NHS
Health Research Authority

Minutes of the meeting of the Confidentiality Advisory Group

09 July 2015 at 9.00am – 3.30pm at Skipton House, SE1 6LH

Present:

Name	Capacity and items present for
Dr Mark Taylor (Chair)	
Dr Kambiz Boomla	
Ms Hannah Chambers (Lay)	
Dr Patrick Coyle	
Professor Barry Evans	
Professor Julia Hippisley-Cox	Not present for item 2
Mr Anthony Kane (Lay)	
Professor Jennifer Kurinczuk	
Ms Clare Sanderson	
Dr Murat Soncul	
Mr C. Marc Taylor	
Ms Gillian Wells	

Also in attendance:

Name	Position (or reason for attending)
Ms Claire Edgeworth	Deputy Confidentiality Advice Manager, HRA
Ms Amy Ford	Senior Confidentiality Advisor, HRA
Mr Ben Redclift	Confidentiality Advisor, HRA

1. INTRODUCTION, APOLOGIES AND DECLARATIONS OF INTEREST

Apologies

Apologies were received from Dr. Robert Carr, Dr Miranda Wolpert and Dr Tony Calland MBE.

Declarations of interest

Professor Barry Evans declared an interest in item 5a due to the role of his employer, Public Health England. Professor Evans confirmed that he had no direct involvement with the project and remained in the room for the discussion.

2. CAG EDUCATION ITEM

a) CPRD – Dr Janet Valentine – Clinical Practice Research Datalink Director (CPRD)

Dr Janet Valentine from NHS England attended to present on CPRD. The item was presented for information only. Dr Valentine confirmed that the slides could be circulated to members.

Action: CAT to circulate slides to CAG members

3. AMENDMENTS TO APPROVED APPLICATIONS

a) Disclosure of commissioning data sets and GP data for risk stratification purposes to data processors working on behalf of GPs [CAG 7-04 (a) 2013]

Scope of application

This application from NHS England on behalf of the relevant data controllers sought support for the activity of risk stratification to be used by clinical commissioners to target specific patient groups and enable clinicians with the duty of care for the patient to offer appropriate interventions. The stated aim of risk stratification was to reduce hospital readmissions through ultimately targeting clinical interventions to high risk patients. A recommendation for class 1, 4, 5 and 6 support was requested to support the disclosure of commissioning data sets (ref CAG 2-03(a)/2013) from the Health and Social Care Information Centre (HSCIC) and GP data from GP systems to data processors working under the instruction of GPs as data controllers; to support disclosure of patient confidential data to enable the indirect care element of risk stratification, namely for the preliminary processing to combine and process primary care and secondary care data; and also to provide a legal basis to enable the Health and Social Care Information Centre (HSCIC) to transfer this information onwards to the relevant data controllers for this purpose.

Amendment request

An amendment request was submitted to the July 2015 CAG meeting which outlined a number of changes that had arisen following the initial outcome. The following changes were specified:

1. Administrative changes that had originated from the consolidation of Commissioning Support Units (CSUs)

2. Transfer of in-house risk stratification services from 5 Clinical Commissioning Groups (CCGs) to Nottinghamshire Health Informatics Service. Nottinghamshire Health Informatics Service was a new risk stratification service supplier.

3. Transfer of in-house management from 3 CCGs to an approved risk stratification supplier –NHS South Central and West CSU.

4. Inclusion of Wirral CCG as a new in-house risk stratification service supplier.

5. Confirmation of new CCGs waiting to undertake risk stratification using established risk stratification service suppliers.

Confidentiality Advisory Group advice

Members discussed the changes proposed and noted that the majority of changes were either administrative only or involved utilised a previously approved risk stratification service supplier. It was agreed that the changes which involved a new risk stratification supplier (points 2 and 4 above) would require further consideration.

<u>New suppliers</u>

The original advice provided by CAG specified that any new suppliers should have in place to be agreed final option(s) in line with the overarching approval provided to NHS England [CAG 2093(a)/2013]. With this in mind, the applicant was asked to provide further information in relation to how the standards applied to the new service suppliers ensured that they were moving towards the proposed end state. The applicant responded with confirmation that the data would be collected and pseudonymised within the Data Services for Commissioners Regional Office (DSCRO) and provided to the risk stratification service supplier in a weakly pseudonymised form if the CCG were a stage 1 Accredited Safe Haven (ASH) or in an anonymised (using pseudonymisation) form.

