NHS
Health Research Authority
Confidentiality Advisory Group

Minutes of the meeting of the Confidentiality Advisory Group
8 August 2013 at 9 am at the Grand Connaught Rooms, WC2B 5DA

Present:

Name	Capacity
Dr Mark Taylor (Chair)	Lay
Dr Kambiz Boomla	
Dr Tony Calland (attending by phone, for items 6a-6b)	
Dr Robert Carr	
Mr Paul Charlton	Lay
Ms Madeleine Colvin	
Dr Patrick Coyle	
Dr Tricia Cresswell (vice-chair)	
Mr Anthony Kane	Lay
Ms Clare Sanderson	
Dr Murat Soncul	
Mr C. Marc Taylor	
Dr Christopher Wiltsher	Lay

Also in attendance:

Name	Position (or reason for attending)
Ms. Natasha Dunkley	Confidentiality Advice Manager
Ms. Claire Edgeworth	Deputy Confidentiality Advice Manager
Professor Andrew George (item 4b)	Chair, National Research Ethics Advisors Panel
Dr Robert Kyffin (item 7 onwards)	London Knowledge and Intelligence Team, Public Health England, observer
Ms. Rebecca Stanbrook	Director of Confidential Advice – section 251
Ms Julie Stone	Non-Executive Director, HRA, observer

1. INTRODUCTION, APOLOGIES FOR ABSENCE AND DECLARATIONS OF INTEREST

Apologies were received from Dr Charlotte Augst, Professor Julia Hippisley-Cox, Professor Jennifer Kurinczuk, Ms Gillian Wells, Mr Terence Wiseman and Mr David Evans.

The following interests were declared:

- Ms Clare Sanderson declared a competing interest in item 5 as one of the applicants, but as this item was an update with no recommendation to be made, it was agreed that she should remain in the room.

- While not a member of CAG and attending in the capacity of representing the HRA approval function, Ms Rebecca Stanbrook indicated that as she was employed by the Medicines and Healthcare products Regulatory Agency, she would leave the room for the duration of the discussion of items 6a and 6b.

- Mr Marc Taylor and Ms Clare Sanderson declared competing interests in items 6a and 6b but remained in the room and took part in the discussion.

- Ms Clare Sanderson declared a competing interest in item 7f as this application involved use of services provided by the Health and Social Care Information Centre, but it was agreed that this did not represent a bar to her remaining in the room and participating in the discussion.

- Dr Tricia Cresswell declared a potential conflict in item 8b as she had previously managed the regional maternity office (Newcastle University)at various times between 1996 and 2006. As she had ceased this role in 2006 with no current affiliation, it was agreed that this was not a current conflict and she remained in the room and participated in the discussion.

2. MINUTES OF THE MEETINGS HELD ON 13-14 JUNE 2013

The minutes were agreed as an accurate record, subject to minor amendments.

3. CAG OFFICE REPORT AND MATTERS ARISING

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 June 2013 meeting applications.

With respect to CAG 4-08(c)/2013, the National Clinical Coding Audit, additional emphasis was requested on staff training. Assurances were provided from the Confidentiality Advice Team (CAT) that this specific point was included within the IG toolkit assessment and that CAT would ask for assurance in relation to this aspect in particular from the IG toolkit assessment. In addition, the SofS representative was informed that it was detailed within the application that all auditors were approved clinical coding auditors under the arrangements specified originally under NHS Connecting for Health. The SofS representative agreed to approve the application as recommended following these additional assurances.

Discussions are still taking place with various Department of Health representatives in order to agree a standardised form of wording to ensure suitable emphasis is placed on appropriate fair processing and patient right of opt-out as part of any approved application, although there are issues in seeking to provide standardised responses that are applicable to all scenarios.

HRA approval decisions

The HRA agreed with the advice provided by the CAG in relation to the June 2013 meeting applications.

Operational and CAT advice updates

Information Governance Toolkit (IGT)

Following on from a presentation delivered within the higher education sector, and various concerns expressed by these potential applicants over how the IGT operates, the CAT has been working with the IG Delivery Team to seek to take forward these concerns. New points of contact have been established within the IG Delivery Team and following the initial workshop it was agreed that the current guidance could be improved to meet the specific requirements of this sector. The guidance was currently being revised by the IG Delivery team.

IRAS changes

It was noted that there had previously been limited ability to revise the IRAS form and questions. The HRA had recently developed the technology to enable question specific guidance to be updated, but not the questions. Ms Edgeworth was currently updating the question specific guidance which is scheduled for completion in September.

The intent is for a new specification to be developed for a new version of IRAS. Ms Dunkley provided the background to this work and noted that while the HRA has requested particular focus to be on the Data Protection compliance section, there was a need to review all questions to ascertain whether they were still relevant and proportionate. Ms Dunkley asked for members to support a review the questions to enable feedback to be provided. The ICO representative had separately agreed to provide a check to any suggestions around the data protection section. Dr Chris Wiltsher, Dr Patrick Coyle and Dr Robert Carr agreed to support this review.

Action: Ms Dunkley to establish sub-group to review IRAS future questions and liaise with ICO

Research Databases CAT review

A proposal had been suggested for the CAT to advise on research database applications that did not require support under the Regulations on general information governance aspects in order to support the HRA assessment project. An initial review of applications had been carried out as part of an exploratory pilot, with a report to be provided by Ms Dunkley to the Director of Operations for consideration. Depending on the proposed volume of applications it was anticipated that this responsibility would be brought into the CAT remit.

Recruitment

The team transferred into the HRA with a vacant post and an existing fixed term contract; the latter had been extended to end December 2013 for Mr Martin Frowd. Progress had been made in relation to the current vacant post and it was anticipated that the vacancy would be advertised in August 2013 for a permanent staff member to enable the CAT to support the move to monthly meetings from April 2014, to support timely review of proportionate review applications and to support the ISO accreditation process and additional projects arising from integration within the HRA.

REC/CAT interaction

A guidance document outlining interaction between REC staff and Members and the CAT has been drafted. This included a process for managing situations where advice provided by the CAT in relation to a query might have an effect on a REC approved study and vice versa. In addition, the document outlined processes for resolving disputes between CAG and RECs and sharing review outcomes. The document aimed to facilitate communication between REC staff and CAT and ensure aligned outcomes from the HRA. In addition to the guidance, the CAT would also be visiting REC offices in September/October to provide training sessions on the role of CAG in order to raise awareness.

Royal Liverpool and Broadgreen University Hospitals NHS Trust (RLBUHT) – consent for consent model

A request for advice in relation to a proposed model for participant recruitment at RLBUHT was received and advised upon by the CAT; the model would seek patient consent to be included within a database which would then be used by researchers to identify potential participants. Participants would provide consent for their data to be included within the database and for further information from their medical records to be used to identify whether they were suitable for inclusion for specific research studies and for researchers to contact them to invite them to take part. Participants would be contacted every two years for further consent to be included within the database. The following advice

was provided, utilising advice originally provided against the South London and Maudsley Trust model:

1. The minimum amount of data necessary should be accessed in order to identify the cohort.

2. Medical record review should only be carried out where necessary and this should be made explicit within the consent form participants were asked to sign.

3. It was unclear whether participants would expect that academics on honorary contracts would have access to their data given that it was advised that RLBUHT staff only would have access. As honorary contracts on their own did not confer right of access to patient confidential data, this should be made more explicit within patient information to ensure that access by academic partners was reflected. Access should then only take place where a substantive contract of employment with RLBUHT or one of their academic partners was in place. Honorary contracts needed to be supported by a substantive contract of employment with disciplinary procedures for breaching confidentiality.

4. RLBUHT had a responsibility to ensure that collaborating organisations had robust information governance safeguards in place to ensure the secure and confidential transfer and storage of personal data. Secure email methods should be incorporated.

5. Those patients that requested removal from the consent for consent database should have their data removed from the database.

