Minutes of the meeting of the Confidentiality Advisory Group

20 February 2020 at HRA Manchester, Barlow House

Present:

Name	Present	Notes
Dr Tony Calland MBE	Yes	CAG Chair
Dr Martin Andrew	Yes	CAG Member
Dr Patrick Coyle	Yes	CAG Vice-Chair
Dr David Evans	Yes	CAG Member
Dr Liliane Field	Yes	CAG Member
Dr Lorna Fraser	Yes	CAG Member
Mr Myer Glickman	Yes	CAG Member
Dr Katie Harron	Yes	CAG Member
Dr Rachel Knowles	Yes	CAG Member
Ms Diana Robbins	Yes	CAG Member
Ms Clare Sanderson	Yes	CAG Member

Also in attendance:

Name	Position (or reason for attending)
Ms Natasha Dunkley	Head of Confidentiality Advice Service
Ms Lindsey Peggs	Senior Confidentiality Advisor
Mr Paul Mills	Research Regulation Specialist
Mr Stephen Roberts	Research Regulation Specialist
Mr Alastair Nicholson	Senior Development Manager/Interim Programme Manager – HRA Approval

1. Introduction, apologies and declarations of interest

2. Consideration items

a. ECC 5-05(a)/2012 - Clinical Practice Research Datalink Service (CPRD) Annual Review

Context

This application is a unique research application that could be considered to provide an 'honest broker' or 'safe haven' processing environment. The CPRD is a function of the MHRA. Due to its national nature, the annual review is considered at full CAG meetings. The application sets out the activity to process a broad range of specified datasets by NHS Digital, and to enable de-identified disclosures to research applicants by the CPRD, following advice from their ISAC group.

At a high level, support under Regulation 5 of the Health Service (Control of Patient Information) Regulations 2002 has been provided for the following aspects:

- NHS Digital to receive identifiers, undertake linkages and provide the CPRD a deidentified dataset. While CPRD is not receiving identifiers

directly, it is important to recognise that for the purpose of transparency, NHS Digital is processing identifiers on behalf of CPRD under this legal support.

- GP practices and specified others (according to the approved 'Master Dataset' list) to transfer confidential patient information to NHS Digital.
- NHS Digital is operating as a processor under the direction of the MHRA (via CPRD). The applicant for the purposes of this application is the CPRD.
- The CPRD do not receive identifiable data from NHS Digital or others under the terms of this support. Any processing by CPRD of confidential patient information must rely upon another legal basis.

Confidentiality Advisory Group advice

Public interest

Members wished to thank CPRD for their annual review submission. The group wish to express that they are highly supportive of the work of the CPRD, which carries a significant public interest in supporting research.

However, members were mindful that the application details date from 2012. In light of changes in the regulatory and legal landscape since that time, some press interest, , the age of the enterprise and the increase in its scale, the CAG feel that this is an appropriate time to request an updated and refreshed application and supporting documentation, in parallel with the process for research databases undergoing ethical review every five years. The CAG must be able to demonstrate to the public that appropriate checks and balances are in place on the work of CPRD, and that the legal basis in place is demonstrated to be operating in accordance with current practices.

As such, members request a new full application and relevant supporting documentation to be submitted for review by CAG, no later than six months from the date of this letter. Full details as to why, as well as what the group would expect to see in an application are detailed further below.

Expansion of CPRD

Members noted that CPRD will likely be undergoing a significant expansion in size over the course of 2020, with the addition of new GP system providers (EMIS and TPP) providing medical record data. Given this expansion, members requested clarity on how this significant increase in inward data flow is managed, as well as an updated list of providers and how they are managed.

Transparency

Members were concerned by the lack of clarity on the CPRD website as to what data CPRD hold, in what format, how long it is held for and how it is disseminated under the terms of regulation 5. In particular, members found it hard to locate clear detail on the legal support in place on the website. The group requested clarification on how CPRD are managing GDPR within their work and requested a review of current transparency materials on the website.

The group also noted the press interest in the robustness of the anonymity of data released, as well as the fact that CPRD have received no complaints. Members would like to better understand what complaints or concerns have been raised other than by the public and how these have been reviewed and addressed. It is noted that the CAG has previously voiced concerns and request detail of how these have been addressed.

