Minutes of the meeting of the Confidentiality Advisory Group

19 March 2020, Meeting via Teleconference

Present:

Name	Present	Notes
Dr Tony Calland MBE	Yes	CAG Chair
Dr Patrick Coyle	Yes	CAG Vice-Chair
Mr David Evans	Yes	CAG Member
Dr Liliane Field	Yes	CAG Member
Dr Simon Kolstoe	Yes	CAG Member
Dr Harvey Marcovitch	Yes	CAG Member
Ms Diana Robbins	Yes	CAG Member
Ms Clare Sanderson	Yes	CAG Alternative Vice-Chair
Dr Murat Soncul	Yes	CAG Alternative Vice-Chair

Also in attendance:

Name	Position (or reason for attending)
Ms Katy Cassidy	Confidentiality Advisor
Mr Paul Mills	Research Regulation Specialist

1. Introduction, apologies and declarations of interest

2. Support decisions

Secretary of State for Health & Social Care Decisions

The Department of Health & Social Care senior civil servant on behalf of the Secretary of State for Health & Social Care has not yet made a decision, following the advice provided by the CAG in relation to the **20 February 2020** meeting applications.

Health Research Authority (HRA) Decisions

The Health Research Authority has not yet made a decision, following the advice provided by the CAG in relation to the **20 February 2020** meeting applications.

3. New Applications – Non-Research

a. 20/CAG/0043 – Adult social care free text analysis

Context

Purpose of application

This application from London Borough of Islington Council set out the purpose of the management of health and social care services which aims to inform the management of health and social care services and provision of care locally.

London Borough of Islington Council and NHS Islington CCG would like to combine datasets from GP practices in Islington, hospital admissions and adult social care, with "free text" data from adult social care records (e.g. assessment forms) to inform the management of health and social care services and provision of care locally. Examples of uses includes (but not limited to) informing the design and implementation of local integrated care systems, and well as providing reasons for delayed transfers of care so service provision can be redesigned to reduce this.

Adult Social Care data containing NHS number, as well as other identifiers contained in free text information, will be transferred to NEL CSU. NEL CSU will pseudonymise the free text information. The pseudonymised dataset will be transferred to London School of Economics for structuring. Finally, GP data (held by NEL CSU) and secondary care data (held by NHS Digital) will be linked by NHS number to provide a final pseudonymised dataset for analysis.

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	People aged 65 and over, using adult social care services in Islington. Those with HIV will be removed from the dataset.
Data sources	London Borough of Islington Council NHS Digital NEL CSU
Identifiers required for linkage purposes	NHS Number

Identifiers required for analysis purposes	Identifiers (e.g. names, addresses) contained within free text information provided by London Borough of Islington Council. This will be held temporarily by NEL CSU whilst they strip the information from identifiers during pseudonymisation.
Additional information	Note that there are three separate functions of NEL CSU involved in this application: NEL Data Flow team: Will apply the free-text de-identification process prior to routing data through DSCRO. NEL DSCRO team: De-identification and data linkage on standard attributes such as NHS number. NEL Data management team: Manages infrastructure used by customers.

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.

Members were assured that the project was in the public interest as undertaking such work and gaining a combined dataset can be used to inform future service provisions within the NHS. It was also noted that this was a pilot project which could be used as a basis for such work more widely.

The members noted the potential uses of the data, but agreed further information was needed on the expectations of the outputs this project will produce.

However, given this was a pilot using sensitive data members agreed that a condition of support will be for the group to receive a report after one year on whether the process achieved its objectives.

Scope

Members noted that this was a pilot and the scope of this support would apply to this project in Islington only. Were other areas to subsequently undertake similar work a separate application for support would be expected.

The group understand that the London School of Economics will, at no time, have any access to confidential information and support will not be provided for the activities undertaken here.

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 were unsure of the exact flows of identifiable information, what information is transferred to whom and when. As such, the members would like further clarity on the flow of identifiable information within this project.