6. If requesting explicit consent every two years there might be issues in relation to the Data Protection Act with the continued inclusion of these patients on the database. Guidance from the ICO had indicated that, where a data controller had previously sought to rely on explicit consent as a schedule 3 condition to process sensitive personal data, they could not then rely on another condition, such as a medical purpose, and therefore if seeking explicit consent every 2 years, continuing to process data from those participants who did not respond might be inconsistent with the DPA. RLBUHT were advised to contact the ICO.

7. The previous response to queries indicated that 'Health care staff trained in C4C consent' would make the initial approach, but taking into account the point made in the Caldicott review that in most cases, the approach to participate should be undertaken by an established member of the care team, initial approaches for inclusion on the database should be undertaken by RLBUHT staff who had been responsible for the care of the patient.

8. Confirmation was sought that consent would be sought for contact research only and the data would not be used for analysis without further consent.

CAG away day

Members were advised that there would be an away day on 29 November. The purpose of this session would be to discuss decisions and precedents set in the previous nine months.

Working Groups update

Practicable alternatives working group

The first meeting of the practicable alternatives working group took place in July 2013. The first meeting included discussions around the scope and presentation of guidance along with plans to ensure that relevant stakeholders were consulted with and informed. Dr Alan Hassey from the Caldicott 2 Review team had agreed to take part in the working group in order to ensure outcomes were aligned with the Caldicott 2 Review and to bring further expertise to the group.

External meetings and events

Information Service Commissioning Group – Information Governance sub-group update

The second meeting of the IG sub-group took place in mid-July and now included representation from Monitor and the UK Council of Caldicott Guardians. Items discussed so far included the draft Department of Health (DH) response to the Caldicott 2 Review and actions around local authorities, risk stratification guidance and accredited safe havens. It was anticipated that the DH response would be due for publication in approximately October 2013. Early indications were that the DH would broadly support the recommendations.

Wales information sharing update

Following discussion at the last CAG meeting, a workshop had been scheduled with Welsh colleagues on 12 September to share information on the CAT activity and work taking place around applications at the office level. Dr Patrick Coyle would also be attending.

ICO information sharing workshop

Following a meeting with Dr Mark Taylor, the CAT and audit colleagues at the ICO, it was agreed that a workshop would be organised in September to provide information on how the CAT reviewed applications.

Action: CAT to arrange meeting and deliver information sharing workshop with ICO

Public Health England (PHE) update

Ms Stanbrook and Ms Dunkley had met with representatives of PHE to review the operation of functions since the changes in remit from 01 April 2013. As responsibility for Regulation 3 (excluding 3(4) had transferred from CAG it was highlighted that some queries had been received where the CAT had been unable to advise due to the change in remit. It was agreed that PHE and CAT would have quarterly meetings with PHE representatives.

Members were updated that a workshop to discuss the potential broadening of the interpretation of Regulation 3 took place on 1 August and Dr Mark Taylor, Dr Tricia Cresswell and Ms Stanbrook attended. The meeting had not tackled the issues of 'other risks to public health' as focus had been on local authorities and their needs for patient confidential data (PCD). The outcome from the meeting was for Dr Robert Kyffin to draft a paper to seek further agreement on what had been discussed in relation to local authorities. Once received, it was expected that Dr Taylor would seek to work with PHE on the extent to which Regulation 3 provided a legal basis for activities, or whether another legal basis would be more appropriate. It was noted that reliance upon Regulation 5 could be advantageous especially if the need for PCD by local authority public health was likely to be a transitional measure as the capacity to deliver pseudonymised data could be developed by other bodies in the future. Work was currently being undertaken by PHE to specify local authority need for identifiers as a temporary measure and also to look at the possibility of standardising the number of legitimate uses of PCD and circumstances when it should be used. Members discussed the possibility of reliance upon Regulation 5 and whether an alternative approach to handling could be developed and analogies were drawn to the arrangements for accredited safe havens and the role of NHS England in monitoring this. Members also noted that the fair processing information provided by NHS England made reference to public health activities and questioned whether this was sufficient to cover the proposed processing of information. In particular, it would be important for PHE to establish a unified understanding of what would be covered. Dr Taylor confirmed that he would update the Group once a list of purposes and need for PCD had been established.

Members discussed who would be advising those operating under Regulation 3 as it is permissive and if there is doubt about the advice, then this could have a detrimental effect on staff operating underneath it. Members noted that as CAG no longer has remit for advising on Regulation 3, that the offer to participate in the workshop and subsequent actions was to be welcomed.

In terms of novating applications to PHE, there were a number of queries still to be resolved. For example, the BINOCAR application had not transferred in its entirety and only two registries had transferred, with the applicant being unaware of the potential PHE novation. Queries had also been raised from the University of Leeds over the status of specialist cancer registries, with other, unexpected, applications transferring into PHE. It had been acknowledged that currently PHE had limited dedicated capacity in place to handle 'section 251' queries in detail at present.

Regulation review update

The National Information Governance Committee of the CQC would have responsibility for advising the SofS on any potential changes to the Regulations; such change had been reported in the HSJ in the context of access to information for commissioning purposes. There had previously been limited engagement from the CQC in relation to this specific responsibility despite requests. The Chair of the HRA was at an event with the CQC Chief Executive and following action from the CAT and HRA Communications, an introduction letter had been sent in order to suggest CAG observer status and to identify a point of contact to collaborate with. Updates would be provided when received.

Applications considered via proportionate review

CAG 5-03(PR1)/2013 – ELN survival follow-up study

This research application from University College London Hospital detailed a study to assess 3 year survival data in a group of patients who have undergone an emergency laparotomy (EL). Access was requested to data collected as part of a national audit of perioperative care which was currently held locally at NHS sites and mortality data from the Health and Social Care Information Centre (HSCIC). Access was requested to name, hospital number, NHS number and date of birth in order to send to the HSCIC and flag patients on the NHS Central Register. Mortality data would be provided to the applicant every 3 months until April 2014 in a pseudonymised format. This application was considered via proportionate review under criteria 4; *time limited access in order to carry out linkages and then pseudonymise the data.*

Members noted that some patients would have died since the original audit was undertaken and that, given the historical nature of the original data collection, consent would be difficult to obtain. It was noted that the application specified that most identifiers would be removed once initial data linkage with the HSCIC had taken place and pseudonymised data only would be disclosed from the HSCIC to the applicant until April 2014. Date of birth and death would be retained in order to calculate intervals; Members advised that these should be removed from the dataset as soon as these calculations had taken place. Members discussed that no attempts appeared to have been made to carry out fair processing in relation to the application. It was suggested that reasonable efforts should be made to inform the cohort in line with the Data Protection Act 1998 and this should include providing them with an opportunity to dissent. Members advised that information should be provided on relevant websites and suggested that consultation with a relevant patient group should take place in order to raise awareness of the activity.

The Group agreed that the minimum criteria under the Regulations appeared to have been met, and therefore advised recommending *conditional* support to the Health Research Authority, subject to confirmation of activities to be undertaken to ensure that reasonable efforts be made to inform the cohort in line with the Data Protection Act 1998, and confirmation that full dates of birth and death would be destroyed once the necessary calculations had taken place using this data.

CAG 5-03(PR2)/2013 - United Kingdom Immune Thrombocytopenia Registry

This research application from Barts Health NHS Trust set out the purpose of studying the natural history of immune thrombocytopenia (ITP), a rare disease characterised by platelet drop and bleeding, estimating prevalence and incidence of comorbid illnesses in the ITP cohort, and describing current treatment pattern and measuring treatment effectiveness. A database was already in place collecting demographic, clinical and treatment data using a fully consent based model. A

recommendation for class support was requested to cover access to Hospital Episode Statistics (HES) and mortality data from the Health and Social Care Information Centre as the consent form did not make reference to this. The additional HES data would be used in order to validate data already collected by the study and enhance the overall data capture. This application was considered via the proportionate review process under *criteria 7 – validity of consent.*

Members noted that the consent form included no reference to central sources being used to collect data in relation to patients and referenced medical records held at the Royal London Hospital only. Members discussed that although references were made to medical records, of which data held by the HSCIC could be considered to be a part of, there was no definitive confirmation that this had been accepted. Due to this, Members agreed that it would be reasonable to recommend support in order to provide a legal basis for the disclosure of the specified data and that this would be in the spirit of the original consent provided.

