Minutes of the meeting of the Confidentiality Advisory Group

20 August 2020 at Meeting via Teleconference

Present:

Name	Present	Position
Dr Tony Calland MBE	Yes	CAG Chair
Dr Martin Andrew	Yes	CAG Member
Dr Malcolm Booth	Yes	CAG Member
Dr Patrick Coyle	Yes	CAG Vice-Chair
Dr Liliane Field	Yes	CAG Member
Mr Tony Kane	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
Mr Marc Taylor	Yes	CAG Member

Also in attendance:

Name	Position (or reason for attending)
Ms Caroline Watchurst	HRA Confidentiality Advisor
Mr Paul Mills	HRA Confidentiality Advice Service Manager
Ms Natasha Dunkley	HRA Head of Confidentiality Advice Service
Ms Charlotte Ferris	Observing

1. Introduction, apologies and declarations of interest

Any declarations of interest are declared below for each application.

2. Support decisions

Health Research Authority (HRA) Decisions

The Health Research Authority agreed with the advice provided by the CAG in relation to the **02 July 2020** meeting applications.

3. Consideration Items

a. 20/CAG/0028 – SAHSU National Data Opt-Out exemption request

Output of item not yet released

b. 15/CAG/0119 – National Data Opt-Out impact paper

Output of item not yet released

4. Annual Reviews

a. ECC 3-04(i)/2011 - Global surveillance of cancer survival (CONCORD programme)

Annual review outcome

As a whole, it was noted that the activity was proceeding as planned and the justification for continuing support had been satisfactorily made.

However, as the annual review indicated that a condition of support had not been achieved, consideration of the annual review was carried out by a full committee of the CAG.

Condition of support change

The 2019 annual review was considered by a full committee of the CAG on 6 June 2019, in which the CAG discussed about patient and public involvement and engagement that has been undertaken by the cancer survival group. The outcome of this consideration was to support the annual review, but provide additional conditions of support, as stated below:

1. A plan to increase patient and public involvement activity in the research activities undertaken by the Cancer Survival Group with support under the Regulations should be established.

2. The plan should be submitted by close of play on Monday 18 November 2019. This will then be considered at the CAG meeting scheduled for Thursday 5 December 2019.

3. Consideration should be given to the specific suggestions provided by the CAG. If these were considered not to be feasible or appropriate, information should be provided to explain why and describe what alternative methods would be progressed instead.

4. Feedback from these planned activities will be required within the next annual review submission. Consideration of the annual review will be assigned to a full CAG meeting, to allow the progress and outcomes to be considered.

On receipt of the 2020 annual review, it was noted that these conditions of support were apparently not undertaken. However, upon discussion with Prof. Coleman it was evident that the 2019 annual review outcome letter was not received. Upon inspection of CAG records, no evidence that the 2019 annual review outcome was sent to Prof. Coleman can be found.

Firstly, the Confidentiality Advice Team apologises for the oversight in not communicating the 2019 annual review outcome to Prof. Coleman. We will review our procedures to ensure that this does not happen again.

The CAG also wishes to place on record its recognition of the high value of the work undertaken by the cancer survival group. The chair of the CAG, Dr Tony Calland, is willing to have a telephone call with Prof. Coleman, if there are any outstanding questions or issues that arise from this letter.

The further documentation provided by Prof Coleman on 16 August 2020 was reviewed by the CAG, noting that the 2019 annual review was not received. Members wished to thank Prof. Coleman for his work in quickly providing such a detailed report.

Provision of a plan to increase patient and public involvement and engagement activities, with feedback on further activities

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. It is part of CAG standard conditions of support that applicants undertake work with patients to seek their views specifically on the use of Confidential Patient Information without consent. This provides additional information and recognition of public support to the CAG when it advises to waive common law duty of confidentiality.

It was noted the supporting information provided by Prof. Coleman detailed how the cancer survival group has worked with patients throughout its lifetime, and members noted the considerable interactions that the group has had with patients.

However the group noted that despite these interactions, there was no detail on specific patient and public involvement on the use of confidential patient information without consent to enable the cancer survival group to achieve its aims.

