NHS
Health Research Authority

Minutes of the meeting of the Confidentiality Advisory Group

30 April 2015 at 10.30am – 4.30pm at Skipton House, SE1 6LH

Present:

Name	Capacity and items present for
Dr Mark Taylor (Chair)	
Dr Kambiz Boomla	
Dr Patrick Coyle (Vice Chair)	Chair, item 5D
Dr Robert Carr	
Dr Tony Calland MBE (Vice Chair)	Chair, item 5C and 6A
Mrs Hannah Chambers	Lay
Professor Barry Evans	
Professor Julia Hippisley-Cox	Not present for item 4A
Mr Anthony Kane	Lay
Professor Jennifer Kurinczuk	
Ms. Clare Sanderson	
Dr Murat Soncul	Not present for item 5A
Mr C. Marc Taylor	
Dr Miranda Wolpert	Not present for item 4A

Also in attendance:

Name	Position (or reason for attending)
Ms Natasha Dunkley	Confidentiality Advice Manager, HRA
Ms Claire Edgeworth	Deputy Confidentiality Advice Manager, HRA
Ms Amy Ford	Senior Confidentiality Advisor, HRA
Mr Ben Redclift	Observer, HRA
Ms Rachel Merrett	NHS England, Item 2
Dr Alan Hassey	HSCIC, Item 3
Mrs Alison Bourke	15/CAG/0133, Item 4A

1. INTRODUCTION, APOLOGIES AND DECLARATIONS OF INTEREST

Apologies

Apologies were received from Ms Gillian Wells and Dr Kambiz Boomla

Declaration of interest

Professor Julia Hippisley-Cox declared an interest in item 4A as she knew the applicant personally and left the room during the consideration of this item.

Dr Murat Soncul declared an interest in item 5A, whilst he was not personally involved in the application, the Psychological Medicine Department in KCL extended to his employer organisation in a clinical context. Dr Soncul left the room during the consideration of this item.

Dr Patrick Coyle declared an interest in item 5A as the application was considered at the Data Access Advisory Group (DAAG) at the Health and Social Care Information Centre (HSCIC) and Dr Coyle was a member of this group. Dr Coyle did not take part in the discussion of this item.

Mr Marc C. Taylor asked members to note that he previously worked with the applicant for item 5A for information only and it was agreed that this did not prevent Mr Taylor from taking part in the discussion.

Professor Barry Evans asked members to note that item 5C requested access to data held by his employed, Public Health England and he had previously worked with the applicant. This was noted for information only and it was agreed that this did not prevent Professor Evans from taking part in the discussion.

2. CAG EDUCATION ITEM

Care.data

Ms Rachel Merrett from NHS England attended to present on the current status of the Care.data programme. The item was presented for information only. Ms Merrett confirmed that the application could be circulated to members following purdah restrictions.

3. CAG EDUCATION ITEM

Validity of Consent

Dr Alan Hassey, interim Chair of the Data Access Advisory Group at the Health and Social Care Information Centre attended to present issues considered by DAAG around the validity of consent. The item was presented for information only.

Action: Dr Hassey to provide details of Data Access Request Service dashboard for members.

4. RESUBMITTED APPLICATIONS

a) Free text field of the THIN database [15/CAG/0133]

This research application from The Health Improvement Network Ltd (THIN) described a research database which contained pseudonymised data from patients who are registered with GP site who participate in the THIN scheme. A recommendation for class 1, 2 and 6 support was requested to access confidential patient information from GP Practices to THIN in the form of free text data. As doctors could record additional information within this field it was confirmed that the data may contain identifiable information such as name and telephone numbers.

Confidentiality Advisory Group advice

Resubmission

This application was considered by CAG in October 2014 and February 2015 and the applicant was advised to explore the proposed alternative of a technical solution that anonymised free text data at source. It was noted that there was a cost and time constraint on the solution. However, members did not consider that this negated the alternative from being used in this scenario.

The resubmitted documentation requested that members reconsider the advice in the short term whilst the applicant worked towards the alternative, further information in relation to the studies currently using free text data and the proposed user involvement was also provided.

Members thanked the applicant for attending the meeting in order to discuss the resubmission.

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.

