up time. The applicants therefore sought to retain patient data by NHS Digital for use in future studies and for the purpose of updating the findings of the current study with even longer follow-up period. The applicants advised that no confidential patient information would be shared with UCL, and the pseudonymized dataset generated for the current study will be deleted within the time frame specified in the application. Future linkage using the identifiable data to be retained by NHS Digital will be done with all necessary permissions in place. This information was reviewed and accepted by the CAG.

10. **Patient and public involvement needs to be undertaken specifically for this application specifically. This needs to include women from the ART cohort and women who will be eligible to be included in the unexposed comparison cohort. Feedback from this activity needs to be provided before the final support outcome letter will be issued.**

The applicants advised that an online, questionnaire-based survey had been developed and distributed to women via social media on the 4th of October 2021. The initial findings from the survey were shared with the CAG.

The CAG reviewed the information on the linked survey. Members asked that the introduction was amended to better reflect the patient information sheet, as it did not

make it clear that their identifiable data will be used in the linkage. Revised wording was provided, which was reviewed and accepted by the CAG.

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 08 October 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 review for **NHS Digital** was confirmed as 'Standards Met' on the NHS Digital DSPT Tracker.

2. New Amendments

20/CAG/0157 – The Oxford Risk Factors And Non-invasive imaging Study: ORFAN

Name	Capacity
Ms Caroline Watchurst	HRA Confidentiality Advisor

Ms Clare Sanderson	CAG Alternate Vice-Chair

Context

Amendment request

This application aims to develop and validate novel imaging biomarkers to predict future heart attacks and other cardiovascular complications. Support is currently in place to allow the disclosure of confidential patient information from participating NHS Trusts to NHS Digital, Barts Health NHS Trust (on behalf of the National Institute for Cardiovascular Outcomes Research (NICOR)), Kings College London (on behalf of the Sentinel Stroke National Audit Programme (SSNAP)), and local NHS Trust NIHR Biomedical Research Centres (BRC's) for the purposes of time limited linkage with clinical datasets, in order for anonymised linked datasets to be disclosed to the applicants at the University of Oxford. Support is currently in place to use confidential patient information regarding 75,000 retrospective patients in the UK (England and Wales only for the purposes of CAG), who have undergone clinical Computed tomography angiography (CTA) scans or unenhanced computed tomography (CT) chest, abdomen and pelvis scans at participating NHS Trusts. The timescale for inclusion in the study is different for each collaborating NHS Trust, however, no patient with a scan before 2010 will be included in the study.

This amendment seeks support to increase the number of patients from 75,000 to 200,000. This is to ensure the study is sufficiently powered to enable applicants to answer the scientific questions related to the risk of cardiovascular disease (CVD) conveyed by COVID-19, and the relationship between pre-existing CVD and COVID-19 infection, which would not be possible without this amendment request.

Confidentiality Advisory Group advice

The amendment requested was considered by Chair's Action. The Alternative-Vice Chair (AVC) was content to support the increase in cohort, as the applicant had provided sound scientific reasoning.

The AVC requested confirmation that there were no other changes to the cohort requested. The applicants confirmed that any patients with a scan before 2010 will remain not included, as per original support letter. Applicants also confirmed that there are sufficient suitable candidates within the 13 organisations in the original support.

Therefore, the applicants confirm they will reach 200,000 patients in total from across the 13 sites, whilst remaining within the specified boundaries of the original support.

The AVC was content to recommend support and thanked the applicant for the clarifications.

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: All organisations processing confidential patient information, including the Trusts where patients are identified will be required to have security assurances in place. However, as there are more than five organisations, the CAT team will not check each one individually; it is the responsibility of the applicant to ensure these are in place.**

2. Confirmation of a favourable opinion from a Research Ethics Committee. **Confirmed 27 October 2022**

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

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

Context

Amendment request

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

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

This amendment sought support to extend the duration of support due to a pause in activity due to Covid-19. The planned end date is now 31 May 2024.