The Group agreed that the minimum criteria under the Regulations appeared to have been met, and therefore advised recommending *provisional* support to the Health Research Authority.

CAG 5-03(PR3)/2013 - Mortality outcome in the London COPD cohort

This research application from University College London sought permission to obtain and use date and cause of death of previous participants in a consented COPD patient cohort. This cohort began in 1995 and 600-700 patients gave written informed consent to members of the study team accessing their medical notes. This consent did not explicitly include permission to link to mortality records to obtain date of death. The study team were routinely informed of date of death where the patient was still in contact with the hospital, but requested permission to use the Health and Social Care Information Centre to determine the current status of patients who were no longer in contact. This application was considered via the proportionate review process under *criteria 2 – Access to deceased persons' records.*

Members agreed that the study was worthwhile and noted that some of the cohort were recruited in the study almost 20 years ago. Members queried whether those that had withdrawn from the study had effectively withdrawn their consent for researchers to access their data. As this was unclear, Members agreed that further mortality data should not be accessed in relation to those that had chosen to withdraw.

The Group agreed that the minimum criteria under the Regulations appeared to have been met, and therefore advised recommending *provisional* support to the Health Research Authority.

CAG 5-03(PR4)/2013 - Cardiff and the Vale University Health Board (Wales) inpatients and day cases survey contributing to an assessment of health status contribution to Quality of Life Years

This service evaluation application from Quality Health set out the purpose of a survey of patients treated in Cardiff and the Vale University Health Board or Velindre NHS Trust hospitals, in order to inform the planning of future services and investigate the impact of health status on overall wellbeing. A recommendation for class 2, 4 and 6 support was requested to cover access to patient contact details to enable survey questionnaires to be sent out. Access was requested to name, address, NHS number and date of discharge. It was noted that the methodology proposed was the same as that approved in many previous survey applications and it had therefore been established that this was appropriate and reasonable. This application was considered via the proportionate review process under criteria 1, *applications to identify a cohort of patients and subsequently to seek their consent.*

Members commented that the information on the front page of the questionnaire did not appear to reflect the processing of personal data included within the application. Members were of the view that this should be amended and were of the view that the second bullet point referred to access by Quality Health prior to the survey being disseminated and that references to the Secondary Use Service might not be recognisable to patients. This appeared to cover access to data beyond that as

specified within the application. Members suggested amending both bullet points to reflect the linkage of information by the Cardiff and Vale Health Board already held in relation to their health care as detailed within the application and that data would be anonymised (by removing information such as name, date of birth and address) and sent for analysis by an organisation contracted to carry out analysis, to ensure that patients were accurately informed of the implications of returning the questionnaire. Members asked that the applicant amend the cover page of the questionnaire to ensure that patients were provided with an accurate description of the further uses of their data for the purposes of this survey.

The Group agreed that the minimum criteria under the Regulations appeared to have been met, and therefore advised recommending *provisional* support to the Secretary of State, subject to the requested amendment of the cover page of the patient questionnaire.

CAG 5-03(PR5)/2013 – Melanoma Lifestyle Study

This research application from the University of Leeds set out the purpose of a study which was part of a programme of work looking at lifestyle and genetic factors affect the risk of melanoma returning after treatment, with a particular focus on the effect of vitamin D. A recommendation for class 1, 3 and 6 support was requested to allow the project manager to identify patients at one site for the purpose of identifying patients in order for the clinical care team to then seek consent to take part in the study. Access was requested to histology reports, digital medical records, case note records or results databases to eligible participants at one site in Leeds. This application was considered via the proportionate review process under criteria 1, *applications to identify a cohort of patients and subsequently to seek their consent.*

Members noted that the study was underway and some difficulties had been experienced in identifying and approaching appropriate individuals who met the eligibility criteria. It was discussed that the specified approach of allowing a project manager to access patient notes on site was reasonable and Members agreed that there appeared not to be an alternative to this time limited access prior to seeking consent.

Applications for support under the Regulations should not be inconsistent with the requirements of the Data Protection Act 1998. The first principle of the DPA requires that reasonable efforts are made to inform data subjects about processing of personal data. Members queried how the applicant would ensure that reasonable efforts were made to inform patients of the processing of their data without consent in this instance. Members received a copy of the presentation which would be displayed within clinics and advised that as a minimum the applicant should introduce a slide to raise awareness of the screening of records by a project manager to identify people suitable for recruitment.

The Group agreed that the minimum criteria under the Regulations appeared to have been met, and therefore advised recommending *conditional* support to the Health Research Authority, subject to the requested amendment to the presentation to be displayed within clinics.

CAG 5-03(PR6)/2013 – 'Heart Watch' Cardiac Rehabilitation: Mortality/Morbidity Audit V3.1

This research application from the University of Hull set out a study to determine patient outcomes following participation in the Heart Watch cardiac rehabilitation programme, and the impact of exercise on cardiorespiratory fitness, through linking the programme's existing dataset to mortality and morbidity data. All participants gave consent for the cardiac rehabilitation programme and to have their clinical exercise and supervised training data routinely collected and used for research purposes. A recommendation for class 1, 4, 5 and 6 support was requested to cover access to mortality and morbidity data from medical records at Leeds Teaching Hospitals' NHS Trust in order to extract and pseudonymise data. Where mortality data was not available from the NHS Trust GP practices would be contacted. Data would be analysed at Leeds Metropolitan University. Access was requested to name, date of birth, date of death and postcode in order to carry out linkages, once linkages had taken place all personal identifiable information would be removed and only the original data custodian at Leeds Metropolitan University (LMU) would retain the key to identification of the

original participants' data. This application was considered via the proportionate review process under criteria 4, *time limited access to undertake record linkage and pseudonymise data.*

Members agreed that the application demonstrated that there would be a public interest in the activity being undertaken. Members noted that consent had been obtained in the first instance but had not included access to additional morbidity and mortality data. In addition, it was noted that consent would be difficult to obtain due to the historical nature of the original data collection and as an estimated 40% of patients would have died. Members agreed that since it appeared that the exercise programme was on going, efforts should be made to amend the current consent form to include the collection of morbidity and mortality data, so that in future, the data collection could be carried out with consent. Identifiable data was required in order to carry out identification of records and linkages. Data would be pseudonymised once entered into the LMU database.

Members commented that the application did not include any information in relation to the fair processing requirements of the first principle of the DPA. Members were of the view that reasonable efforts should be made to inform patients that access to data at the Trust was taking place by displaying information in relation to the study and also including details of how a patient could opt out of further access to their data.

The Group agreed that the minimum criteria under the Regulations appeared to have been met, and therefore advised recommending conditional support to the Health Research Authority, subject to provision of patient information materials for display, including details of the opt-out mechanism, and amendment of the consent form for prospective participants to ensure that future data collection would be undertaken on a consented basis.

Amendments to approved applications

ECC 6-02(FT4)/2012 - Lifelong health and wellbeing of the 'Scotland in Miniature' cohort

The original research application from the University of Edinburgh requested identifiable data (name, date of birth and NHS number) to be provided to the Scottish NHS Central Register who would then transfer data for those patients who had moved or been treated in England and Wales to MRIS. Linkage between HES, MRIS and study data would take place within the Health and Social Care Information Centre (HSCIC) who would access identifiable data on the applicant's behalf and link the data sets. A dataset including date of death only would be provided to applicants. MRIS would also carry out mailing of invitations to a follow up study for those surviving patients who were in England and Wales. Support was requested for a small minority of patients who had moved to England or Wales only.