As such Members wished to ensure that the CPRD has sufficient transparency in all of its processes such that patients know their data is in CPRD, how CPRD processes their data and how data is used in research. This should be addressed by the applicants and the CAG provided with all transparency materials, both for use on the website and those provided to GPs for use. If no transparency or patient information materials are provided to GPs, members agreed that standard materials for GPs to display should be produced and provided to the group.

Working with GP Practices

It is understood that signing up to CPRD is a one-off process for GPs. It is quite possible for practices, as they merge, develop etc., to not know that they are signed up to CPRD, and are legally covered under s.251. As such members requested details

on how GPs providing data are managed against the changing primary care landscape. For example, are practices required to periodically re-sign? Further, have GDPR implications on data sharing agreements been accounted for?

High risk applications

The process agreed originally for high risk applications was, following internal risk assessment against criteria, if CPRD/ISAC were of the view that the proposed disclosure involved a high risk of re-identification, the reasons for this would be provided to CAG for review, who would then advise whether the recipient should submit an application to receive potentially identifiable information.

Whilst high risk applications used to be shared with the CAG, members noticed that the CPRD has not reviewed any in the past two years. The group would like further information on the CPRD's risk stratification criteria, with examples of how risk reduction has mitigated high risk applications to a lower risk category. Details of the processes and criteria used should be provided.

Release of data

Members wished to understand better the processes for release of data and downstream sharing. The group agreed that any data sharing agreements, and terms and conditions for use of the data should be provided.

Patient and Public Involvement and Engagement

Given the significant increase in scale of CPRD, members felt that this required fresh undertakings of appropriate and relevant Patient and Public Involvement and Engagement. This should specifically address the use of confidential patient information without consent within the CPRD context the scale of the dataset as well as the possible usages.

The group continues to have some concerns about the appropriate lay representation in the work of the Independent Scientific Advisory Committee (ISAC). Members

requested details of the current membership of ISAC, including specific details around lay quoracy.

Confidentiality Advisory Group advice conclusion

The CAG agreed that the minimum criteria under the Regulations appeared to have been met and that there was a public interest in this activity continuing, and therefore advised recommending support to the Health Research Authority, subject to compliance with pre-existing standard conditions, and the specific conditions of support as set out below.

Specific conditions of support

The CAG agreed, in light of the significant expansion of the study and the concerns around transparency and high risk applications, that a new s251 application should be submitted to the CAG. This should be submitted no later than **08 December 2020.**

The new application should address the following:

1. Existing application detail to be reviewed and where no longer accurate, a tracked change version (Word) to be provided. The CPRD original application consisted of a suite of documents and these should all be updated and submitted, with a covering letter highlighting each change.

2. Revisit and strengthen transparency – both on the CPRD website and documentation to be provided to practice.

3. Detail how significant an increase the inward data flow is with the expansion, and how this is managed.

4. Describe how GPs providing data are being managed against the changing primary care landscape

5. Provide an updated list of providers

6. Master dataset list. The members appreciate the clarity and layout of this document and advised the updated version submitted to CAG for the purpose of legal support should not be amended from its current format.

7. Detail what complaints have been raised in the past two years from sources other than the public, and how they have been reviewed and addressed.

8. Clarify the risk categorisation and associated processes, particularly around the risk mitigation used for reducing risk such that no referral is made to CAG. This should be accompanied by real examples in mitigating high risk applications.

9. Undertake new Patient and Public Involvement and Engagement that should address the use of confidential patient information without consent, the scale of the dataset as well as the possible downstream usages.

10. Provide details of the current membership of ISAC, including specific details around lay quoracy

11. Provide the data sharing agreement that is used to release data, as well as the associated terms and conditions.

b. 20/CAG/0019 – UK National Haemophilia Research Registry (Resubmission of 17/CAG/0175)

Context

Purpose of application

This application from UK Haemophilia Research Registry sets out the purpose of medical research which aims to use the data within the National Haemophilia Database for research purposes.

