Minutes of the meeting of the Confidentiality Advisory Group

05 March 2020 at HRA London, Skipton House

Present:

Name	Present	Notes
Dr Tony Calland MBE	Yes	CAG Chair
Dr Malcolm Booth	Yes	CAG Member
Ms Sophie Brannan	Yes	CAG Member
Dr Lorna Fraser	Yes	CAG Member
Dr Katie Harron	Yes	CAG Member
Dr Rachel Knowles	Yes	CAG Member
Mr Andrew Melville	Yes	CAG Member
Ms Clare Sanderson	Yes	CAG Alternative Vice-Chair
Mr Marc Taylor	Yes	CAG Member
Ms Gillian Wells	Yes	CAG Member

Also in attendance:

Name	Position (or reason for attending)
Ms Katy Cassidy	Confidentiality Advisor

1. Introduction, apologies and declarations of interest

2. Support decisions

Secretary of State for Health & Social Care Decisions

The outcomes from the CAG in relation to the **06 February 2020** meeting applications are pending.

Health Research Authority (HRA) Decisions

The outcomes from the CAG in relation to the **06 February 2020** meeting applications are pending.

3. New applications – research

a. 20/CAG/0032 – CRIS Linkage with the Police National Computer (PNC)

Context

Purpose of application

This application from South London and Maudsley NHS Foundation Trust set out the purpose of establishing a research database, to provide evidence to help patients, their families, treating clinicians, and health and justice policy makers understand the offender related risk factors for poor outcomes of major mental illness throughout life.

The applicants will combine data from the Clinical Records Interactive Search (CRIS) system, held by South London and Maudsley NHS Foundation Trust, with the Ministry of Justice (MoJ) extract of the Police National Computer (PNC).

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	Patients aged under 18 years and adults aged 18 years and over referred to SLAM services within England between 01 January 2007 and 31 December 2019. The applicants anticipated that 40,000 patients aged under 18 years and 470,000 adult patients would be included.
Data sources	1. Clinical Records Interactive Search (CRIS) system, held by South London and Maudsley NHS Foundation Trust (SLaM) 2. The Ministry of Justice (MoJ) extract of the Police National Computer (PNC)
Identifiers required for linkage purposes	1. Name 2. Date of birth 3. Postcode – unit level
Identifiers required for analysis purposes	1. Date of death 2. Postcode – sector level 3. Gender

	4. Occupation 5. Ethnicity 6. Month and year or birth

Confidentiality Advisory Group advice

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

Public interest

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

Use of the research database in further research

The Group requested further information on the management of applications from other research to use the database. Members requested confirmation that any applications made to use the data would be for a medical or health and social care purpose and be of benefit to the patient population.

Practicable alternatives

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

- **Feasibility of consent**

The applicant advised that it was not feasible to seek consent from patients due to the size of the cohort. There was also a risk of bias, as some patients may be at a high risk of re-offending and this group, alongside those with the most serious mental illnesses, are least likely to respond to a request to consent. The applicants sought to represent the general clinical population and minimise the risk of re-identification by collecting as large a sample as possible.

The names and addresses of patients would also need to be disclosed to the applicants in order to facilitate contact, which would also be a breach in the Common Law Duty of Confidence. The Group agreed that it was not feasible to seek consent.

- **Use of anonymised/pseudonymised data**

Confidential patient information was required to link data from CRIS to the MoJ extract of the PNC. The Group accepted that this could not be undertaken in any other way.

Justification of identifiers

The data linkage between CRIS and the MoJ extract of the PNC would be undertaken once. The Group agreed that the identifiers to be used were sufficient for this purpose. Members noted that the information would quickly become out of date and asked if any further data linkages were planned.

Members noted that information on pending convictions was also included and queried whether this was necessary. The Group also queried if the nature of the conviction needed to be included. If so, justification for collecting this level of detail needed 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.

The applicant explained that an opt-out process was in place for CRIS and a mechanism for the removal of patients' data was built into the system. This was explained in the CRIS information leaflet and on the website. The applicants will also continue to publicise the use of patient data in research.

The Group asked if the National Data Opt-Out, undertaken by NHS Digital, would also be applied and, if so, how this would be managed.

Members noted that the link to the PNC was not clear in the patient information and asked that this was revised to make the link explicit.