The advice provided previously noted that the applicant sought short term support whilst the alternative was adopted and agreed that the steps taken by the applicant to move towards the alternative were positive. However, members agreed that there was insufficient evidence that the detriment of not collecting the free text information for 6 months whilst the alternative was explored would mean that support should be recommended in the interim and therefore the applicant continue to pursue the alternative and that support should not be recommended in the interim. It was confirmed that the proposed technical solution would begin collecting depersonalised text from the time that the new collection software was activated. However, there would be no function to collect the data retrospectively. Examples of the sort of medical research work that would cease without the support of this application for interim continued use of the text were detailed within the applicant's response.

Members asked the applicant to explain why it would not be possible to collect free text data retrospectively once the proposed pseudonymisation at source technology was in place. The applicant confirmed that whilst it may be possible it would be particularly complex and costly to carry the extraction out retrospectively. It was confirmed that data continued to be collected in the interim without support in order to complete studies currently being undertaken.

Members queried how the proposed solution would differ from current practice, it was confirmed that currently most words that were considered to be potentially identifiable would be removed automatically upon receipt by the applicant. However, some words which were considered to be 'allowable words' could refer to both clinical conditions and names of individuals or places and therefore be considered to be potentially identifiable. This information would have to be removed manually. The proposed solution would mean the automatic process would be carried out prior to disclosure; however a manual check would still be required.

Public interest and scope

Members noted the short study details included within the resubmission currently receiving free text data. Members agreed that there was insufficient information with which to make a judgement as to the urgency and necessity to process free text information as detailed within the application, noting that an alternative was being developed. Members were unclear how essential access to free text data would be for the named studies and agreed that there would need to be further information demonstrating the added value. Members also agreed that they were unable to determine that the proposed scope of extraction (for all patients included within the database) was proportionate compared to the need for the 5 specified studies to access free text data in the interim period.

CAG role and continued processing of data

It was confirmed that the current request was considered in line with the requirements of the Regulations that CAG provided advice under and that the CAG did not have any remit to stop processing of any kind. Therefore, in relation to the studies currently

being undertaken, members were clear that any advice that the application did not meet the requirements of the Regulations did not remove any lawful basis for the current processing of data or prohibit continued processing in any way. However, the applicant was advised that the responsibility was on them to determine whether there was a current legal basis for the processing.

User involvement

Members queried whether the applicant had made any progress in relation to the previous advice that efforts should be made to ensure that views of patients were incorporated in to the design of the research database. The applicant confirmed that this was on hold following the outcome of the CAG application.

Patient information leaflets

Members were informed that the current version of the patient information poster had been reviewed by the Information Commissioners Office (ICO). The applicant confirmed that the poster would be translated into Welsh where required. Members commented that they were of the view that the wording on the poster could be clearer, however it was noted that the applicant had already sought advice from the ICO in relation to this aspect.

Confidentiality Advisory Group advice conclusion

In line with the considerations above, the CAG agreed that the minimum criteria under the Regulations did not appear to have been met as there was insufficient information regarding the current requirement to process free text information without consent, and therefore advised that the application was not supported.

Members noted that this advice and the subsequent decision that the application did not meet the requirements of the Regulations did not remove any lawful basis for the current processing of data or prohibit any continued lawful processing. However, the applicant was advised that the responsibility was on them to determine whether there was a current legal basis for the processing.

5. NEW APPLICATIONS – Research

a) Alcohol use in the Armed Forces: Linkage of a military cohort study to English, Scottish and Welsh secondary healthcare records [15/CAG/0136]

This research application from Kings College London described the aim to assess future service use and costs associated with alcohol use and mental disorders amongst members of the military. Other specified aims included identifying the future healthcare needs of military personnel and veterans; through linkage, to identify the physical health conditions where help is most commonly sought; to predict if an

individual is likely to be admitted to hospital for a physical health condition and to assess costs to the NHS resulting from high levels of alcohol use and mental health problems.

A recommendation for class 1, 4 and 6 support was requested to enable the Health & Social Care Information Centre (HSCIC) and the Secure Anonymised Information Linkage (SAIL) Database at the University of Swansea to receive identifiable information to enable linkage and to return an anonymised dataset back to the applicant.