The amendment also sought support to change the location of where data is stored and analysed to an accredited Trusted Research Environment (TRE) managed by the Health Informatics Centre (HIC), located at University of Dundee. The TRE will receive all the routine datasets from each respective data provider and the manually collected data from the University of Nottingham database(s). An updated flowchart has been provided. In addition, there will be two different processes for how data is able to be sent to the TRE. The first process, which was supported as part of the original application, involves national databases receiving a request from the GBS3 team to provide all data from a hospital/ trust during a specific time period. The relevant data is then provided directly by the national databases to the TRE and will include the NHS number, date of birth and postcode to enable linkage with other datasets from other databases. The second process for receiving datasets is a change from the original application and involves these national databases being provided with the relevant NHS number, date of birth and postcode of women and babies (which will have already been provided by the process 1 national databases). Once this information has been provided to these process 2 databases, they can provide the specific data on each woman and baby directly to the TRE. This process applies to Badgernet, National Neonatal Research Database (NNRD) and Paediatric Intensive Care Audit Network database (PiCANet), This new process has been added as the teams at NNRD,

PiCANet and Badgernet confirmed they were unable to provide the data using the original process.

This amendment sought support for the addition of Office for National Statistics (ONS) mortality data, from NHS Digital, as a new routine data source. Date of death and cause of death are required to capture early neonatal deaths and maternal deaths which happen at home and were not followed by a hospital visit.

The amendment also sought support for the addition of two new participating sites as data processors - Homerton University Hospital NHS Foundation Trust and Kettering General Hospital NHS Foundation Trust.

CAG has also accepted the minor changes to study documents including protocol, as notifications.

Confidentiality Advisory Group advice
The amendment requested was considered by Chairs' Action, who was content to support the amendment, noting the changes appear reasonable and relatively minor in risk.

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

Specific conditions of support

The following sets out the specific conditions of support.

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

   The NHS Digital **20/21** DSPT review for **the University of Nottingham and the DSPT equivalent for NHS Digital** were confirmed as 'Standards Met' on the NHS Digital DSPT Tracker (checked 24 January 2022)

Due to the number of organisations involved it is the responsibility of University of Nottingham, as controller, to ensure that all organisations processing confidential patient information without consent meet the minimum required standard in complying with DSPTs, and take remedial action if they become aware of any that fall below this, or where any concerns are raised. These will not be individually checked by CAT as there are more than 5 organisations.

Health Informatics Centre at the University of Dundee – HSC-PBPP approval confirmed 04 November 2021

2. Confirmation of a favourable opinion from a Research Ethics Committee.
   Confirmed 28 January 2022

PIAG 4-08(d)/2003 – National Confidential Inquiry into Suicide and Safety in Mental Health (NCISH)

Name	Capacity
Ms Caroline Watchurst	HRA Confidentiality Advisor

Context

Amendment request

The National Confidential Inquiry into Suicide and Safety in Mental Health (NCISH) has existing support to collect confidential patient information for the NCISH core database on patients who died by suicide when under the recent care, or recently discharged from, specialist mental health services.

In this amendment, the applicants sought support to extend the duration of support until 31 March 2024, in line with funding from HQIP.

The amendment also sought support to include a protocol (the 'NCISH datasheet checking protocol for services' document) which clarifies the process of identifying

those who meet the criteria of a patient suicide. This is merely an administrative addition, and does not alter the scope of ‘s251 support. The CAG have therefore accepted this as a notification only.

Confidentiality Advisory Group advice
The amendment requested was considered by the Confidentiality Advice Team. The CAT agreed that this was a minor change and did not impact on the aims of the study or the scope of support.