Members noted the sensitivity of using free text data from adult social care records. Whilst it is understood that these records will be stripped of identifiers members were uncertain of what identifiable information may be included in the free text, the accuracy of the free text records and what information the pseudonymised version of the free records will contain in relation to criminality and safeguarding. Members agreed further information on these points would be required.

The application also makes reference to a structured dataset and the group agreed more information on what this contains, including any identifiable information, would be requested.

- **Feasibility of consent**

The group were assured that, due to the large numbers of service users, consent was not feasible.

- **Use of anonymised/pseudonymised data**

Access to confidential information is necessary to link information of users from multiple sources in order to provide a combined dataset.

'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 group noted the use of a privacy notice that will be placed on the website of the London Borough of Islington Council, but noted that the provided notice uses technical language. Members suggested a layered approach to transparency is used, that is provide initial simple information with a link to further information if the reader requires it.

Members noted that the applicant said a patient notification communication will be used but they did not submit the material with the application. It was agreed the communication material should be provided before support can be given.

The group agreed that the applicant should confirm that the national data opt-out will apply. If not, a justification should be provided.

Members noted that patients with EMIS opt out codes in their records will be excluded. The group requested information on how opt outs will be managed if systems other than EMIS are used.

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 group were content that the Patient and Public Involvement and Engagement undertaken was reasonable. However, considering the potential importance and sensitivity of the group asked whether the applicant has considered linking wider with other established patient groups.

Patient Cohort

Members noted the conflicting responses in the application form Section 1(i) of the application form mentions 3000 service users, whereas section 3(q) refers to 15000 receiving long term support. Members therefore agreed for clarification on the approximate number of service users whose records will be used under this support.

The group understands that those with HIV are excluded from this project and wondered whether any other groups are excluded.

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 Secretary of State for Health and Social Care 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. Provide further information on the structured dataset, how it is produced, what information is contained and whether any identifiable information is within it.

2. What identifiable items may be in the free text data?

3. Please comment on the accuracy of the information contained in the free text data.

4. What information will the pseudonymised version of the free text data contain with respect to safeguarding or criminality?

5. What will the dataset look like when returned?

6. Consider a layered approach for privacy information, provided updated materials, or justification why a layered approach is not to be used.

7. Provide patient communication materials before support will given

8. Provide further clarity on the flow of identifiable items, from source to use, how this will happen and when.

9. Clarify the approximate numbers of service user records to be used in this project.

10. Clarify opt out procedures if systems other than EMIS are used.

11. Confirm plans on using the national data opt out.

12. Consider linking with a wide PPI group for continued patient engagement.

13. Confirm if any exclusions, other than those with HIV, apply.

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. Provide a report to the CAG no later than one year after support given on whether the process used has achieved the objectives of the project.

2. Confirmation provided from the IG Delivery Team at NHS Digital to the CAG that the relevant Data Security and Protection Toolkit (DSPT) submission(s) has achieved the 'Standards Met' threshold. See section below titled 'security assurance requirements' for further information. **Pending: assurance remains outstanding for London Borough of Islington Council, Islington Clinical Commissioning Group and NEL CSU.**

4. New Applications – Research

a. 20/CAG/0039 – Phenotyping individuals with elevated mean pulmonary arterial pressure and elevated pulmonary vascular resistance in the United Kingdom

Context

Purpose of application

This application from Royal Free London NHS Foundation Trust set out the purpose of medical research which aims to compare patient and clinical outcomes, treatments, hospitalisation and mortality in patients with different levels of dynamic blood flow to their mean pulmonary arterial pressure (mPAP) and pulmonary vascular resistance measurements and diagnosis (PVR).

Pulmonary hypertension (PH) has long been defined by the presence of mean pulmonary arterial pressure (mPAP) ≥25 mm Hg as measured by resting right heart catheterization (RHC). However, accumulating evidence suggests that individuals with a lower mPAP or pulmonary vascular resistance (PVR) could be considered abnormal and at risk of disease progression. This study aims to describe and compare patient and clinical characteristics, biomarkers, therapies, quality of life, and prognosis among patients categorized in cohorts based on different levels of mPAP and PVR.