Confidentiality Advisory Group Advice

This application was referred to the HRA Confidentiality Advisory Group (CAG) by the Health and Social Care Information Centre (HSCIC) Data Access Advisory Group (DAAG). Noting that the application had been submitted after the published CAG deadline, this application was considered by the CAG on an exceptional basis at its discretion. The reason for the referral from DAAG was stated to be that the HSCIC, as data controller, did not consider the consent materials to adequately describe the flows of information to the HSCIC for the purpose of linking with a HES data extract. DAAG had indicated that they did not consider re-consenting to be practicable due to numbers and the project timescale and had advised seeking advice from the HRA CAG.

The following provides a summary of the points discussed that led to the CAG advice recommendation.

Public interest

Members noted the link to the Murrison Report 'Fighting Fit: a mental health plan for servicemen and veterans 2010' that was indicated to be an underlying policy directive and noted that while there would be no direct benefit to participants, agreed that the issue of military mental health was a relevant issue with a high public interest in the potential outcomes.

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 were clear that participants had previously provided consent for the researcher team to be provided with access to their medical records (including secondary care records), and the sole issue under consideration was the flow of data to the HSCIC. It was agreed that the existing consent did not make explicit that the HSCIC would undertake the linkages but members were sympathetic to the fact that the HSCIC did not exist at the time the consent was originally obtained and that future plans for linkage had not been defined at the time.

Members reviewed the response provided as to why re-consent would not be feasible. The response clarified that there had been a loss of contact with some participants due to the highly mobile nature of this specific cohort. It was explained that up to date addresses were not present for all participants and a proportion would be deceased. The issue of lack of contact was stated to be particularly important for individuals who had left the service where only a work address may be present. The consequence was that this could result in losing more ex-serving, rather than serving, personnel, which could result in a biased sample. The response also clarified that attempts to seek further consent may result in responses from only a small proportion of participants who had previously provided consent as consent had originally been obtained during 2007-2009. Time constraints over contacting approximately 9000 participants within the study timescale were noted particularly in light of the context of the HSCIC developing position around consent requirements.

Members noted this explanation and agreed that sufficient information had been provided to justify the position that seeking further consent from participants would not be feasible in this instance.

The Group agreed that use of anonymised or pseudonymised data would not be sufficient as the HSCIC (England) and SAIL (Wales) would need to receive identifiers in order to undertake linkage activities prior to return of a pseudonymised dataset.

Justification of identifiers

Identifiers for linkage purposes were stated to be name, NHS number, date of birth and sex. Identifiers for analysis purposes were stated to be government office region, gender and age (already present in consented cohort), date of admission and discharge. Members agreed that the identifiers appeared reasonable and justifiable to achieve the purposes of the activity.

Patient notification

'Patient notification' is an aspect arising specifically in the context of applications made under the Health Service (Control of Patient Information) Regulations 2002 when submitting an application via the Confidentiality Advisory Group (CAG). It is separate to the legal requirement of fair processing under the Data Protection Act 1998.

For CAG purposes, its focus is on the steps taken by the applicant to maintain public confidence in the appropriate processing of data through transparency and openness. The methods used by the applicant will need to demonstrate how these aims of transparency and openness are to be achieved in a way that is proportionate to the proposed activity. The view of the CAG is that the more extensive the data collection then the risks to public confidence will be greater if individuals are not aware will subsequently shape the efforts regarded as proportionate and appropriate to ensure a 'no surprises' approach.

Members noted the applicant plan to inform participants consisted of the following steps that would take place prior to any data flowing to the HSCIC or SAIL:

1. Overview of study on King's Centre for Military Health Research website that would include a patient objection mechanism

2. Additional information to be provided on the 'information for participants' webpage including details on data flows and linkages

3. Specific newsletter to be provided containing specific detail of this study, research objectives, patient objection mechanism and will outline those included in the study(those who did not provide consent will not be included)

4. The fourth step outlined a general newsletter sent by email or post that would take place within 6 months

Noting that consent was already in place for the applicants to receive the cohort's medical records meant that the CAG agreed that the applicant approach to 'patient notification' was considered proportionate and appropriate, on the basis that reasonable time is provided for the cohort to receive the information above and raise any objection, prior to any data flows. Members advised that the specific newsletter (point 3) should be sent via email/post to ensure all reasonable steps are taken to inform this mobile population of the activity, rather than relying on potentially broader information dissemination specified in step 4 that may reach more of the cohort after data has flowed.