Members noted that the original advice was provided prior to the final option(s) being agreed and that the primary concern was that there would be a significant number of new risk stratification suppliers offering services using the old standards which would not support movement towards the end state. Since the advice was provided it was noted that that the proposed final option(s) had changed and that the proposed new risk stratification suppliers were either an existing ASH or could demonstrate that they were moving towards the end state by utilising a pseudonymised methodology. Members therefore agreed that it would be reasonable to recommend that the support was extended to include these suppliers.

<u>Future standards</u>

Members discussed that, due to the change in end state and in order to provide clarity for any further requests, it would be helpful for the applicant to provide information in relation to the standards applied to new and existing risk stratification service suppliers which ensured that they were moving towards the proposed end state. It was requested that this be provided at the next update report due in October 2015.

Patient objections

Following an external query the applicant was asked to confirm how they were ensuring that patient objections were respected. The applicant confirmed that patient dissent was undertaken at the point of GP extraction and verified at the DSCRO as part of the pseudonymisation service.

Confidentiality Advisory Group conclusion

In line with the considerations above, CAG agreed that the minimum criteria under the Regulations appeared to have been met for this amendment, and therefore advised recommending support to the Secretary of State for Health. This was subject to further information being provided at the next review stage in relation to the standards applied to new and existing risk stratification service suppliers which ensured that they were moving towards the proposed end state.

4. RESUBMITTED APPLICATIONS

a) Case-control Study for Campylobacter in the under 5s [15/CAG/0157]

This application from University of Liverpool set out the purpose of an epidemiological case – control study to investigate children's' lifestyles, behaviours and environmental factors which made children ill from Campylobacter. The study would review the differences between children that have been ill with Campylobacter (cases) and those that have not been ill with diarrhoea and vomiting (controls). The research team would also examine the type of Campylobacter that infected the children and also assess the differences in awareness of food safety practices relating to chicken in the home and the value of preventing illness by estimating the amount that people would be willing to pay to avoid Campylobacter related illness.

The cases within this study would be identified by Public Health England through faecal samples that tested positive for Campylobacter. Letters of invitation and information leaflets will be sent to the parent/guardian of children with laboratory – confirmed cases from Public Health England. The application had sought support to enable Public Health England to write to the identified cohort. This part of the application had been previously been approved at the April 2015 meeting.

The applicant had also previously sought support for the purpose of obtaining contact details from the Health and Social Care Information Centre (HSCIC) in order for the research team to write to healthy individuals to ask them to participate within the study. The applicant had confirmed that confidential patient information for all children under the age of 5 would need to be extracted from all English NHAIS systems. This part of the application was not approved at the April 2015 meeting.

The application for support was first reviewed through the precedent set process and was deferred to the April 2015 meeting by the chair. The applicant resubmitted the application to the July meeting to provide additional information as specified within the letter dated 18th May 2015.

A recommendation for class 2, 3 and 6 support was requested to allow access to an authorised user for the purpose of obtaining and using information about past or present geographical location and also to select and contact patients to seek consent.

Confidential patient information requested

Access was requested for the Health and Social Care Information Centre (HSCIC) to access name, address and age in years and months for the healthy control cohort.

Confidentiality Advisory Group advice

Public Interest

Members agreed that this was a medical purpose as defined within the s251 (1) NHS Act 2006 and also agreed that the activity carried out would likely to provide a public interest due to the risk to the family and children.

Public Health England – Control Letters to Healthy Cohort

Members noted that the Health and Social Care Information Centre (HSCIC) did not provide a service where the organisation would write to cohort on behalf of the applicant.

Members raised concerns in relation to the writing to a large quantity of healthy children aged five and asking to participate within the study. Members discussed as to whether the healthy control cohort was required for the study and agreed that the purpose of the comparator was to obtain unbiased and unmatched controls. Members advised that the letter to the control cohort should be sent from an NHS organisation on behalf of the applicant and requested further clarification as to whether Public Health England (PHE) could provide this service, as the organisation would be writing to case identified cohort, as per original application and subsequent support. It was advised that support would still be required due to the confidential patient information disclosure from HSCIC to Public Health England in order to write to the healthy control cohort.

