NHS
Health Research Authority

Minutes of the meeting of the Sub Committee of the Confidentiality Advisory Group

NOVEMBER 2018

Present:

Name	Capacity	Items
Dr Tony Calland MBE	Chair	1.b, 1.c, 1.d,1.e.
Ms Clare Sanderson	Chair	1.a.
Dr Murat Soncul	Chair	2.a.
Dr Malcolm Booth	CAG Member	2.a.
Mr David Evans	CAG Member	1.c, 1.d.
Dr Liliane Field	CAG Member	1.a.
Mr Myer Glickman	CAG Member	1.b, 1.d.
Mr Simon Kolstoe	CAG Member	1.b, 1.e.
Professor Jennifer Kurinczuk	CAG Member	1.c, 1.e.
Dr Harvey Marcovitch	CAG Member	2.a.
Mr Marc Taylor	CAG Member	1.a.

Also in attendance:

Name	Position (or reason for attending)
Miss Kathryn Murray	Senior Confidentiality Advisor, HRA

1. NEW PRECEDENT SET REVIEW APPLICATIONS – RESEARCH

a) 18/CAG/0195 – Does surgery for asymptomatic carotid stenosis reduce the long term risk of dementia, stroke, death and other important health outcomes? Extended UK post-trial follow-up of the Asymptomatic Carotid Surgery Trial (ACST-1). Phase 2

Context

Purpose of application

This application from the University of Oxford set out the purpose of medical research which aims to undertake a follow-up of patients who were previously consented participants in the ACST-1 trial, to evaluate the prevalence of dementia in this patient cohort. The ACST-1 trial randomly allocated participants with tight narrowing of the carotid artery to either immediate carotid surgery (endarterectomy) or to avoid surgery unless they had symptoms. The trial recruited patients between 1993 and 2003 and reported findings, for patients who underwent endarterectomy, that the risk of stroke was reduced by five years and for at least 10 years after the operation. There is suggestion that the narrowing of the carotid artery carries a higher risk of developing dementia.

The proposed follow-up study will measure cognitive impairment in living patients within the original ACST-1 patient cohort, via a single postal assessment requesting completion of a validated questionnaire 'Informant Questionnaire on Cognitive Decline in the Elderly'. The application has been submitted to the CAG to enable the survival status to be checked for the historic participant cohort and contact information held with consent to be updated via the NHS Spine by NHS Digital, to enable postal invitations and questionnaires to be distributed. Longer term follow-up of the ACST-1 cohort was carried out in 2016, via linkage with administrative datasets held by NHS Digital. This linkage confirmed that a proportion of the original cohort was now deceased – these individuals would not be included in the proposed application activity.

A recommendation for class 2, 3 and 6 support was requested to cover activities as described in the application.

Confidential patient information requested

Cohort

The historic patient cohort of the ACST-1 trial. 195 patients from the original cohort of 230 were known to be alive at last follow-up. This sub-cohort would be followed up via NHS Digital, prior to invitation to the proposed study.

Confidential patient information will be disclosed from the University of Oxford to NHS Digital to facilitate linkage with NHS Spine and ONS information to perform survival checking. The following items of confidential patient information are required for the purposes stated:

- Name – linkage,
- NHS Number – linkage,
- Date of birth – linkage,
- Full postal address – to facilitate postal invitation,
- Date of death – analysis,
- Sex – analysis.

Confidentiality Advisory Group advice

Public interest

The CAG was assured that the application defined an appropriate medical purpose, which was medical research. Members were assured that the proposed activity was within the public interest, as it was recognised that increasing knowledge around any link between the risks of developing dementia with the narrowing of the carotid artery, would have wider patient benefits.

Background to the Proposal

The CAG noted a reference within the protocol document which stated that previous linkage via NHS Digital had been carried out with support under the Regulations. A review of historic records presented

application reference 16/CAG/0122, which was supported in October 2016. This application appeared to describe an initial phase of the protocol, which linked the ACST-1 cohort with HES, ONS and the MHMDS (Mental Health Minimum Dataset). However, it was noted that the current application did not directly reference this historic submission or the relationship between the two proposals. Members agreed that further information would be requested from the applicant to confirm that the two proposals were linked and to clarify the relationship between them.

Practicable alternatives

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

- Feasibility of consent

The Group recognised that the applicants held patient contact details with consent. The purpose of the application for support under the Regulations was to carry out a mortality status check on patients and update contact details prior to sending invitations to participate in the proposed study. Members agreed that sight of the original patient information materials from the ACST-1 trial was required, to ensure the proposed activity would fall within the reasonable expectations of patients who consented to the historic trial between 1993 and 2003. Members agreed that it was not feasible to seek consent from the cohort of the proposed activity, as patient mortality status and current contact information was required to facilitate the consenting process.

- Use of anonymised/pseudonymised data

Processing of confidential patient information was required in order to facilitate linkage with the wider administrative datasets held by NHS Digital and the subsequent invitation process. No queries were raised in this area.