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 **University of Manchester - National Confidential Inquiry into Suicide and Homicide** was confirmed as ‘Standards Met’ on the NHS Digital DSPT Tracker (checked 15 February 2022)

2. Confirmation of a favourable opinion from a Research Ethics Committee
   Confirmed non substantial 12 January 2022

20/CAG/0112 – Ethnic Density and Psychosis in a British Pakistani Population: an investigation using data from the East Lancashire Early Intervention Service

Name	Capacity

Ms Caroline Watchurst	HRA Confidentiality Advisor

Context

Amendment request

This application from the University of Liverpool aims to determine whether living in areas with a higher proportion of one's own ethnic group protects against the risk of developing psychosis in British Pakistani groups in a region of Northern England. Support is in place to allow the disclosure of confidential patient information from East Lancashire Early Intervention Service (ELEIS) at Lancashire & South Cumbria NHS Foundation Trust to the research team at the University of Liverpool.

This amendment sought support to change the Chief Investigator from Dr Ross White to Dr Victoria Vass. This amendment also sought support to extend the duration of support until 30 September 2022.

Confidentiality Advisory Group advice

The amendment requested was considered by the Confidentiality Advice Team. The CAT agreed that this was a minor change and did not impact on the aims of the study or the scope of support.

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 **University of Liverpool and East Lancashire Early Intervention Service (ELEIS) at Lancashire &**

South Cumbria NHS Foundation Trust were confirmed as 'Standards Met' on the NHS Digital DSPT Tracker (checked 15 February 2022)

2. Confirmation of a favourable opinion from a Research Ethics Committee. **Confirmed 10 December 2021**

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

Name	Capacity
Ms Caroline Watchurst	HRA Confidentiality Advisor

Context

Amendment request

This application gained support under the Regulations to legitimise access to confidential patient information on site at GP practices by the Pharmacist undertaking the review of the GP trainee prescribing practices. The confidential patient viewed is about patients who have been prescribed medication by a GP Trainee within a participating practice during the study duration. In the original application, it was stated that there would be 20 GP trainees recruited to the study and 200 prescriptions will be assessed per trainee, requiring access to approximately 4,000 patient records.

This amendment requests support to widen the recruitment pool of potential GP trainees from only those in their final year (ST3s) to additionally including GP trainees in their second year of training (ST2s). The applicant has confirmed that they are still only aiming to recruit 20 GP trainees, and therefore this change does not represent an expansion of the processing of confidential patient information without consent.

The applicants also wish to use promotional material to advertise the study, but this does not represent a change in confidential patient information arrangements, and is accepted by CAG as notification only.

This amendment also request support to include an additional 10 CCGs as data processors in the form of participating sites. These are listed below;

NHS North East Hampshire and Farnham CCG

NHS Fareham and Gosport CCG

NHS Isle of Wight CCG

NHS North Hampshire CCG

NHS Portsmouth CCG

NHS South Eastern Hampshire CCG

NHS Southampton City CC

NHS West Hampshire CCG

NHS Oxfordshire CCG

NHS Salford CCG

Confidentiality Advisory Group advice
The amendment requested was considered by the Confidentiality Advice Team who raised no issues with the amendment, and noted this was no more disclosive than the original supported design.

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:
   Not checked due to the number of research sites involved. Support is recommended on the basis that the applicant ensures the required

security standards are in place at each site prior to accessing confidential patient information with support under the Regulations.

2. Confirmation of a favourable opinion from a Research Ethics Committee.
   Confirmed 25 January 2022

19/CAG/0209 – Advanced cardiovascular risk prediction in the acute care setting

Name	Capacity
Ms Caroline Watchurst	HRA Confidentiality Advisor

Context

Amendment request

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

In this amendment, the applicants are seeking support to extend the duration of support until 22 December 2023, in order for data analysis to be completed. They application has been significantly delayed by the pandemic.

Confidentiality Advisory Group advice

The amendment requested was considered by the Confidentiality Advice Team. The CAT agreed that this was a minor change and did not impact on the aims of the study or the scope of support.

