Minutes of the meeting of the Confidentiality Advisory Group

04 June 2020 at Meeting via Teleconference

Present:

Name	Present	Notes
Dr Tony Calland MBE	Yes	CAG Chair
Ms Clare Sanderson	Yes	CAG Alternative Vice-Chair
Dr Lorna Fraser	Yes	CAG member
Dr William Bernal	Yes	CAG Alternative Vice-Chair
Ms Sophie Brannan	Yes	CAG member
Prof Jennifer Kurinczuk	Yes	CAG member
Ms Gillian Wells	Yes	CAG member
Ms Diana Robbins	Yes	CAG member
Dr Harvey Marcovitch	Yes	CAG member

Also in attendance:

Name	Position (or reason for attending)

Ms Katy Cassidy	Confidentiality Advisor
Ms Caroline Watchurst	Confidentiality Advisor
Dr Paul Mills	Senior Confidentiality Advisor/Service Manager
Ms Natasha Dunkley	Head of Confidentiality Advice Service

1. Introduction, apologies and declarations of interest

2. Support decisions

Secretary of State for Health & Social Care Decisions

There were no applications that required a decision to be made by the Department of Health & Social Care senior civil servant on behalf of the Secretary of State for Health & Social for the **07 May 2020** meeting.

Health Research Authority (HRA) Decisions

The Health Research Authority agreed with the advice provided by the CAG in relation to the **07 May 2020** meeting applications.

3. Consideration Items

a. 20/CAG/0069 - Camden and Islington: Clinical Record Interactive Search (C&I CRIS) Linkage with Hospital Episode Statistics (HES) and Civil Registration Mortality Data (resubmission of 19/CAG/0032).

Context

Purpose of application

This application from University College London (with the controller for the activity confirmed to be Camden and Islington NHS Foundation Trust) set out the purpose of medical research

which aims to establish a research database linking the mental health records of patients treated within the Camden and Islington NHS Foundation Trust area with data from NHS Digital.

The Camden and Islington Research Database is already established and contains mental health data generated within the boroughs of Camden and Islington. This database was established using the South London and Maudsley NHS Foundation Trust (SLaM) Clinical Records Interactive Search (CRIS) methodology in 2012. South London and Maudsley NHS Foundation Trust acts as processor for the Camden and Islington Research Database.

Confidential patient information in relation to patients treated by mental health services in the Camden and Islington boroughs will be disclosed by South London and Maudsley NHS Foundation Trust (SLaM) Clinical Data Linkage Service (CLDS) to NHS Digital in order to facilitate linkage with Hospital Episodes Database and ONS mortality data. This information will be supplemented by anonymised information from HES and ONS relating to patients within the named London boroughs who were not detailed within the existing mental health database.

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	The cohort in the proposed study linkage will include patients of Camden and Islington NHS Foundation Trust with active records during the period from 1 January 2012 to 31 December 2018. It is estimated that 140,000 patients were included in the Camden and Islington NHS Foundation Trust CRIS database.

Data sources	1. Camden and Islington NHS Foundation Trust C&I Database records.
Identifiers required for linkage purposes	1. Full name 2. NHS number 3. Date of birth 4. Sex 5. Postcode,
Identifiers required for analysis purposes	1. Sex 2. Postcode 3. Date of death 4. Ethnicity

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. The CAG agreed that the application was in the public interest.

Scope

This was a resubmission of an application that had previously been given a deferred outcome. During the review of the previous submission, the CAG had queried the legal basis that the applicants would rely on when creating the database, as it appeared that confidential patient information contained in the Camden and Islington Research Database, which originated within the Camden and Islington NHS Foundation Trust, would be held within the South London and Maudsley (SLaM) NHS Foundation Trust. In this resubmission, the applicants had clarified that the Camden and Islington Research Database would be held within a data warehouse which was supplied by South London and Maudsley NHS Foundation Trust. The Clinical Record Interactive Search (CRIS) system, created by the SLAM NHS Foundation Trust would provide the secure technical environment or firewall into which confidential patient information required for the Research Database would flow, but staff from SLaM NHS Foundation Trust would not have access to the confidential patient information within the

Research Database. The confidential patient information would be anonymised within CRIS once the data had been processed.

The CAG agreed that the relationship between Camden and Islington NHS Foundation Trust and SLaM NHS Foundation Trust was that of a Data Controller and Data Processor. Usually, SLaM NHS Foundation Trust received confidential patient information which was de-identified using CRIS. In this application, it appeared that the confidential patient information in the Research Database remained within the database belonging to Camden and Islington NHS Foundation Trust, but will be de-identified using CRIS. The CAG requested clarification that the relationship between Camden and Islington NHS Foundation Trust and SLaM NHS Foundation Trust was analogous to a data controller contracting with an IT system supplier to undertake processing of data on their behalf. If this was the case, then information about the contract between the two organisations needed to be provided.