Patient and Public Involvement and Engagement

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

The applicant explained that service user and carer involvement had been key in the development of CRIS. The BRC Data Linkage Service User and Carer Advisory Group had been created. This group meet regularly to discuss projects presented by researchers. The linkage that is the subject of this application was first presented to the Advisory Group on 15 September 2016. The Advisory Group acknowledged the importance of the linkage due to significant public interest. The project was re-presented on 7 December 2017. Minutes from the meetings were provided to the CAG.

The project was also presented to several national Patient and Public Involvement workshops, including the National Youth Patient advisory group and the MQ Mental

Health Data Science Public Involvement panels. The applicants plan to form a group made up of young people and parents to advise on the refinement of the research objectives, the development of privacy notices and the dissemination of findings. This group will meet several times in the early stages of the project and then again in the last few months of this part of the project cycle.

The CRIS Oversight Committee is chaired by a service user and also includes representation from the Child and Adolescent Mental Health Services, the SLaM Caldicott Committee and the R&D Office. This Oversight Committee considers and approves all proposed uses of CRIS, and co-ordinates dissemination activities to SLaM staff and service users.

The Group noted that the patient and public involvement and engagement appeared to have taken place 3 to 4 years ago and asked that evidence of more recent involvement was provided. Members also asked that feedback from those who may be included on the PNC database was provided. The linkage between CRIS and the MoJ PNC extract needed to be discussed. The patient and public involvement also needs to be held to test whether the panel members are content with the use of confidential patient information without consent as proposed in this application

Confidentiality Advisory Group advice conclusion

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

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

Request for further information

1. Confirm that any applications made to use the data will be for a medical or health and social care purpose and of benefit to the patient population.

2. Clarify why information on pending convictions is included and whether this is necessary.

3. Clarify if any further data linkages are planned.

4. Advise whether the nature of the conviction needs to be included. If so, justification for collecting this level of detail needs to be provided.

5. Clarify if the National Data Opt-Out, undertaken by NHS Digital, will be applied and, if so, how this will be managed.

6. The link to the PNC data needs to be made clear in the participant facing documentation.

7. Further patient and public involvement and engagement needs to be carried out. This needs to include feedback from those who may be included on the PNC database. The linkage between CRIS and the MoJ PNC extract also needs to be discussed. Use of confidential patient information without consent as proposed in this application also needs to be tested.

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. **Pending**

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: South London and Maudsley NHS Trust (by NHS Digital email 06 December 2019) has confirmed 'Standards Met' grade on DSPT 2018/19)**
   - **DSPT pending for the Ministry of Justice**

b. 20/CAG/0034 – Detecting clinical deterioration in respiratory hospital patients using machine learning

Context

Purpose of application

This application from the University of Nottingham set out the purpose of medical research that aims to develop a new early warning score to detect when patients who are in hospital with respiratory problems are getting worse and may need extra treatment.

Early warning scores are used in NHS hospitals to detect when patients are deteriorating and might need extra medical treatment. Currently used scoring systems are good at detecting sepsis and internal bleeding but sometimes they can fail to pick up breathing problems. They also don't work very well in some patients with long-term breathing problems because the score can be high all the time, even when patients are stable. This can result in doctors being called to see patients who don't need any

extra treatment which can distract them from those who really need help. This project has been funded by the Medical Research Council and aims to develop a better scoring system for monitoring people with breathing problems in hospital.

The applicants will examine how often doctors are called to see patients with breathing problems each day and the extra treatments given as a result. Information about 22,000 patients who were admitted to hospital with breathing problems will be collected and 1000 cases examined in detail. Support under s251 is sought in order for researchers, who are not members of the direct care team, to access electronic and paper records within Nottingham University Hospitals NHS Trust for patients under the care of adult respiratory medicine services from 2014 until the present day. An anonymised dataset will then be provided to the University of Nottingham for analysis.

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	Approximately 22,000 patients aged 18 years and over who were admitted to Nottingham University Hospitals NHS Trust under the care of respiratory medicine services between 2014 and the present day.
Data sources	1. Electronic and paper medical records held within Nottingham University Hospitals NHS Trust

Identifiers required for linkage purposes	1. Hospital ID number
Identifiers required for analysis purposes	1. Date of death 2. Gender

Confidentiality Advisory Group advice

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

Cohort

The Group noted that patients treated at Nottingham University Hospitals NHS Trust between 2014 and the present day would be included. Members asked that the applicant provided a defined start and end date, between which patients would be included, e.g. 01/01/2014 – 31/12/2019.