The amendment request detailed the applicant receiving a separate identifiable dataset including patient name from the HSCIC which confirmed who out of the cohort had died. This was so that the applicant could be assured which individuals should not be contacted again and so that data could be linked back to study data held by the University. Mortality data only would be included within this separate identifiable dataset.

The amendment request was forwarded to the Chair who agreed that, on the understanding that there was no possibility of linkage between the two datasets that would re-identify the HES data, the amendment request could be recommended for approval. The Chair also noted the conditions established by the Scottish Privacy Advisory Committee and advised that the applicant should ensure that these were also applied to the processing of English and Welsh data.

ECC 6-05(a)/2011 - Do Children Born After Assisted Reproduction Have A Higher Mortality Than Those Born After Spontaneous Conception? A Population Based Pilot Linkage Study
ECC 4-03(g)/2012 - General Health & Hospital Admissions in Children Born after ART; A Population Based Linkage Study

These two applications from the same applicant were considered together as a single amendment.

ECC 6-05(a)/2011

This research application set out a study that sought to compare death rates amongst non-donor children born after assisted reproductive technology (ART) as recorded on the HFEA Register. This would be compared against death rates of the childhood population as a whole as recorded by the Office for National Statistics (ONS).

ECC 4-03(g)/2012

This research application set out details of a study to identify whether children born from assisted reproductive technologies are at greater risk of health problems and an increased risk of hospital admissions. Support was requested to enable linking of HFEA records to ONS birth records, and to enable the Health and Social Care Information Centre to link to MRIS and HES records.

The amendment request detailed the following changes:

1. Merging the two applications as they referred to the same cohort and referencing the study as ECC 4-03(g)/2012.
2. The linkage process in its entirety would now be undertaken within the Health and Social Care Information Centre (HSCIC).
3. 2 control cohort members would now be matched to every ART cohort member rather than 3 as specified within the original application.
4. A pilot phase would be introduced into the study, testing the linkage methodology for those children born within 1998.
5. The inclusion of a sibling cohort; de-identified data only would be provided by the HSCIC in relation to this cohort so support would not be required for this aspect of the amendment.
6. Extend the inclusion criteria from all children born after ART between 1992-2008 to all children born between 1 August 1991 to 30 September 2009.

This amendment was forwarded to the Chair who noted that the specified amendments did not increase the identifiability of the requested data and the most significant change was the change in data source from ONS to the HSCIC. It was noted that the extent of HFEA data requested would be increased, as summarised in point 6 above. The Chair noted the initial assessment of the public interest in the activity taking place by the CAG predecessor the Ethics and Confidentiality Committee, and agreed that support should be recommended for access to an extended HFEA dataset. The change of reference number was noted and would be reflected on the register of approved applications on the HRA website.

PIAG 2-08(e)/2002 - BINOCAR

The BINOCAR audit application from Queen Mary University of London (QMUL) had approval to collect identifiable data on all cases of congenital anomalies within the population of England and Wales. A number of regional and disease specific registers of congenital anomalies provided continuous epidemiological monitoring of the frequency, nature, cause and outcomes of congenital anomalies. Confidential information including mother and baby name, address, postcode, NHS number, date of birth and baby date of death were collected from a number of NHS organisations and other outcome datasets.

The submitted amendment request detailed allowing a member of Department of Health (DH) staff access to National Down Syndrome Cytogenetic Register (NDSCR) data in order to compare with DH notification data. The aim of the activity would be to try and match each termination recorded in the NDSCR with that recorded by DH and determine whether the case had been correctly notified to DH. Cases would be matched using postcode and date of birth of mother. All matching would take place at the Wolfson Institute at the University of London on an encrypted DH laptop and NDSCR data would be removed from DH laptops following the matching process.

The amendment requested was forwarded to the Vice Chair who noted that BINOCAR held termination data in relation to congenital anomaly surveillance with support under the Regulations and DH held termination data under the Abortion Act and Regulations for the purpose of monitoring as

required by the Act. It was agreed that it was important to ensure that the DH data was accurate in order to meet the requirements of the Act. It was noted that minimal identifiers would be used to carry out linkages and NSDCR data would be accessed for a time limited period at the Wolfson Institute using security measures outlined within the BINOCAR system level security policy. It was agreed that a recommendation of support could be provided for this specific purpose, subject to confirmation that removable media would be managed in accordance with the existing BINOCAR policy.

Updates on existing applications

ECC 4-03(e)/2012 – Patient Outcomes Registry

This research application from University College London set out details of the establishment of a research database derived from national cardiac audit data that would link care across pathways. The aim was to develop further the research potential of audit data to understand better the causes of coronary heart disease, timing and evolution of risk, and the interplay between biological, interventional and environmental factors. The application was considered by the ECC in July 2012 and provisional approval, subject to conditions, was granted by the Secretary of State on 1 August 2012 on ECC advice. The 1 August 2012 outcome letter set out that the request had been provisionally approved, subject to provision of a favourable opinion from a research ethics committee; an update to patient leaflets to reflect the change in processing purpose; and written confirmation as to who would be the data controller for this purpose, HQIP or UCL.

A brief conversation in person took place with Zoe Fearnley, at the time Chief Operating Officer – NICOR at University College London, on 14 January 2013 to reiterate the need for a response, but it was understood that Ms Fearnley subsequently left UCL. No further response was received with respect to the conditions of approval between January and June 2013. The Confidentiality Advice Team therefore wrote to NICOR on 3 June 2013, to emphasise that although the Confidentiality Advisory Group was keen to support relevant research activities, since more than seven months had passed since this provisional approval was issued and no record had been received on how the conditions had been satisfied, this had now been flagged as an application for closure and would be closed unless a response to all conditions was received within 4 weeks. In accordance with the original provisional outcome letter, it was highlighted that identifiable data related to the TAVI audit could not be processed within the scope of this approval, as the data controller arrangements for this audit differed from the other NICOR activities.

Following the reminder letter to NICOR, a favourable opinion from a research ethics committee was provided on 5 June, along with a copy of the patient information leaflet. A letter was received from HQIP on 26 June 2013 that confirmed UCL would be the data controllers for the purposes of managing all aspects of this research database. As the conditions of approval were now satisfied, final approval was granted by the Health Research Authority on 28 June.

In the meantime, while the application's status was still provisional, an amendment request had been submitted on 22 May 2013 which detailed access to all non-sensitive HES fields for patients included in the Cardiac Rhythm Management Audit, National Heart Failure Audit, National Adult Surgery Audit, National Audit of Percutaneous Coronary Interventions and Myocardial Ischaemia National Audit Project. The Patient Outcomes Registry would be used for collecting and storing all HES and mortality data and HES data would not be stored within the individual audit domains. It was confirmed that the data would be pseudonymised and that links would be achieved using the unique MRIS member number. The data would be used for both research, in line with this application, and audit, in line with the purposes specified in ECC 1-06(d)/2011. (Support for the use of HES data for audit purposes would be provided by the Secretary of State for Health in a separate letter). The amendment request was forwarded to the CAG Chair who agreed that a recommendation of support could be provided for the inclusion of pseudonymised non-sensitive HES data.

ECC 5-05(a)/2012 – Clinical Practice Research Datalink (CPRD)

A teleconference had been arranged to discuss the decision-making process of ISAC on 12 August. This would be attended by the ISAC Chair, Dr Tricia Cresswell and Dr Jenny Kurinczuk.

4. CAG DEVELOPMENT

4a. Future development agenda items

A proposal to include session in relation to pertinent and contemporary topics on future CAG meeting agendas was presented by the Vice Chair. The aim of these sessions would be to ensure the Group provided better informed advice and shared individual Members' areas of knowledge and experience. Each session would be led by a Member of CAG to ensure relevancy. A schedule of suggested topics was presented to the Group for comment.