The Group noted that the applicant had explained that the database would be administered solely by staff from Camden and Islington NHS Foundation Trust. However, it appeared that IT staff from SLaM NHS Foundation Trust would be able to access the database. Members requested clarification over who would have access to the database.

Further data linkages would be made to NHS Digital. Confirmation was requested that the disclosures of confidential patient information were made by the Camden and Islington NHS Foundation Trust, as Data Controller for the Research Database.

The CAG noted that the Research Database would be linked to wider datasets, with the potential of creating a very rich dataset. Members advised that further linkages could not be undertaken without seeking further support under s251, either by amendments or by submitting new applications.

Items of confidential patient information required

The CAG requested that the items of confidential patient information required for both the data linkage and the comparator cohort were clarified. Members also asked for confirmation that no sensitive data items would be included in the dataset, particularly for the comparator cohort.

Data flows

The CAG agreed that much of the confusion about the project was due to confusion of the use of SLaM processes and the CRIS system. SLaM is both a physical place and also an IT system, and it was not clear whether references to SLaM were to the physical hospital or their IT system. The Group suggested that two data flows were provided, one showing the structure of the CRIS system and another showing the data flows within the structures.

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**

Approximately 140,000 patients were included in the Camden and Islington NHS Foundation Trust CRIS database. The Group agreed that the numbers of patients involved meant that consent was not feasible.

- **Use of anonymised/pseudonymised data**

Confidential patient information is required to facilitate the linkage with administrative datasets held by NHS Digital. Members agreed that this could not be undertaken in any other way.

'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.

When issuing a deferred outcome to the previous application, the CAG had requested that the patient facing information materials were updated to more clearly explain the role of SLaM and to make patients' right to dissent more prominent. The Fair Processing Notice also

needed to be updated to refer to current data protection legislation. The applicant provided updated documents with this submission.

The CAG agreed that further amendments were required. The involvement of SLaM had been explained in some documents but not all. The dissent process was also prominent in documents but not others. Members asked that these documents were revised to ensure consistency. The patient facing materials also need to contain assurance that patient care will not be affected should patients dissent.

The CAG noted that a telephone number and email had been provided for patients to contact to register dissent. Members asked that the applicants consider including a postal address as well and that feedback on this was provided at the first annual review.

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.

When issuing a deferred outcome to the previous application, the CAG had requested further evidence that the Camden Mental Health Service User Group was supportive of the processing of confidential patient information without consent required to facilitate the proposed study linkage.

For this particular linkage, the applicants have consulted directly regarding data linkages in CRIS at Camden and Islington NHS Foundation Trust. They have established a Data Science Patient and Public Involvement (PPI) group, which has representation from service users at Camden and Islington NHS Foundation Trust to discuss CRIS and proposed linkages. Minutes from a meeting held on 11 July 2019 were provided, evidencing that the PPI group discussed the linkage to HES and ONS mortality data. The comments received were broadly supportive and discuss undertaking this linkage through SLaM.

The CAG noted the information provided and asked that patient and public involvement and engagement continued to be undertaken while the project was ongoing. Members also asked that the ongoing patient and public involvement was strengthened by ensuring that both lay members and professional members from within Camden and Islington NHS Foundation Trust are included.

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. Two new data flow diagrams are required, one showing the structure and the other showing the data flows within the structure.

2. Provide clarification over who will have access to the database, including whether IT staff from SLaM NHS Foundation Trust will have access.

3. Provide clarification that the relationship between Camden and Islington NHS Foundation Trust and SLaM NHS Foundation Trust is analogous to a data controller contracting with an IT system supplier to undertake processing of data on their behalf. If this is the case then information about the contract between the two organisations needs to be provided.

4. Provide clarification that the disclosures of confidential patient information will be made by the Camden and Islington NHS Foundation Trust, as Data Controller for the Research Database.

5. Confirm that data from the Research Database will not leave the Camden and Islington NHS Foundation Trust data warehouse, and that the CRIS processing system will be used within the data warehouse to undertake the pseudonymisation and anonymisation process.

6. The items to be used in both the data linkage and the comparator cohort need to be clarified.

7. Provide confirmation that no sensitive data items would be included in the dataset, particularly for the comparator cohort.

8. Confirm that patient and public involvement will continue while the project is ongoing.

9. The patient and public involvement needs to be strengthened by ensuring that both lay members and professional members from within Camden and Islington NHS Foundation Trust are included.