Care teams at six hospitals (Royal Free London NHS Foundation Trust, Sheffield Teaching Hospitals NHS Foundation Trust, Imperial College Healthcare NHS Trust, Royal Brompton and Harefield NHS Foundation Trust, Royal Papworth Hospital NHS Foundation Trust, The Newcastle Upon Tyne Hospitals NHS Foundation Trust) will collect data from all patients who had a Right Heart Catheterisation (RHC) between January 1, 2009 - December 31, 2016 (approximately 2900). Data will be encrypted and provided to the study team at the Royal Free London NHS Foundation Trust. The data will include confidential information (Name, date of birth and NHS number). The Royal Free will collate the data from the hospitals and request linkage with HES data (for Date(s) of hospitalization) and ONS data (for date of death).

A recommendation for class 1, 4 and 5 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 who had a Right Heart Catheterisation (RHC) between January 1, 2009 - December 31, 2016 at one of participating hospitals. Approximately 2900 patients.
Data sources	1. Royal Free London NHS Foundation Trust 2. Sheffield Teaching Hospitals NHS Foundation Trust (Royal Hallamshire Hospital) 3. Imperial College Healthcare NHS Trust (Hammersmith Hospital) 4. Royal Brompton and Harefield NHS Foundation Trust (Royal Brompton Hospital) 5. Royal Papworth Hospital NHS Foundation Trust 6. The Newcastle Upon Tyne Hospitals NHS Foundation Trust (Freeman Hospital)
Identifiers required for linkage purposes	1. Name 2. NHS number 3. Date of birth
Identifiers required for analysis purposes	1. Date of birth 2. 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 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 of the public interest as gaining an understanding of whether patients with a lower mPAP or PVR are at risk of disease progression will allow for further benefits for this group of patients.

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 understood that five of the English NHS Trusts will provide identifiable information to the Royal Free, prior to linkage with NHS Digital and the Office for National Statistics. In order to minimise flows of identification members queried why the identifiable information could not be transferred direct from each hospital to NHS Digital and the Office for National Statistics.

- **Feasibility of consent**

The group were assured that, due to the sample size and the retrospective nature of the patient group involved, it was not feasible to seek consent.

- **Use of anonymised/pseudonymised data**

Access to confidential information was necessary to enable the patient cohort to be identified and to facilitate linkage between the data sources.

Justification of identifiers

Members queried whether all identifiers listed for both linkage and analysis were absolutely required. The applicants should provide further justification for the need for use of each identifier in both the linkage and analysis of data in order to reassure the group of the need for each.

'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.

Members noted the lack of any form of patient notification within the application. The applicant must describe what patient notification routes will be used, providing the materials to be used before support can be given.

Members also noted brief details on how patient opt out will be managed. However, the group wishes for further clarification how both local and nation opt outs will be managed.

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 thought a good attempt had been made on Patient and Public Involvement and Engagement and noted the summary sheet provided. However, members were unclear on the specific questions asked in the survey, and wished for these questions to be provided to the group.

Legal basis for collection of data at NHS Trusts

The group noted that each NHS Trust will collect confidential information and transfer this to the Royal Free NHS Trust. Whilst members acknowledged that who undertakes this in each NHS Trust may differ, no details were provided on the status of the staff extracting this data, and whether s251 support was required for this activity.

Study Objectives

The group noted that it appeared there was multiple primary objectives of the research in the protocol, and suggested there should be one primary objective, with others listed as secondary objectives.

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. Can NHS Trusts provide the confidential dataset direct to NHS Digital/Office for National Statistics, rather than via the Royal Free London NHS Foundation Trust? If not, please provide justification why the confidential information must go via the Royal Free London NHS Foundation Trust.