The NHD (National Haemophilia Database) is a long running database that collects data about patients with bleeding disorders within the UK, which includes patient identifiers Whilst the database has been used historically for care purposes the applicants wish to use the data contained within the database for research purposes.

Whilst data has been collected using a consented model since 2000, it was not deemed sufficient for research purposes. This application seeks support to use the data contained within the database until patients consent to its use for research purposes, or where consent is not possible. Data will be released to research teams under the processes detailed within the protocol.

A recommendation for 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 within the National Haemophilia Database.
Data sources	1. Records within the National Haemophilia Database
Identifiers required for linkage purposes	1. Name 2. NHS Number 3. GP Registration

	4. Date of Birth 5. Date of Death 6. Postcode 7. Previous Names 8. Gender

Confidentiality Advisory Group advice

The following sets out the Confidentiality Advisory Group advice which formed the basis of the decision by the Health Research Authority.

Public interest

The CAG noted that this activity fell within the definition of medical research and was therefore assured that the application described an appropriate medical purpose within the remit of the section 251 of the NHS Act 2006.

Members fully accepted the great public interest in the research elements in the request, as well as in the National Haemophilia Database itself. The lawful reuse of the data in the NHD to improve patient care is laudable and should be supported.

Legal Basis

However, members had serious concerns on the legal basis on which the National Haemophilia Database (NHD) is operating under presently, and this is the reason for deferral. It is noted that the applicant regards the NHD as performing functions under direct clinical care which, in the applicant's opinion, means the NHD does not require s251 support. However, noting the evidence in the application, the NHD would seem to be a form of non-local audit/surveillance, which would require s251 to have a legal basis. The reliance on direct clinical care does not legitimise both elements.

If it is the case that NHD has no legitimate legal basis, the group cannot advise for s251 support for the research element without first addressing the underpinning legal basis of the NHD. Members suggested that two separate applications will be required – one for the NHD, and a second for the research element of the NHD. Please note that any future support provided cannot be made retrospectively.

As noted earlier, members would like to support the applicant in this endeavour and offer an informal meeting with the CAG Chair and members of the CAG to discuss the NHD and a route forward.

Reason for deferral

1. The group have serious questions on the legal basis underpinning the NHD, and suggest the applicant requires two separate applications for s251 support – one for the NHD itself and a second for the research element.

Once received the information will be reviewed initially by a sub-committee of all Members present at this initial review, prior to consideration at the next available CAG meeting. Deadlines for future CAG meetings are available on the HRA website and you should contact the Confidentiality Advice Team to book the application onto the next available meeting.

3. New applications – research

a. 20/CAG/0006 – Long-term safety of cabergoline in hyperprolactinaemia

Context

Purpose of application

This application from Queen Mary University of London set out the purpose of medical research which aims to determine whether there is a link between cabergoline at low doses and the development of fibrotic heart disease.

The drug cabergoline is used in low doses for the treatment of benign pituitary tumours called 'prolactinoma'. There is evidence that the drug may cause heart valve disease so anyone taking cabergoline has heart scans every 6-12 months. This project seeks to determine if there is a link at low doses. To do this the project team seeks to use the Discovery data service to identify all eligible patients taking cabergoline (cases) and 5 matched controls for each case. The bulk of this data will be pseudonymised. Only when a case took cabergoline and subsequently developed a cardiac problem will the NHS number of that patient be collected in order to determine if that patient had an echocardiogram at Barts Health NHS Trust. If so, the scans will be re-reviewed by a consultant cardiologist.

Section 251 support is requested for use of the NHS number to access patient records and collect echocardiograms. Whilst the applicant is employed by Barts Health NHS Trust and works in the same department, he may not necessarily have been providing direct care to the patients. Section 251 support is also requested for a consultant cardiologist from Queen Elizabeth Hospital Birmingham to come to Barts Health NHS Trust to re-review scans. Whilst every effort will be made to minimise access to identifiable data, the consultant will likely see names, dates of birth and NHS/hospital numbers as this information is embedded on to the images.

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

Confidential patient information requested

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

Cohort	From previous work on anonymised data, the team estimate 24 patients that have taken cabergoline and developed heart problems.