Justification of identifiers

The items of confidential patient information requested were appropriate and proportionate to achieve the proposed activity. No issues were raised in this area.

Exit Strategy

It is generally a principle that steps should be taken to move away from this potential support; such as through the seeking of consent or removing identifiable information once completed. The Group recognised that the intended exit strategy from support under the Regulations was for patients to provide consent to their involvement in the follow-up trial. However, it was recognised that some patients may not respond to the invitation to participate and others may actively decline and confirmation was required around how this sub-cohort of patients would be managed.

Members recommended that the invitation materials were updated to invite participants who no longer wished to be followed up, to request that their details were anonymised and to withdraw their ongoing consent as part of the follow-up study. In these circumstances, the applicants would only need to anonymise data in relation to those patients who actively requested this. The applicant would be asked to consider the overall exit strategy for the study, providing an overview of how this would be managed together with any revised documentation for consideration.

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 an unconsented activity should go ahead. The CAG commended the impressive activity which had been undertaken in this area throughout the project design. The Alzheimer's Society was heavily invested in the proposal and would also be involved in the dissemination of the research findings. It was agreed that this was appropriate to the proposed activity and no issues were raised in this area.

Patient Notification and Dissent

It is a general principle of the CAG, when recommending 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 Data Protection Act 2018. The applicant had stated that information about the follow-up study had been placed on the University website dedicated to the ACST-1 trial. It was also noted that information would be displayed on the Alzheimer's Society website, which would provide a link back to the trial site.

Members reviewed the information on the Alzheimer's Society website and it was commented that this did not appear to accurately describe the follow-up which was proposed in the protocol. The website text referenced telephone interviews with family members, but did not mention postal questionnaires. It was also noted that the link from the Alzheimer's Society website to the trial site did not work. It was noted that the updated text may not go live until all regulatory approvals were in place for the study; however, the Group agreed that sight of the updated text to be displayed on the Alzheimer's Society website would be requested, together with assurance that the link was now active.

Confidentiality Advisory Group advice conclusion

The CAG agreed that they were supportive in principle, however further information would be required prior to confirming that the minimum criteria under the Regulations had been met and therefore advised recommending provisional support to the Health Research Authority, subject to satisfactory responses to the request for clarification and compliance with the specific and standard conditions of support as set out below.

In order to complete the processing of this application, please respond back to the following request for further information within one month. A covering letter addressing the below points should be provided, together with any supplementary or revised documentation for review.

Request for further information (Summary)

1. Provide further information around the relationship between the proposed application activity and that which received a recommendation of support under the Regulations via application 16/CAG/0122.
2. Copies of the original information and consent materials used in the ACST-1 trial should be provided for consideration.
3. Further consideration should be given to the management of patients who do not respond to or actively decline the invitation to participate in this follow-up study, and the ongoing retention of any confidential patient information held with support under the Regulations and, if appropriate, historic consent. Provide details of an exit strategy in relation to this sub-cohort of patients, together with any revised recruitment materials as necessary.
4. Provide a copy of the text which would be displayed on the Alzheimer's Society website.
5. Confirm that the link between the Alzheimer's Society website and the study website has been activated.

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, the HRA will confirm approval.

Specific conditions of support (Provisional)

1. Favourable opinion from a Research Ethics Committee (**Pending**).
2. Confirmation from the IGT Team at NHS Digital of suitable security arrangements via Information Governance Toolkit (IGT) submission (**Confirmed – University of Oxford- Medical Sciences Division-Nuffield Dept. of Population Health-Clinical Trials Service Unit and NHS Digital both have a published satisfactory reviewed grade on version 14.1, 2017/18**).

b) 18/CAG/0201 - Retinal injuries resulting from handheld laser devices: Incidence and epidemiology

Context

Purpose of application

This application from the Leeds Teaching Hospitals NHS Foundation Trust set out the purpose of medical research which aims to establish the incidence of laser-related retinal injuries in the UK, the range of presenting symptoms and signs, natural history, prognosis and complication rates. In addition the information generated could support changes to regulation of manufacture and sale of laser devices as well as providing an evidence base for future public health campaigns.

The study will operate via the established BOSU methodology, which has been approved in principle by the CAG, to enable treating ophthalmologists to report to the BOSU unit that they have seen a case within their clinic. The BOSU unit will pass details of the reporting clinician to the applicant, to enable follow-up with a data collection questionnaire. Reporting will be carried out across a 13 month period, beginning in early 2019. A follow-up questionnaire will also be shared six months following initial reporting.

A recommendation for class 1, 5 and 6 support was requested to cover activities as described in the application form.

Confidential patient information requested

Cohort

An individual of any sex or age with a unilateral or bilateral retinal lesion with changes in visual function and fundal examination consistent with macular thermal injury in England and Wales, treated in a participating site across the 13 month reporting period. It is estimated that there would be approximately 90-150 cases across the UK per annum.