As such, members agreed to extend the condition of support and requests that the applicant provides, as part of the next annual review, a report detailing the patient and public involvement and engagement work undertaken by the cancer survival group to specifically seek views on the use of confidential patient information without consent. Doing so will satisfy the CAG that the use of confidential patient information without consent in this work has recently been tested and supported by patients.

Consideration of the establishment of a separate advisory panel of cancer patients

Members noted that Prof. Coleman argued it is not the right time to develop such a group because of the impact of COVID-19 and the cancer survival group is undergoing a reorganisation, which includes a review of the membership of the Advisory Panel and the CONCORD Steering Committee. The group were content with argument but felt that further consideration of this proposal could be made following the completion of the internal review and reorganisation.

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

Security assurance

It is a policy requirement of the Department of Health and Social Care in England that relevant entities processing confidential patient information under support maintain a satisfactory security assurance level for the duration of support, with similar arrangements in Wales. The need to maintain appropriate security assurance is a condition of support for all applications.

The current status of relevant entities processing information under support is as follows:

1. The NHS Digital DSPT review for Cancer Survival Group in the London School of Hygiene and Tropical Medicine was confirmed as 'Standards Met' on the NHS DSPT Tracker (checked 12 August 2020)

Specific conditions of support (updated)

The following sets out the updated specific conditions of support applied against this application reference.

1. At the next annual review, provide further consideration on the establishment of a separate advisory panel of cancer patients.
2. At the next annual review, provide a report of the patient and public involvement and engagement undertaken specifically on the use of confidential patient information within the work of the cancer survival group.

The Register of Approved Applications on the HRA website will shortly be updated to reflect the changes in the specific conditions of support.

Declarations of Interest

There were no declarations of interest.

5. Revised Applications

a. 20/CAG/0086 - YouScreen: A pragmatic implementation feasibility clinical trial of offering HPV self-sampling to cervical screening non-attenders within the NHS cervical screening programme in England

Context

Purpose of application

This application sets out the medical purpose to provide evidence that self-sampling can improve cervical screening coverage in England and can increase detection and treatment of high grade Cervical Intraepithelial Neoplasia.

In England, a national cervical screening programme offers screening to all women aged 25-64 using a call/recall system. A challenge with introducing new tests into call/recall-based screening programmes is establishing robust pathways for accurately identifying the relevant population, recording and reporting test results and setting the correct recall intervals. It is clear that different interventions are needed to address non-participation; but little is known about which approaches might be most suitable for which women. The longstanding issues with low coverage in North East London and North Central London provide an impetus to start offering self-sampling ahead of the national screening programme. The project will serve to test the new pathways for delivery, establish robust pathways for accurately identifying the relevant population, recording and reporting test results and setting the correct recall intervals, generate lessons to help ensure a smooth transition for a national or London-wide roll-out and provide the evidence-base for implementing self-sampling at scale.

Parts of this study are consented. However, the applicants are seeking support for three elements.

- **Identification of patients for mailout.** Eligible women will be identified through the national cervical screening database, NHAIS, which is owned by NHS England and Public Health England. Each month from the date the practice is included in the study, a list of women who reach the 15 month anniversary of their last test due date without being screened (by self-sample or by standard cervical screening -HPV primary testing) will be extracted from NHAIS. NHAIS will send the list of eligible women to the

Cervical Screening Administration Service (CSAS) who are responsible for sending invitations and reminders for the call/recall Cervical Screening Programme in England. CSAS will then send the list to a Docmail with the appropriate level of information governance standards to securely handle NHS data The print company will send a pre-notification letter to women (on behalf of the GP practices and the Cervical Screening Programme) informing them that they are overdue cervical screening and that a self-sampling kit will be posted to them. Within 1-2 weeks of sending the letter, Docmail will send women a self-sampling kit along with a brief invitation letter.

- **For NHAIS to search and extract data of all eligible women at participating GP practices** on all cervical screening test dates and results (including self samples, cytology and HPV tests) during the study, date of last cervical screening test prior to study and other related information. A pseudonymised dataset will be provided to KCL.