Members agreed that the proposal to include future items to promote knowledge sharing and learning would be beneficial and should be adopted. Members noted the schedule and agreed that all the topics suggested would be relevant. It was suggested that additional items could be included in relation to the Secure Anonymised Information Linkage (SAIL) methodology and standardisation of requirements, based on past advice, in relation to national audit data flows.

It was noted that one of the topics, impact of specific groups/settings on practicability of seeking consent, did not currently have a Member allocated as lead. This was a significant item and any work would need to be aligned with the HSCIC Code of Practice in terms of handling objections. It was agreed that Paul Charlton and Mark Taylor would lead this item.

The upcoming away day was also discussed and Members were advised that the intention was to review decision making and extract key principles in order to ensure consistent decision making at this meeting, rather than within the proposed CAG development sessions. The intent was to review significant applications, in order to develop position papers informed by evidence and look across the gamut of advice provided to ensure and check for consistency. Internal and external stakeholders would also be invited once a position had been articulated. It was indicated that CAG should review the requirements under Regulation 7, for example, the equivalent duty of confidentiality to that of a healthcare professional, and how this would translate to non-NHS applicants. Comment was made that CAG could review requirements in relation to confidentiality policies and enforcement of conditions of support. It was noted that the National Research Ethics Advisors Panel (NREAP) were undertaking similar reviews in order to ensure that RECs undertook consistent decision making. Members emphasised that need to approach this activity from the broader HRA perspective; ensure alignment and be aware of implications and mitigations in the event of differing approaches.

Action – CAT to finalise schedule and circulate to Members.

4b. REC review and considerations - presentation from Professor Andrew George; Chair of National Research Ethics Advisor Panel (NREAP) at the HRA

Professor Andrew George attended to present REC considerations of research applications to the Group in order to ensure that Members were aware of aspects reviewed by the REC, so as to make sure that CAG considerations did not move into the REC remit where possible and promote closer communication between CAG and RECs.

Following the presentation, Members queried whether RECs reviewed the science of a research application. It was confirmed that RECs had moved away from critiquing the science of a study as this was undertaken by the sponsor and the REC would look to the results of peer review to determine the validity of the science.

Members highlighted that CAG needed to be assured of the public interest in an activity taking place and in order to carry out this judgement it was necessary to determine whether the activity could meet the stated aims. In addition, applicants should seek to demonstrate the public interest in the outcomes if they could be met. It was noted that RECs do not generally follow the principle of retrospective consent e.g. in emergency scenarios.

Members also identified that it would be helpful to understand the criteria to be followed when using PCD to generate anonymised information and the subsequent impact on fair processing, and to understand and seek clarity on how RECs approach this.

The Chair thanked Professor George for attending and highlighted that CAG would be interested to work with NREAP if any guidance were to be produced in relation to the ethical considerations of seeking consent from patients in certain circumstances; given that the Group needed to be assured that consent was not feasible prior to providing a recommendation of support. CAG would also be interested in taking part in the shared ethical debate (SHED) and it was suggested that this could include an application that also required legal support under the Regulations.

5. NHS England – update on patient information leaflet and retention [CAG 2-03(a)/2013]

In follow-up to the original NHS England commissioning application and June update report, Members had requested copies of and clarity on the items specified below; a summary of the discussions and actions are set out accordingly.

Patient information: fair processing and patient objection

In order to achieve compliance with this specific condition of support, Members were provided with a draft version of a leaflet. Members had previously been informed that the intention was for NHS England to utilise the 'care.data' mechanism for fair processing, which would involve a number of national data flows being included within this mechanism. Members had previously expressed concern over seeking to incorporate disparate information flows within one mechanism but understood that this was a pragmatic decision, although with ensuing risks that would need to be carefully managed.

Members noted that the leaflet reflected future data flows, and not those for which legal support currently exists under the approval. The CAG noted that while the intent was to provide a layered approach to fair processing and that there would be an additional layer of complexity in using the 'care.data' mechanism, at a generic level the information provided to patients should be factually accurate to reflect the existing data flows. For example, there was reference to limited personal data being processed by Accredited Safe Havens but this did not reflect the current transitional arrangements in place which involved far greater identifiable information flows which were expected to continue for some time while ASH accreditation was being developed. Members therefore advised that steps should be taken to ensure the existing transitional support was reflected within this approach to fair processing, and requested definitive confirmation on how this would be achieved at the October CAG meeting. Members also commented that the leaflet was unclear in terms of what information would be flowing e.g. whether this included sexual health information, and to whom, and this clarity would be welcomed.

Retention period

Members appreciated that there was some uncertainty over precise retention periods at present and noted NHS England would be reviewing the current Code of Practice. Members were unclear on whether the information would be de-identified or identifiable and whether it applied to ASHs or those handling information during this transitional phase, and sought greater clarity on this aspect as there was a view that relevant organisations should not be accruing large amounts of identifiable information.

It was accepted that this was a draft document, so Members raised the point that there should be specific retention periods for specific, known data flows where feasible. Members were also unclear whether relevant organisations would be retaining information that could reasonably be held by the HSCIC.

In conclusion, Members also sought specific feedback on what would happen to the identifiable information provided to organisations as part of this transitional support in terms of retention when said organisations achieved ASH status, and how oversight on this would be managed.

Privacy Impact Assessment

Due to annual leave Members did not receive an update at the date of the meeting. However, confirmation had subsequently been received from the Information Commissioner's Office that confirmed they were content with the documentation provided and this would shortly be published on the website. CAG had been advised by the ICO that no further action was required following publication.

6. Clinical Practice Research Datalink updates [ECC 5-05(a)/2012]

6a. CPRD free text update

The CAG discussed a briefing paper provided by CPRD that sought an endorsement of the current CPRD approach to processing free text information incidentally received. The Group thanked CPRD for the report, but confirmed that the Group had no remit to review or endorse the processing of identifiable information received outside the scope of an existing approval.

6b. Review of CPRD disclosures & ISAC decision-making

In line with previous correspondence provided to the applicant, Members agreed to defer further consideration of this update until after the teleconference that had been arranged for 12 August, on the understanding that the teleconference was intended to provide further contextual understanding of the risk assessment process. Members agreed that without this contextual background the current spreadsheet could not be usefully interpreted.

7. New applications – non research

7a. National COPD Audit [CAG 5-07(a)/2013]

This audit application from the Royal College of Physicians (RCP) set out the purpose of a pilot activity to test the submission of secondary care clinical audit dataset to inform the National COPD Audit. The application provided details of future plans in order to put the current pilot request into context. The initial pilot phase would identify any necessary amendments to the dataset and data collection systems. The British Thoracic Society (BTS) would collect identifiable data and anonymised data only would be passed to the RCP. A recommendation for class 1, 5 and 6 support was requested to cover access to identifiable data items for the pilot phase to test collection of information, including patient identifiable items, for the purpose of reviewing appropriateness, feasibility and reliability of the secondary care clinical audit dataset. Access was requested to NHS number, date of birth, date of death and postcode.

Members noted that the application included details of the main audit activity which was anticipated to follow the pilot. Members agreed that there was significant public benefit in the aims of the main activity and noted that the pilot activity would help achieve these outcomes.

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 discussed whether consent would be feasible via the local clinical care teams considering that the pilot activity required data in relation to 250 patients in total. The applicant asserted that consent would not be feasible as already busy clinicians were being asked to review notes and extract a large amount of data for each patient and seeking consent would result in a significant additional burden and may result in them being unable to take part in the activity. Members recognised the issues raised by the applicant. However, it was agreed that there might be benefit in testing the feasibility for consent at pilot phase to determine whether clinicians would have sufficient

capacity to seek consent. This would allow any further applications to provide evidence that consent was not feasible if this was found to be the outcome. Members noted that in order to test the audit system it would be necessary to use identifiable data items and agreed that testing the system would support the future audit activity. Members noted that patient posters had been provided which referred to a patient information leaflet and agreed that this would need to be reviewed prior to support being provided.