Members noted that the letter to the control cohort had not been provided and asked for the applicant to submit the letter to be reviewed by CAG members outside of the CAG committee.

Members noted that opportunity for patient opt-out would be made available at the point where parent/guardians of the health control cohort would not respond/or dissent to the letter and the accompanied consent model.

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. Confirmation as to whether Public Health England could provide the service whereby the organisation writes to the healthy control cohort on behalf of the applicant.

2. Submission of the letter drafted for the Healthy Control Cohort.

Specific conditions of support

1. Confidential patient information should only be retained until the activity of selecting and contacting patient had been completed. The identifiers should not be retained for the duration of the study or the specified retention period for the overall study data.

2. Favourable opinion from a Research Ethics Committee.

3. Confirmation from the Information Governance Toolkit (IGT) Team at the Health and Social Care Information Centre of suitable security arrangements via IGTK submission.

5. NEW APPLICATIONS – Research

a) National Study of HIV in Pregnancy and Childhood (NSHPC) [15/CAG/0153]

This application from UCL Institute of Child Health set out the purpose of a study which was established in 1986 originally as a study of AIDS in children living in UK and Ireland and was extended in 1989 to cover pregnant women with HIV and their infants. Over the last 25 years core funding had been provided by the Department of Health, the Health Protection Agency and now Public Health England.

It was noted that parts of the protocol relating to the BPSU and flagging aspects had been previously included within an application to PIAG (PIAG/BPSU 2-10 (a)/2005).

A recommendation for class 1, 2, 4, 5 and 6 support was requested to cover the disclosure of confidential patient information to University College London. Confidential patient information from NHS Trusts in relation to HIV positive pregnant women (via 'green card' method) and children diagnosed with HIV (via 'orange card' BPSU method) and date from the HSCIC in relation to death and cancer registration was requested.

Confidential patient information requested

Access was requested to NHS number, Hospital ID, date of death, date of birth and sector level postcode in order to carry out linkages and for de-duplication purposes.

Confidentiality Advisory Group advice

Public interest

Members agreed that the surveillance purposes outlined within the application were clear and that it was important that these continued without interruption.

Definition of activity purpose and legal basis

- Surveillance

Following consultation with Public Health England, it had been advised that the broad purposes of the data collection constituted a national surveillance programme and therefore PHE were of the view that this would fall under Regulation 3 of the Health Service (Control of Patient Information) Regulations 2002, which fell under PHEs own remit. Members therefore noted that the surveillance aspects of the activity would not require separate support from the Secretary of State under Regulation 5.

- Research

Members considered that, whilst there was a clear surveillance purpose which would fall within Regulation 3, there were additional research uses to the data processed within the database and these would not fall within Regulation 3 as this covered specific purposes which did not extend to research. Support under Regulation 5 may therefore be required to allow the use of data for additional research purposes and members agreed that it was unclear whether the research purposes could be sufficiently separated to ensure that the initial data flow could fall solely within Regulation 3.

If the research aspects could be sufficiently differentiated from the surveillance aspects so that only effectively anonymised data only would be required for the research

purpose and that identifiable data would only be collected for surveillance, it could mean that separate support under Regulation 5 would not be required. For example, if an anonymised research database could be created.

In order to clarify the situation it was agreed that the applicant should submit an outline of the specific research purposes and the data flows associated with these to help determine whether CAG needed to consider support under Regulation 5. The applicant should ensure that all uses of identifiable data for research purposes were justified and were possible reduce the amount of identifiers required.

If support was required, members agreed that the outline document requested would help to determine whether a) general support for research purposes would be appropriate because the purposes of data flows were so intertwined, or b) secondary access to anonymised data only would be sufficient for the primary research purposes and applications to access identifiable data for research purposes could then be made on a case by case basis as required.

Members agreed that they were generally supportive of the application and therefore would welcome the opportunity to obtain clarity and an application under Regulation 5 for the research aspects of the activity if this was required.

Additional data flows to CHIPS and other UK HIV datasets

Members noted the additional data flows to CHIPS and other UK HIV datasets and advised that if identifiable data was required, an application should be made to cover these data flows. It was confirmed that any additional data flow of identifiable data would need to be subject to a separate application, given that the responsibilities and purposes for these activities were different.