- **For CCGs to use confidential patient information to collect information** around when sampling kits were offered, who offered the kit, test dates and results during the study and free text information on the reason for declining a kit. Processors will access the dataset to collect the required information and provide this in a pseudonymised format to the research team. Support is required as the processors do not have a legal basis to access the NHS Number of participants – which is required to translate into the common pseudonym. Data collection will be three to four times during the study, and will include free text.

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

Confidential patient information requested

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

Cohort	Mailout: Women aged >=25 and <=64 years old registered at one of the participating practices, who are eligible for cervical screening under the NHS Cervical Screening Programme (NHSCSP) in England and have reached the 15-month anniversary of their last test due date without being screened. (estimated 19000 women). Linkage for all eligible women: Women aged >=25 and <=64 years old registered at one of the participating practices, who are eligible for cervical screening under the NHS Cervical

	Screening Programme (NHSCSP) in England and who are overdue by at least 6 months (estimated 95000 women)
Data sources	1. NHS Digital (National Health Application and Infrastructure Services) 2. Clinical Effectiveness Group (on behalf of Tower Hamlets CCG) 3. North East London Commissioning Support Unit (on behalf of Barnet and Islington CCG) 4. Camden GP IT (on behalf of Camden CCG)
Identifiers required for linkage purposes	1. Full name 2. Address including postcode 3. NHS number 4. GP practice National Code (Organisational Code)
Identifiers required for analysis purposes	1. Regional level postcode 2. 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.

In line with the previously deferred application, members were highly supportive of this application which had a clear medical purpose and a substantial public benefit.

Scope

Members commended the applicants for providing clarity within the application on the scope of support requested. The data flow diagrams were vastly improved and members identified no issues with the scope of support.

Legal Basis

The primary reason for the previous deferral was around the use of confidential patient information from those that did not return samples, who are deemed not to have consented. As such support could not be requested for the transfer of data for these patients.

The revised application and documentation is clear that the return of a sample does not provide consent to access information from NHAIS and CCGs, and the applicants seek support for all data collected from NHAIS and CCGs. Given these updates, members recommended that support can now be advised for the transfer of this data.

The group also commended the applicants for not seeking blanket support for all data transfer, such as the laboratory data, where consent can be used as a legal mechanism.

Practicable alternatives

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

- **Minimising flows of identifiable information**

Members noted that data minimisation will be applied, and that King's College London will not receive any identifiable information.

The group noted that the applicants were requesting free text data from GP records, and that they were exploring the possibility of using drop down menus to instead of free text for the reasons why women decline screening. Members strongly advise the applicants use drop down boxes instead of free text where possible.

- **Feasibility of consent**

The group agreed that consent is not practicable, given that the activities will involve a large number of women and the lack of capacity of organisations to undertake these activities.

Members noted that another group of women will be approached opportunistically by GPs when presenting at the practice. The group suggested that it is made clear to women that the approach is part of a research project, not a new service.

- **Use of anonymised/pseudonymised data**

It was agreed that the use of anonymised/pseudonymised data was impracticable for this application, and that the use of confidential patient information was required to complete the activities.

'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 considered the patient notification materials and were generally content with the documentation. However, the group advised the applicants check the accuracy of the patient information sheet around access to records, following updates made after the initial deferral.

Further, whilst noting it is not directly within the remit of the CAG, members suggested that the section on pregnancy is moved to earlier in the patient information sheet to ensure that all women read this part.

Members acknowledged praise in the deferral letter how the opt out mechanism was developed in consultation with patients and were content with the mechanism described.

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 further points were raised on the patient and public engagement, which the group previously praised for its good demonstration of listening to, and acting on,

the discussion held with user groups.

Confidentiality Advisory Group advice conclusion

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

Specific conditions of support (Final)

The following sets out the specific conditions of support.

1. Review the accuracy of the wording in the patient information sheet around access to records and update the information sheet as necessary

2. Provide further consideration into using drop-down menus for recording the reasons for women declining a test. Detail into the progress of this consideration should be provided at the first annual review.