The following items of confidential patient information will be disclosed from treating ophthalmologists to the applicants at Leeds Teaching Hospital NHS Trust to enable sample validation, removal of duplicate entries and facilitation of the six month follow questionnaire:

- Date of birth (in MM/YY format only),
- Postcode,
- Sex.

Confidentiality Advisory Group advice

Public interest

The CAG was assured that the application defined an appropriate medical purpose, which was medical research. Members agreed that there was a clear public interest justification for the research, which was to help determine the incidence of laser-related retinal injuries provide information on clinical history, and support future prevention.

Practicable alternatives

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

- Feasibility of consent

The application would follow the established BOSU methodology, which CAG had agreed in principle. It was recognised that operating the study on a consent based model had the potential to introduce bias into the study, which may impact the viability of the study analysis, which is looking at prevalence of the condition. Members were satisfied that consent was not feasible for the proposed activity.

- Use of anonymised/pseudonymised data

Confidential patient information was required to enable sample validation, the removal of duplicate entries and to facilitate the follow-up questionnaire, which could not be otherwise achieved. No issues were raised in this area.

Justification of identifiers

The Group was assured that the patient identifiers were appropriate and proportionate facilitate the proposed activity and raised no issues in this area.

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 an unconsented activity should go ahead. It was not specified within the application whether any specific activity had been carried out in this area to test the acceptability of using confidential patient information for the study purposes. The applicant stated the historical studies which were carried out using the BOSU methodology evidenced that this was deemed acceptable.

Whilst the CAG recognised that the BOSU methodology was acceptable, it was still a requirement to evidence that patients and the public were supportive of research into the focus condition. Applications to use the BOSU methodology were generally considered by the Royal College of Ophthalmologists lay advisory group as part of the approval process. Members agreed that confirmation would be sought from the applicants that this review had been undertaken.

Patient Notification and Dissent

It is a general principle of the CAG, when recommending 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 the Data Protection Act 2018. The applicant had provided a copy of a poster which would be displayed in eye hospitals to promote the study.

Members commented that, in previous applications using the BOSU methodology, posters had been supported by information leaflets and information on the Royal College of Ophthalmologists website. Clarification would be sought from the applicant around this point, with copies of any wider documentation required for review.

Patients were able to object to the use of their data within the study by informing their treating clinician. The Group recognised that this was in line with wider applications under the BOSU methodology and raised no queries in this area.

Data Protection Compliance

It is a requirement within the Regulations that any approved activity cannot be inconsistent with the General Data Protection Regulation and Data Protection Act (DPA) 2018. Further information was required from the applicant to confirm what lawful basis for processing was being relied upon in relation to data (GDPR, Article 6) and special category data (GDPR, Article 9), to evidence compliance with Article 5(1a).

Confidentiality Advisory Group advice conclusion

The CAG agreed that the minimum criteria under the Regulations appeared to have been met, however, further information would be required and therefore advised recommending provisional support to the Health Research Authority, subject to satisfactory responses to the request for clarification and compliance with the specific and standard conditions of support as set out below.

In order to complete the processing of this application, please respond back to the following request for further information within one month. A detailed covering letter should be provided to address the below points, together with any supporting documentation.

Request for further information

1. Clarify whether, as part of the BOSU application process, the study was reviewed by the Royal College of Ophthalmologists lay advisory group.

2. Confirm whether information leaflets will be provided to eye hospitals to provide patients with further information about the study. Provide a copy of the document for consideration.

3. Confirm whether the study would be promoted on the Royal College of Ophthalmologists website. Provide a copy of the text for consideration.

4. Confirm the lawful basis which is being relied upon for processing data (Article 6) and special category data (Article 9).

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, the HRA will confirm approval.

Specific conditions of support (Provisional)

1. Favourable opinion from a Research Ethics Committee (**Pending**).
2. Confirmation from the IGT Team at NHS Digital of suitable security arrangements via Information Governance Toolkit (IGT) submission (**Pending – Leeds Teaching Hospitals NHS Foundation Trust has a published satisfactory reviewed grade on V14.1, 2017/18**).

c) 18/CAG/0202 - Emergency Medical Dispatcher recognition of maternity emergencies using the International Academy Medical Priority Dispatch System: a mixed methods study

Context

Purpose of application

This application from London Ambulance Service NHS Trust (LAS) set out the purpose of medical research which aims to evaluate how accurately emergency medical dispatchers triage pregnancy, childbirth and miscarriage related emergency calls by linking information recorded at the time of emergency call with outcome data recorded in the HES database held by NHS Digital. These calls are triaged via questions provided in 'Protocol 24'. The study will also include a qualitative element, of focus groups with emergency medical dispatch staff; however, this be will operated on a consented basis and is out of scope for the CAG consideration.