Data sources	1. Discovery Data Service (data service of all hospital and GP records in North East London) 2. Barts Health NHS Trust
Identifiers required for linkage purposes	1. NHS Number
Identifiers required for analysis purposes	1. Name 2. Date of birth 3. NHS/Hospital number (The above are embedded onto the images that will be re-reviewed)

Confidentiality Advisory Group advice

The following sets out the Confidentiality Advisory Group advice which formed the basis of the decision by the Health Research Authority.

Public interest

The CAG noted that this activity fell within the definition of medical research and was therefore assured that the application described an appropriate medical purpose within the remit of the section 251 of the NHS Act 2006.

Members were concerned at the small sample size of the study and whether this project would provide an outcome that justified the use of confidential data without consent.

Scope of support

Members queried the role of the Discovery Data Service, and whether they had a legal basis to process confidential information in order to provide NHS number of relevant patients to Barts Health NHS Trust, and pseudonymised data to Queen Mary University of London.

Practicable alternatives

Members considered whether a practicable alternative to the disclosure of confidential patient information without consent existed in accordance with Section 251 (4) of the NHS Act 2006, taking into account the cost and technology available.

- **Feasibility of consent**

It was noted by members that the research team did not want to use consent as 24 was the minimum number to give scientific validity. However, given the apparent low numbers of patients (approximately 24), members queried why consent was not practicable, especially if many of these patients are expected to be seen at regular intervals for heart scans. Further, the research team is using the national opt out system, which may reduce the numbers of patients even without the use of consent.

- **Use of anonymised/pseudonymised data**

It was noted that NHS number was required to identify patients at Barts Health NHS Trust, and that the echocardiograms were embedded with patient name, date of birth and hospital/NHS number. However, members queried why echocardiograms could not be re-reviewed by members of the direct care team at Barts Health NHS Trust to prevent a breach of confidentiality.

'Patient Notification' and mechanism for managing dissent

It is part of the CAG responsibility to support public confidence and transparency in the appropriate sharing and use of confidential patient information. Access to patient information without consent is a privilege and it is a general principle of support for reasonable measures to be taken to inform the relevant population of the activity and to provide a right to objection and mechanism to respect that objection, where

appropriate. This is known as ‘patient notification’. This is separate to the local obligation to comply with the principles of the General Data Protection Regulation and Data Protection Act 2018.

The applicant provided a poster that would be displayed within patient areas at Barts Health NHS Trust. Members commented that the poster was well designed and were content with the poster. The applicant also indicated a notice would be displayed on Barts Health NHS Trust website, but no copy of the text was provided to members. Members confirmed that they would like to see the text.

Patient and Public Involvement and Engagement

Meaningful engagement with patients, service users and the public is considered to be an important factor for the CAG in terms of contributing to public interest considerations as to whether the unconsented activity should go ahead.

The applicant sought support from the Pituitary Foundation and members noted the responses. However the response from the Pituitary Foundation did not detail the responses and especially whether the participants were comfortable with the use of confidential data without consent

Incidental findings

The group were also concerned about the approach to patients in the event of incidental findings, and thought the research team could consider this further.

Confidentiality Advisory Group advice conclusion

In line with the considerations above, the CAG agreed that further information would be required from the applicant in order for a recommendation under the Regulations to be provided.

Request for further information

1. Provide further justification why consent for this small number of patients, where contact may reasonably be expected, is not practicable.

2. Provide further evidence that the approach proposed, using approximately 24 patients taking cabergoline and subsequently developing cardiac problems, will provide a statistically significant outcome and therefore ensure scientific validity.

3. Further justify why data for all of the approximately 24 patients is necessary, especially considering the national data opt out will apply.

4. Detail why the echocardiograms of patients cannot be reviewed by members of the direct care team at Barts Health NHS Trust, rather then by an external cardiologist, in order to prevent a breach in confidentiality.

5. Provide the legal basis for the operations of the Data Discovery Service. Do not use links or copied text from their website.

6. Confirm the extent of the consultation undertaken by the Pituitary Foundation used to inform their response, including details asked to members. Confirm if members were asked about the provision of incidental findings to patients as well as processing confidential data without consent.