3. Ensure that GPs make aware to opportunistic patients that the approach is part of a research study, not as part of a new service.

4. This support does not extend to processing North Central London Central Commissioning Group, because satisfactory NHS Digital review of their Data Security and Protection Toolkit (DSPT) is not in place. The applicants are advised to seek 19/20 NHS Digital assurances for this organisation, and submit an amendment to add this to the scope of support once NHS Digital has satisfactorily reviewed the 19/20 submission.

5. It is recommended, but not a condition of support, that information around pregnancy is moved to earlier in the patient information sheet.

6. Favourable opinion from a Research Ethics Committee. **Confirmed 28 April 2020**

7. 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. **The NHS Digital 18/19 DSPT review for NHS Digital, CFH Docmail, North of England CSU, Clinical Effectiveness Group at QMUL, and North East London Commissioning Support Unit were confirmed as 'Standards Met' on the NHS DSPT Tracker (checked 04 August 2020).**

   There is no record of 18/19 NHS Digital review for North Central London Central Commissioning Group. The applicants are advised to request this review from NHS Digital.

Declarations of Interest

There were no declarations of interest.

6. New applications – Research

a. 20/CAG/0087 - Research database for Cambridgeshire & Peterborough NHS Foundation Trust

Context

Purpose of application

This application sets out the medical purpose to provide evidence that self-sampling can improve cervical screening coverage in England and can increase detection and treatment of high grade Cervical Intraepithelial Neoplasia.

In England, a national cervical screening programme offers screening to all women aged 25-64 using a call/recall system. A challenge with introducing new tests into call/recall-based screening programmes is establishing robust pathways for accurately identifying the relevant population, recording and reporting test results and setting the correct recall intervals. It is clear that different interventions are needed to address non-participation; but little is known about which approaches might be most suitable for which women. The longstanding issues

with low coverage in North East London and North Central London provide an impetus to start offering self-sampling ahead of the national screening programme. The project will serve to test the new pathways for delivery, establish robust pathways for accurately identifying the relevant population, recording and reporting test results and setting the correct recall intervals, generate lessons to help ensure a smooth transition for a national or London-wide roll-out and provide the evidence-base for implementing self-sampling at scale.

Parts of this study are consented. However, the applicants are seeking support for three elements.

- **Identification of patients for mailout.** Eligible women will be identified through the national cervical screening database, NHAIS, which is owned by NHS England and Public Health England. Each month from the date the practice is included in the study, a list of women who reach the 15 month anniversary of their last test due date without being screened (by self-sample or by standard cervical screening -HPV primary testing) will be extracted from NHAIS. NHAIS will send the list of eligible women to the Cervical Screening Administration Service (CSAS) who are responsible for sending invitations and reminders for the call/recall Cervical Screening Programme in England. CSAS will then send the list to a Docmail with the appropriate level of information governance standards to securely handle NHS data The print company will send a pre-notification letter to women (on behalf of the GP practices and the Cervical Screening Programme) informing them that they are overdue cervical screening and that a self-sampling kit will be posted to them. Within 1-2 weeks of sending the letter, Docmail will send women a self-sampling kit along with a brief invitation letter.

- **For NHAIS to search and extract data of all eligible women at participating GP practices** on all cervical screening test dates and results (including self samples, cytology and HPV tests) during the study, date of last cervical screening test prior to study and other related information. A pseudonymised dataset will be provided to KCL.

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

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Identifiers required for linkage purposes	1. Full name 2. Address including postcode 3. NHS number GP practice National Code (Organisational Code)
Identifiers required for analysis purposes	1. Regional level postcode 2. Ethnicity
Additional information	

Confidentiality Advisory Group advice

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

Public interest

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

In line with the previously deferred application, members were highly supportive of this application which had a clear medical purpose and a substantial public benefit.

Scope

Members commended the applicants for providing clarity within the application on the scope of support requested. The data flow diagrams were vastly improved and members identified no issues with the scope of support.