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 University of Manchester was confirmed as 'Standards Met' on the NHS Digital DSPT Tracker (checked 15 February 2022)

2. Confirmation of a favourable opinion from a Research Ethics Committee.
   Confirmed as non substantial 31 January 2022

21/CAG/0049 – Do Safe and Well Visits delivered by the Fire and Rescue service reduce falls and improve quality of life among older people? A randomised controlled trial (FIREFLI)

Name	Capacity
Ms Caroline Watchurst	HRA Confidentiality Advisor
Dr Murat Soncul	CAG alternative vice-chair

Context

Amendment request

The applicants have existing support to allow the disclosure of confidential patient information from the Exeter database held by NHS E&I to the Humberside Fire and Rescue Service, and Kent Fire and Rescue Service, via NHS Digital's PCRM, so that suitable patients can be approached for consent to take part in the study. The support also covered the potential exposure of research staff to confidential patient information when assisting with the mailing of recruitment packs.

This amendment sought support to include a new data flow required to identify eligible patients for consent. The applicant has experienced difficulties in receiving the data originally required from NHS Digital, and so in order to start recruitment has identified a less disclosive manner in which to start approaching patients. The Fire Service already receives address data from Experian, which is not confidential patient information, but is probabilistic demographic data used to identify households that are likely to contain someone over 70 years of age/ in the demographic groups the Fire and Rescue Service target for the offer of Safe and Well visits. Experian, the Fire Service, and the applicant has confirmed that the data provided by Experian can be used in order to send invitation letters to addresses in order to begin recruitment. This new flow does not require 's251' support as it is not a breach in the common law duty of confidentiality.

The applicant has requested that the originally supported method of identifying eligible patients using confidential patient information from the NHS remain in place, as it is still the preferred method as this targets the eligible population more precisely. The applicant will continue preparations for both methods of recruitment, however currently the only method available is the Experian data, and the amendment is therefore required in order for the applicant to begin recruitment.

Confidentiality Advisory Group advice
The amendment requested was considered by Chairs' Action. The Alternate Vice-Chair was content with this proposal.

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

Specific conditions of support

The following sets out the specific conditions of support.

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

The NHS Digital **2020/21** DSPT reviews for **the University of York, Humberside Fire and Rescue Service** and **Kent Fire and Rescue Service** are confirmed as '**Standards Met'** by email to the CAG inbox (11 November 2021)

2. Confirmation of a favourable opinion from a Research Ethics Committee. **Confirmed 07 February 2022**

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 second of the reviews due to take place in 2021, which will investigate the care of patients with Community-Acquired Pneumonia (CAP). This has been delayed until early 2022 due to the Covid-19 pandemic.

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 CAP. There is concern that the quality of care across the UK, regarding CAP, is not consistent, and this topic has become even more relevant since the pandemic has highlighted issues regarding CAP.

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

Confidentiality Advisory Group advice
The amendment requested was considered by Chair's Action. The Vice-Chair agreed that the amendment request was a straightforward amendment for NCEPOD to use its well-established method to audit Community-Acquired Pneumonia as part of its regular programme, and was content to recommend support.

Confidentiality Advisory Group advice conclusion
In line with the considerations above, the CAG agreed that the minimum criteria under the Regulations appeared to have been met for this amendment, and therefore advised recommending support to the 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 15 February 2022)**

21/CAG/0032 – Non-statutory Medical Examiner System – second phase

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

Context

Amendment request

The applicants have existing support to allow the disclosure of confidential patient information for deceased patients, who were cared for by other healthcare providers, such as GPs, independent healthcare providers, and NHS Trusts and NHS foundation trusts which do not host a medical examiner office, to the medical examiners within host NHS trusts.

Support under Regulation 5 was sought to provide a legal basis for this activity until primary legislation was introduced to put the system on a statutory footing. This was expected to be in place from April 2022.

The applicants are seeking to extend the duration of support until 31 March 2023 as the primary legislation is not yet in place. Provisions for the statutory system are contained in the Health and Care Bill and are currently being progressed through parliament. The Department of Health and Social Care have advised that they do not expect the statutory system to be in place before summer 2022. However, the applicants seek support until 31 March 2023 in case of further delays.

Confidentiality Advisory Group advice

The amendment requested was considered by Chairs Action, who was content with his amendment request for duration.