10. Further steps need to be undertaken to disseminate information about the project more widely, including use of social media.

11. The patient facing materials need to be amended as follows:

    a. A statement assuring patients that dissenting from the study will not affect the care they receive needs to be included.

    b. The documents need to be revised to ensure that the involvement of South London and Maudsley NHS Foundation Trust and the dissent process are explained consistently across all documents.

12. Provide confirmation that an amendment or new application will be submitted should the applicants intend to undertake linkages to data sets other than those included in this application.

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. The applicants are to consider whether an address for patients to register dissent could be included in the patient notification materials, and to provide feedback on this at the time of the first annual review.

2. Favourable opinion from a Research Ethics Committee. **Pending**

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. **South London and Maudsley NHS Foundation Trust and NHS Digital have a confirmed 'Standards Met' grade on DSPT submission 2018/19 by checking the NHS Digital DSPT Tracker on 21 May 2020.**

4. New Applications - Research

a. 20/CAG/0065 - QUEST 3 Additions

Context

Purpose of application

This application from King's College London sets out the purpose of medical research which aims to make contact with families lost to follow up during the course of the QUEST study.

Autism Spectrum Disorder (ASD) is a severe lifelong developmental disability affecting about 1% of the children and characterized by impaired social communication and stereotyped and restricted interests. 70-90% of children with ASD have significant additional psychiatric disorders that impair their everyday functioning and reduce quality of life for themselves and their families. In 2008 the research team recruited 277 families with children 4-8 years diagnosed with ASD (the "QUEST" study), were followed up in 2015-16 (Wave 2) and 2017-18 (Wave 3). The QUEST study team are now seeking to add DNA samples and family history information to provide valuable information on additional potential additional risk factors.

During the course of the study 14 families were lost to follow up. Following the previous s251 application, which received a deferred outcome, the applicants are now applying to use the confidential patient information they have to obtain up to

date contact details via the NHS Personal Demographics Service, run by NHS Digital and accessed through South London and Maudsley NHS Foundation Trust, in order to re-establish contact. The team plan to then consent those that make contact. For those who do not make contact the team will delete the details gained from the Personal Demographics Service.

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	QUEST participants for whom the study team have lost contact with (n=14)
Data sources	6. NHS Personal Demographics Service (accessed via South London and Maudsley NHS Foundation Trust)
Identifiers required for linkage purposes	1. Name 2. NHS Number
Identifiers required for analysis purposes	5. Name 6. NHS Number 7. Date of Birth 8. Gender 9. Unit level postcode 10. Last known address 11. Date of Death
Additional information	Note that the identifiers for analysis are those obtained from the PDS for trying to re-establish contact in order to consent. Date of death to ensure no inappropriate contact.

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. The applicants were seeking to establish how many patients involved in the QUEST study had developed severe mental health problems or behavioural issues later in life.

Members advised that the CAG opinion was finely balanced between the potential public benefit of including patients who had been lost to follow-up versus the potential intrusion of approaching patients who had made the decision to dissent by not responding to previous communications. The CAG agreed that the application had a public interest, however further justification needed to be provided to explain why it was necessary that the 14 patients who did not respond to the last contact continued to be included.

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**

The CAG considered whether it was feasible for the direct care team to seek up-to-date contact details for patients. Members noted that it was likely that patients may no longer be treated by the direct care team, who would therefore have access to the same contact details as those held by the research team, which had been used in previous attempts to re-contact patients.

- **Feasibility of consent**

The applicants sought support under s251 in order to obtain up-to-date contact details for patients who had taken part in the QUEST study but had been lost to follow-up. Once the contact details had been obtained, the study team will attempt to re-contact patients to seek consent. Participation will then proceed on a consented basis. The CAG noted that many patients who were children when first recruited into the study would now be aged over sixteen years and therefore considered to be adults. The Group advised that both patients and their parents should be approached for consent, if the patients were now adults, and asked that the applicant advised how this would be approached.

- **Use of anonymised/pseudonymised data**

The study team need to process confidential patient information in order to link data from the QUEST study to the NHS Personal Demographics Service in order to obtain up-to-date contact patient identifiable information for patients who have been lost to follow-up. The CAG agreed that this could not be done in any other way.

'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 applicants had not provided any patient notification materials, as the data linkage for which support is sought will be undertaken in order to obtain contact details so that patients can be contacted to seek consent. A dissent mechanism also had not been created.