Patients will be retrospectively included in the study, using the previous 3,000 calls which were triaged via protocol 24. The CAD reference (Computer Assisted Dispatch) will be used together with wider variables collected at the time of the emergency call to identify patients from wide records and access confidential patient information required to facilitate linkage with wider datasets. Information will be disclosed by LAS to NHS Digital in order to link with the HES dataset in order to extract relevant information about the care provided.

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

Confidential patient information requested

Cohort

The inclusion criteria for the retrospective data will be any adult patient (>16 years) triaged using MPDS protocol 24 by the London Ambulance Service NHS Trust during the data collection period. Neonatal data (such as date of birth/death and level of neonatal care) will be used to help determine the emergency situation for the mother at the time of 999 call. The most recent 3,000 eligible calls will be included in the study.

The following items of confidential patient information are required for the purposes cited:

- Name – sample validation and linkage,
- NHS Number – sample validation and linkage,
- Date of birth – sample validation and linkage,
- Postcode (unit level) – sample validation and linkage,
- Ethnicity – analysis.

Confidentiality Advisory Group advice

Public interest

The CAG was assured that the application defined an appropriate medical purpose, which was medical research. Members were assured that the proposed activity was within the public interest as the

research aimed to answer some important questions around the triage of pregnancy-related emergency calls.

Practicable alternatives

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

- Feasibility of consent

The study aimed to include a larger retrospective patient cohort for which the operation of a consent-based model was not possible due to time and resource constraints. Members were assured by the rationale provided and were in agreement that consent was not feasible for this proposal.

- Use of anonymised/pseudonymised data

Confidential patient information was required to facilitate linkage with the wider datasets held by NHS Digital, which could not be otherwise achieved. No issues were raised in this area.

Justification of identifiers

The items of confidential patient information specified were appropriate and proportionate to facilitate the proposed activity. Members noted that the requirement for date of death had been referenced within the application, but had not been specifically requested. Clarification around whether this additional identifier was required would be sought from the applicant.

Exit Strategy

It is generally a principle that steps should be taken to move away from this potential support; such as through the seeking of consent or removing identifiable information once completed. Confidential patient information was required to support the data linkage process only and analysis would be undertaken on a linked pseudonymised dataset.

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 an unconsented activity should go ahead. No specific activity had been carried out in this area; however, the applicant had stated that a patient representative would be appointed to the study team.

Members agreed that the applicant would need to undertake some activity to test the acceptability of using confidential patient information without consent for specified study purposes. It was suggested that the London Ambulance Service may have an established patient group which could be approached for views around the study. It was recognised that there was planned activity in this area, with the appointment of a lay representative and seeking views on the dissemination of the research findings. The Group was content to provide a recommendation on this basis; however, it was agreed that feedback would be required within six months around the activity undertaken in this area. This should provide details of the activity carried out, an overview of the demographics of the group approached together with the feedback provided. If the responses given are negative, the CAG will take this into account when considering whether support should continue, or whether further actions are necessary.

Patient Notification and Dissent

It is a general principle of the CAG, when recommending 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 the Data Protection Act 2018. The applicant had confirmed that study-specific information would be placed on the London Ambulance Service website; however, this text was not provided for consideration. Members agreed that sight of this text was required prior to any final recommendation coming into effect.

The Group was unclear how a study-specific objection mechanism would be operated. It was suggested that this could be facilitate locally at the Ambulance Trust, prior to any linkage via NHS Digital. It was agreed that an oversight of how a project-specific dissenting mechanism would be operated was required prior to any recommendation of support coming into effect.

Data Protection Compliance

It is a requirement within the Regulations that any approved activity cannot be inconsistent with the General Data Protection Regulation and Data Protection Act (DPA) 2018. Further information was required from the applicant to confirm what lawful basis for processing was being relied upon in relation to data (GDPR, Article 6) and special category data (GDPR, Article 9), to evidence compliance with Article 5(1a).

Confidentiality Advisory Group advice conclusion

The CAG agreed that they were supportive in principle, however further information would be required prior to confirming that the minimum criteria under the Regulations had been met and therefore advised recommending provisional support to the Health Research Authority, subject to satisfactory responses to the request for clarification and compliance with the specific and standard conditions of support as set out below.

Request for further information

1. Clarify whether date of death is required for the purposes of study analysis. If so, confirm in what format this would be supplied and provide a clear justification for its requirement.

2. Provide a copy of the study-specific website text for consideration.

3. Explain how a study-specific objective mechanism would be operated.

4. Confirm the lawful basis which is being relied upon for processing data (Article 6) and special category data (Article 9).

Specific conditions of support (Provisional)

1. Project-specific patient and public involvement and engagement activity should be carried out to test the acceptability of using confidential patient information without consent for the study purposes. Feedback from this activity is required within six months of support coming into effect. If the responses given are negative, the CAG will take this into account when considering whether support should continue, or whether further actions are necessary.