Clarification over identifiers

Members noted that question 42 on page 17 specified that names and addressed were collected but that patient names and addresses were not. Members requested clarification in relation to whose names and addresses were being referred to within the question.

Patient objections

Members queried what provisions had been made to allow objection to research purposes and agreed that reassurances in relation to how this would be managed would need to be provided if support was to be requested for the research purposes.

Redcap

Members requested further information in relation to the Redcap system and whether this was software provided to the applicant or whether data would be held on a Redcap server. If the latter, members queried where this server would be based.

Confidentiality Advisory Group advice conclusion

In line with the considerations above, the CAG agreed that further information would be required from the applicant in order for a recommendation under the Regulations to be provided.

Further information required

The following information should be provided for the October 2015 meeting to allow the CAG to continue their consideration of the application:

1. Submission of an outline of the specific research purposes and the data flows associated with these to help determine whether CAG need to consider support under Regulation 5.
2. Confirmation whose names and addresses would be accessed in line with CAG advice outlined above.
3. Confirmation what provisions could be made to allow objection to research purposes.
4. Confirmation of details of the Redcap system and where data will be processed.

b) Primary care based text reminders in colorectal cancer screening [15/CAG/0156]

This application from University College London (UCL) set out the purpose to investigate the effectiveness of a primary care-based text message reminder to promote CRC screening uptake in London. In England, the NHS Bowel Cancer Screening Programme (BCSP) aims to screen 60% of the eligible population every two years. Increasing evidence demonstrates that General Practitioner (GP) endorsement promotes CRC screening uptake and there is a growing interest in the use of text message reminders to increase participation in cancer screening. Mobile numbers stored on the Primary Care Practices clinical system will be used. This study would be conducted in 180 primary care practices in London and is expected to run for two months.

Eligible patients (i.e. patients who are being invited to participate in the bowel cancer screening programme for the duration of the study, registered with a participating GP practice) would be identified by a member of the direct care team at the London Bowel

Cancer Screening Hub. Patients would then be randomly allocated to receive usual care (i.e. control) or usual care plus a primary care-based text message reminder to return their kit (if they have not done so already) seven weeks after the kit was dispatched. The text message would act as a prompt to return the tests kits if they have not already done so.

The study would use a Patient Care Messaging (PCM) system (provided by an MHealth company i.e. iPlato), who would automatically match screening eligible individuals to their GP records and randomise them to the control or intervention group (using CCG specific randomisation lists) within the server.

At the end of the study the hub would send a fully anonymised dataset to the researchers at UCL for analysis.

Purpose of application

Support was requested to allow the disclosure of confidential patient information from GP records and the London Bowel Cancer Screening hub to iPlato to enable them to link episode level data on screening participation with mobile phone records held by the GP.

Confidential patient information requested

A recommendation for class 4 & 6 support was requested to cover access to NHS number, GP practice code, date of birth, consent status and mobile phone number.

Confidentiality Advisory Group advice

Patient notification

Members considered whether there was potential for the participating practices to send a text to all patients prior to disclosure of mobile numbers to inform patients and allow individuals to opt out. Whilst patient consent may have been provided for the use of text reminders from GP practices, members noted that patients might be unaware that they were being enrolled in a randomised trial. The committee considered whether patients should be made aware of the uses of their data and made aware of the study before receiving the text reminder. After discussion it was noted that this was likely to affect the study outcomes and was therefore not practical for the research purpose.

Justification of identifiers

It was noted that there was uncertainty in relation to whether the data being reviewed by researchers was fully anonymised and that if this were not the case the applicant should be reminded that appropriate contracts should be in place.

Further clarification was also required from the applicant in relation to the need to collect deprivation scores.

It was noted that the application stated that where two people resided at the same address both would be allocated to either the control or intervention group to avoid one person receiving a reminder and the other not. However it was not clear from the application how iPlato would know that two participants resided at the same address and be able to allocate both participants to the control or intervention group when they would have no access to address information.

Patient involvement

The group noted that it appeared that little patient involvement had taken place in relation to the activity and advised that where patient information was to be obtained without consent, greater efforts should be made to engage with the public.