2. Provide justification for all identifiers required for both linkage and analysis of the data.

3. Provide details of the patient notification work to be undertaken and provide all materials to be used.

4. Clarify how both local and national patient opt outs will be managed for the study.

5. Provide a list of questions asked in the patient survey.

6. Confirm the status of staff extracting the data in each NHS Trust, whether they have an existing legal basis and whether support is required for this activity.

7. Suggest listing one primary objective, with all others being secondary objectives

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. Favourable opinion from a Research Ethics Committee. **Confirmed March 2020**

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

b. 20/CAG/0043 – The Prognostic Performance of the Enhanced Liver Fibrosis Test in UK Patients with Chronic Liver Disease Assessed 20 Years After Recruitment to the EUROGOLF Study (EVenti)

Context

Purpose of application

This application from The Royal Free London NHS Trust set out the purpose of medical research which aims to determine the value of using the enhanced liver fibrosis test (ELF) as part of an evaluation of liver disease risk in middle life.

An original cohort of 921 participants (497 in the UK) were consented into the EUROGOLF study between 1998 and 2000, which identified and validated the ELF test. In 2008/09 the investigators interrogated the 497 records in the UK which established it was at least equal, if not superior to, a liver biopsy in predicting liver related and all cause mortality at 7 years. It has now been 20 years since participants were enrolled and many patients have likely reached clinical endpoint. The applicants wish to link NHS number to HES and cancer registry data from NHS Digital and date of death from Office for National Statistics. The resulting data will be used to understand the value of the ELF test as part of an evaluation of liver disease in middle life.

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 patients recruited into the original EUROGOLF study
Data sources	1. NHS Digital 2. Office for National Statistics
Identifiers required for linkage purposes	1. NHS number
Identifiers required for analysis purposes	1. Date of birth 2. Date of death 3. Postcode

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 understood and wishes to place on record their feeling that the application has a good medical purpose. Members felt the research is very much in the public interest, with the ability to be able to reduce the need for liver biopsies. Members wished to work with the applicants on a future application, as detailed below, to enable this research to be undertaken

Scope of support

Members noted that the application is requesting support for NHS Digital to transfer confidential information to the Royal Free London NHS Foundation Trust. However, it also appears that support is required for the transfer of NHS number from the Royal Free London NHS Foundation Trust to NHS Digital. The group wishes the applicant to confirm this.

Due to this transfer of confidential information from the Royal Free London NHS Foundation Trust, the CAG will require a letter of support from the Caldicott guardian in any resubmission.

Legal Basis

Members understand that participants originally gave consent on the understanding that identifiable data will be held for two years. As such, the group had several queries on the legal basis for holding the identifiable information for 20 years. It is this lack of information on which the deferral has been given.

Members were unclear on the terms of the original consent for the original EUROGOLF study, and requested to see the original participant information sheet and consent form.

Given the understanding that consent was given to hold identifiable information for two years, members were unclear on the legal basis to hold identifiable information since this time.

The group also noted that a follow up study was undertaken in 2008/09, but were unclear on both the legal basis for using identifiable information without consent in the follow up, and for holding this identifiable information since 2008/09, and requested clarification.

The Group agreed that, should a revised application be submitted by the applicant for consideration by the CAG, the application form and supporting documentation would require revision to reflect the above.

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, on the basis of the time since original consent and that many patients may have reached a clinical endpoint, it was not feasible for the research to be carried out on the basis of consent.

- **Use of anonymised/pseudonymised data**

Members noted that the use of identifiable information is required for linkage by NHS Digital. However, members queried whether NHS Digital will be able to link using NHS number only. The group queried whether the research team had consulted NHS Digital about this aspect.

‘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.

Members noted that no patient notification has been considered, nor any notification materials have been provided. Before any resubmission the group agreed the applicants should ensure that they have a proper patient notification procedure in place and provide the notification materials with the application.

The group also noted limited information regarding managing patient objections, both locally and nationally. Any resubmission should be clear how patient objections will be managed and how the nation data opt out will be applied.

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 commended the applicant on the Patient and Public Involvement and Engagement that has been undertaken. Particular compliments were given on the richness of the responses obtained from a small pool of applicants, due to the care taken to explain the research.