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

Confirmation from the IGT Team at NHS Digital of suitable security arrangements via Information Governance Toolkit (IGT) submission (**Confirmed - NHS Digital and London Ambulance Trust NHS Foundation Trust have published satisfactory reviewed grade on V14.1 2017/18**).

d) 18/CAG/0203 - Not Intervening as a form of care: an ethnographic study of palliative care

Context

Purpose of application

This application from London School of Hygiene and Tropical Medicine set out the purpose of medical research which aims to investigate the importance of actively not doing something when caring for patients, which is in contrast to the common assumption that good and appropriate medicine is always about acting and intervening. To investigate this, the applicants will compile detailed case studies of palliative care at University College Hospitals London NHS Foundation Trust. This will involve the applicants undertaking observations at the Trust site of palliative care team meetings and the daily routines of staff members. There will also be wider interview activity undertaken for which consent will be provided and is thus out of scope for the consideration of the CAG.

The study involves three phases:
1) Shadowing palliative care staff in their daily work on pre-arranged days – verbal consent will be sought from patients and relatives during this element and is out of scope for CAG considerations,
2) Consented interviews with patients about their care and
3) Observations at staff meetings to understand how care, treatments and interventions are discussed and how and when decisions are made by staff. It is this final observation element which involves a breach of the common law duty of confidentiality for which the application has been submitted to the CAG.

During the observations of the palliative care staff meetings and other professional meetings where patient care strategies are discussed, attending researchers may be incidentally exposed to confidential patient information during the course of the discussions. As there will be no patient consent for this observation element, this presents a breach of patient confidence for which the applicants are seeking support under the Regulations to legitimise the access. Confidential patient information is not required for the purposes of the study and will not be recorded by attending researchers. Over the course of a 12 month observation period, the applicants intend to observe around 80 staff meetings, which are held twice weekly (one relating to hospital care and one to community care).

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

Confidential patient information requested

Cohort

The study focus is patients who are under the care of the Palliative care teams under study (University College Hospitals London and Camden/Islington Community team).

Confidential patient information is not required for the purposes of the study; however, is likely to be disclosed during the course of the staff meetings.

Confidentiality Advisory Group advice

Public interest

The CAG was assured that the application set out an appropriate medical purpose, which was medical research. Members were assured that there was public interest in developing further knowledge around the decision-making process and clinical non-intervention in the provision of palliative care.

Practicable alternatives

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

- Feasibility of consent

The applicants state that seeking consent from patients would be impracticable as individual cases may be discussed in the team meetings before patients had been seen by members of the care team. It had been agreed with the clinical leads that researchers would not be present during the discussion of cases relating to patients who lacked capacity to consent for themselves. It was explained that the researcher would be asked to leave the room and would only return on invitation of the Chair.

The Group were not assured by the rationale provided that consent was not feasible for the project. It was commented that palliative care patients were likely to be in frequent contact with the clinical care team, whether cared for in hospital or in the community, which would present an opportunity to seek consent. It had been confirmed that the MDT meetings could be separated to exclude the researcher from discussions around patient who lack capacity. Members were unclear why the same split could not be applied in relation to patients who had and had not provided consent to the researcher being present. The CAG recognised that there may be wider constraints on this process; however, the applicant would be asked to consider this point and provide further justification to support why consent is not feasible for this specific phase of the study.

- Use of anonymised/pseudonymised data

It was explained that wider practicable alternatives were discussed with the clinical lead collaborators. It was agreed that attempting to replace patient names with letters/numbers in an oral presentation was not appropriate as this may lead to clinical risk, i.e. if this led to confusion during discussions, which could then be harmful for patients. It was recognised that confidential patient information was not required for the study analysis and would not be recorded. The Group was assured by the rationale provided and agreed that this did not present a feasible alternative.

Justification of identifiers

The CAG acknowledged that confidential patient information was not required for the study purposes – any access would be incidental. No queries were raised in this area.

Exit Strategy

The applicant had confirmed that no confidential patient information would be recorded during the meeting observations; however, this may be incidentally disclosed. Once meeting observations had been completed, there would be no further requirement for support under the Regulations. The CAG raised no queries in this area.

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 an unconsented activity should go ahead. Two patient representatives had been appointed to the study's advisory group, both of whom have previous experience of palliative care as a carer. It was confirmed that these individuals had been involved since the design phase of the project and were supportive of the project. Members recognised that these individuals would continue to support the project as it progressed. It was agreed that the activity which had been undertaken in this area was appropriate and proportionate to the study.

Patient Notification and Dissent

It is a general principle of the CAG, when recommending support, for reasonable measures to be taken to inform the relevant population of the activity and to provide a right to object and a 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 (GDPR) and the Data Protection Act (DPA) 2018. Members noted that the display of study posters was referenced within the protocol; however, the purpose of these documents appeared to be informing staff, not patients and carers, that the research was being undertaken.