Legal basis

The primary reason for the previous deferral was around the use of confidential patient information from those that did not return samples, who are deemed not to have consented. As such support could not be requested for the transfer of data for these patients.

The revised application and documentation is clear that the return of a sample does not provide consent to access information from NHAIS and CCGs, and the applicants seek support for all data collected from NHAIS and CCGs. Given these updates, members recommended that support can now be advised for the transfer of this data.

The group also commended the applicants for not seeking blanket support for all data transfer, such as the laboratory data, where consent can be used as a legal mechanism.

Practicable alternatives

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

- **Minimising flows of identifiable information**

Members noted that data minimisation will be applied, and that King's College London will not receive any identifiable information.

The group noted that the applicants were requesting free text data from GP records, and that they were exploring the possibility of using drop down menus to instead of free text for the reasons why women decline screening. Members strongly advise the applicants use drop down boxes instead of free text where possible.

- **Feasibility of consent**

The group agreed that consent is not practicable, given that the activities will involve a large number of women and the lack of capacity of organisations to undertake these activities.

Members noted that another group of women will be approached opportunistically by GPs when presenting at the practice. The group suggested that it is made clear to women that the approach is part of a research project, not a new service.

- **Use of anonymised/pseudonymised data**

It was agreed that the use of anonymised/pseudonymised data was impracticable for this application, and that the use of confidential patient information was required to complete the activities.

'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 considered the patient notification materials and were generally content with the documentation. However, the group advised the applicants check the accuracy of the patient information sheet around access to records, following updates made after the initial deferral.

Further, whilst noting it is not directly within the remit of the CAG, members suggested that the section on pregnancy is moved to earlier in the patient information sheet to ensure that all women read this part.

Members acknowledged praise in the deferral letter how the opt out mechanism was developed in consultation with patients and were content with the mechanism described.

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 further points were raised on the patient and public engagement, which the group previously praised for its good demonstration of listening to, and acting on,

the discussion held with user groups.

Confidentiality Advisory Group advice conclusion

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

Specific conditions of support (Final)

The following sets out the specific conditions of support.

1. Review the accuracy of the wording in the patient information sheet around access to records and update the information sheet as necessary

2. Provide further consideration into using drop-down menus for recording the reasons for women declining a test. Detail into the progress of this consideration should be provided at the first annual review.

3. Ensure that GPs make aware to opportunistic patients that the approach is part of a research study, not as part of a new service.

4. This support does not extend to processing North Central London Central Commissioning Group, because satisfactory NHS Digital review of their Data Security and Protection Toolkit (DSPT) is not in place. The applicants are advised to seek 19/20 NHS Digital assurances for this organisation, and submit an amendment to add this to the scope of support once NHS Digital has satisfactorily reviewed the 19/20 submission.

5. It is recommended, but not a condition of support, that information around pregnancy is moved to earlier in the patient information sheet.

6. Favourable opinion from a Research Ethics Committee. **Confirmed 28 April 2020**

7. 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. **The NHS Digital 18/19 DSPT review for NHS Digital, CFH Docmail, North of England CSU, Clinical Effectiveness Group at QMUL, and North East London Commissioning Support Unit were confirmed as 'Standards Met' on the NHS DSPT Tracker (checked 04 August 2020).**

   There is no record of 18/19 NHS Digital review for North Central London Central Commissioning Group. The applicants are advised to request this review from NHS Digital.

Declarations of Interest

There were no declarations of interest.

b. 20/CAG/0092 - Transforming research with routinely collected linked clinical data using an umbrella ethics and governance approach at Newcastle Hospitals

Context

Purpose of application

This application from Newcastle upon Tyne Hospitals NHS Foundation Trust set out the purpose of medical research which aims to link data from datasets held within Newcastle upon Tyne Hospitals NHS Foundation Trust for use in research projects under this 'umbrella' application.