The CAG noted that historic guidance from the Information Commissioner's Office is that non-response must be treated as dissent. The applicants had provided a response from the Information Commissioner's Office to a query which they had submitted as advised previously by CAG. However, the ICO's response did not address the particular issue of whether non-response should still be treated as dissent for this activity. Members asked that the applicants re-contact the Information Commissioner's Office to query this point specifically. Members agreed that only patients whose contact details had changed prior to the preceding contact

attempt can be re-contacted, as a failure to reply by those deemed to have received the previous contact letter is currently regarded as representing dissent. Only details for patients meeting these criteria could be supplied to and used by the researchers.

The Group agreed that patients should be contacted by letter only and that contact should not be made by telephone.

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.

No evidence showing that the processing of confidential patient information, as proposed in the application, had been discussed during patient and public involvement and engagement had been provided. The applicants advised that this question had not specifically been discussed with their patient and public involvement group, but that the importance of taking a longitudinal perspective to how problems develop and change over time had regularly been discussed. When patients who had previously been included in wave 1 had been contacted about wave 2, only one patient expressed that they were upset about being contacted and a small number asked to leave the study.

The CAG agreed that patient and public involvement needed to be undertaken around the specific issue of accessing confidential patient information without consent and feedback from this provided.

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.

Following advice from the CAG, the Health Research Authority recommended that the application was deferred to the Secretary of State for Health.

Further information required

The following information should be provided to allow the CAG to continue their consideration of the application:

1. Further justification needs to be provided to explain why it is important that the 14 patients who have been lost to follow-up are re-contacted.

2. Advice is to be sought from the Information Commissioner's Office about the specific issue of whether non-response to contact is considered as dissent.

3. Advise how contacting both the parents and patients would be approached, if the patients who were recruited when children are now adults.

4. Confirmation needs to be given that only patients whose contact details had changed prior to the preceding contact attempt would be re-contacted. If the applicants wanted to contact patients who details were unchanged, justification needs to be provided.

5. Confirmation needs to be given that patients will be contacted by post only and not by telephone.

6. Patient and public involvement needs to be undertaken around the specific issue of accessing confidential patient information without consent and feedback from this provided.

b. 20/CAG/0063 - A population-based comprehensive lymphoma registry

Context

Purpose of application

This application from Nottingham University Hospitals NHS Trust set out the purpose of medical research with the aim of creating and managing a lymphoma registry.

The incidence of lymphoma is rising faster than any other common cancer in the Western world and there is increasing awareness of the complex abnormalities driving these diseases, permitting rapid therapeutic advances. However, the paucity of large, high-quality population-based datasets remains a clear area of unmet research need within the UK. The applicants envisage this database as a pioneering effort in the UK to better catalogue and understand lymphomas on a very large scale. Large volume, population-based, 'real world' data will allow accurate descriptions of natural history and clinical outcomes, with sufficient follow-up duration to allow identification of unmet clinical need and thus inform therapeutic options for clinicians worldwide. National bodies (such as the Public Health England National Cancer Registration and Analysis Service) already require individual hospitals to collect data on individual patients

with lymphoma. However, there are significant issues with the granularity and accuracy of data collected. Diagnostics are not well recorded, in particular the many (>60) subtypes of lymphoma as well as response and outcome data being incomplete. Our definitive database, also able to constantly collect new prognostic indices, as they are reported in the literature, as well as report outcomes for specific patient groups, diseases and therapies, will significantly enhance the quality of data available for research.

This registry is being developed by Nottingham University Hospitals NHS Trust to collect data on all new lymphoma cases from January 2020. This database would start with patients from Nottingham University Hospitals NHS Trust (for which support is not requested for) and extend to other Trusts in the East Midlands region. This would begin with University Hospitals Leicester NHS Trust and Sherwood Forest Hospitals NHS Trust (for which support is being requested) and extend thereafter. At each external Trust, an employee from Nottingham University Hospitals NHS Trust, would access confidential information of patients to identify eligible patients and record the required information into the database. The database would contain age at diagnosis and gender only, as well as a pseudonymised identifier. The key to link the patients (accessible by only the database manager) would be stored securely at Nottingham University Hospitals NHS Trust. The applicants expect to access and upload the data from each Trust to the central database on a yearly basis, with no determined end date. External parties would be able to access the pseudonymised database, subject to the access processes the applicants have put in place.

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 patients newly diagnosed with lymphoma from 01 January 2020 at University Hospitals Leicester NHS Trust and Sherwood Forest Hospitals NHS Trust.
Data sources	1. Patient medical records at University Hospitals Leicester NHS Trust and Sherwood Forest Hospitals NHS Trust

Identifiers required for linkage purposes	1. Hospital Number 2. NHS Number 3. Name
Identifiers required for analysis purposes	1. Age at diagnosis 2. 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. The CAG agreed that the application was in the public interest, noting that incidence of lymphoma was rising.