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

Further information is required to address the below points. A detailed covering letter should be provided to support the revised application submission, which addresses the below points and sets out where revisions have been made to the revised CAG application.

1. Given consent appears to have been given for holding identifiable information for 2 years, what has been the legal basis for holding the information since then.

2. Please provide the EUROGOLF participant information sheet and consent form. If not available please provide explicit detail on what was detailed about the length of time for holding identifiable information.

3. What was the legal basis for the 2008/09 follow up, and for holding identifiable information since then?

4. Ensure a resubmission contains a proper patient notification process, providing any materials with the application.

5. Any resubmission should be clear about how patient objections will be managed, and how the national data opt out will apply.

6. Confirm whether support is required for the transfer of identifiable information from the Royal Free London NHS Foundation Trust to NHS Digital.

7. Provide a letter of support from the Caldicott Guardian.

8. Consider consulting with NHS Digital whether linkage using NHS number is feasible.

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.

c. 20/CAG/0042 – The Listening Place – Research Database

Context

Purpose of application

This application from The Listening Place sets out the purpose of medical research which aims to create a research database from users of the service, and providing confidential information to researchers upon request.

The Listening Place (TLP) is a charity that offers support from trained listening volunteers to anyone over the age of 18 who no longer feels like life is worth living. TLP is a London based charity and has a strict confidentiality policy in order to overcome the barriers that traditionally prevent suicidal people from sharing their thoughts and plans People can self-refer to TLP, but most referrals come from the NHS or other charities. TLP would now like to use the data collected as part of routine care in a research database. It is being established to answer questions about suicidal ideation, suicidal behaviour, and the role of face-to-face talking, in the context of a supportive relationship provided by TLP. Its purpose is to allow scientific research to be conducted using TLP data; to increase understanding of suicide; and support the aim of NICE to evaluate non-clinical interventions for suicide.

Researchers will be able to request access to information held by TLP. If the request is approved, the researcher will be provided with a tailored copy of the database. This

will include date of birth, postcode, gender, ethnicity, London borough of residence and occupation, for which support is requested.

A recommendation for class 1 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 service users of TLP
Data sources	1. TLP clinical care database
Identifiers required for analysis purposes	1. Date of birth 2. Postcode (unit level) 3. Gender 4. Ethnicity 5. London Borough of residence 6. Occupation

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 understood and wishes to place on record their feeling that the application has a good medical purpose. Members felt the aim of the research has good intentions, and can see the value of increasing the understanding of suicide

Scope of support

Members noted that the application is requesting support for a research database. However, all members thought, whilst the intentions were good, the project is not creating a research database. Instead it is asking for support for researchers to collect data from clinical systems upon request. The application does not create a separate, non-identifiable database, instead, a bespoke dataset will be created from each dataset. Further these datasets will contain identifiable information.

Given this is not creating a separate research database, and given each researcher requesting access will have access to identifiable data, the group felt it could not support the application. Instead members felt, in its current form, a separate application for support would need to be made for each research project that would access data from TLP.

The Group agreed that, should a revised application be submitted by the applicant for consideration by the CAG, the application form and supporting documentation would require revision to reflect the above.

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 consent is not feasible due to the temporary contact that a user may have with the service, and difficulties in contacting them retrospectively. Members also noted the sensitivities in requesting consent from a user as soon as they reach out to TLP.

- **Use of anonymised/pseudonymised data**

Members noted that identifiable information will be provided upon request to each researcher. For example, data of birth required to manage duplicate records. In any future applications, the researcher to carefully determine which identifiable information is needed, and whether alternatives apply. For example, ensuring clinical systems manage duplicate records so that date of birth does not need to be provided.

'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.

Members noted that no patient notification has been considered, nor any notification materials have been provided. Before any resubmission the group agreed the applicants should ensure that they have a proper patient notification procedure in place and provide the notification materials with the application.