7. Provide more careful consideration on the approach to patients with incidental findings.

8. Provide the electronic text notice that will be used on Barts Health NHS Trust website.

Once received the information will be reviewed initially by a sub-committee of all Members present at this initial review, prior to consideration at the next available CAG meeting. Deadlines for future CAG meetings are available on the HRA website and you should contact the Confidentiality Advice Team to book the application onto the next available meeting.

b. 20/CAG/0027 – Congenital Heart Audit – Measuring Progress in Outcomes Nationally

Context

Purpose of application

This application from University College London set out the purpose of medical research which aims to develop tools for routinely measuring congenital heart disease outcomes that are considered meaningful and appropriate by stakeholders and can inform the delivery and commissioning of services for patients.

Congenital heart disease requires lifelong clinical input and significant healthcare utilisation. In 2015, NHS England called for better reporting of quality of services, beyond the current focus on 30-day survival following paediatric cardiac surgery. This project will draw on a number of data sources to:

- Define the scope of adult procedures for national reporting, identify what outcomes to measure;
- Explore potential risk factors, and develop a fair way of reporting surgical outcomes;
- Investigate longer-term outcomes tracking people with representative diagnoses through a combined dataset, describing their long-term survival, and the number of operations within and outside the anticipated treatment plan;
- Develop prototype software tools to calculate and display longer-term and adult outcomes providing meaningful information to patients and commissioners of CHD services.

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

Confidential patient information requested

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

Cohort	Approximately 130,000 children and adults with congenital heart disease. From birth, no upper age limit. England only.
Data sources	1. The LAUNCHES dataset [18/CAG/0180] 2. National Adult Cardiac Surgery Audit (NACSA) [17/CAG/0071] – pseudonymised, linked to the LAUNCHES dataset. 3. National Congenital Anomaly and Rare Disease Registration Service (NCARDRS) [CAG 10-02(d)/2015] – pseudonymised, not linked 4. Clinical audit data from Barts Health NHS Trust – pseudonymised, not linked
Identifiers required for linkage purposes	1. Name 2. NHS number 3. Hospital ID no. 4. Date of birth 5. Postcode

Identifiers required for analysis purposes	1. Hospital Name 2. Place of occurrence of death (categorical: one of home/hospice/hospital/care home) 3. Gender 4. Ethnicity 5. Month and year of birth (not day). 6. Age at procedures, hospital admissions etc (to four decimal places). Age to 4 decimal places is needed to sequence events that happen on the same day (e.g. two procedures on the same day).
Additional information	The application set out an online forum hosted by three charities - Somerville Foundation (TSF), Children's Heart Federation (CHF) and Little Hearts Matter (LHM); this is not within the scope of the proposed support.

Confidentiality Advisory Group advice

The following sets out the Confidentiality Advisory Group advice which formed the basis of the decision by the Health Research Authority.

Public interest

The CAG noted that this activity fell within the definition of medical research and was therefore assured that the application described an appropriate medical purpose within the remit of the section 251 of the NHS Act 2006.

Members were assured that the project was within the public interest, as it would provide a more complete overview of both adult and child congenital heart disease patient outcomes, improve risk stratification of the interventions used to treat these

patients, and provide a greater level of information for these patients about their treatment options, the risks involved, and potential outcomes.

Scope

The CAG clarified that the scope of this application covers confidential patient information relating to both child and adult congenital heart disease patients, and that this would include extension of the use of the LAUNCHES dataset [18/CAG/0180] for this project.

The members recognised that it may be necessary for data to be collected and used on an ongoing basis for this project. The CAG decided that the data sources and uses should be reassessed periodically to ensure that they continue to be relevant and necessary to achieve the purposes of the project. This point should be specifically addressed in the annual review reports to be submitted to the CAG.

The CAG acknowledged that the online forums are outside the scope of section 251 support. Some of the members had concerns that it may not be clear to participants that their details will be visible to other members of the forum. As an advisory point only, the CAG suggested that it should be made clear on the posters advertising the forums that these groups will be a discussion amongst individuals, and each member of the group will be visible to the others.