General Practice information

Members commented on the material attached to the application that would be provided to GP's and noted that some referenced data items that would be going to iPlato and that others didn't. It was also unclear if GP practices would be informed of the process for registering patient objections. Members recommended that clear information should be provided to GP's on all the data items going to iPlato as well as on the process for opting out patients.

Confidentiality Advisory Group advice conclusion

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

Specific conditions of support

1. Confirmation that the data being reviewed by researchers was fully anonymised.
2. Confirmation that GP's would be informed of all information going to iPlato and be provided with information on registering patient objections.
3. Clarification in relation to how iPlato will know if two participants live at the same address if they have no access to addresses.
4. Efforts should be made to engage with patients in relation to the study prior to the start.
5. Clarification regarding the requirement for deprivation scores.
6. Favourable opinion from a Research Ethics Committee.

7. Confirmation from the Information Governance Toolkit (IGT) Team at the Health and Social Care Information Centre of suitable security arrangements via IGT submission.

c) Acute hospital care for frail older people [15/CAG/0160]

This application from the University of Newcastle set out the purpose of conducting an epidemiological cohort study to investigate and provide high quality evidence to support the delivery of Comprehensive Geriatric Assessment (CGA) on a hospital wide basis. The purpose of the study is to investigate how CGA is defined and recognised, how and in what form was CGA currently organised and delivered within the UK, who received CGA and to identify the benefits.

The applicant sought support in order for confidential patient information collected from previous studies by the Newcastle University, Nottingham University and Southampton University, to be disclosed to the Health and Social Care Information Centre (HSCIC) for the purpose of data linkage to create HES IDs for Hospital Episode Statistics (HES) data held by the Nuffield Trust. The HSCIC would forward the HES IDs and a unique identifier to the Nuffield Trust in order for the Nuffield Trust to link HES data to the clinical data using the unique identifier for each patient. The applicant also specified the intention to pursue pseudonymisation at source for the purpose of linking clinical data sets with social care data. The applicant had been informed by the Confidentiality Advice Team (CAT) that support would not cover social care data and the applicant confirmed that separate discussions with social care was currently taking place.

A recommendation for class 1, 4 and 6 support was requested to allow access to an authorised user for the purpose of extracting and anonymising information and also to link patient identifiable information obtained from one or more source.

Confidential patient information requested

Data from specified universities in relation to NHS Number, name, date of birth, address and postcode were requested to flow to the HSCIC for the purpose of data linkage. The HSCIC would forward pseudonymised data to the Nuffield Trust.

Confidentiality Advisory Group advice

Public interest

Members agreed that this was a medical purpose as defined within the s251 (1) NHS Act 2006. Members agreed that the activity carried out would likely to provide a significant public interest due to the need to examine the delivery of Comprehensive Geriatric Assessment (CGA), who receives CGA and its benefits.

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.

Members noted that consent was sought for previous similar studies and that the applicant was seeking support to extend the consent from the specified studies to permit access to confidential patient information for this new study. Members advised that referring to extending the consent from previous studies was inaccurate in the context of the Health Services (Control of Patient Information) Regulation 2002. Therefore, it was advised that support under these regulations enabled the common law duty of confidentiality to be set aside but did extend the consent.

Members also noted that consent was not practicable due to the retrospective nature of the cohort as it was likely that individuals would be deceased.

Justification and retention of identifiers

Members agreed that the specified identifiers, with the exception of Date of Birth, were necessary in order for HSCIC to conduct the data linkage activity. Members requested the applicant to justify why date of birth was required for data linkage. Members noted that the application specified that the data was to be retained for seven years. Members requested clarification as to whether the data is to be retained including the identifiers.

Patient and public involvement

Members noted the efforts the applicant had made to develop a good patient and public involvement work stream. Members requested the applicant provide an action plan detailing implementation deadlines.

Patient notification and objection

Members noted that the applicant did not provide sufficient information in relation to patient notification and providing an opportunity to object. Members requested further clarification regarding the mechanism in place for individuals to object. Members advised that patient notification on the Nuffield Trust website would not be sufficient and that patient notifications should be added to the websites of the universities who had conducted the previous studies.

Confidentiality Advisory Group advice conclusion

The CAG agreed that the minimum criteria under the Regulations appeared to have been met and that there was a public interest in projects of this nature being conducted,

and therefore advised recommending support to the Health Research Authority, subject to compliance with the specific and standard conditions of support as set out below.