Scope

The Database Manager from Nottingham University Hospitals NHS Trust will access confidential patient information within that Trust in order to extract the required data. The Database Manager will also attend multi-disciplinary team meetings at University Hospitals Leicester NHS Trust and Sherwood Forest Hospitals NHS Trust in order to record the required data. Support is sought for the Database Manager to process confidential patient information at University Hospitals Leicester NHS Trust and Sherwood Forest Hospitals NHS Trust, as they are not a member of the direct care team.

The applicants advised that support was not sought for the Database Manager to process confidential patient information at Nottingham University Hospitals NHS Trust, as they are a member of the direct care team. The CAG was unsure whether this was correct and asked the applicant to confirm the legal basis under which the Database Manager will process confidential patient information at Nottingham University Hospitals NHS Trust.

The Group noted that the applicants had received funding from a pharmaceutical company and requested clarification on whether the funder would be allowed access to the database.

The application contained references to 'free text' and members requested clarification on whether any free text would be accessed. If so, the Group requested further information on how this would be accessed and if any data would be extracted from free text.

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 applicant explained that data needed to be collected from all patients with lymphoma in order prevent the introduction of bias to the registry. Data from seriously unwell patients was needed in particular and this group were the most difficult to reach. The applicants also advised that some patients were only diagnosed with lymphoma at post-mortem.

The applicants expected that 800-1000 patients would be added to the registry each year and that seeking consent from this number of patients would not be feasible. The CAG agreed that the number of patients involved meant that seeking consent would not be possible.

- **Use of anonymised/pseudonymised data**

The information in the research database would be minimised to age at diagnosis and gender only, with no requirements for specific dates. A 'key' database would be retained, which access to would be limited, in order to collect further data on patients as they progressed. The Group requested confirmation that the key database would be held separately and accessed only by the Data Manager.

Clarification of identifiers

The CAG requested that the applicant clarify the identifiers that would be used for data linkage and retained for analysis purposes.

'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 had not described a patient notification or dissent mechanism in the application. A draft poster had been provided, but the dissemination process had not been described. The poster also stated that the participating hospitals would anonymise the data and that it would not be possible to trace data back to individual patients. This was misleading, as the Data Manager would process information at the participating Trusts and would also retain a link file, therefore it was possible to trace patients back.

The CAG agreed that further work needed to be undertaken around patient notification and dissent. Members suggested that relevant charities were approached and asked to display information on their websites.

A telephone number was given for one member of staff and an email address for another for patients to register dissent. The Group agreed that the dissent mechanism needed to be strengthened. Members queried how dissent would work at a local level, whether the Data Manager would look for evidence of dissent or whether the records of dissenting patients would be flagged beforehand and not provided to the Data Manager. Confirmation needed to be provided on whether the National Data Opt-Out would be applied, once this came into place in September 2020.

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 has provided a letter of support from Lymphoma Action, which included reference to using data without explicit consent. The applicant also conducted a survey with patients with lymphoma, to which they received 16 responses. Whilst the introduction to the survey makes it clear that this would be undertaken without explicit consent, it does not say in either the introduction or questions that confidential patient information would be accessed by those outside of the direct care team. Responses to questions are broadly positive, with one labelling this as contentious.

The CAG agreed that clear information needed to be provided on whether the specific issue of processing of confidential patient information outside of the direct care team, without consent being sought from individual patients, had been discussed during patient and public involvement and engagement. Feedback from these discussions needed to be provided.

The Group agreed that lay representation needed to be included on the Access Committee and requested confirmation that this would be done.

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. Confirm the legal basis under which the Database Manager will process confidential patient information at Nottingham University Hospitals NHS Trust.

2. Clarify whether the pharmaceutical company that provided funding for the database will be allowed access to the database.

3. Confirm that the key database will be held separately and accessed only by the Data Manager.

4. Clarify the identifiers that will be used for data linkage and retained for analysis purposes.

5. Clarify whether any free text will be accessed. If so, provide further information on how this will be accessed and if any data will be extracted from free text.

6. The poster needs to be revised to explain that confidential patient information will be processed by those outside of the direct care team and remove the statement that it won't be possible to trace data back to individuals.

7. Relevant charities are to be approached and asked that information about the project is displayed on their websites.

8. Further details on how the dissent process will work at a local level needs to be provided.

9. Confirmation needs to be provided on whether the National Data Opt-Out will be applied, once this comes into place in September 2020.

10. Clarification needs to be provided on whether the specific issue of processing of confidential patient information outside of the direct care team, without consent being sought from individual patients, has been discussed during patient and public involvement and engagement. Feedback from these discussions needs to be provided.

11. Confirm that lay representation will be included on the Access Committee.

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.