Members highlighted that any approval cannot be inconsistent with the provisions of the Data Protection Act 1998 and the onus remains for applicants to satisfy themselves that they remain compliant with any other legal provisions. Advice on the Data Protection Act 1998 should be sought from the Information Commissioner's Office (ICO).

Additional points

Members noted that access without consent had not previously been tested with service users as the intent had been to proceed on consented basis. Previous engagement for the original consented cohort had focused on question development and study questions were piloted through visits to military bases. Noting some user involvement would be undertaken via the Steering Group, members advised that it may be beneficial to enhance engagement with service personnel.

It was noted that this was a short term study and that support was expected to expire at the end of the 12 month period. It was advised that an end study report must be provided at the end of this period, confirming that all bodies processing identifiable information under this support have ceased and all identifiable information is deleted where an alternative legal basis is not in place.

Confidentiality Advisory Group advice conclusion

The CAG agreed that the minimum criteria under the Regulations appeared to have been met 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. Sufficient time must be allowed by the applicant to ensure that information on the proposed activity is provided, using all reasonable communication methods, in advance to the cohort to enable time for review and any objections to be made. This should take place prior to any data flowing to the HSCIC / SAIL.

2. Data generated in Scotland is excluded from the scope of this approval due to the restrictions of the Health Service (Control of Patient Information) Regulations 2002, and an alternative legal basis should be identified to link with this data.

3. Favourable opinion from the Research Ethics Committee or REC confirmation to be provided that a specific amendment is not required for this non-consented activity. Pending.

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

5. Once linkages have been undertaken between the data from the military cohort study and secondary healthcare records, an end closure report should be submitted no later than 12 months following final approval, confirming that the HSCIC and SAIL have deleted all relevant information and there is no further processing of identifiable information taking place under support.

b) Case-control study for Campylobacter in the under 5s [15/CAG/0128]

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 would 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. The applicant had also 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 identified that confidential patient information for all children under the age of 5 would need to be extracted from all English NHAIS systems.

The application for support was first reviewed through the precedent set process and had been deferred to the April 2015 meeting by the Chair.

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.

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 raised concern 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. It was highlighted that as the applicant identified a practical alternative mechanism within the application, support was therefore, not recommended or required to select and contact a large cohort for the healthy control through the HSCIC. The practicable alternative for the healthy control cohort specified within the application was for the applicant to ask the consented cohort to invite friends and family who have well children aged five years or invite participants through mumsnet.com.

Patient Communication and Transparency

Members noted that within the patient communication materials, the content referred to both Campylobacter and food poisoning. Members advised that wording should be clear and consistent throughout the materials. Members also advised that if the practical alternative could not be adopted and a further submission was not met. The letter to the healthy control cohort should be included within the application and explicitly state the purpose for including healthy five year olds as a control within the study.

Identifiers

Members noted that the applicant confirmed that identifiers would have been removed once the activity of selecting and contacting patients had been completed and highlighted that identifiers would not be retained for the duration of specified retention period for the overall study data.

Confidentiality Advisory Group advice conclusion

Cases

In line with the considerations above in relation to the activity which was to be undertaken by Public Health England, the CAG agreed that the minimum criteria under the regulations appear to have been met, and therefore advised that the application was supported. Members agreed that the purpose of this part of the application was to obtain consent from the patients and therefore, it would not be feasible for the research team to obtain consent prior to the specified Public Health England activity.

Control cohort

In line with the considerations above in relation to identification and contacting of the healthy control cohort, the CAG agreed that the minimum criteria under the Regulations did not appear to have been met, and therefore advised that the application was not supported.

Members advised that should the applicant wish to re-submit the application for support, the following factors must be considered:

1. Members noted another practical alternative would be to request Health and Social Care Information Centre (HSCIC) to randomise the sample and to write directly to the cohort rather than forwarding the confidential patient information to the applicant. This would still require s251 support due to the confidential patient information disclosure to the HSCIC and would prevent further disclosure to the research study team.

2. Letter to the healthy control cohort should be developed to explicitly state the purpose of including the healthy five year olds cohort as a control within the study.