It was noted that this application was for the pilot activity only and would form part of a suite of applications to be submitted in relation to the COPD audit. Members advised that this recommendation related to the pilot activity only and that there were not enough details regarding the main activity to allow an assessment of whether a future application would satisfy the minimum threshold of the Regulations. The outcome of this application should therefore not be considered to be indicative of any future outcomes.

Members queried whether the applicant had considered whether the web tool could separate demographic data from clinical data and attach a unique reference number for each patient. Demographic data could then be submitted directly to the Health and Social Care Information Centre (HSCIC) and clinical data to BTS. The HSCIC could then provide pseudonymised data containing the unique reference number to BTS which would allow the linkage of clinical data to be carried out using pseudonymised data only and limit those organisations accessing identifiable data.

The Group agreed that the minimum criteria under the Regulations appeared to have been met, and therefore advised recommending *conditional* support to the Secretary of State for Health, to apply only to the pilot activity and subject to provision of the patient information leaflet and consideration of whether a consent based approach could be tested while carrying out data collection for the pilot.

7b. National audit of management of Hepatitis B in pregnancy
[CAG 5-07(b)/2013]

This audit application from University College London set out a national clinical audit of the management of pregnant women with hepatitis B and their babies over a 12 month period. The audit would measure current practice against the NHS Infectious Diseases in Pregnancy Screening Programme standards with respect to referral of all women screening positive for hepatitis B or with a prior diagnosis, and evaluate specialist and perinatal management of hepatitis B positive women and their infants. A recommendation for class 4, 5 and 6 support was requested to cover access to data from maternity services on around 3000 pregnant women screening positive for hepatitis B or with a prior diagnosis of hepatitis B. NHS number would be requested in order to carry out data linkages. Month and year of birth of mother would be used to help de-duplication. Date of birth of infant would be used to establish timing of interventions in relation to delivery. Access was requested to NHS number, date of birth of infant, month and year of birth of mother.

Members agreed that this was an important audit and were supportive in principle of the activity. Members noted the applicant's assertions that consent might be difficult for the audit activity as small numbers would necessitate that data for as many women as possible would need to be included, particularly in relation to the second stage which would include only those patients of high infectivity.

Members noted that identifiable data would be required in order to carry out data linkages and infant date of birth would be required for analysis purposes; however the application identified the possibility of using date shifting in order to de-identify data for the purposes of analysis. Members agreed that this should be utilised which would then result in a pseudonymised dataset being used for analysis.

Regulation 7 (2) of the Health Service (Control of Patient Information) Regulations 2002 determined that processing under the Regulations could only be undertaken by a health professional or a person who in the circumstances owed a duty of confidentiality which was equivalent to that which would arise if that person were a health professional. Members were concerned that it appeared that UCL staff members would not have standard confidentiality clauses within their employment contracts and advised that, in order to ensure that this requirement was met, those staff with access to confidential patient information should be asked to sign confidentiality agreements.

Members noted that query response 1 specified that screening coordinators would be provided with written information to be given to screen-positive women which would also include information relating to opt out. Members requested that the applicant provide this audit specific information leaflet prior to any final approval, and that this should include information regarding how a patient could register an objection to the processing.

It was noted that the Infectious Diseases in Pregnancy Screening Programme was currently being updated and Members advised that the text quoted within query response 1 was now inaccurate as it referred to the National Information Governance Board, which was abolished at the end of March 2013. Members therefore requested that the leaflet be updated to reflect the current arrangements under which the Secretary of State for Health provided approvals under the Regulations for non-research activities such as audit.

Members requested further information in relation to the outcomes of patient consultation with pregnant women with hepatitis B at UCL antenatal viral hepatitis clinic to gain views on the acceptability of uses of confidential patient information without consent.

The Group agreed that the minimum criteria under the Regulations appeared to have been met, and therefore advised recommending *conditional* support to the Secretary of State for Health, subject to provision of a copy of the audit specific information leaflet and further information on the outcomes of patient consultations, confirmation that staff with access to confidential patient information would be asked to sign confidentiality agreements, and confirmation that date shifting would be used to de-identify data prior to analysis.

7c. UK Transcatheter Aortic Valve Implantation (TAVI) Registry, UK Renal Denervation Registry (UKRDNR), and National Neuromodulation Registry (NNR) [CAG 5-07(c)/2013]

This audit application from University College London described three national audit datasets:

1) TAVI – a record of all TAVI procedures performed in the UK since the introduction of the technique in 2007. The dataset included demographic data, indications, procedural details and outcomes up to hospital discharge. Follow up data would be collected at 1 and 3 years.
2) UKRDNR – a UK registry of patients undergoing renal denervation for hypertension.
3) NNR – a database including all patients undergoing neuromodulation.

The datasets would be analysed with the aim to drive improvements in the quality of care. Findings would be shared with participating Trusts and aggregate analysis reports published. A recommendation for class 4, 5 and 6 support was requested to cover access by NICOR to identifiable data on patients undergoing the relevant procedures, to track patients across NHS organisations and to link to national datasets such as Hospital Episode Statistics (HES) and ONS mortality data. Access was requested to name, NHS number, date of birth, date of death and postcode.

Members agreed that there was a significant public interest in carrying out the specified audit activities. Members recognised that consent for national audit activities was particularly difficult due to the large numbers of patients involved who were treated across a number of NHS organisations and the reliance upon seeking consent via local clinical care teams. It was noted that identifiable data would be required in order to carry out data linkages but that this would be deleted at the earliest opportunity once data linkage activities had been completed.

Members noted that the applicant's response to query 4 indicated that Census Lower Level Super Output Area could be derived from postcode, rather than full postcode being retained. It was advised that the applicant pursue this option at the earliest opportunity to ensure that identifiable data items were de-identified as soon as possible.

Members reviewed the patient information leaflet and noted that references were made to the National Information Governance Board (NIGB), which had been abolished at the end of March 2013.

Members requested that the applicant ensure that these references were updated to reflect the approval from the Secretary of State for Health. In addition, the Group requested that the patient information leaflet should include references to all the specified audits.

Members noted that they had previously reviewed an application from UCL which indicated that confidentiality clauses were not included as standard within UCL staff contracts. It was noted that a previous condition of support for ECC 1-06(d)/2011 had been to ensure that those staff who processed data as part of the approval had such clauses within their contracts. Members requested confirmation that these were in place for those staff handling confidential patient information for the purposes of the current application.

The Group noted that the application specified that identifiable data required for linkages would be deleted once linkages had taken place. Members requested confirmation that deleted in this context referred to secure electronic shredding of data.

The Group agreed that the minimum criteria under the Regulations appeared to have been met, and therefore advised recommending provisional support to the Secretary of State for Health, subject to clarification that data deleted would be irreversibly destroyed; provision of a letter of support from the Caldicott Guardian or equivalent; amendment of patient information materials to remove references to the NIGB, clarify that approval was provided by the Secretary of State for Health, and explicitly list all audits; confirmation that postcode would be reduced to Census Lower Level Super Output Area at the earliest opportunity; and confirmation that contracts of employment for staff involved in the specified activities included confidentiality clauses.

7d. National Emergency Laparotomy Audit [CAG 5-07(d)/2013]

This audit application from the Royal College of Anaesthetists set out a study aiming to identify and disseminate best practice in the delivery of care to patients undergoing emergency laparotomy in order to reduce associated morbidity and mortality. A recommendation for class 4, 5 and 6 support was requested to cover access to identifiable data on patients aged 18 and over undergoing emergency laparotomy in England and Wales between 1 December 2013 and 30 November 2015, and to link this data to Hospital Episode Statistics (HES), ONS mortality data and Intensive Care National Audit and Research Centre (ICNARC) data. Linkages would be carried out by the Health and Social Care Information Centre's Data Linkage Service. Access was requested to NHS number, hospital number, date of birth, date of death and postcode.