A communications mechanism would be need to be established to publicly raise the profile of the study and offer an objection mechanism to those patients who did not want a researcher to observe discussion of their care. This strategy would need to account for patients cared for in hospital and the community. Members agreed that clarification was required from the applicant around how this communications strategy would operate with sight of any documentation to support it and an overview of how an objection mechanism would be operated and respected.

Research Ethics Committee Favourable Opinion

It is a requirement under the Health Service (Control of Patient Information) Regulations 2002 that those processing confidential patient information without consent can do so once approved by the Health Research Authority (following advice from the CAG), and providing a favourable ethical opinion is in place. The applicant had explained that the REC favourable opinion was already in place for the study, with the exception of the MDT meeting observation element. A substantial amendment had been submitted to the REC for this element of the study and a decision remained pending on this. Confirmation was required that a favourable opinion had been issued for the amendment prior to any final recommendation of support coming into effect.

Confidentiality Advisory Group advice conclusion

The CAG agreed that they were supportive in principle, however further information would be required prior to confirming that the minimum criteria under the Regulations had been met and therefore advised recommending provisional support to the Health Research Authority, subject to satisfactory responses to the request for clarification and compliance with the specific and standard conditions of support as set out below.

In order to complete the processing of this application, please respond back to the following request for further information within one month. A detailed covering letter addressing the below points should be provided, together with any supporting documentation.

Request for further information (Summary)

1. Further justification is required to support the determination that consent is not feasible for the MDT meeting observation element of the study.

2. Provide an overview of the communications strategy which will promote the study amongst patients, in hospital and the community. Any documentation prepared to support this should be provided for consideration.

3. Explain how a study-specific dissenting mechanism would be operated.

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, the HRA will confirm approval.

Specific conditions of support (Provisional)

1. Favourable opinion from a Research Ethics Committee (**Pending**).
2. Confirmation from the IGT Team at NHS Digital of suitable security arrangements via Information Governance Toolkit (IGT) submission (**Confirmed – University College London Hospitals NHS Foundation Trust has a published satisfactory reviewed grade on V14.1, 2017/18**).

e) 18/CAG/0204 - When to suspect Cauda Equina Syndrome in patients presenting to the Emergency Department with back pain

Context

Purpose of application

This application from the University of Birmingham set out the purpose of medical research which aims to investigate whether there is any difference in presenting symptoms for patients who received an MRI scan to assess for potential Cauda Equina Syndrome, which is compression of the lower spinal cord, between patients who received a positive and negative diagnosis in order to assess whether there are features which are more specific to a positive diagnosis.

The student applicant will retrospectively review patient records of those who underwent an MRI scan following presentation at the emergency department, for suspected cauda equina syndrome over a two year period. Access to the full patient record is required to enable a pseudonymised dataset to be extracted for analysis.

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

Confidential patient information requested

Cohort

The cohort consists of patients presenting to the Emergency Department at London North West Healthcare NHS Trust with back pain and neurological signs or symptoms for suspected cauda equina syndrome, who underwent an MRI scan over a two year period between 2016 and 2018.

Access is required to the full hospital record to enable relevant clinical details to be extracted for analysis. The analysis dataset would not include any items of confidential patient information.

Confidentiality Advisory Group advice

Public interest

The CAG was assured that the application defined an appropriate medical purpose, which was medical research. Members acknowledged the study presented a wider public benefit, through gaining a better understanding of the presenting symptoms for Cauda Equina Syndrome.

Cohort

Clarification of the precise inclusion timeframe for the study was required from the applicant, to determine the scope of the cohort to be included.

Practicable alternatives

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

- Feasibility of consent

The application did not provide a clear justification to support why consent was not feasible for the proposed study. The Group recognised that the study involved a retrospective patient cohort for which there was established precedent for seeking support under the Regulations. However, it was agreed that the applicant would be asked to provide a justification to support the determination that consent was not feasible within the parameters of the specific proposal.

- Use of anonymised/pseudonymised data

Members recognised that, as a student proposal, it was unlikely that the direct care team would have the capacity to undertake the data extraction on behalf of the project. Confidential patient information was not required for the purposes of analysis; however, the student investigator would require access to the complete record in order to extract the relevant information for analysis.

Exit Strategy

It is generally a principle that steps should be taken to move away from this potential support; such as through the seeking of consent or removing identifiable information once completed. Support was required for duration of record access only as the study analysis would be carried out on a pseudonymised dataset.

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 an unconsented activity should go ahead. The application did not provide not specify that any activity had been carried out in this area. It appeared that the relevant questions within the CAG application form had been misunderstood.

The Group recognised the limitations of the student proposal, both in terms of time and resources. It was accepted that the proposed study was small-scale, with limited intrusion and risk for the patient population involved. However, it was still necessary to undertake some activity in this area to seek

assurance from patients and the public that the use of confidential patient information was acceptable for the study purposes.