3. Members noted that the response to the Data Protection questions within the application was insufficient and therefore, the applicant should visit the Information Commissioners' Office (ICO) website to seek further guidance, in particular surrounding fair processing.

4. 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.

c) Comparison of bleeding after ACS between ticagrelor and clopidogrel [15CAG0134]

This application from Aintree University Hospitals NHS Foundation Trust set out the purpose of conducting a study of patients who have been treated for Acute Coronary Syndrome (ACS) with either ticagrelor or clopidogrel and corresponding patient bleeding. The study will involve six Mersey network sites in the review of patient records for the last 2500 patients who received clopidogrel for ACS as a new prescription prior to a change in guidelines, and then the same review will be conducted on the last 2500 ticagrelor patients. HES data would be received to identify relevant patient admissions and mortality data will be collected to supplement/confirm locally held information.

A recommendation for class 1, 4 and 6 support was requested to cover access to an authorised user to extract and anonymise information and link patient identifiable information obtained from more than one source.

Confidentiality Advisory Group advice

Public interest

Members noted the further information provided in relation to the public interest in the activity taking place, in particular it was noted that the inclusion criteria went beyond that of previous studies.

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.

CAG had previously requested further information and explanation regarding reasons why consent was not considered to be feasible. Members noted the additional information provided and agreed that consent for retrospective patients would not be feasible given that the patients may have been treated up to five years ago. However, members were of the view that consent may be possible for those patients being treated prospectively and requested that the applicant attempt to gain consent for these patients.

Patient notification

Members noted that patient information posters had been developed to inform patients about the processing. It was noted that the poster did not provide an opportunity to opt out of the processing via local clinical care teams and members requested that the applicant ensure that patients could opt out locally prior to any information being accessed by researchers.

Members suggested that the applicant ensure that Information Commissioner's Office guidance in relation to privacy notices was followed to ensure that the requirements under the Data Protection Act 1998 to provide fair processing information were met.

User involvement

Members were pleased to note that the applicant had consulted with a patient group in relation to the study.

Confidentiality Advisory Group advice conclusion

In line with the considerations above, 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. Consent should be sought from patients who are treated prospectively.

2. The patient information poster should allow a mechanism to register patient objection locally and this is respected.

3. Favourable opinion from a Research Ethics Committee.

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

6. AMENDMENTS TO APPROVED APPLICATIONS

a) National Oesophago-Gastric Cancer Audit [ECC 1-06(c)/2011]

This application from the Health and Social Care Information Centre provided details of a follow-on audit of the National Oesophago-gastric (OG) cancer audit, due to commence in April 2011. The Audit would examine the quality of care received by patients with oesophago-gastric cancer in England and Wales. Linking with the first Oesophago-gastric Cancer Audit would allow for results to be

published on a longitudinal basis and so highlight areas where care had improved and where improvement was still needed.

A recommendation for class 3, 4, 5 and 6 support was sought to collect data on all patients aged 18 and over who had been diagnosed with oesophago-gastric cancer between 1 April 2011 and March 2014 in England and Wales. Support was also sought to permit linkage with the first National OG audit in order to carry out longitudinal analyses, and to extend the cohort in April 2012 to include patients in England and Wales diagnosed with High-Grade Dysplagia. In particular, the audit requested access to NHS Number, postcode, sex, and date of birth. Linkages would be carried out with mortality data, HES, PEDW and the Casemix Programme within the ICNARC datasets.

Amendment request

The amendment request specified a change to the exit strategy specified within the original application. The amendment specified that in subsequent years consent had proved not to be feasible and the applicant confirmed that a number of issues in pursuing this approached had been identified. It was noted that the annual reviews were approved at each stage). Formal confirmation that the movement away from seeking consent had been reviewed by CAG was requested.

The applicant outlined a number of reasons why consent would not be feasible within the amendment request.

Confidentiality Advisory Group advice

Members reviewed the request and agreed with the reasons detailed within the amendment and previous annual reviews that consent would be considerably difficult to obtain whilst maintaining sufficient coverage for audit purposes. Members agreed that the audit aims were in the public interest and agreed that this amendment could be approved.

Confidentiality Advisory Group conclusion

In line with the considerations above, it was 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.