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. See section below titled ‘security assurance requirements’ for further information. **Confirmed**

Due to the number of organisations involved it is the responsibility of NHS England and NHS Improvement, as controller, to ensure that Trusts hosting the medical examiners meet the minimum required standard in complying with DSPTs, and take remedial action if they become aware of any that fall below this, or where any concerns are raised about a Trust.

20/CAG/0116 - Quality and Outcomes in Oral and Maxillofacial Surgery (QOMS)

Name	Capacity
Dr Patrick Coyle	CAG Vice Chair
Ms Kathleen Cassidy	Confidentiality Advisor

Context

Amendment request

The applicants have existing support to allow the disclosure of confidential patient information from participating trusts in England and Wales to the Barts Cancer Care (BCC) Safe Haven Environment. The applicants are seeking to include items related to the Sentinel Lymph Node Biopsy (SLNB).

The SLNB is a diagnostic procedure to assess early stage oral cavity and oropharynx cancers. The procedure is relatively new in the UK, therefore the NICE Head and Neck Cancer Quality Standard recommends that hospitals measure the proportion of people with early stage oral cavity cancer who do not need cervical access as part of surgical management and who have sentinel lymph node biopsy as an alternative to elective neck dissection. Hospitals are also asked to record the surgery-related morbidity and length of stay for people with early-stage oral cavity cancer. The SLNB data will be collected as an extension of the QOMS registry as part of the current data collection cycle (2021-2024). After this period, it will be reviewed based on results and evidence in published literature.

The applicants also seek to collect confidential patient information in retrospective projects. The initial CAG application included a provision to collect data for the oncology and reconstruction component of the registry. This data was to be anonymised data where possible. The applicants have reconsidered whether collecting anonymised data is feasible and are now seeking to include confidential patient information, such as NHS or hospital numbers in each project, and patient dates of birth and postcodes. The applicant advised that amendments would be submitted to the CAG to provide a list of the data items for each project.

In this amendment, the applicants specifically seek to collect retrospective data for orthognathic surgery. This project would be a one-off, with no planned extension and would cover the period 01 January 2017 – 31 December 2019. Patient NHS numbers, date of birth, gender and dates related to their treatment milestones will be collected. Data, including items of confidential patient information, will be retained for 2 years following the end of data collection in order to allow verification for data quality and analysis.

Confidentiality Advisory Group advice

The amendment requested was considered by the Confidentiality Advisory Group at the 20 January Full CAG meeting.

The CAG agreed that support for the amendment to include confidential patient information collected for retrospective projects, specifically to collect retrospective data for orthognathic surgery could not be recommended. Members noted that the collection of retrospective data significantly expanded the scope of the project and asked that a new application was submitted. This application should include the current activity undertaken for the Quality and Outcomes in Oral and Maxillofacial Surgery (QOMS) and the collection of SLNB data, as well as the proposed retrospective linkages. The rationale for using patients' hospital number to link to HES, the information needed for linkage to HES and how this would be undertaken needed to be provided. Alternatives to using patient postcodes, such as using Lower Super Output Area, should be explored and, if they can't be used, justification given on why not. Further patient and public involvement needed to be undertaken when preparing the new application. The patient notification materials also needed to be revised and expanded to include the retrospective data linkage.

The CAG agreed to recommend support for the addition of items related to the Sentinel Lymph Node Biopsy, provided that clarification was provided over the data flows involved.

The applicant provided responses to the below queries:

1. **Further details on the revised data flows, including the flow of information for the SNLB, need to be provided.**

The applicant advised that no changes to the data flow were required, as the new items collected for the SLNB are an extension of the current Oncology & Reconstruction dataset. The dataflow for SLNB therefore remains the same as the one submitted in the original CAG application. The CAG noted this information and raised no further queries.

2. **Please clarify whether the SLNB data is obtained from an existing, centralised database or if this data collection will require an additional data flow from each participating trust? If the former, please provide further details on this database.**

The applicants explained that some surgeons may maintain records for their own patients. The applicants aim to establish a centralised data collection for SLNB. An additional data flow will be required from each participating trust. The applicants will apply to each participating trust to update the existing approval to include SLNB. The CAG noted this information and raised no further queries.