Members also asked if the applicants could provide a more precise number of patients, rather than an approximate number.

Scope of support

The data extraction was described as a one-off and also as an annual extraction. Members asked for clarification on whether data was extracted annually, or if this was a one-off occurrence.

Public interest

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

- **Feasibility of consent**

The applicant advised that it was not feasible to seek consent from the number of patients required. Restricting the analysis to patients who could be traced would require a disclosure of confidential patient information to the research team in order to undertake the tracing of patients. The results of the study may also be biased if restricted only to those still alive and contactable. The Group accepted that it was not feasible to seek consent.

- **Use of anonymised/pseudonymised data**

The Group asked if it was possible that members of the direct care team, with an existing legal basis to access confidential patient information, could access the patient records to extract an anonymised dataset, which could then be provided to the researchers at Nottingham University. This would remove the need for support under Section 251.

If the direct care team could not undertake the data extraction, the Group asked that further information was provided on the confidential patient information the applicants would have access to, i.e. would the whole record be accessed so that the required information could be extracted, or would the access be limited.

Justification of identifiers

The Group noted that patient's date of death would be retained for analysis. Members queried whether length of hospital stay could be used instead. If not, justification needed to be provided as to why length of hospital stay was not sufficient.

'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 advised that Nottingham University Hospitals NHS Trust is currently in the process of implementing the National Data Opt-out and will be compliant by March 2020. The list of NHS numbers for patients selected for this application will be sent to the Messaging Exchange for Social Care and Health, who will return the list with the NHS numbers of patients who had opted-out removed.

Records of local opt-outs will also be kept, which are coded as 'Patient Declines Consent To Use Information For Secondary Purposes' and 'Patient Does Not Wish to Participate in Research'. Patients for whom these codes apply will not be included in the study.

The CAG noted this information. Members noted that no patient notification materials had been provided and asked whether there were any plans to publicise the application and provide patients with the opportunity to dissent from the inclusion of their data in the research. The Group suggested that posters were placed in A&E and relevant clinical areas. The applicants should also consider providing information about the research on the University and Trust websites. The patient notification materials should include information on how patients can dissent from inclusion.

Patient and Public Involvement and Engagement

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

The applicant explained that they would meet regularly with the respiratory Patient and Public Involvement Group at the NIRH Nottingham Biomedical Research Centre. During these meetings, the group were updated on the research and feedback and ideas on progressing the research were requested. The group would also be involved in disseminating the results of the research.

The plain English summary of the study had been sent to the respiratory Patient and Public Involvement Group and their views sought on whether they would support the use of confidential patient information without consent. Feedback from this was that the group were supportive, as long as the data were only used for the specified purpose and appropriate safeguards were adhered to.

The CAG noted this information and requested that more detail was provided regarding the membership of the Patient and Public Involvement Group. Details should be provided around the format of the activity, the demographics of those involved and the information which was provided together with an overview of the feedback which was provided.

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 whether the direct care team can undertake the data extraction and provide the research team with an anonymised dataset, removing the need for support under Section 251. If this was not possible, then a clear justification needs to be given of why this cannot be done.

2. Provide clarification on the confidential patient information the applicants would have access to, i.e. would the whole record be accessed so that the required information could be extracted, or would the access be limited.

3. More details about the patient and public involvement and engagement carried out needs to be provided. Details should be provided around the format of the activity, the demographics of those involved and the information which was provided together with an overview of the feedback given by participants.

4. A patient notification strategy needs to be devised. This may include posters placed in A&E and relevant clinical areas and providing information about the research on the University and Trust websites. The patient notification materials should include information on how patients can dissent from inclusion. The patient notification strategy and materials need to be provided to CAG.

5. Clarify whether the data extraction will be a one-off occurrence, or if it would be carried out annually.

6. A defined start and end date, between which patients would be included, e.g. 01/01/2014 – 31/12/2019, needs to be provided.

7. A more precise number of patients, rather than an approximate number, needs to be provided.

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. **Pending**

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

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

c. 20/CAG/0035 – The SINEPOST study

Context

Purpose of application

This application from the University of Sheffield set out the purpose of medical research which aims to determine whether ambulance service clinical data can predict an avoidable attendance at the Emergency Department in adults using classification models.