7. MINUTES OF THE MEETING HELD ON 26 MARCH 2015

The minutes of the meeting held on 26 March 2015 were approved subject to minor changes. The Chair confirmed that they had escalated CAG advice in relation to establishing precedent for patient notification plans for integrated care pioneers to the National Data Guardian in line with the action from the March meeting,

8. CAG CHAIR REPORT

External meetings

Integrated pioneer applications

Dr Mark Taylor and Ms Natasha Dunkley attended a meeting with Karen Wheeler, National Director for Transformation and Corporate Operations at NHS England, to discuss applications for support from 'integrated pioneer' sites.

CPRD

Dr Mark Taylor met with Dr Janet Valentine, Clinical Practice Research Datalink (CPRD) Director at the Medicines and Healthcare products Regulatory Agency (MHRA). Dr Taylor agreed that it would be useful for Dr Valentine to speak to CAG about the changes being made to CPRD and to further explore how CPRD and CAG might work together in the future.

Action: CAT to schedule CPRD education session for upcoming CAG meeting.

9. CAG OFFICE REPORT

For information

Secretary of State Approval Decisions

The Department of Health 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 April 2015 meeting applications.

HRA approval decisions

The Health Research Authority agreed with the advice provided by the CAG in relation to the April 2015 meeting applications.

External meetings

CAG/HSCIC interface

Dr Mark Taylor, Ms Natasha Dunkley, Dr Tony Calland and Mr Bill Davidson attended a meeting with HSCIC to continue discussion and development of CAG/HSCIC interface prior to start of new role.

HRA projects

Dr Mark Taylor had drafted scenarios for Guidance on Participant Identification; these had been sent to Ms Natasha Dunkley and Ms Amanda Hunn for comment.

Dr Mark Taylor reported that work had started to the draft the IRAS Information Governance questions for the HRA approvals programme, mapping against requirements of v12 IG Toolkit.

Amendments to Approved Applications

Homicide by Patients with Schizophrenia: a case-control study - ECC 7-05(b)/2011

This research application from the University of Manchester set out details of a case control study which would compare those patients with schizophrenia who kill and those who do not. The study would look for difference in demographics and also in the treatment that was received. The methodology would utilise data from the National Confidential Inquiry into Suicide and Homicide (NCISH) for cases, which had previously received a recommendation of support (PIAG 4-08(d)/2003).

A recommendation for classes 4, 5 and 6 support was requested to provide a legitimate basis to access HES data on 750 controls, matched by age and sex to cases. HES data would be used to identify consultants in order to send questionnaires relating to the patient's care and treatment.

Access to HES data including local patient ID, NHS number, sex, date of birth, admission date, discharge date and consultant code was requested. A questionnaire requesting information on the patient's demographic characteristics, clinical and forensic history and aspects of their care and treatment would then be completed by the relevant local care team.
Amendment request

An amendment request was received seeking to extend the period for which data was collected for an extra fourteen months, from 31 January 2015 until 31 March 2016. The amendment requested was reviewed by the Confidentiality Advice Team who noted the change and advised to continue the submission of annual reviews.

In line with the considerations above, the Confidentiality Advice Team 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.

NHS Central Register Applications

The NHS Central Register application are historical applications that previously had support under the NHS central register application (ECC 2-04(c)/2010) to receive mortality, GP registration or cancer data. The HSCIC previously acted as the first point of contact for all applications and had sent out letters to all affected customers.

The following table provides an update on the current status of Central Register applications.