The group also noted limited information regarding managing patient objections. Any resubmission should be clear how patient objections will be managed.

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 limited Patient and Public Involvement and Engagement undertaken, with questions not being explicit about using confidential information without consent. Members suggest, for any future applications, more thorough work is undertaken in this area. This should include considering setting up and coordinating an ongoing Patient and Public Involvement and Engagement group to oversee research applications.

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

Further information is required to address the below points. A detailed covering letter should be provided to support the revised application submission, which addresses the below points and sets out where revisions have been made to the revised CAG application.

1. This application is presented as a research database application, yet the activities are not aligned with this. Instead, it is more of a request for researchers to access clinical data upon request given no separate research database is being created.

2. In its current form, the CAG cannot give support for this application. Instead, the CAG would expect separate applications from each researcher requesting access to identifiable information from The Listening Place.

3. In preparing any future application, consider mechanisms of patient notification and provide any notification materials with the application.

4. In preparing any future application, consider further the Patient and Public Involvement and Engagement, as well as setting up an ongoing group to oversee research work at The Learning Place.

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.

d. 20/CAG/0050 - What is the prevalence of distal surface caries (DSC) in the lower second molar when screening patients with bitewing radiographs: A multi-center study

Context

Purpose of application

This application from the University of Manchester sets out the purpose of medical research which aims to investigate the prevalence of distal surface caries (DSC) in the second mandibular molar adjacent to an impacted wisdom tooth.

In the UK, clinical guidelines state that impacted wisdom teeth should be left in place unless strict criteria are met. As a result, some clinicians feel that there is an increasing incidence of caries that develops in both teeth. Evidence suggests a high reported prevalence of distal surface caries (DSC) in second mandibular molars. But this prevalence may be high because it represents a population of referred hospital

patients and does not relate to the prevalence in the general population. The wisdom tooth guidelines in the USA and Brazil recommend early removal of wisdom teeth with an emphasis on prevention unlike the UK.

This study proposes to investigate the prevalence of distal surface caries (DSC) in the second mandibular molar adjacent to an impacted wisdom tooth by examining existing radiographs of patients who attended the Manchester Dental Hospital for routine dental examination. The researcher will access the Trust Picture Archiving and Communication System (PACS) and review radiographs of 1012 consecutive patients meeting the inclusion/exclusion criteria. The hospital ID will also be provided to the student supervisor and head of the radiology department to also review the radiographs to ensure the findings are accurately recorded.

In addition, the study is working with centres in Brazil and the USA to compare the prevalence of DSC in the UK vs US and Brazil, due to differing guidelines.

A recommendation for class 1 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	1012 consecutive patients meeting the inclusion/exclusion criteria between 01/01/2009 – 31/12/2019.
Data sources	1. Manchester University NHS Foundation Trust (Manchester Dental Hospital)
Identifiers required for linkage purposes	1. Hospital ID

Identifiers required for analysis purposes	1. Postcode (to calculate deprivation scores on site)

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 felt there was sufficient public interest, noting the outcomes of the research could provide important insights into wisdom tooth management which may impact future guidelines.

Scope

The group queries the status of the two expert reviewers (student supervisor and head of the radiology department), and whether they had a legal basis to access the hospital systems to view images. Members agreed for the applicant to clarify this and for the applicant to confirm whether or not support is required for the expert viewers to receive the hospital number and view images on hospital systems.

Members noted some disparity on the lower age limit of participants. The protocol and Q17 of the application form indicates it is 30, but Q16 of the application indicates it is 35. Members agreed to seek clarification.

The group noted that the study involved centres in Brazil and the USA, which are outside the scope of this support, but wished to place on record that no identifiable information should be sent there.

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 were content that flows of identifiable information have been kept to the minimum necessary to undertake this project.

- **Feasibility of consent**

The group understood that, due to the numbers involved and the retrospective nature of the study, seeking consent was not feasible, although they felt this was not well expressed within the application.