Paramedics have specialist knowledge and skills in helping people in emergencies. The bulk of ambulance service patients who call have problems that are described as ‘urgent’. These are cases where the patient may need access to healthcare and medical help, but there is only a very small chance that the problem is life threatening. The care of urgent patients is complex and trying to find the right place for their care can be hard. In 2014 in Yorkshire, up to 16.9% of patients could have avoided being taken by ambulance to the Emergency Department (ED). This group of patients had no special tests or treatments and were sent home. This means they had a minor problem that could have been managed elsewhere. When the ED is busy, ambulances have to wait a long time to handover the care of their patients. This delay stops ambulances being free to respond to the next emergency. These problems mean paramedics need to make sure the ED is the right place for their patient before they take them there. This project aims to develop a tool to help with that decision by showing the paramedic the likelihood of treatment at an ED being of benefit to the patient.

The applicants are seeking support under s251 to access the Electronic Patient Care Record at Yorkshire Ambulance Service NHS Trust and to obtain Emergency Department Care data from NHS Digital. The first stage of the study requires that data from the Yorkshire Ambulance Service NHS Trust is linked to data from a large hospital via NHS Digital, in order to provide show us the complete patient journey from their call for help through to leaving the ED. An anonymised dataset will then be provided to the applicants at the University of Sheffield. This information will be used to create a tool that identifies patients who may not need to be taken to the ED. The public will be invited to face-to-face meetings to help the researcher produce a lay summary of this phase. In the second stage, data from the Yorkshire Ambulance Service NHS Trust will be linked to Emergency Department Care data from NHS Digital for a different hospital, to see if the test can work in different settings.

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

Confidential patient information requested

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

Cohort	467329 patients treated by Yorkshire Ambulance Service NHS Trust and by the two participating Trusts.
Data sources	1. Electronic Patient Care Record at Yorkshire Ambulance Service NHS Trust 2. Emergency Department Care data provided by NHS Digital
Identifiers required for linkage purposes	1. Name 2. NHS number 3. Date of birth 4. Date of death 5. Postcode -unit level
Identifiers required for analysis purposes	1. Postcode – sector level

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 noted that the application had a clear medical purpose and was within the public interest.

Scope

Data from the Electronic Patient Care Record at Yorkshire Ambulance Service NHS Trust would be combined with Emergency Department Care data for two organisations. The names of these organisations had not been specified in the application and members asked that the names of these organisations were provided.

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 Group accepted that it was not feasible to seek consent from patients, due to the size of the cohort.

- **Use of anonymised/pseudonymised data**

Confidential patient information was required to link data from the Electronic Patient Care Record at Yorkshire Ambulance Service NHS Trust to Department Care data for the two participating organisations, held by NHS Digital. This could not be undertaken in any other way.

'Patient Notification' and mechanism for managing dissent

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

to provide a right to objection and mechanism to respect that objection, where appropriate. This is known as ‘patient notification’. This is separate to the local obligation to comply with the principles of the General Data Protection Regulation and Data Protection Act 2018.

The applicant explained that the National Data Opt-Out would be applied by NHS Digital once the data was sent to them from Yorkshire Ambulance Service NHS Trust. These patients would be removed from the dataset. An anonymised dataset was then returned to the applicants, at which point it would not be possible to identify and remove individual patients who registered dissent. The Group noted this information and was satisfied that the National Opt-Out would be applied by NHS Digital.

Members observed that patient notification was not planned and asked that this was undertaken. Suitable ways of notifying patients should be explored during patient and public involvement and engagement. The Group also suggested that information about the study be included on the Yorkshire Ambulance Service NHS Trust website and that the applicant consider promoting the application in local newspapers. A summary of feedback about patient notification was requested.

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 Sheffield Emergency Care Forum (SECF), a Public Involvement and Engagement forum situated at the University of Sheffield, had been consulted regarding the application. This project has been included as a standing agenda item at their quarterly meetings. A grant had also been provided from the Research Design Service, which had been used to conduct three public involvement events. A Whatsapp group had also been created with members of the public who had helped in the design of the research. The purpose of the Whatsapp group is to have a longitudinal conversation with the public about the project as it progresses.

Use of confidential patient information has been discussed with three different public involvement groups. Feedback from these discussions was supportive.

The Group noted the patient and public involvement held and asked that further involvement was undertaken around developing a patient notification strategy.

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. Provide the names of the two organisations whose Emergency Department Care data would be combined by NHS Digital with the Electronic Patient Care Record from Yorkshire Ambulance Service NHS Trust.