4. Favourable opinion from a Research Ethics Committee. **01 May 2020**

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.

    - **University Hospitals Leicester NHS Trust has a confirmed 'Standards Met' grade on DSPT submission 2018/19 by checking the NHS Digital DSPT Tracker on 21 May 2020.**

    - **Nottingham University Hospitals 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.**

    - **Security assurances for Sherwood Forest Hospitals NHS Trust have not been confirmed by NHS Digital. Support cannot be provided until security assurances are in place, and you are advised to follow the process below to request NHS Digital security assurances for this organisation.**

c. 20/CAG/0068 - SLaM CRIS - NPD linkage

Context

Purpose of application

This application from King's College London (with the controller for the activity confirmed to be South London and Maudsley NHS Foundation Trust) set out the purpose of medical research which aims to create a linked education and mental health dataset for research purposes.

In 2016 the South London and Maudsley (SLaM) NHS Trust created a linked education and mental health research database of nearly 30,000 patients (s251 support provided). However, the current database only contains information regarding young people in the SLaM region up to and including 2013. Given a variety of factors, this resource is significantly more outdated

than would initially be expected. The applicants now wish to update this database to create dataset which covers all school-aged children and young people (between 4 and 19 years) who reside in the SLaM and local catchment area in order to undertake further research.

SLaM will identify the cohort and provide (a) a pseudonymised dataset (data for the cohort identified only by a pseudonym) to Office for National Statistics (ONS) and (b) identifiable information (including the allocated pseudonym) to the Department for Education (DfE). DfE will use the identifiable information to access corresponding pupil data on the National Pupil Database (NPD). DfE will transfer the cohort dataset (identified only by the allocated pseudonym) to the ONS, who will link the SLaM and DfE data into one dataset. Any researchers wishing to access this dataset will have to gain permission from the oversight committees of SLaM, DfE and ONS.

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	All children and young persons between 4-19 years who have accessed SLaM services between 1 January 2008 and 31 August 2019.
Data sources	1. Medical records in the SLaM CRIS database 2. National Pupil Database held by DfE
Identifiers required for linkage purposes	1. Name 2. Date of birth 3. Address 4. Sex 5. Postcode
Identifiers required for analysis purposes	1. Year of birth 2. Postcode (at district level) 3. Gender 4. Ethnicity

Additional information	Because of the changes related to DfE data hosting policies, the applicants require a complete refresh of the linkage as the DfE from 1 January 2008, not from the end of the previous data collection.

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. The Group agreed that the application was in the public interest, noting that one in eight children and young people have a diagnosable psychiatric disorder which impacts on their educational attainment.

Scope

The application alluded to a similar project created by Cambridgeshire and Peterborough NHS Foundation Trust. Both projects had been discussed with a service user group at Cambridge and Peterborough NHS Foundation Trust. The CAG asked the applicant to clarify that the project run by Cambridge and Peterborough NHS Foundation Trust was separate to this application.

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 applicants explained that the size of the database meant that consent was not feasible. The exposures and outcomes they were investigating were potentially rare, and complete data

ascertainment was required in order to identify these. The applicants also hoped to avoid introducing bias into the resultant register. The Group agreed that the size of the cohort and concerns over bias meant that consent was not feasible.

- **Use of anonymised/pseudonymised data**

Confidential patient information was required in order to link the National Pupil Database to the SLaM dataset. This could not be undertaken in any other way.

'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 had provided a generic patient information leaflet which described the work of CRIS, as well as providing information about the CRIS project as a whole and how patients could dissent from the inclusion of their data. The applicant also provided the text that would be displayed on the public facing website.

The Group note that the letter for patients, which was included in the application, explained that patients could opt-out, but did not contain assurance that their treatment would not be affected. Members asked that this was included.

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.

This project was discussed at the Maudsley BRC Data Linkage Service User and Carer Advisory Group, as well as at a second service user group at Cambridge and Peterborough

NHS Foundation Trust, in relation to the sister project. Feedback from these events was supportive. The CAG raised no queries in this area.

Exit strategy

Support was given for the creation of the database via a one-off data linkage from the SLaM NHS Foundation Trust to the National Pupil database at the Department for Education. The applicants anticipated that the data linkage would take six months to complete, at which point the identifiers would be removed. The CAG raised no queries in this area.

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 patient information letter needs to be amended to contain assurance that patients' treatment would not be affected if they dissented from inclusion in the project.

2. Confirm that the project run by Cambridge and Peterborough NHS Foundation Trust is separate to this application.

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.