- **Use of anonymised/pseudonymised data**

Whilst care will be taken, members understood the need for the researcher to access clinical systems for collecting the data, and were assured that the minimum necessary identifiable information will be viewed/collected. For example, postcodes will not be collected, instead deprivation scores calculated from source. Members also understood that hospital ID will be shared for expert reviewers to confirm the findings.

'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 group noted the lack of any patient notification materials, and the justification that the transient nature of patients accessing the services of Manchester Dental Hospital meant that patients in the cohort of this study would unlikely see the notification. This was considered at length by members, who agreed that some form of patient notification should be undertaken, at least on the Trust website. Any form of notification should include details of an opt out process (see below).

Members were also unclear on the opt out process to be used, and whether the national data opt out would apply. Responses from the applicant indicate a lack of understanding about opt outs for use of data in research, which is separate from any provisions under GDPR. Any notification, as detailed above, should provide readers with a way of them requesting to opt out of their data being used in research.

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 felt that the Patient and Public Involvement and Engagement was quite weak and thought it would be stronger if a group was convened to explain the context of the study and what would happen, and then ask the group for opinions. The group agreed to query if further Patient and Public Involvement and Engagement was planned, and for justification to be provided if 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. Clarify the exact role of the student supervisor and head of the radiology department, and whether they have a legal basis to access identifiable information without consent. Please clarify if support should be extended to cover the activities of these people.

2. Provide clarity on the proposed patient notification approach, as well as providing the materials to be used. Any patient notification must include detail on an opt out process.

3. Provide clarity on the lower age limit of participants.

4. Confirm whether any further Patient and Public Involvement and Engagement is planned. If not, provide a justification.

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. Favourable opinion from a Research Ethics Committee. **Confirmed January 2020**

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

5. Annual Reviews

a. CAG 10-02(d)/2015 – Public Health England National Congenital Anomaly and Rare Disease Registration Service

b. PIAG 03(a)/2001 – National Cancer Registration and Analysis Service (NCRAS)

Annual Review submission

The review provided an update against the previous queries the CAG had raised regarding the 2019 annual review submission. This consisted of a request for further information around the relationship between the Independent Advisory Panel on Data Release (IAPDR), the Data Release Advisory Board (DRAB) and the Office of Data Release (ODR). Information about the steps taken to implement a plan to fully replace legacy information sheets with new materials and confirmation that future publications of the information sheet would include a contact telephone number to enable patients to register dissent were also requested. The CAG asked that age appropriate children and young people information materials were created and supplied and that the patient-facing video available via the National Disease Registration website was updated to include further information around the differing uses of patient data

(registration and research), to inform patients that data would be made available to third parties and explain the right to object to the use of data.

Confidentiality Advisory Group advice

Further information is required around the relationship between the Independent Advisory Panel on Data Release (IAPDR), the Data Release Advisory Board (DRAB) and the Office of Data Release (ODR)

The application provided details on how each of the above organisations was involved in the review and approval of data releases and which group was responsible for approving data releases and the quoracy involved in this process.

The applicants were asked to advise whether the decision-making process included any lay input. The applicants advised that there was no lay involvement in any stage in the PHE process for reviewing and approving requests for third-parties to access personally identifiable or depersonalised data for secondary use purposes. They relied on the lay representation included in the national review processes overseen by the HRA, which governs the processing of personally identifiable and depersonalised data for secondary use purposes.

The applicants explained that those who applied to receive data from PHE, including the National Cancer Registry were not asked to submit annual reviews to the ODR. The applicants expected that the majority of these requests would be for studies that would last one or two years and have s251 support, and would therefore provide annual reports to the CAG.

The Group noted that the roles of the ODR, DRAB and the IAPDR had been well-explained. Members requested confirmation that all of the applications for data would have been reviewed by the CAG and would have support under s251 in place. If any applications would not be reviewed by CAG, then details of the review process needs to be provided. The CAG stressed the importance that independent lay contribution was included in the review of applications which were not reviewed by the REC and CAG.