2. Confirm that patient and public involvement will be undertaken around developing a patient notification strategy. Please provide a summary of the feedback received about the patient notification put in place within three months of support under s251 being confirmed.

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. **Pending**

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: NHS Digital (by NHS Digital email 10 June 2019) and Yorkshire Ambulance Service NHS Trust (by NHS Digital email 07 January 2019) have confirmed 'Standards Met' grade on DSPT 2018/19).**

- DSPTs pending for the two organisations whose Emergency Department Care data would be combined by NHS Digital with the Electronic Patient Care Record at Yorkshire Ambulance Service.

d. 20/CAG/0036 – Predicting recurrence/regrowth of non-functioning pituitary adenoma

Context

Purpose of application

This application from University College London Hospitals NHS Foundation Trust set out the purpose of medical research which aims to investigate the natural history of non-functioning pituitary adenomas and the risk factors for recurrence and regrowth.

Non-functioning pituitary adenomas are the most common pituitary tumours and because of the lack of hormone secretion, often patients present late with symptoms and signs of low pituitary hormone secretion and invasion of the optic nerves and nearby structures. Treatment and follow-up remain a challenge despite complete surgical resection. Several studies showed a very high recurrence rate up to 60% even several years after the operation. There have been case reports of recurrence up to 15 years after having successful surgery. Knowledge of the factors associated with recurrence is very limited and the optimal treatment regimen and duration of follow-up treatment has not yet been established.

The applicants will conduct a retrospective observational study, evaluating information and data of patients who were treated for non-functioning pituitary adenoma at University College London Hospitals NHS Foundation Trust. Data will include the natural history and clinical presentation of these patients, their biochemical and radiological results as well as analysis of sample tissue obtained at the time of surgery. The patients will be identified from tissue analysis records and then the data is collected from their medical records, including admission notes, letters, investigation results and surgery details. Patients hospital numbers will be removed before the data analysis and no confidential patient information identifiable information will be analysed by the statistician within University College London.

A recommendation for class 1, 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	Patients aged 18-95 years old with recurrent non-functioning pituitary adenoma who were treated surgically at University College London Hospitals NHS Foundation Trust. 800 patients will be included.
Data sources	Electronic and paper medical records held at University College London Hospitals NHS Foundation Trust
Identifiers required for linkage purposes	Hospital ID number

Identifiers required for analysis purposes	Gender

Confidentiality Advisory Group advice

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

Public interest

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

Scope

The Group noted that the researcher was described as a member of the direct care team at several points in the application. Members requested clarification on whether any processing of confidential patient information would be undertaken by those outside of the direct care team, without consent from individual patients, at any point. If no processing of confidential patient information will be undertaken by those outside of the direct care team, then support under s251 is not required.

The Group requested confirmation that no items of confidential patient information would be shared with University College London and that an anonymised dataset only would be shared outwith the direct care team.

Cohort

The CAG requested further details on how the cohort size of 800 patients had been decided on and further justification on why it was necessary that all 800 patients were included.

Practicable alternatives

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

- **Feasibility of consent**

The Group agreed that further justification needed to be provided on why consent cannot be sought.

- **Use of anonymised/pseudonymised data**

Confidential patient information is required for the applicants to access the records of suitable patients in order to extract an anonymised dataset for transfer to University College London for analysis. The Group accepted that this could not be undertaken in any other way.

'Patient Notification' and mechanism for managing dissent

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

The Group noted that a patient notification strategy or dissent mechanism had not been created. The National Data Opt-Out was now mandatory and members asked whether the list of patients would be shared with NHS Digital, so that they could apply the National Data Opt-Out.

Patient notification also needs to be undertaken to promote the study and offer patients the opportunity to dissent from the inclusion of their data in the application activity. Patient and public involvement should be undertaken in creating the notification strategy and dissent 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 that no patient and public involvement and engagement had been undertaken. Members advised that patient and public involvement needed to be undertaken to obtain views on the use of confidential patient information without consent as proposed in the application. Patients and the public involvement should also be undertaken to devise a patient notification strategy and dissent mechanism.

Confidentiality Advisory Group advice conclusion

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

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

Request for further information

1. Confirm if any processing of confidential patient information would be undertaken by those outside of the direct care team, without consent from individual patients, at any point.