Members agreed that support would be recommended on a conditional basis, to enable activity to be carried out in this area as the study progressed, so as not to detrimentally impact on the study timescale. It was suggested that an established patient group at the Trust could be approached to consider the study and use of confidential patient information. A repot would be required within six months of support coming into effect around the activity which had been carried out, together with an overview of feedback provided by the patients and public approached. If the responses given were negative, the CAG would take this into account when considering whether support can continue, or if further information was required.

Patient Notification and Dissent

It is a general principle of the CAG, when recommending 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 the Data Protection Act 2018. It did not appear from the detail provided within the application form that any provision had been made in this area to inform patients of the use of data in the study.

The applicant would be required to establish a communications mechanism to promote the study in the public arena and facilitate a means for patients to raise a dissent to the use of their data in the study. The Group suggested that posters could be displayed in the patient waiting areas of the emergency department. This information could also be supported by information on the Trust and University websites. The information should also include provision of an objection mechanism. Sight of this documentation would be required prior to any recommendation of support coming into effect.

The applicant would be asked to confirm that patient records would be checked for evidence of historic dissent for secondary research purposes when information is extracted.

Data Protection Compliance

It is a requirement within the Regulations that any approved activity cannot be inconsistent with the General Data Protection Regulation and Data Protection Act (DPA) 2018. Further information was required from the applicant to confirm what lawful basis for processing was being relied upon in relation to data (GDPR, Article 6) and special category data (GDPR, Article 9), to evidence compliance with Article 5(1a). Further information was available on the Health Research Authority website around GDPR compliance which may be helpful in explaining the requirements in this area.

Confidentiality Advisory Group advice conclusion

The CAG agreed that the minimum criteria under the Regulations appeared to have been met, however, further information would be required and therefore advised recommending provisional support to the Health Research Authority, subject to satisfactory responses to the request for clarification and compliance with the specific and standard conditions of support as set out below.

Request for further information

1. Provide further information to justify why consent is not feasible for the project.

2. Explain the communications strategy for the study which will promote this in the public arena. Provide copies of any documentation to support this.

3. Consider how a project-specific objection mechanism could be operated for the study and provide details.

4. Confirm that records would be checked for evidence of historic dissent and that any objection would be respected.

5. Confirm the lawful basis which is being relied upon for processing data (Article 6) and special category data (Article 9).

Specific conditions of support (Provisional)

1. Project-specific patient and public involvement and engagement activity should be carried out to test the acceptability of using confidential patient information without consent for the study purposes. Feedback from this activity is required within six months of support coming into effect. If the responses given are negative, the CAG will take this into account when considering whether support should continue, or whether further actions are necessary.

2. Favourable opinion from a Research Ethics Committee (**Confirmed**).

3. Confirmation from the IGT Team at NHS Digital of suitable security arrangements via Information Governance Toolkit (IGT) submission (**Confirmed – London North West Healthcare NHS Trust has a published satisfactory reviewed grade on V14.1 2017/18**).

2. NEW PRECEDENT SET REVIEW APPLICATIONS – NON RESEARCH

a) 18/CAG/0183 - 2019 Community Mental Health Survey

Context

Purpose of application

This non-research application from Picker, CQC and NHS England set out the purpose of administering the 2019 Community Mental Health Survey, to gauge patient experience and views of the service they received. A recommendation of support was requested to enable the transfer of patient identifiable data from mental health providers, to an approved survey contractor for the purpose of mailing out questionnaires. The vast majority of trusts involved were expected to opt to use an approved survey contractor, either: Picker Institute Europe, Quality Health and Patient Perspective.

All 56 eligible mental health provider Trusts will be asked to conduct the survey, drawing a sample of service users according to set criteria, and following standardised materials and procedures for all stages of the survey. The aim was to ensure organisations carry out patient surveys in a consistent and systematic way, using a standardised methodology and survey instrument, to build up a national picture of people's experience.

The end product from this survey will be a set of aggregate statistical data that does not contain patient identifiable information. This statistical dataset is used for a wide variety of purposes to support ongoing improvement in overall patient experience by NHS Trusts and CCGs and by CQC, to inform its regulatory functions.

NHS Patient Survey Programme

This survey is part of the NHS Patient Survey Programme, and as such follows the same methodology as other surveys within the programme. The methodology is approved in principle by the CAG, and applications are usually considered via the Precedent Set pathway.

New approaches are often piloted within the NHS Patient Survey Programme. For the current application (Community Mental Health Survey 2019), the following interventions would be added as part of a pilot:

- Dissent posters being available in the ten most commonly spoken languages in England. Trusts can display these optional posters alongside the mandatory English poster to maximise reach for their service user population.
- The inclusion of relevant Trust email and postal address information, if available, on dissent posters alongside a contact telephone number for service users to contact should they wish not to participate
- An earlier first reminder letter, sent 5 working days after the first mailing has been sent rather than 2 – 3 weeks which was standard practice previously.
- No longer including a CQC flyer within mailing packs to respondents.
- Piloting email augmentation in the survey by including a link to an online questionnaire in the initial postal letter. This would be followed up by a reminder email, which included a link to the online questionnaire. *The primary aim of this pilot was to increase response rates overall and from lesser heard groups. A secondary aim of the pilot will be to determine whether a potential move towards a mixed mode (paper and digital) methodology for this survey and the NPSP is possible in future years. The eligibility criteria for the intervention will be different from the main stage survey as email contact is necessary. Therefore service users must have an email address listed to be eligible for sampling.* For clarity, please note that the Survey Coordination Centre do **not** receive any names, postal addresses or email addresses.