The Newcastle-upon-Tyne Hospitals NHS Foundation Trust is moving to the use of electronic patient records, allowing for these to be used for a wide range of research that has the potential to improve patient care. For example; a better understanding of disease patterns and risk factors for disease, as well as new information on how effective treatments are in the real world, how to make diagnoses more efficiently, and a better understanding of how healthcare services are used by patients.

Researchers wishing to access the data will apply through the Newcastle-upon-Tyne Hospitals NHS Foundation Trust. The application will be considered by the Data Access Committee, which includes lay representation. On approval through this committee the required data will be linked from the datasets, held by Newcastle-upon-Tyne Hospitals NHS Foundation Trust. This involves access to identifiable data by a member of staff who does not have a legal basis under common law to do so. A deidentified dataset will then be created and shared with the researcher, who will need to access the data through Trust systems.

The applicants are seeking 'umbrella' support to use this methodology for any applicants that apply for data from Newcastle upon Tyne Hospitals NHS Foundation Trust. A separate, permanent research database is not being created. Instead, bespoke datasets will be created from Newcastle upon Tyne Hospitals NHS Foundation Trust medical records upon request.

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 accessing Newcastle upon Tyne Hospitals NHS Foundation Trust service since 2009 and have a Trust record.
Data sources	1. Newcastle upon Tyne Hospitals NHS Foundation Trust
Identifiers required for linkage purposes	1. Name 2. NHS Number 3. Hospital ID 4. Date of Birth 5. Postcode (unit level)
Identifiers required for analysis purposes	1. Postcode (District level)
Additional information	Note that whilst the Trust electronic record went live in 2009 some patients with an electronic record may have scanned information from contacts prior to 2009, and these will be included in the research.

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 considered that the application had a medical purpose. Whilst the group supports and understands the premise of the application, there were a number of points for clarification affecting the public interest.

Scope

It was noted that the applicant submitted a CAG application form as a research database application. However, the submission does not relate to the creation of a permanent database, separated from clinical records. Rather it is for bespoke linkages of clinical data, undertaken upon request.

Members agreed that it is not considered a research database and queried the applicant's position on this, requesting further consideration.

The applicants also stated the proposed methodology "….*will reduce the burden of future approvals on both ethics committees and local regulators*….". The group queried how proposed research applications will have proper ethical oversight without case by case scrutiny by an NHS ethics committee, although noted that this was an issue for consideration by the ethics committee themselves.

It was noted that support was requested for a member of staff to access confidential patient information to enable linkages, who does not have a current legal basis to do so. The group queried whether the support was requested for an individual, or for a team of people to undertake these linkages.

Given that it is therefore unclear for what purpose 'section 251' support is being requested (for creation of a research database or another specific research purpose) and that the IRAS question set for CAG (and the CAG considerations) differ depending on whether or research database is selected in the project filter, the group agreed that they could not provide a decision for this application with the current information provided. The group requested the applicants consider the activities being undertaken, refresh the application accordingly and submit a revised 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.

- **Minimising flows of identifiable information**

The applicants noted that researchers would not have access to identifiable information, and generally had no concerns over this. It was noted that the data may include scanned information from pre-2009. Members commented how the scanned information will be reliably anonymised.

- **Feasibility of consent**

Given the uncertainty whether this is a research database, members were unable to make a judgement about the feasibility of consent in all cases. Members await a revised application form to be able to consider this aspect.

- **Use of anonymised/pseudonymised data**

Members agreed that the proposed activities required could not be undertaken with anonymised/pseudonymised data only.

It was noted a pseudonymisation key would be held in case of the need for reidentification of a patient. The group queried how the access arrangements would ensure that only those with a justified purpose are able to access the key.

Governance Procedures

The group were unclear on the governance arrangements to manage and approve research requests. The protocol provided by the applicants did not offer sufficient detail to guide the panel in assessing and managing the risks that might lead to re-identification. Members also sought clarity on the representation of the panel that will approve such requests. As well, the group noted that the quoracy arrangements for approving such requests was three people, which was considered too low. Members requested that the applicant revisits the quoracy arrangements to ensure proper oversight requests.