Confirm that steps were taken to implement a plan to fully replace legacy information sheets with new materials

The applicant advised that PHE provided every oncology unit in England with an appropriate supply of hard copies of the National Cancer Register patient information leaflet on a quarterly basis. The last supplies of the previous leaflet were sent out in October 2018 and distribution of the new leaflet began at the start of 2019. All oncology units have been asked to use the revised leaflet once their supplies of the old one have been exhausted.

The Group noted this information. Members advised that patient information materials should be regularly updated to maintain clarity and to fully explain the data items that would be included on the register, and the proposed use of data. Commitment to ongoing review and updating was requested.

Confirm that future publications of the information sheet would include a contact telephone number to enable patients to raise a dissent

The applicants advised that the inclusion of a contact telephone number in the National Cancer Register information leaflet had been considered by the Cancer Register Director and the NCRAS senior team. An email and postal address was included on the leaflet for members to contact the team with queries or register dissent. The applicants advised they had decided that the current level of patient and public contact with NCRAS is not of a scale that can justify the allocation of finite PHE resources to providing an appropriately supported telephone contact service.

The applicants recognised that the absence of a contact telephone number may be an impediment to patients or members of the public contacting the cancer register, however two communication channels were provided and none of the partner organisations or stakeholders had raised any concerns with NCRAS about the absence of a telephone contact route. The decision would be reviewed regularly.

The Group noted this information but agreed that a contact number was still required. Members noted that PHE may not have the capacity to staff a dedicated telephone number for NCRAS queries, due to the COVID-19 pandemic at the time the annual review was considered by the CAG, but requested that the decision not to provide a telephone number was reconsidered as soon as possible.

Provide copies of the age appropriate children and young people information materials for consideration

The applicant advised that work had been undertaken jointly between PHE and the Teenage Cancer Trust to develop cancer registration information materials aimed at young people, however this had taken longer than expected. The applicants anticipated that the materials would be ready for publication shortly and an update would be provided at the next annual review.

An explanation of the work undertaken so far was provided. The CAG noted that the leaflet was well-designed and appropriate. Members agreed that a telephone number also needed to be included in the leaflet, in line with the request described above.

The patient-facing video which is available via the National Disease Registration website should be updated to include further information around the differing uses of patient data (registration and research), to inform patients that data would be made available to third parties and explain the right to object to the use of data. A timeframe for these updates would need to be provided.

The applicant advised that the patient-oriented video available on the National Disease Registration Service website had been developed by PHE with the support of the Understanding Patient Data initiative to help broaden the ways in which information about the National Cancer Register was provided. The video did not contain full details of all the data items collected by the Cancer Register, how this was protected and used, and who it would be shared with, or how patients could opt-out, as this information was included elsewhere on the website. The applicants confirmed that they had no plans to revise this video.

The Group noted this response. Members observed that the National Disease Registration Service website had been updated during the last year to include cancer data stories, however these were included as a separate section of the website and not the patient facing page. The group asked whether reference to these stories could be included within the patient facing page.

Updates to the NDRS website had been made following feedback provided by patients.

Members requested further details on this feedback provided and who had been consulted.

Confidentiality Advisory Group advice conclusion

The CAG agreed that the applicant had demonstrated there was a continuing public interest in support continuing in its current form and therefore provided a positive recommendation to the Secretary of State for Health and Social Care and the Health Research Authority, subject to the conditions set out below.

Specific conditions of support

1. Provide confirmation that all applications for data would have been reviewed by the CAG and would have support under s251 in place. If any applications would not by reviewed by CAG, then details of lay involvement in the review process need to be provided.

2. Commit to undertaking ongoing review and updating of the patient information materials.

3. The cancer data stories on the National Disease Registration Service website need to be included or referenced in the patient facing page of the website.

4. Provide further details on the feedback that had been provided to inform the updates to the NDRS website and who had been consulted.

Response was requested within six months of the date of this outcome letter which would be considered at the next available full CAG meeting.

6. Minutes of the meeting held on 20 February 2020

To follow

7. 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