A recommendation for class 3, 5 and 6 support was requested to cover activities as described in the application.

Confidential patient information requested

Data from mental health providers in relation to people aged 18 and over who had been in contact with NHS mental health services in the three month period, 1 September to 30 November 2018, and who were receiving specialist care or treatment for a mental health condition, including those who receive care under the Care Programme Approach (CPA).

The **mailing file** is used to address questionnaires to the appropriate person, and is sent to the **Approved Contractor**. It contains:

- Trust code
- A standardised unique identifier code,
- Title (Mr, Mrs, Ms, etc.)
- First name
- Surname
- Address Fields
- Postcode

The **sample data file** is used to link demographic data to the survey responses, to aid analysis and to enable checks to be carried out for any errors in how the sample was drawn and is sent to the **Coordination Centre**. This file contains:

- Trust code
- The unique identifier code (as above)
- Year of birth
- Gender
- Ethnic category

- Day of last contact
- Month of last contact
- Year of last contact
- CPA status
- CCG code
- Mental Health Care Cluster Codes

Pilot study

As part of the pilot work, between 5-10 Trusts participating in the pilot work will also be asked to include the following:

- Email address for intervention and control pilot sample only.

Confidentiality Advisory Group advice

Public interest

The CAG was assured that the application defined an appropriate medical purpose, which was the management of health and social care services. Members were assured of the ongoing public interest in the NHS Patient Survey Programme as a service evaluation tool, gaining knowledge on patient experience.

Practicable alternatives

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

- Feasibility of consent

The Group recognised that the proposed application would operate via the standardised methodology for surveys facilitated by the Picker Institute Europe; which had been supported in principle by the CAG. The applicant explained why the surveys could not be operated on a prior consenting basis within the application – the Group was assured that this rationale remained relevant and appropriate to the current submission. Members considered the rationale and acknowledged that patients would have the choice around whether to respond to the survey request when received. It was agreed that consent was not feasible for the proposed activity and no further issues were raised in this activity.

- Use of anonymised/pseudonymised data

Confidential patient information was required to facilitate distribution of the survey, which could not otherwise be achieved. No issues were raised in this area.

Justification of Identifiers

The Group was satisfied that the items of confidential patient information requested were appropriate and proportionate to the facilitation of the survey.

Exit Strategy

The CAG acknowledged that the primary exit strategy was patient consent via the return of a completed survey. The mailing file may be kept until the reporting stage of the survey (a maximum of 12 months) in

case of anomalies or errors discovered during sample validation. Following which, the file would be destroyed. No issues were raised in this area.

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 an unconsented activity should go ahead. The applicants had confirmed that an Advisory Group was held in June 2018 to discuss questionnaire content and methodologies. The stakeholders included representatives from CQC, NHS England and the Survey Coordination Centre, plus two Patient Experience leads from mental health Trusts, two Experts by Experience, and a representative from the mental health charity MIND. Feedback from the session was provided for information purposes. The applicant explained that the information materials and questionnaire document would also be submitted for discretionary review by an NHS Research Ethics Committee. Members received the information and raised no issues in this area.

Patient Notification and Dissent

It is a general principle of the CAG, when recommending support, for reasonable measures to be taken to inform the relevant population of the activity and to provide a right and mechanism to respect objection, where appropriate. This is known as patient notification. This is separate to the local obligation to comply with the principles of the Data Protection Act 2018. The applicants had provided copies of posters which had been produced to promote the survey and would be provided for display in participating Trusts. It was recognised that Trusts would be requested to include a contact telephone number together with postal and email addresses to facilitate patient dissent. The posters had also been made available in the ten most commonly spoken languages in the England, to make the information accessible to a wider audience. The Sub-Committee considered the documentation and raised no issues.

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 Secretary of State for Health and Social, subject to compliance with the specific and standard conditions of support as set out below.

Specific conditions of support (Final)

3. Confirmation from the IGT Team at NHSD Digital of suitable security arrangements via Information Governance Toolkit (IGT) submission (**Confirmed – Picker Institute Europe, Quality Health and Patient Perspective all have a published reviewed grade on V14.1, 2017/18).**

Anthony L. Calland — 24/01/2019

Signed – Officers of CAG — Date

Appendix 1. CAG Sub Group Minutes

Kmurray	24/01/2019.
Signed – Confidentiality Advice Team	Date