Specific conditions of support

1. Justification for the purpose of utilising date of birth for data linkage.
2. Clarification regarding whether identifiers would be retained for seven years.
3. Submission of an action plan detailing implementation deadlines of the patient and public involvement work stream.
4. Confirmation that patient notification would be added to university sites where the previous studies were conducted.
5. Clarification regarding the mechanisms for patients to object.
6. Favourable opinion from a Research Ethics Committee.
7. Confirmation from the Information Governance Toolkit (IGT) Team at the Health and Social Care Information Centre of suitable security arrangements via IGT submission.

6. NEW APPLICATIONS – Non-Research

a) The fracture liaison service database [15/CAG/0158]

This application describes a database, commissioned by the Health Care Quality Improvement Partnership (HQIP), to support the implementation of the Department of Health's Prevention Package for Older People by collecting high quality data to raise the standard of care and improve the patient pathway consistently with the Quality Outcomes Framework in primary care.

A recommendation for class 1,4 & 6 support was requested to cover access to data from The Fracture Liaison Service (FLS) and Office of National Statistics (ONS) and Hospital Episodes Statistics (HES) data from the Health and Social Care Information Centre in relation to men and women aged 50 years and over with a fragility fracture.

Confidential patient information requested

Access was requested to name, postcode, NHS number, date of birth and date of death. Name would be used to verify NHS number only and would then be deleted.

Confidentiality Advisory Group advice

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.

Members accepted the assertion about the numbers of the cohort being impractical to gain consent, however they requested that the applicant be reminded that patient capacity issues cannot be given as a reason for not seeking consent as the mechanisms within the Mental Capacity Act 2005 should be followed.

Justification of identifiers

It was noted that name was included in the items for data retention and that data would be retained for three years following completion of the audit, however the applicant had confirmed that name could be removed once the NHS number had been verified and therefore would not need to retain this data item beyond this point. Members requested that the applicant provide confirmation on the need to retain the data for this time period and report on the retention of complete NHS number as well as the name at annual review stage.

The application made reference to anonymous data being shared with the Royal College of Physicians, members asked for confirmation of the constitution of the anonymised dataset and which organisations the dataset would be shared with.

It was unclear how patient objection would work and if the data would be deleted of those who opted out. Members requested further clarification around these issues.

Patient Information Sheet

Members commented that the patient information sheet was potentially ambiguous. For example, the patient information sheet referred to the fact that the study "would collect data on how they operate" which could be misleading to the public who might imply a medical operation from the wording. Members noted that comprehensive guidance on the production of patient information sheet's was available on the HRA website and advised the applicant to consult this guidance and revise the PIS to ensure that it is clear and comprehensible to the public. The applicant was requested to provide a copy of the revised PIS to the committee.

Additional points

It was noted that the application mentioned that patients could make a request about the data held about them, a Subject Access Request (SAR). However it was unclear how this could be achieved when no identifiers were held by the RCP, members requested confirmation in relation to how this would be achieved.

Confidentiality Advisory Group advice conclusion

The CAG 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 Secretary of State, 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. The applicant should provide further information about the organisations the data was being shared with and the data items being shared.
2. The applicant should provide clarification on what was meant by anonymous data.
3. The applicant should provide clarification of how Subject Access Requests (SAR's) could be made.

4. The applicant should provide clarification of how patient objection would work and confirm that the data of those who opted out would be deleted and not be retained.
5. The applicant should provide further explanation in relation to why data needed to be retained for the specified period.
6. The applicant should report on the completeness of valid NHS number at annual review stage to ensure that this additional step and collection of name was necessary.
7. The applicant should provide members with an updated version of the re-worded Patient Information Sheet.

Specific conditions of support

8. Confirmation from the IGT Team at the Health and Social Care Information Centre of suitable security arrangements via Information Governance Toolkit (IGT) submission.

7. FOR DISCUSSION

a) Precedent set review -- managing non-response

Members discussed an item presented by the Confidentiality Advice Team (CAT) in relation to following up requests for responses from members when considering precedent set applications and amendments via sub-committee. Members confirmed that they were content with the process outlined; a minor change was noted in relation to the response time for the Chair if an application was reallocated. Members suggested that they could help by responding to emails from CAT immediately to confirm that they had received it so that there was no ambiguity. It was also suggested that CAT reissue requests for confirmation of personal mobile phone numbers and emails which could be used to alert members to emails.