Members agreed that the audit activity specified was important and noted that emergency laparotomy was a procedure which had a high mortality rate. Members noted that the emergency nature of the procedure in question would mean that consent was particularly difficult to obtain, and that identifiable data would be required in order to carry out data linkages.

Members noted that the data flow diagram included within the application did not detail the transfer data to the Health and Social Care Information Centre for them to carry out linkages to HESID. Members requested that the data flow diagram be updated to ensure that an accurate record of the activity was retained.

It was noted that the application specified that NHS number ascertainment was not complete within all datasets and therefore additional data items such as date of birth and postcode would be required in order to carry out data linkages. Members requested further information in relation to the level of NHS number ascertainment within the datasets and the impact of only using data in relation to those patients that have an NHS number present. If this would be feasible, Members queried whether linkages could be undertaken using NHS number only. In addition, Members queried whether the applicant could undertake any activities to increase the level of NHS number and ascertainment.

Members queried how long identifiable data would be retained for. It was noted that NHS number would be retained in order to enable long term survival analysis; however it was unclear whether date of birth and postcode would be destroyed following the conversion of date of birth to age and postcode to Index of Multiple Deprivation.

Members noted that an example leaflet, rather than the explicit audit information leaflet, had been included within the application and agreed that they would need to review the audit specific information leaflet. In addition, Members queried how it would be ensured that patients would be provided with the information sheet where possible.

The Group agreed that the minimum criteria under the Regulations appeared to have been met, and therefore advised recommending provisional support to the Secretary of State for Health, subject to provision of an amended data flow diagram including flows to and from the HSCIC; clarification of the level of NHS number ascertainment within the datasets, the impact of including only those patients whose NHS number was included within the audit and consideration of whether data linkage could be carried out using NHS number alone; confirmation that date of birth and postcode would be destroyed after conversions had taken place; provision of a letter of support from the Caldicott Guardian or equivalent; and provision of the audit specific patient information leaflet and details on how it would be made available to patients.

7e. PCNL in England: Safety and Effectiveness Study using Linked Data from Hospital Episode Statistics and the BAUS PCNL Registry [CAG 5-07(e)/2013]

This audit application from the Royal College of Surgeons of England set out a study aiming to develop an accurate and comprehensive dataset for the study of safety and effectiveness in outcomes from percutaneous nephrolithotomy (PCNL) in England. A recommendation for class 4, 5 and 6 support was requested in order to link Hospital Episode Statistics (HES) data on all patients undergoing PCNL in England between 1 January 2007 and 1 January 2012 with the PCNL registry already held by the British Association of Urological Surgeons. Access was requested to NHS number, date of birth and postcode.

Members agreed that the specified audit activity was important and that the intended outcomes would be of public benefit. Members noted that the retrospective nature of the datasets meant that consent would not be feasible. Identifiable data was requested in order to carry out linkages between HES and BAUS PCNL registry.

Members noted the applicant's assertions that the PCNL registry currently held identifiable data but that this was available to individual local clinicians only and provided in a pseudonymised format to central BAUS staff for the purposes of the registry. Members queried how data would be re-identified centrally for the purposes of the audit, noting that currently only local clinical care teams could access identifiable data and where identifiable data for the purposes of linkage would be retained and for how long.

Members noted that submissions to the BAUS PCNL registry were on a voluntary basis and queried whether there would be sufficient information in order to meet the aims of the activity. It was suggested that a comparison of the two datasets using anonymised data should be carried out and this would ensure that sufficient data was included within the PCNL registry, prior to accessing identifiable data.

Members requested confirmation that the conversion of identifiable data specified within section q would be carried out prior to disclosure to the RCS, which would result in no identifiable data being available to RCS. In addition, as the HES database could provide details in relation to Index of Multiple Deprivation, it was queried whether linkages could be undertaken using NHS number and date of birth only.

The Group was obliged to operate within a legal framework in terms of the advice provided. In particular, section 251 of the NHS Act 2006 indicated that any approvals made by the Secretary of State for Health under the Regulations could be inconsistent with the provisions of the Data Protection Act 1998. In line with this, Members discussed whether the application met the transparency requirements of the first principle. It was noted that no patient information or other activities to raise patient awareness had been specified within the application. Members requested that the applicant

consider methods to raise awareness of the processing of confidential patient information for the purposes of the activity.

Where identifiable patient information was to be accessed without an individual's consent it was important that views were obtained from the patient population to demonstrate the public interest in the activity, to gain views from the patient population in relation to the acceptability of the use of confidential patient information without consent and to raise awareness of the activity. Members noted that some consultation had taken place and asked that the applicant consider further ways in which patients and the public could be engaged with in relation to the activity, for example via a patient group. This would also help raise awareness of the activity in line with the comments regarding fair processing.

The Group agreed that the minimum criteria under the Regulations appeared to have been met, and therefore advised recommending *provisional* support to the Secretary of State for Health, subject to clarification on re-identification and retention of PCNL registry data for the purposes of the audit; clarification whether linkages could be undertaken using NHS number and date of birth only; confirmation that a comparison of the HES and PCNL registry data had been carried out to confirm that the level of ascertainment within the PCNL registry was sufficient to meet the requirements of the activity, prior to disclosure of confidential patient data; provision of a patient engagement plan and further methods to raise patient awareness of the processing of confidential data for this activity.

7f. National Vascular Registry [CAG 5-07(f)/2013]

This audit application from the Royal College of Surgeons of England set out a project aiming to establish a National Vascular Registry; a collaboration between the Vascular Society of Great Britain and Ireland and the Clinical Effectiveness Unit of the Royal College of Surgeons of England. The registry would investigate the standard of care for patients undergoing abdominal aortic aneurysm (AAA) repair, carotid endarterectomy and interventions for peripheral arterial disease. This Registry was an evolution of two existing national projects: the National Vascular Database and the Carotid Interventions Audit. A recommendation for class 4, 5 and 6 support was requested in order to collect data from patients undergoing emergency procedures, from whom consent could not be sought. Consent would be sought from patients undergoing elective procedures. Data in relation to patients undergoing AAA repair would be linked to National AAA Screening Programme data, data in relation to patients undergoing surgery for peripheral arterial disease would be linked to data from the National Diabetes Audit and data in relation to patients with carotid arterial disease with National Stroke Audit data. Access was requested to NHS number, date of birth and postcode.

Members agreed that the specified audit activity was important and the outcomes would be of benefit to patients.

Members commented that the data flows did not appear to be sufficiently clear within the application form and requested that a data flow diagram be provided. This should include details in relation to when data was pseudonymised and would ensure that an accurate record of the activity was retained.

It was noted that the applicant had specified that consent would be obtained prospectively where feasible for those patients who were well enough to provide this. Members advised that the applicant should also ensure that provisions were in place in order to obtain consent from those who were lacking capacity in line with the Mental Capacity Act. It was noted that identifiable data was requested in order to carry out data linkages.

Members noted that the patient information leaflet included within the application specified that personal details would only be accessed by staff involved directly in an individual's treatment. Members commented that this appeared not to be accurate given that the National Vascular Database had submitted an application to link to other datasets. Members advised that any patient information leaflets produced for the current activity should ensure that they reflected the flow of data to a third party.

The Group agreed that the minimum criteria under the Regulations appeared to have been met, and therefore advised recommending *conditional* support to the Secretary of State for Health, subject to provision of a data flow diagram, including confirmation of when data would be pseudonymised, and provision of patient information leaflets and consent materials.

8. New applications – research

8a. Investigation of subdural haemorrhages in infants and forensic outcome [CAG 5-08(a)/2013]

This research application from Lancashire Teaching Hospitals NHS Foundation Trust set out a study to determine why people who inflict head injury in the form of shaking upon infants are not convicted, and if medical evidence could be improved or medical practice altered to increase conviction rates of perpetrators. A recommendation for class 4, 5 and 6 support was requested to provide demographic details of 20 children treated for subdural haemorrhage to a police researcher in order for them to identify police records and provide a summary of the prosecution case to the applicant. No clinical data would be transferred. Access was requested to name and date of birth for the purposes of identifying patients within the policy database.