5. Favourable opinion from a Research Ethics Committee. **Pending**

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

- **South London and Maudsley NHS Foundation Trust and the Office for National Statistics have a confirmed 'Standards Met' grade on DSPT submission 2018/19 by checking the NHS Digital DSPT Tracker on 21 May 2020.**

- **Security assurances for the Department for Education has a confirmed 'Standards Met' grade on DSPT submission 2018/19 by check of the DSPT Tracker on 11 June 2020.**

7. New Applications – Non-Research

a. 20/CAG/0075 – National Cardiac Audit Programme (NCAP) – Private Patients

Context

Purpose of application

This application from Barts Health NHS Trust set out the purpose of the management of health and social care services which aims to incorporate private patient data from England and Wales as part of the NCAP database.

The applicants are seeking support to collect confidential patient information for all private patients treated in England and Wales, as part of the NCAP database. This includes all private patients treated both in the NHS or in independent sector hospitals, including overseas patients. Data will be collected prospectively and will be linked with the following datasets:

a) NHS Digital: Patient and hospital level HES data and ONS mortality data (civil registrations); National Audit of Cardiac Rehabilitation; and General Practice related data (including prescribing data)

b) NHS Wales Information Services: Hospital and patient level Patient Episode Database for Wales (PEDW) data.

c) Barts Health NHS Trust [NICOR]: The UK Transcatheter Aortic Valve Implantation (TAVI) Registry, conducted under s251 support reference number: 17/CAG/0152 (Replacement of CAG 5-07(c)/2013); and the NICOR Commissioning through Evaluation Registries/Audits (CAG reference 17/CAG/0153).

As private patients are explicitly excluded from the NCAP contract, HQIP or NHS England are not the data controllers for the private patients' data. Barts Health [NICOR] will act as the data controller for all private patients' data in the NCAP, whether patients were treated in the NHS or in the independent healthcare sector. Both HQIP and CQC have provided letters of support in this submission for collection of private patient data.

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	Private patients in England and Wales (treated at either NHS or independent hospitals) under one of the following 6 cohorts: - All adult hospitalised heart attack patients. - All adult patients undergoing major heart surgery. - All adult patients with an unscheduled admission to hospital with heart failure. - All cardiac or intrathoracic great vessel procedures carried out in patients under the age of 16 years. All adult congenital cardiac procedures performed for a cardiac defect present from birth. - All patients with implanted devices or receiving interventional procedures for the management of cardiac rhythm disorders. - All patients on whom a percutaneous coronary intervention (PCI) procedure is performed. Data will be collected prospectively

Data sources	1. All NHS Trusts/independent hospitals in England and Wales that treat private patients 2. NHS Digital 3. NHS Wales Information Services 4. Barts Health NHS Trust
Identifiers required for linkage purposes	1. NHS Number 2. Postcode of usual address at date of diagnosis 3. Date of Birth 4. Patients Name 5.
Identifiers required for analysis purposes	1. Postcode of usual address at date of diagnosis 2. Date of Birth 3. Date of death

Confidentiality Advisory Group advice

The following sets out the Confidentiality Advisory Group advice which formed the basis of the decision by the Secretary of State for Health and Social Care.

Public interest

The CAG noted that this activity fell within the definition of the management of health and social care services and was therefore assured that the application described an appropriate medical purpose within the remit of the section 251 of the NHS Act 2006. The Group agreed that the application was in the public interest and had a clear medical purpose.

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 applicants advised that consent was not feasible due to the emergency nature of the admissions. Patients may also have died or experienced complications that would make seeking consent difficult or impossible. Data from these patients was required to ensure the

validity of the dataset. The applicants also expressed concern that seeking consent via outpatients would potentially introduce bias.

The applicant explained that historically, when the professional societies originally set up the UK wide national cardiovascular clinical audits, they had included all healthcare providers, both NHS and private providers. This provided a larger dataset when analysing information to assess the performance of individual hospitals or clinicians.

Some private healthcare providers had submitted data to NICOR using consent as the legal basis under the Common Law Duty of Confidence. Others were submitting pseudonymised or anonymised data. The submission of anonymised data meant that data linkage to ONS mortality data could not be undertaken for these patients in order to determine survival rates and other treatment outcomes.

In 2017, the Caldicott Guardians and Medical Directors of all centres submitting data to NICOR had confirmed that they were satisfied with the legal basis under which their organisation submitted confidential patient information to NICOR. Following the introduction of the General Data Protection Regulation (GDPR) in 2018, some centres reviewed their legal basis for submitting confidential patient information to national audits and paused their submissions, as they did not believe that their existing consent process adequately covered their data submissions. Support was being requested to provide an alternate legal basis, so that their submission of confidential patient information to the audits could continue.