Conditional Approval/Final Approval

Study	CAG Reference	Approval Status	Specific Conditions

Familial Risk of Prostate Cancer	CR15/ 2014	Conditional Approval	Submission of Information Governance Toolkit (IGTK)
UK Study of Families Of Ataxia Telangiectasia Patients	CR16/ 2014	Conditional Approval	Submission of Information Governance Toolkit (IGTK) and REC favourable opinion
Epidemiological Study of BRCA1 & BRCA2 Mutation Carriers.	CR17/ 2014	Conditional Approval	Submission of Information Governance Toolkit (IGTK)
-Carephilly Ischaemic Heart Disease Study -Speedwell Study – Longitudinal Study of Ischaemic Heart Disease -Early Life Origins of Insulin Resistance	CR20/ 2014	Conditional Approval	Submission of Information Governance Toolkit (IGTK) and to follow specified exit strategy using anonymised data.
ISIS 2: Streptokinase Aspirin after Myocardial Infarction.	CR21/ 2014	Conditional Approval	Submission of Information Governance Toolkit (IGTK) and REC favourable opinion.
ISIS Study of Causes of Heart Attacks.	CR24/ 2014	Conditional Approval	Submission of Information Governance Toolkit (IGTK) and REC favourable opinion.
British Doctors Follow Up Study	CR25/ 2014	Conditional Approval	Submission of Information Governance Toolkit (IGTK) and REC favourable opinion.
Study of Birth Cohort From Hertfordshire	CR28/ 2014	Conditional Approval	Submission of Information Governance Toolkit (IGTK) and REC favourable opinion.
Sheffield Birth Cohort	CR29/ 2014	Conditional Approval	Submission of Information Governance Toolkit (IGTK) and REC favourable opinion.
National Paediatric Leukaemia Clinical Trials	CR36/ 2014	Conditional Approval	Submission of Information Governance Toolkit (IGTK) and REC favourable opinion..
Addition - Cambridge	CR38/ 2014	Final Approval	Submission of Information Governance Toolkit (IGTK) and REC favourable opinion.

Applications Included within Extension

The Confidentiality Advice Team had sent out a letter to applicants who could evidence that a REC had reviewed the original application on behalf of Catherine Blewett, HRA Improvement and Liaison Manager. The letter outlined the requirement for applications to be submitted to a Research Ethics Committee through a bespoke proportionate process to ensure current ethical standards were met. Support under the Health Service (Control of Patient Information) Regulations 2002 provided for these applications had been recommended to be extended until the 31 May 2015 under Chair's action. Following this date, support would revert to conditional only and applicants would need to provide confirmation of a favourable REC opinion in order for final support to be continued. Applicants were also advised that it was likely that

the required confidential patient information could not continue to be provided after this date until the REC favourable opinion had been confirmed.

Study	CAG Reference
Women with Benign Breast Disease	CR18/2014
Environmental Factors in Early Life and Ischaemic Heart Disease.	CR19/2014
MRC/BHF Heart Protection Study	CR22/2014
Early Breast Cancer Trial Lists Collaborative Group	CR23/2014
THRIVE: Treatment of HDL to reduce the Incidence of Vascular Events	CR27/2014
Mortality of Gulf War Veterans	CR30/2014
National Registry for Radiation Workers	CR31/2014
NWTPS (Nuclear Weapons Test Participants Study)	CR32/2014
Mortality Workers and Windscale Calder Works	CR33/2014
Study of the Effectiveness of Additional reductions in Cholesterol and Homocysteine	CR34/2014
MRC Study of Assessment of older people in the community (MRC Older People Study)	CR35/2014
3 Consecutive National CLL Clinical Trials which Recruited Patients between 1984 and 2004	CR37/2014
Health of Civil Servants 2	CR39/2014

Updates on Existing Applications

Access to healthcare and impact on health inequalities 15/CAG/0001

This application from University of Leeds set out the purpose of a study which aimed to investigate the relationship between distance/transport accessibility to healthcare services and health inequalities. The study would focus on patients with Rheumatoid Arthritis and Osteoarthritis.

A recommendation for class 2 and 6 support was requested to cover access to Hospital Episode Statistics (HES) data in relation to hospital appointments for Osteoarthritis or Rheumatoid Arthritis across a 3 year period (approximately 20,811 per year). Confidential patient information was also requested from NatCen in relation to the English Longitudinal on Aging (ELSA) cohort (approximately 3,300). Access was requested to the datasets outlined including postcode.

The application was considered at the January 2015 meeting and members agreed that they were supportive. The applicant was asked to explore whether it would be

feasible to provide relevant training to HSCIC staff to allow them to apply the relevant software on their behalf and utilise this option if available. The applicant received the confirmation from the HSCIC that they would be unable to apply the software on the applicant's behalf and final approval was subsequently confirmed. The response from the Health and Social Care Information Centre (HSCIC) was provided for member's information.

10. ANY OTHER BUSINESS

Information Commissioners Office (ICO) webinar – Troubled Families evaluation

Ms Hannah Chambers provided a brief summary of the webinar held by the ICO on 23 April 2015. The Chair thanked Ms Chambers for attending the webinar and providing information to members.