When discussing this application Members were mindful that the Regulations made under section 251 specified that the purpose of an application must be considered a medical purpose as defined within the NHS Act 2006, s251(12). Members considered the purposes specified by the applicant in response to the IRAS questions regarding the principal and secondary research objectives and discussed whether the specified purposes could be considered to fall within the definition of medical purposes. In conclusion, the Group agreed that they did not consider that the principal objectives, as currently defined within the application, reflected a medical purpose. Therefore, as the minimum threshold of the Regulations had not been met, the application could not be recommended for support.

Members also noted the Information Commissioners Office representative's opinion that the purpose did not fit within the definition of medical purpose as defined within the Data Protection Act 1998 (DPA) and therefore the applicant was advised that they would need to ensure that another schedule 3 condition was identified to ensure that the processing met the requirements of the DPA.

The Group advised that the minimum criteria under the Regulations had not been met.

8b. Survival of children born with congenital heart disease [CAG 5-08(b)/2013]

This research application from Newcastle University set out a study to determine survival for all children with congenital heart disease and examine predictors of survival using demographic data. A recommendation for class 1, 4 and 6 support was requested to provide BINOCAR data to the Health and Social Care Information Centre (HSCIC) and a linked BINOCAR and ONS dataset to the Regional Maternity Survey Office (RMSO) at Newcastle upon Tyne Hospitals Trust. The aim was for the RMSO to carry out survival analysis and provide a pseudonymised dataset to Newcastle University. Access was requested to name, date of birth and postcode in order for the HSCIC to link BINOCAR data to mortality data.

Members agreed that there was a significant public interest in the proposed linkage and research study taking place. Members noted that the large amount of retrospective data held within existing datasets that was required for this study meant that consent would not be feasible.

It was noted that further information provided by the applicant following recent correspondence with the Health and Social Care Information Centre had confirmed that the data linkage would be undertaken within the HSCIC. The HSCIC would convert postcodes into Index of Multiple Deprivation and date of birth and death into number of days survived.

Members could not identify any fair processing specified within the application. Members noted that providing information in relation to the processing of this retrospectively collected data would be challenging. However, in line with the fair processing requirements of the first principle of the Data Protection Act 1998 (DPA), Members reiterated that reasonable efforts should be made to ensure that patients are aware of the uses of their data. The Group requested that the applicant consider methods to raise awareness of the processing and provide details of methods to the Confidentiality Advice Team.

The Group agreed that the minimum criteria under the Regulations appeared to have been met, and therefore advised recommending *conditional* support to the Health Research Authority, subject to provision of further information on reasonable efforts to be made to inform the cohort of the processing of confidential patient information.

8c. A prospective surveillance study to define rates of carriage, transmission and infection by healthcare-associated pathogens in adjacent hospital and community settings [CAG 5-08(c)/2013]

This research application from the University of Cambridge set out a prospective surveillance study to define rates of carriage, transmission and infection by healthcare-associated pathogens in adjacent hospital and community settings, using a combination of epidemiological investigation and bacterial genome sequencing. The proposed study would include approximately 65,000 patients admitted to Addenbrooke's Hospital over a one year period and 251 residents admitted to a specified nursing home during the same period. A recommendation for class 4 and 6 support was requested for a research nurse to access records of those patients admitted to Addenbrooke's and found to be infected. Identifiable data was requested in order to track patients admitted to both the hospital and the nursing home and remove duplicate entries. Access was requested to name, NHS number, hospital number and date of birth in order to carry out data linkage.

Members agreed that the study outcomes specified within the application would be of public benefit. Members noted that they had previously considered a similar request in relation to the hospital arm of the study (ECC 8-05(h)/2011) and agreed that in this scenario consent would not be considered to be feasible.

Members noted that, in relation to the nursing home cohort, the proposed samples would not be routinely collected and would be for the purposes of the study only. Members advised that when carrying out swabs consent would need to be obtained from patients in relation to this procedure, and were therefore of the view that consent could also be obtained for the use of confidential patient information at this stage.

Members noted the applicant's assertions that provisions would need to be made at the nursing home for those individuals who were unable to consent for themselves. It was highlighted that support under the Regulations could not be applied where individuals lacked capacity as the Mental Capacity Act provided guidelines to follow in these circumstances. The applicant was therefore advised to follow these guidelines.

A patient information poster had been included within the application. Members advised that the applicant should ensure that this was displayed within Addenbrooke's Hospital in relevant patient areas. Members noted that there was a method to allow objection via the research team themselves and advised that there should also be a method whereby the patient could opt out directly via a member of their own clinical care team. Members requested that the applicant update the patient information to reflect this option.

The Group agreed that the minimum criteria under the Regulations appeared to have been met for part of the application in relation to those patient treated within Addenbrooke's Hospital, and therefore advised recommending *partial conditional* support to the Health Research Authority, subject to revision of the patient information poster to include details of mechanisms by which patients could register an objection to processing via their local clinical care team. It was agreed that this

recommendation of partial conditional support would be communicated to the appropriate Research Ethics Committee once known.

8d. Cancer risks in the British rubber manufacturing industry [CAG 5-08(d)/2013]

This research application from the Institute of Occupational Medicine set out a study to determine whether specific chemicals used within the rubber manufacturing process increase the risk of cancer. A recommendation for class 1, 4 and 6 support was requested in order to flag approximately 40,000 workers, who were aged 35 or over in 1967 and worked in the rubber industry, on the NHS Central Register and receive updates from the Health and Social Care Information Centre (HSCIC) in relation to cancer and deaths. The Institute of Occupational Medicine (IOM) would receive data from the Health and Safety Executive in relation to workers who took part in an original study undertaken by the HSE predecessor in 1967. They would then pass demographic data to the HSCIC who would use this to trace the cohort and provide identifiable data to IOM. Access was requested to central register data including name, NHS number, date of birth and date of death to allow linkages to take place.

Members agreed that the activity detail was important and the outcomes would be of benefit. Members noted that the majority of the cohort would have died as the original HSE data was collected for a study undertaken in 1967. It was therefore agreed that seeking consent for the study would not be feasible.

The application specified that identifiable data would be required in order to link the HSE data to the requested NHS Central Register data from the HSCIC and analysis would be undertaken using pseudonymised data only. However, it was noted that this would include full dates of birth and death. In response to query 3, the applicant had asserted that date of birth and death would be required at analysis stage in order to determine length of follow up. Members discussed anonymisation standards and commented that including full date of birth and death in the dataset would make this potentially identifiable. Members agreed that the dates of birth and death should be reduced to month/year prior to disclosure to the University of Manchester and that if full dates were required further justification would need to be provided for this. If full dates were included within the dataset provided to the University of Manchester, this would be considered to be confidential patient information and confirmation of satisfactory security arrangements for the University would be required.

Members noted that the applicant had asserted that patient involvement would not be appropriate for this study as it was not a study of patients. Members reiterated that although the original data from HSE was not patient data, the subsequent information requested from the HSCIC in relation to cancer and mortality would be.

Members advised that contacting relevant trade unions to inform them of the study and seek any feedback in relation to the study from their members appeared to be appropriate. This would also help raise awareness of the study in line with the requirements of the first principle of the Data Protection Act 1998.

The Group agreed that the minimum criteria under the Regulations appeared to have been met, and therefore advised recommending *provisional* support to the Health Research Authority, subject to confirmation of support from the Information Custodian, confirmation that the dataset disclosed to the University of Manchester would include month and year of birth and death only, and provision of an engagement and feedback plan involving relevant trade unions, with any feedback received to be reported in the first annual review submission.

9. ANY OTHER BUSINESS

There was no other business to transact and the meeting came to a close.