Members noted that support could only be recommended if there was no other practicable alternative, such as consent. In reviewing the relevant application text, members noted that there may have been some confusion over the requirements for consent under GDPR and the level of appropriate consent under the Common Law Duty of Confidence. In noting that GDPR consent requirements set out a high threshold, members noted the thresholds are not the same when considering the validity of consent in relation to the common law duty of confidence. Members advised that support related to obligations under the Common Law Duty of Confidence only. The Group was therefore unsure whether the consent previously used could continue to be used to avoid a breach of the common law, noting the threshold for appropriate consent was lower.

Members were also unclear on why written consent could not continue to be sought if the care providers involved had previously done so successfully. Members asked for examples of the consent forms previously used to be provided so that members could ascertain whether the consent was sufficient to satisfy the Common Law Duty of Confidence and conclude whether seeking support was necessary.

In addition to providing the relevant consent information, members asked that the applicants clarify how many of the organisations involved had submitted confidential patient information using consent from patients as the lawful basis to disclose the information. Members also asked the applicant to provide an indication of how many patients, whose confidential patient information would previously have been submitted to NICOR with consent as the legal basis, would now be included on an unconsented basis.

- **Use of anonymised/pseudonymised data**

Using pseudonymised or anonymised datasets would mean it is unable to link to the datasets required. The CAG raised no queries in this area.

'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 applicants provided a fair processing notice/privacy notice. The application also contained references to a Patient Information Leaflet, but this had not been provided with the application. In correspondence with the Confidentiality Advice Team, the applicant had clarified that the patient information leaflet had been combined with the privacy notice, so that patients only needed to refer to one document.

The CAG noted that the fair processing notice/privacy notice was a lengthy and complex document and expressed concern that the document would not be easily understandable to a lay audience. Members advised that, should the application be resubmitted, then the fair processing notice/privacy notice was provided separately to the patient notification materials. The patient notification materials should be created in collaboration with patient representatives, to ensure that the information provided was suitable for a lay audience. The materials also need to make it explicit that private patients will be recruited and that Barts Health NHS Trust were the data controller and not HQIP.

The CAG also advised that patient information materials were made available in languages other than English, noting that private patients may include patients who have travelled to the UK from other countries for treatment and may not speak English as a first language.

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.

NICOR have a Patient Representative Group, comprising of about 20 members, which meets on a quarterly basis. NICOR also has a national patients and public virtual panel, comprised of approximately 50 members but which is planned to expand to 200 members, who are contacted via surveys, social media and email.

Patients are represented on the NCAP Stakeholder Board and as part of the operational Domain Expert Groups to conduct audit activities important to patients and to provide outputs from the audit in a suitably understandable manner.

NICOR conduct focus groups and Roadshows, which includes patients and members of the public as well as other relevant stakeholders, and collect feedback from the key stakeholders, including patients and members of the public, regarding what is important to them and what they would like to see in our annual reports.

The applicants advised that the patient and public involvement undertaken demonstrated that there is an understanding of the role and value of the audits. No supporting evidence on the patient and public involvement undertaken had been provided with the application. The CAG agreed that it was unclear whether views had been sought from private patients and advised that patient and public involvement needed to be undertaken with private patients, should an application for support be resubmitted.

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.

Further information required

The following information should be provided to allow the CAG to continue their consideration of the application:

1. Further information is required in order to clarify why written consent cannot continue to be sought from patients;

    a. Clarify why written consent cannot continue to be sought from patients.

    b. Provide examples of the consent forms that were previously used to seek consent.

    c. Provide an indication of how many patients, whose confidential patient information would previously have been submitted to NICOR with consent as the legal basis, would now be included on an unconsented basis.

2. The fair processing notice/privacy notice needs to be separate to the patient notification materials.

3. Patient notification materials need to be provided;

    a. The notification materials should be created in collaboration with patient representatives, to ensure that the information provided is suitable for a lay audience.

    b. It needs to be made explicit that private patients will be recruited.

    c. It needs to be made clear that Barts Health NHS Trust are the data controller and not HQIP.

    d. The patient information materials were made available in languages other than English, noting that private patients may include patients who have travelled to the UK from other countries for treatment and may not speak English as a first language.

4. Patient and public involvement is to be undertaken around the use of confidential patient information with patients treated in private healthcare providers.

5. It is confirmed that support cannot be applied retrospectively to data already collected. It is for the applicant to ensure that a relevant alternative legal basis is in place for this collected data.

6. Confidential patient information collected for the purposes described in the application cannot be used for research purposes. Where this required by the applicant, a separate amendment to the relevant supported application should be submitted, should the application for support be resubmitted and support given.

8. Office Report

A report was provided to the CAG members on the work of the Confidentiality Advice Team.

9. 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