Practicable alternatives

Members considered whether a practicable alternative to the disclosure of confidential patient information without consent existed in accordance with Section 251 (4) of the NHS Act 2006, taking into account the cost and technology available.

- **Feasibility of consent**

The CAG was assured that it was not feasible to seek consent for this proposal on the basis of the size of the historical patient cohort which would be included (130,000 patients), but noted that this was not emphasised in the application as strongly as it

might have been. The group accepted the additional justifications provided, that the patients may be deceased, contact may cause distress, and a high level of completeness is necessary analysis.

- **Use of anonymised/pseudonymised data**

Access to confidential patient information was necessary to enable the patient cohort to be identified and to facilitate linkage between the clinical data sources to be used in analysis, which could not be otherwise achieved.

Justification of identifiers

The CAG accepted the justification that the identifiers specified in the application for linkage are necessary because this project will use the same algorithm as was used previously for the LAUNCHES dataset [18/CAG/0180]. The CAG accepted use of identifiers specified in the application for analysis, including precise age at the time of procedures to allow identification of the order of procedures occurring in the same day.

'Patient Notification' and mechanism for managing dissent

It is part of the CAG responsibility to support public confidence and transparency in the appropriate sharing and use of confidential patient information. Access to patient information without consent is a privilege and it is a general principle of support for reasonable measures to be taken to inform the relevant population of the activity and to provide a right to objection and mechanism to respect that objection, where appropriate. This is known as 'patient notification'. This is separate to the local obligation to comply with the principles of the General Data Protection Regulation and Data Protection Act 2018.

The CAG noted that the posters relate to the online forums, and do not address the data activities being undertaken within the scope of section 251 support. The CAG advised that a different poster could be used to describe data aspects. The CAG commented that the posters for adults and children are similar, and more could have been done to make the posters for children appropriate for the target age group.

The CAG commented that the privacy notice covers most of the necessary points but that it is long and densely worded. The CAG agreed that the information should be provided in a layered format, so that the initial information is high level, but provides links to more detailed information for those who are interested. The CAG noted that the privacy notice does not make reference to the project being undertaken with section 251 support. It is important to include this, as it is part of the legal basis for the activities. The CAG decided that information about the project and how patients can opt out should be made available on the University College London website, and the websites of the charities involved in the online focus groups, and that the information regarding the opt out process should be displayed before the linkage takes place.

The CAG noted that the privacy notice for the study provides links to the individual datasets used as the sources for this project for patients to opt out from a specific dataset. The CAG considered that there should be less onus on the patients to identify which dataset they want to opt out from and decided that there should be a project-specific central point of contact to advise patients if they are unsure about what they want to opt out from.

Patient and Public Involvement and Engagement

Meaningful engagement with patients, service users and the public is considered to be an important factor for the CAG in terms of contributing to public interest considerations as to whether the unconsented activity should go ahead.

The CAG commented that there was limited patient and public involvement specifically around the use of confidential patient information without consent for this project, and more engagement would be expected for a project of this size. The CAG agreed that it is insufficient to rely upon the patient and public involvement work done previously for the LAUNCHES dataset [18/CAG/0180]. The CAG also noted that the application will involve data of adult surgical patients who have not had a previous diagnosis of congenital heart disease, and that representatives of this group had not been consulted regarding this use of data.

The CAG decided that further patient and public involvement, specifically regarding the use of confidential patient information without consent for this project, must be completed before support can be recommended.

Supporting documents

The CAG noted that the letter of support provided is from the Senior Information Risk Owner (SIRO) of University College London School of Life and Medical Sciences, but the letter of support must be provided from the Caldicott Guardian. The CAG also agreed that a letter of support must be provided from HQIP as the data controller of the National Adult Cardiac Surgery Audit (NACSA) dataset that will be used for the linkage on this project.

The CAG agreed that the flow diagram provided needs to be clearer about what data is directly identifiable, pseudonymised, or anonymised, and which activities are being done within the scope of section 251 support and which are not.

Confidentiality Advisory Group advice conclusion

The CAG agreed that there was a public interest in this activity, were supportive in principle of this activity proceeding, and therefore recommended to the Health Research Authority that the activity be provisionally supported. However, further information and actions would be required prior to confirming that the minimum criteria and established principles of support have been adequately addressed.