If no processing of confidential patient information will be undertaken by those outside of the direct care team, then support under s251 is not required. If support under s251 is required, then the below points need to be addressed.

1. Clarify if the list of patients would be shared with NHS Digital, so that they could apply the National Data Opt-Out.

2. Carry out patient and public involvement to obtain views on the use of confidential patient information without consent as proposed in the application. Provide a summary of the feedback received from patients and the public and how it supports the use of patient information in this way.

3. Carry out patient and public involvement also to devise a patient notification strategy and dissent mechanism. Provide a summary of the feedback received from patients and the public and how it supports the patient notification and dissent mechanism.

4. Confirm that no items of confidential patient information will be shared with University College London and that an anonymised dataset only would be shared outwith the direct care team.

5. Provide further justification on why consent cannot be sought.

6. Clarify how the cohort size of 800 patients has been decided on and whether it is necessary that all 800 patients are included.

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. **Pending**

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 – University College London Hospitals NHS Foundation Trust has a confirmed 'Standards Met' grade on DSPT submission 2018/19 by NHS Digital email dated 30 August 2019).**

e. 20/CAG/0038 – The C3 Study – Version 1 (The short and long-term cardiovascular consequences of critical illness: The C3 Study)

Context

Purpose of application

This application from the University of Oxford set out the purpose of medical research which aims to establish if it is possible to predict who is at risk of subsequent strokes and heart attacks and their likelihood of survival, and to discover if there is any association between these adverse events and the care patients have received whilst they were unwell.

The benefit of care in Intensive Care Units (ICU) has historically been measured as survival. Over the last three decades, the survival of patients admitted to ICU has improved markedly and attention is now focused on the long-term health problems related to ICU care in survivors. Many of these problems significantly impact patients' lives and the associations with the ICU stay are poorly understood, partly as they may occur many years later.

The applicants will study strokes and diseases of the heart and blood vessels, conditions that are common after treatment on ICU. Evidence from other countries suggests that these may be more common after care on ICU, possibly due to the patients' underlying illnesses and the long-term effects of ICU treatments during critical illness. It is not currently possible to identify which patients are at risk of heart attacks and strokes. There are well established treatments to avoid these conditions in the community and this research will help decide who should be considered for these treatments following a critical illness.

The applicants will create a new database, containing data routinely collected in ICU, such as patients' vital signs, treatments and blood tests. These records will be linked to NHS long-term follow-up data, so that it can be established which patients are at risk of heart attacks and strokes up to several years after discharge from ICU. How much the treatments patients received on ICU contributed to this risk will also be explored. Support is sought for the applicants to link confidential patient information from six participating Trusts to the National Institute for Cardiovascular Outcomes Research (NICOR) Audit database and linkages to HES and ONS data at NHS Digital.

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

Confidential patient information requested

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

Cohort	Patients aged 16 years and over, admitted to an intensive care unit for greater than 24 hours. Two cohorts were included, a retrospective cohort of patients treated between 01 January 2006 and 31 October 2020. The prospective cohort will include patients treated between 1 November 2020 to 31 July 2023 120,000 patients were expected to be included.
Data sources	Intensive care Clinical Information System (CIS) at 6 participating Trusts Hospital electronic patient records at 6 participating Trusts HES and ONS data at NHS Digital National Institute for Cardiovascular Outcomes Research Audit database, hosted by Barts Health NHS Trust on behalf of HQIP
Identifiers required for linkage purposes	Name NHS number Date of birth Date of death Postcode – unit level
Identifiers required for analysis purposes	Date of death Postcode – unit level Gender Occupation Ethnicity

Confidentiality Advisory Group advice

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

Public interest

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

Scope of support

The Group noted that retrospective and prospective cohorts were included. Information on outcomes and ongoing care would be available for the retrospective cohort via the further data linkages made to HES and ONS data, however this would not be available for the prospective cohort. The CAG queried the value of including a prospective cohort, given that the purpose of the study was to assess long term outcomes and no follow-on data was available for this group.

Six Trusts would participate in the study. Four of these, the Oxford University Hospitals NHS Foundation Trust, The Royal Berkshire NHS Foundation Trust, Imperial College Healthcare NHS Trust and Kings College Hospital NHS Foundation Trust, were listed in the application. The applicant advised that the names of the two additional Trusts would be provided via an amendment, once these organisations had been identified.