Action: CAT to request confirmation of email/phone numbers that could be used to alert members to emails sent to HRA mailboxes.

Action: CAG members to confirm receipt of emails when possible with anticipated timescales for response.

b) Precedent set review - establishing process for seeking clarification from applicant

Members discussed an item presented by the Confidentiality Advice Team in relation to seeking clarification from applicants where further information was required following member review. The process was noted for information.

c) Education items

Members discussed an item presented by the Confidentiality Advice Team in relation to education items. Members were asked to consider a number of points in relation to this including:

9am start for education items

Some members raised concerns that it would be difficult to attend meetings where these started at 9am. It was noted that 9am start times had been scheduled in order to ensure that education items would not have any impact on normal business and that it was difficult to determine whether the agenda could accommodate a later start time in enough time to schedule speakers. However, member concerns were noted and it was agreed that the current approach would be reviewed in November to determine whether 9am starts were still necessary.

Action: CAT to review requirement for 9am start in November 2015.

Education item minutes

Members discussed the assignment of education sessions for bi-monthly CAG committees and the requirements of the speakers and members. Members agreed that prior to presenting the education session for committee members, speakers should be informed that members cannot provide definitive advice, minutes would not be formally recorded and sessions would remain confidential.

The Vice – Chair tabled a proposed list of future educational items in order of priority, subject to the availability of the speaker. The Vice-Chair invited members to confirm any changes in relation to the order of the education sessions.

8. MINUTES OF THE MEETING HELD ON 30 APRIL 2015

The minutes of the meeting held on 30 April 2015 were confirmed as an accurate record.

9. CAG OFFICE REPORT

For information

Secretary of State approval decisions

The DH senior civil servant on behalf of the Secretary of State for Health (SofS) agreed with the advice provided by the CAG in relation to the July 2015 meeting applications.

Health Research Authority (HRA) approval decisions

The HRA agreed with the advice provided by the CAG in relation to the July 2015 meeting applications.

Amendments to approved applications

Longitudinal Study of Young People in England (LSYPE) [CAG 1-03(PR3)/2014]

Context

Purpose of application

This application from Centre for Longitudinal Studies at the Institute for Education, University of London, sets out the purpose of a longitudinal study, previously managed and funded by the Department of Education (DfE) from 2004 until 2012. In 2013, the Economic and Social Research Council (ESRC) took over the funding of the study and management transferred to the Centre for Longitudinal Studies (CLS).

The aim of the study was to examine how health, wealth, education, employment and attitudes are linked, how they change over time and how they could vary between different people, at different points in time.

A recommendation for class 2, 3, 4 and 6 support was requested to cover access to:

1) GP registrations and addresses from the Health and Social Care Information Centre (HSCIC) so that individuals could be contacted and invited to continue participating in the study.
2) Notification from the Health and Social Care Information Centre (HSCIC) of deaths, embarkations (i.e. emigrations) and exits/entry from the NHS.

Amendment request

It was noted that as of the 2nd December 2014, the Institute of Education (IOE) joined University College London (UCL) as a single Faculty School, to be known as the UCL Institute of Education. The data controller for LSYPE therefore, was now UCL.
An amendment was submitted to request a change in data controller from the Institute of Education (IoE) to University College London (UCL) with no change to the purposes, data sources, data items or data flows.

Confidentiality Advice Team advice

The amendment requested was forwarded to the CAT who noted the submission of a satisfactory Information Governance toolkit.

Confidentiality Advice Team conclusion

In line with the considerations above, CAT agreed that the minimum criteria under the Regulations appeared to have been met for this amendment, and therefore advised recommending support to the Health Research Authority.

Updates on existing applications

ECC 8-05(d)/2011 - Do specialist cancer services for teenagers and young adults (TYA) add value?