In order to complete the processing of this application, please respond back to all of the request for further information, and actions required to meet the specific conditions of support where indicated, within one month.

Request for further information

1. The data flow diagram is to be updated to clearly set out what data is anonymous, pseudonymised, and identifiable, and which parts of the data flows will be subject to section 251 support.

2. The privacy notice is to include a project-specific point of contact for opt out enquiries to help any patients who are uncertain about what they want to opt out from.

3. The privacy notice and opt out information is to be made available on the University College London website, and the websites of the charities involved in the online focus groups. This information is to be displayed before the linkage takes place.

4. Further patient and public involvement, specifically regarding the use of confidential patient information without consent for this project, must be completed before section 251 support can be recommended. The patient and public should be asked for their views on the use of the data without consent and any negative views reported back to CAG

5. The privacy notice is to be presented in a layered format, so that the initial information is high level, but provides links to more detailed information for those who are interested.

6. The privacy notice is to reflect that confidential patient information is being accessed and used for this project under section 251 support.

Once received, the information will be reviewed by a sub-committee of members in the first instance and a recommendation and decision issued as soon as possible. At this stage it may be necessary to request further information or refer to the next available CAG meeting. If the response is satisfactory and the outstanding actions listed in the specific conditions of support are met, a final support outcome will be issued.

Specific conditions of support (Provisional)

The following sets out the provisional specific conditions of support. These may change in the final outcome letter depending on the responses to queries.

1. Letters of support must be in place from HQIP (as data controller for the National Adult Cardiac Surgery Audit (NACSA) dataset) and the Caldicott Guardian of University College London (as data controller for this project).

2. The applicant must reassess the need for support on an ongoing basis (i.e. consider whether all of the data sources and uses continue to be necessary). The CAG expects this point to be specifically addressed in the annual reviews submitted.

3. Favourable opinion from a Research Ethics Committee. **Confirmed 14/02/2020.**

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: University College London (by NHS Digital email 02 July 2019), University of Leeds (by NHS Digital email 28 August 2019), ICNARC (by NHS Digitial email 29 May 2019), NHS Digital (by NHS Digital email 10 June 2019) and Public Health England (by NHS Digital email 02 September 2019) have confirmed 'Standards Met' grade on DSPT 2018/19.**

Confirmed: Barts Health NHS Trust - NHS Digital have confirmed qualified assurance against the organisation's 2018/19 DSPT submission on the basis that the Trust has not met the 95% standard relating to staff security awareness training.

As a result, the following specific condition of support has been added: all staff involved in processing data under this section 251 support must have successfully completed local security awareness training before processing any data.

c. 20/CAG/0028 – Small Area Health Statistics Unit Research Database

Context

Purpose of application

This application from Imperial College London sets out the purpose of medical research which aims to maintain a research database focussing on research of environmental health risks.

This is a request for renewal of s251 support from the CAG for the Small Area Health Statistics Unit (SAHSU) Research Database. SAHSU has been ongoing since 1987, and this request is to allow continued collection and linkage of a number of datasets (listed below). The database will be used by research studies, primarily focussing on environmental health risks.

Support is requested to allow the disclosure of the following confidential information to SAHSU for linkage and research purposes:

- HES data from NHS Digital containing details of all admissions (inpatient and day cases), critical care and Accident and Emergency attendances for patients treated in NHS hospitals in England. This includes the linked HES/Civil Registration mortality data for out of hospital deaths.
    - Confidential information provided: date of birth, mother's date of birth, gender, ethnicity and NHS number. Geographical information includes patient residential postcode.
- Data from the Office for National Statistics (ONS) on live births, stillbirths, and mortality registration data. (Note: SAHSU is currently in negotiation with NHS Digital to provide future access to this registration data, in addition to the health data described above).
    - Confidential information provided: date of birth/death, age at the event, spouse's age, parental ages and occupations, socioeconomic status, gender, ethnicity, and NHS number. Geographical information includes patient residential address
- PHE provides SAHSU with annual extracts of cancer incidence/treatment data for the resident population of England.
    - Confidential information provided: NHS number, date of birth, ethnicity, gender. Geographical information includes patient residential postcode.