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 the specified part of 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 Barts CR-UK Centre was confirmed as 'Standards Met' on the NHS Digital DSPT Tracker (checked 13 December 2021)

3. Annual Review Approvals

20/CAG/0003	Study of cancer risks in ataxia telangiectasia heterozygotes
20/CAG/0106	The SUFFICE-CoV Study
19/CAG/0219	Pancreatic Cancer Epidemiology V0001
CAG 8-03(PR2)2013	UK Register of Fatal anaphylactic reactions
18/CAG/0159	Environment and family risk factors for children's hospital admissions
20/CAG/0121	Strengthening disclosure in NHS Maternity Care
19/CAG/0094	The Coagulum Study - Version 1.0
16/CAG/0064	The UK Renal Registry: a research database
15/CAG/0127	Cellular Immunity to herpesvirus infection: studies with EBV and CMV
19/CAG/0059	National Early Inflammatory Arthritis Audit
CR12/2014	Oxford Vegetarian Study
21/CAG/0008	CPRD 2020 resubmission (ECC 5-05(a)/2012)

18/CAG/0091	Connected Bradford - Linked Education and Health Research Database
20/CAG/0064	Health, Education and Social outcomes of children with VI/SVIBL
17/CAG/0050	Educational Outcomes in Children Born after ART
20/CAG/0087	Research Database for Cambridgeshire and Peterborough NHS Foundation Trust
20/CAG/0068	SLAM-CRIS/NPD Linkage
19/CAG/0188	A population based study of genetic predisposition to prostate cancer
19/CAG/0084	Breast Pathology Database
19/CAG/0096	A Randomized Pilot Study of REVISiT
18/CAG/0124	Automated Cancer Diagnosis and Prognosis Using Digital Images (v. 1)
20/CAG/0137	The BCAE Study
19/CAG/0161	Early cryoprecipitate in major trauma haemorrhage: CRYOSTAT-2
17/CAG/0015	ARK-hospital
17/CAG/0156	Rectal Cancer Oncological Complete Response Database (OnCoRe)
21/CAG/0007	The National Neonatal Audit Programme
20/CAG/0013	Correlates of cognitive changes in epilepsy
20/CAG/0123	REACT - AMI Study
17/CAG/0151	ARREST
18/CAG/0024	POPStar
20/CAG/0147	GCS-NeuroCOVID paediatric substudy
17/CAG/0184	Epilepsy 12 Audit
20/CAG/0143	CTSU clinical trial follow-up service for EBCTCG

19/CAG/0221	AREG, EREG and EGFR: response to anti-EGFR agents in colorectal cancer
18/CAG/0182	UK Prospective Diabetes Study (UKPDS) Legacy Study
18/CAG/0044	Long term follow up of ASCOT trial into Electronic Records (LATER)
18/CAG/0177	5 and 10 year follow up of the WRAP trial (WRAP Up)
17/CAG/0189	Early Onset Depression (EOD-UK & ROI)
18/CAG/0175	The PJI Study
21/CAG/0017	OPTIC-19
19/CAG/0101	Oxford Cerebrovascular Research Database
20/CAG/0020	Healthcare Usage of Bariatric/Metabolic Surgery
18/CAG/0002	Associations between diabetes and education
18/CAG/0052	BPSU survey of severe Chronic Fatigue Syndrome/Myalgic Encephalopathy
CAG 8-02(a)/2014	Assuring Transformation: Data collection by Clinical Commissioning Groups to populate patient registers and reporting
CAG 8-02(b)/2014	Data collection by NHS England Area Teams responsible for commissioning secure mental health and child and adolescent mental health services to populate patient register and reporting
CAG 8-02(c)/2014	Assuring Transformation: Enhanced Quality Assurance Process Data flow (Disclosure by HSCIC to NHS England)

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, Professor William Bernal and Dr Murat Soncul	*04th April 2022*
Signed – Confidentiality Advice Team	Date
Caroline Watchurst Confidentiality Advisor	*28th March 2022*