‘Patient Notification’ and mechanism for managing dissent

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

The applicant provided no patient notification materials with the application, clarifying that the Trust are developing of a Patient Engagement Platform application to provide a mechanism to inform patients about this umbrella governance process, about the research that is taking place for patients to opt out of their data being used for research.

Members were not content to recommend support without seeing patient information materials. As well, the group queried what additional notification routes will be used for the proportion of patients who may not have access to electronic applications and requested further detail on the notification aspects.

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 Patient and Public Involvement and Engagement undertaken to date as detailed in the initial queries raised by the Confidentiality Advice Team. However, members felt that the evidence provided did not show sufficient feedback on the use of confidential patient information without consent for the purposes described and requested further work and evidence to be provided.

Confidentiality Advisory Group advice conclusion

In line with the considerations above, the CAG agreed that, on the basis of the information provided, they did not have sufficient information to provide a recommendation under the Regulations.

Further information required

To support a future application(s), the below points should be taken into consideration. A detailed covering letter should be provided to support the revised applications 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. As such, the applicants should consider whether or not this is a research database application, and provide an updated application form to reflect these considerations

2. Provide further information on the governance of application requests to generate bespoke research data sets, including:
    a. Further detail the issues that may increase the risk of reidentification and how they are expected to the managed.
    b. Further detail the representation on the panel considering research requests.
    c. Review the quoracy arrangements of the panel considering research requests, with the CAG suggesting that this should be more than three people.

3. More information on the proposed use of the Patient Engagement Platform application is requested, detailing how patient notification and opt out will work.

4. More details are requested clarifying how patients will be notified and provided the opportunity to opt out prior to an electronic application being implemented, and the approach to notifying those patients who are unable or unwilling to use the electronic application.

5. Undertake further patient and public involvement and engagement, specifically around the use of confidential patient information without consent is requested.

6. Provide clarity whether the informatics officer undertaking the linkages under any support is to be a single named individual, or potentially a team of individuals.

7. Provide detail on how scanned information from pre-2009 will be anonymised prior to release to researchers.

8. Provide information on the terms and conditions of access that will be placed on researchers.

9. Confirm that the pseudonymisation key will only be accessed by those undertaking linkages of data under any support.

Once a new application is received the information will be reviewed 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.

Declarations of Interest

There were no declarations of interest.

7. New applications– Non-Research

a. 20/CAG/0085 - 2020 NHS Adult Inpatient Main Stage Survey – Mixed Methods

Context

Purpose of application

This non-research application submitted by Ipsos MORI on behalf of the Care Quality Commission, sets out the purpose of conducting the 2020 NHS Adult Inpatient Survey.

The Adult Inpatient Survey is the most established survey within the NHS Patient Survey Programme (NPSP). The NPSP was initiated in 2002 by the then Department of Health, and is now overseen by the Care Quality Commission (CQC), the independent regulator of health and social care in England. The 2020 Adult Inpatient survey will be the eighteenth carried out to date, and the first mainstage to be completed using a mixed method approach, following a pilot of the approach during 2019.

Following a pilot in the 2019 survey, the survey will use a mixed methods approach for conducting the surveys. Trusts will collect information of all eligible patients and, following suitability checks, will share confidential patient information with the coordination centre

(IPSOS MORI) and one of three approved contractors (Patient Perspective, Quality Health or Picker Institute Europe). The contractors will distribute questionnaires to patients using the approach detailed below, as successfully piloted:

	Mode of contact
Contact 1	Postal letter inviting the patient to take part online
Contact 1.1	SMS reminder timed to arrive with the initial letter including a link to the survey
Contact 2	Postal reminder inviting the patient to take part online
Contact 2.2	SMS reminder timed to arrive with the second letter including a link to the survey
Contact 3	Postal reminder along with a paper questionnaire

Whilst the survey remains similar to previous years, COVID status has been added to the data requested for analysis so the applicants can distinguish between these patients for reporting purposes.

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

Confidential patient information requested

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

Cohort	Inpatients aged 16 years old or over who were discharged from acute and specialist NHS hospitals in November (and earlier for smaller trusts), having had at least one overnight stay in hospital.