- WCISU provides SAHSU with an annual extract of cancer incidences data for the resident population of Wales.
    - Confidential information provided: NHS number, date of birth, ethnicity, gender. Geographical information includes patient residential address

A recommendation for class 1, 2, 4, 5, and 6 support was requested to cover access to confidential information from NHS Digital, Office for National Statistics, Public Health England and the Welsh Cancer Incidence Surveillance Unit.

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 in England and Wales.
Data sources	1. NHS Digital 2. Public Health England 3. Office for National Statistics 4. Public Health Wales NHS Trust (Welsh Cancer Intelligence & Surveillance Unit)
Identifiers required for linkage purposes	1. NHS number 2. Date of Birth 3. Date of Death 4. Address 5. Postcode
Identifiers required for analysis purposes	

Additional information	

Confidentiality Advisory Group advice

The following sets out the Confidentiality Advisory Group advice which formed the basis of the decision by the Health Research Authority.

Public interest

The CAG noted that this activity fell within the definition of medical research and was therefore assured that the application described an appropriate medical purpose within the remit of the section 251 of the NHS Act 2006.

Members noted the important public interest in this long-established research database, with the public interest being full justified.

Practicable alternatives

Members considered whether a practicable alternative to the disclosure of confidential patient information without consent existed in accordance with Section 251 (4) of the NHS Act 2006, taking into account the cost and technology available.

- **Minimising flows of identifiable information**

Members noted the robust processes in place to minimise the flows of identifiable information, and the limiting of access to identifiable information so that research teams only receive pseudonymised data.

- **Feasibility of consent**

Members were content that, with the large volumes of patient data required, consent was not a practicable alternative.

- **Use of anonymised/pseudonymised data**

It was understood that identifiable information was required to link information, but members were pleased with the processes in place to ensure that research teams using the database only receive pseudonymised data.

'Patient Notification' and mechanism for managing dissent

It is part of the CAG responsibility to support public confidence and transparency in the appropriate sharing and use of confidential patient information. Access to patient information without consent is a privilege and it is a general principle of support for reasonable measures to be taken to inform the relevant population of the activity and to provide a right to objection and mechanism to respect that objection, where appropriate. This is known as 'patient notification'. This is separate to the local obligation to comply with the principles of the General Data Protection Regulation and Data Protection Act 2018.

A privacy notice was provided with the application. However, members felt that this was long and, at times, in technical language. Members though a shorter lay version, that links to the full version should be considered by the applicants. Doing so would use a layered approach to transparency, as advocated by the ICO.

Patient and Public Involvement and Engagement

Meaningful engagement with patients, service users and the public is considered to be an important factor for the CAG in terms of contributing to public interest considerations as to whether the unconsented activity should go ahead.

Members noted the extensive outreach work undertaken by the applicants, the use of a community advisory board as well as specific engagement related to individual

research projects. However members thought the applicants could consider much wider publicity of the work of SAHSU to the wider public.

Patient Opt-Out

Members noted that the national data opt out will apply, but also though the applicants could consider project specific opt out.

Confidentiality Advisory Group advice conclusion

The CAG agreed that the minimum criteria under the Regulations appeared to have been met and that there was a public interest in projects of this nature being conducted, and therefore advised recommending support to the Health Research Authority, subject to compliance with the specific and standard conditions of support as set out below.

Specific conditions of support

1. Applicants to consider a shorter, simpler form of privacy notice in lay format, linking to the full privacy notice.

2. Applicants to consider more publicity of the work of SAHSU to the wider public

3. Applicants to consider a project specific opt out. Applicants should either commit to doing so in a specific time frame, or provide justification why this will not be undertaken.

4. Favourable opinion from a Research Ethics Committee. **Confirmed June 2017**

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

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

4. Chair’s Report

A report from the Chairman was received for February 2020

5. Any other business

No other business was raised.

The Chair thanked Members for their attendance and the meeting was closed.

Signed – Chair	Date
Signed – Confidentiality Advice Team	Date