The Group queried whether the research team would access confidential patient information at participating Trusts in order to identify suitable patients and extract the data required for linkage, or whether the participating Trusts would identify suitable patients and undertake the data extraction.

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 Group noted that the application contained references to linkages with ICNARC. The applicant had advised that ICNARC data would not be linked to directly, but would be included in the Clinical Information System at the participating Trusts, where it would be extracted from. The controller of this data was therefore the Trust and not ICNARC.

Patient specific free text would be extracted from patient records and processed using Natural Language Processing at source. The Group requested clarification on whether the free text would be anonymised before it left the participating Trust and if the data was checked to ensure it was anonymised. If so, clarification on who would do this checking is needed.

The Group noted that patients' hospital numbers would be required for data linkage. This would not be of use to NHS Digital, who would require the NHS number. Members asked the applicant to clarify why the hospital number was required for linkage.

The complete postcodes of patients would be retained so that their deprivation score could be calculated. Members asked if NHS Digital could undertake the calculation, thereby removing the need for the applicants to hold the complete postcode.

- **Feasibility of consent**

The Group accepted that it was not feasible to seek consent from the 120,000 patients that the applicants hoped to include.

- **Use of anonymised/pseudonymised data**

Confidential patient information was required to link data from the participating Trusts to the ICNARC, NICOR and HES and ONS datasets held by NHS Digital. The Group accepted that this could not be done in any other way.

'Patient Notification' and mechanism for managing dissent

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

The applicant explained that the study would be promoted on the Nuffield Department of Clinical Neurosciences and C3 study websites. This information would contain contact details for patients who wished to dissent from inclusion. The same details would e provided to the participating Trusts. A privacy statement would also be displayed on the study and departmental websites and the text of this was provided with the application. The National Data Opt-Out would also be applied.

The Group requested that a patient notification is developed, which is separate to the privacy statement. Participating Trusts also need to agree to display the notification appropriately. Further patient and public involvement and engagement should be carried out when devising the patient notification strategy. A project-specific opt-out process also needs to be devised.

The details of patients who made contact with the study team to request dissent were stored in a ledger at each participating site. Once the study closed, these ledgers will be deleted. The National Data Out-out is also applied by NHS Digital. Members asked if it was necessary to have both methods and whether NHS Digital applying the National Data Opt-out would be sufficient.

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.

A patient and public involvement strategy had been developed by the applicants, with assistance from the Research Design Service. The project was presented to the Oxford ICU Patients' Forum, an inclusive group of ex-patients, relatives, nursing and rehabilitation experts, as well as lay members of the community. Feedback from this discussion was positive. The Forum offered to continue to work with the applicants during the course of the project. One or two members of the Forum will be the applicant's primary contacts with the applicants during the study.

Members from the Oxford Post-critical Illness Patient Group will also be involved. Funding is in place for continuing patient and public involvement. The Group noted the patient and public involvement carried out and asked that further activity was undertaken around developing a patient notification strategy.

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

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required for linkage, or whether the participating Trusts will identify suitable patients.

2. Clarify whether the free text would be anonymised before it left the participating Trust and if the data was checked to ensure it was anonymised. If so, clarification on who would do this checking is needed.

3. Provide further information on the value of including a prospective cohort, given that no follow-on data was available for this group.

4. Clarify why the hospital number is required for linkage.

5. Advise if NHS Digital can undertake the calculation, thereby removing the need to hold the complete postcode.

6. A patient notification and project-specific dissent process needs to be developed, separate to the privacy statement, and submitted to CAG for review. Participating Trusts also need to agree to display the notification appropriately.

7. Advise if it is necessary to hold both the ledger of dissenting patients at participating sites and whether NHS Digital applying the National Data Opt-out is sufficient.

8. Further patient and public involvement and engagement needs to be carried out to devise the patient notification strategy. Feedback from this needs to be provided to the CAG.

9. Confirm that an amendment will be submitted to include the further two sites that will take part in the study.

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.

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

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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: Oxford University Hospitals NHS Foundation Trust (by NHS Digital email 08 November 2019), Imperial College Healthcare NHS Trust (by NHS Digital email dated 21 November 2019), Barts Health NHS Trust (NHS Digital DSPT Tracker checked 10 March 2020) and NHS Digital (by NHS Digital email 10 June 2019) have confirmed 'Standards Met' grade on DSPT 2018/19).**

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

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

- **DSPT pending for the Royal Berkshire NHS Foundation Trust.**

6. 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