The applicant had submitted an annual review for this study and notified that in relation to the amendment approved on the 18th September 2014, there were six adverse events related to the incorrect transfer of information from the following NHS Trusts to Quality Health:

1. Patients submitted as having cancer when they did not have a cancer diagnosis from the following NHS Trusts:
   a. South Tees Hospitals NHS Foundation Trust
   b. Hampshire Hospitals NHS Foundation Trust
   c. Nottingham University Hospitals NHS Trust
   d. Heart of England NHS Foundation Trust (two events)
2. Patients finding out they had cancer after receiving information from Quality Health from Leeds Teaching Hospitals NHS Trust.

The applicant confirmed that these adverse events occurred as a result of:

i) Incomplete checks by the designated person within the Trusts (patient details needed to be checked before transferring to Quality Health to ensure the inclusion criteria were fulfilled (age, diagnosis of cancer and time since diagnosis);
ii) Patients not being told they had cancer due to it being a low grade or the diagnosis had not been confirmed when the letters were sent;
iii) Some events were due to bad coding practice, i.e. cancer diagnosis codes being applied before histology was confirmed.

After being contacted by patients the applicant provided immediate support and contacted Quality Health. Quality Health's protocol involves contacting patients to give additional reassurance and contacting the associated Trust in order for a senior member of the clinical team to contact the patient to apologise for the error and provide support and reassurance. This protocol was followed in all cases and no further complaints were received.

CAG Chair and CAT response to reported adverse events

The Chair and CAT met to discuss mitigating actions and actions to be taken forward. It was agreed that the CAT Team would contact the applicant to advise them to escalate

the adverse events to each of the organisation's Information Governance (IG) leads for assessment. It was also agreed for the applicant to ask each IG lead to provide CAT with a statement of confirmation that the breach had been considered and to forward the lessons learnt resulting from the assessment. CAT has also requested the applicant to forward a list of contact details for each IG lead.

CAT are currently conducting a review of the issues which have arisen and will be drafting a paper detailing lessons learnt, CAG risks for consideration (for example, implications for other studies/applications and reputational damage) and proposed recommendations for further implementation and will form part of the Office Report appendices for the August full committee.

15/CAG/0146 Insights in Care

This application was considered at the June 2015 meeting where CAG provided a recommendation that, due to the specific controls described, support would not be necessary. In light of the issue specified above in ECC 8-05 (d)/2011, it was identified that this affected two patients within the Heart of England Foundation Trust with the root cause potentially due to inaccurate coding practice or non-checking of names prior to dissemination to Quality Health. These applicants have therefore been contacted setting out whether the coding/checking issue above impacts on the activity previously considered by the CAG and if so, the lessons learnt and mitigations that have or will be implemented; this is to provide assurance that there is appropriate governance over the activity considered by the CAG so as to ensure the recommendation remains valid.

10. CHAIRS REPORT

Information Commissioners Office meeting

The CAG Chair and Natasha Dunkley, Confidentiality Advice Manager, met with representative from the Information Commissioners Office (ICO). It was discussed how to ensure that, despite material similarity in tests to be applied when determining if 'fair processing' obligations under the Data Protection Act 1998 (DPA) and expectations regarding adequate 'patient notification' for purposes of advising support under Health Service (Control of Patient Information) Regulations 2002. It was noted that it was important that it remained clear to CAG applicants that it was ICO responsibility to advise on and assess compliance with DPA and CAG's responsibility to advise only on the application of the Regulations.

The Chair advised members that it was not within CAG's remit to advise specifically on the application or regulation of the DPA. However it was noted that there was crossover given the requirement of the Regulations that applications should not be inconsistent with the DPA. The current CAG application form requested information from applicants

in relation to how the DPA requirements were met. It was suggested that if further assurances were required the data controller could be asked to confirm that they had aligned the activity to their responsibilities under the DPA, with reference to the ICO guidance. If there were outstanding concerns following this these could either be raised with the ICO by CAG or the applicant could be asked to consult with the ICO directly.

Attendance at Nuffield Council of Bioethics

The CAG Chair attended Nuffield Council of Bioethics led roundtable discussion of Nuffield Report on biological and health data under to address question of “Building Sustainable Public Trust in the Responsible Use of Health and Care Data”

11. ANY OTHER BUSINESS

a) REC & CAG Information Exchange

This was provided for member comment. Members were asked to forward any comments on to the Confidentiality Advice Team.

Action: CAG members to provide any comments in relation to the Information Exchange item to CAT.