	Exclusions: • deceased patients • children or young persons aged under 16 years at the time of sampling • obstetrics/maternity service users, including spontaneous miscarriages • patients admitted for planned termination of pregnancy • psychiatry patients • day cases • private patients (non-NHS) • any patients who are known to be current inpatients patients • patients without a UK postal address or patients whose address was unusable because it was incomplete • any patient known to have requested their details are not used for any purpose other than their clinical care, including those responding to posters displayed on hospital wards referring to the survey (the survey instructions request that all responses to posters are logged and used for this purpose).
Data sources	1. Electronic patient records within acute and specialist Trusts in England
Identifiers required for linkage purposes	1. Title 2. Initials or first name 3. Surname 4. Address Fields including postcode 5. Mobile phone number 6. Patient unique identifier
Identifiers required for analysis purposes	1. Trust code 2. Patient unique identifier 3. Postcode 4. Year of Birth 5. Gender 6. Ethnic Category 7. Mobile phone indicator 8. Day of the month of admission 9. Month of admission 10. Year of admission 11. Day of the month of discharge 12. Month of discharge 13. Year of discharge 14. Length of stay 15. Treatment Function Code 16. ICD-10 or ICD-11 (Chapter Code)

	17. Covid-19 diagnosis (derived from ICD-10 codes U07.1 COVID-19, virus identified and U07.2 COVID-19, virus not identified) 18. Treated as a suspected or confirmed covid-19 case 19. CCG code 20. Treatment Centre Admission 21. Admission Method 22. Hospital Site Code on Admission 23. Hospital Site Code on Discharge
Additional information	

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 agreed that the activity has a medical purpose and was in the public interest.

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**

It was noted that this survey newly includes information on the COVID-19 status of patients, which is sensitive information. Whilst agreeing that the information on COVID-19 would elicit important information for analysis, members queried the flow of this sensitive information, and whether this will be disclosed to mailing contractors. The group felt that this information does not need to be shared with the mailing contractors and requested justification if it were.

- **Feasibility of consent**

The group agreed that consent is not feasible, given the potential to introduce bias, and the lack of capacity of Trust staff.

- **Use of anonymised/pseudonymised data**

Members were content that the use of anonymised or pseudonymised information was not practicable, given the need to distribute information to patients.

'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 an overview of the patient notification and awareness raising mechanisms offered to Trusts. Whilst the excellent leaflet and other examples of publicity suggested to Trusts were noted, members queried whether the applicants have considered other routes that may be available to raise awareness, given that patient attendances may be curtailed due to COVID restrictions

Members also were content that the applicants had adequately explored the use of an SMS opt out mechanism and were in agreement with the decision and reasoning not to use an SMS opt out mechanism.

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 noted the patient engagement activity that has been undertaken to date, including the acceptability of an SMS opt out. Members noted a condition of support in the supported outcome letter for the 2019 NHS Adult Inpatient Survey – Mixed Methods Standalone Pilot (19/CAG/0102) which stated "*The use of confidential patient information without consent for the purposes of the survey should be explored as part of the planned patient engagement activity. Feedback on the activity, together with an overview of the views expressed by patients, should be provided for consideration by the CAG at an interim report within six months of the date of this outcome*." The group were not aware if receiving any report on the use of confidential patient information without consent and requested the outputs of this work.

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 detail on how use of confidential patient information without consent for the purposes of the survey has been explored as part of planned patient engagement activities, providing an overview of the feedback.

2. Consider using other notification methods of the survey to raise further publicity among patients

3. Provide detail on the flow on information related to COVID-19 status, including:

a. Whether the mailing contractors receive this information.
b. If mailing contractors will receive this information, provide a justification why these organisations receive the COVID-19 status.

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. 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. **The NHS Digital DSPT submission for Ipsos MORI, Patient Perspective, Quality Health and Picker Institute Europe were confirmed as 'Standards Met' by NHS Digital by check of DSPT tracker (03 August 2020)**

Declarations of Interest

There were no declarations of interest.

8. 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