Ethics and Confidentiality Committee (ECC) Meeting – Wednesday 6 February 2013

ECC Members:

Dr Mark Taylor (*Chair*), Mrs Pauline Brown, Dr Tony Calland, Dr Robert Carr, Dr Patrick Coyle, Dr Tricia Cresswell (*item 4c onward*), Dr Fiona Douglas, Ms Alison Emslie, Dr Colin Harper (*items 1-4a*), Mr Stephen Hinde, Professor Julia Hippisley-Cox, Mr Terence Wiseman and Mr Chris Wiltsher.

Confidentiality Advisory Group Members in attendance:

Dr Charlotte Augst (*items 1-4b*), Dr Kambiz Boomla, Mr Paul Charlton, Ms Madeleine Colvin, Ms Clare Sanderson (*items 1-4b)*, Mr Murat Soncul and Mr C Marc Taylor.

In attendance:

Dr Alan Doyle (*NIGB Director*)(*items 1-4b*), Ms Natasha Dunkley *(Approvals Manager) (items 1-4b, 4d-4e, 4g onward*), Ms Claire Edgeworth *(Deputy Approvals Manager),* Mr David Evans *(Information Commissioner's Office) (items 1-4d),* Mr Martin Frowd *(NIGB Senior Business Support Officer),* and Mr Peter Hall *(observing, Department of Health).*

1. Welcome and apologies

Apologies were received from Professor Jane Kaye and Ms Gillian Wells.

2. Declarations of Interest

Dr Robert Carr declared an interest in item 3a as the applicant was his wife, and left the room for the duration of this item. Mr Murat Soncul declared an interest in items 3b and 4a as he was employed by the applying organisation, and left the room for the duration of these two items. Dr Mark Taylor declared an interest in item 4g as he was employed by the same organisation as the applicant, although he had no direct association with the applicant; he remained present but relinquished the Chair to Dr Tricia Cresswell for the duration of this item.

2a. Minutes of last meeting & matters arising

The minutes of the 6 and 7 December 2012 meetings were agreed as an accurate record.

Matters arising

<u>Legal advice</u>

The Chair provided an update against a request for advice in relation to application ECC 6-05 (b)/2012 HES Linkage to Private HES that had been submitted to Department of Health lawyers in November 2012. The advice sought was in relation to whether data generated within a private healthcare context could fall within the remit of the Regulations. The application had been considered at the December 2012 meeting and Members agreed that due to the nature of the activity a final recommendation could not be made until this advice had been provided. A provisional oral opinion had been provided to Dr Andrew Harris when he was serving as Chair, however, as Dr Harris was no longer a member this oral opinion had not been considered sufficient to allow the committee to proceed with its advice provision. Consideration had been given to seeking legal advice elsewhere but it had been confirmed that it was DH policy to seek legal expertise via the

established route. Members were informed that Ms Rebecca Stanbrook would be meeting with Mr Peter Hall and would raise the issue; the delay had also been escalated to Dame Fiona Caldicott. Members expressed their disappointment over this significant delay that was frustrating the provision of advice and an approval decision.

National Commissioning Board (NCB) application

Ms Dunkley provided an update against the status of a potential NCB application and sought advice from the Committee on next steps. Members were reminded that the intention had been for the NCB to put in an application to the February 2013 meeting; members had arranged for a sub-group to be available in early January 2013 to review the application in advance so a recommendation could be provided to the other members of the Committee at the February meeting. The NCB had notified the office in December 2012 that the application would not be progressing while internal discussions took place.

Dr Taylor informed members that he had undertaken an initial discussion with NCB representatives in December 2012 to set out the basic considerations of meeting the Regulatory framework. Members agreed that the proposed application would cover a significant amount of national dataflows, and they would be happy to work with representatives to help advise on the application. However, due to the national and significant nature it was agreed that it would not be possible to provide advice via the proportionate review process. It was also agreed that due to the uncertainty over when the application would be provided, the abolition of ECC and current work taken to establish the CAG, that it would not be possible to hold an exceptional meeting to discuss this application.

It was agreed that Ms Dunkley would feed back this position, and members of CAG were asked to volunteer to attend this sub-group as the advice given would be presented as a recommendation to the first CAG meeting.

Handling of historical applications from the Health & Social Care Information Centre

It was noted that the Central Register applicator would no longer require support from 01 April 2013 where the data collection would be covered under the HSCIC's statutory powers. However, this support also included approval for approximately 167 historical flagging studies that would require continuing support for deaths and cancer notifications. It was agreed that Ms Edgeworth would work with the HSCIC to design a process and timescales to manage the handling of these. It was agreed that in order to manage this issue, support for the Central Register should continue for an interim 12 month period in order to review each historical application and establish whether support should continue.

2b. NIGB Office Report [ECC 8-02 (b)/2013]

For information

Secretary of State (SofS) approval decisions

The DH senior civil servant on behalf of the SofS agreed with the advice provided by the ECC in relation to the December 2012 meeting applications. Members were informed that the SofS representative has changed to Mr Peter Hall, Deputy Director of Information & Transparency.

Operational transition

Work is ongoing in the NIGB Office to revise and harmonise electronic folder structures in advance of the transfer to hosting by the HRA. This work is intended to be complete by the end of February, in order that a single overarching folder, containing all relevant electronic documents, can be transferred to HRA systems in March. Parallel work is ongoing to streamline the paper filing system, comprising applications received prior to 2009. This work is largely complete and has resulted in a 40% reduction in the volume of paper files stored by the Office through elimination of duplicate paper files.

A data quality overhaul of the Register of applications has been ongoing since April 2012 to ensure that all data held is correct and complete, including application and outcome dates, annual review dates, contact details, classes of support and Data Protection Act registration. This project is now 50% complete and new applications are being added to the Register to a higher standard of detail than was previously consistently the case. This work will need to continue into the 2013-14 financial year, but will be significantly simplified and streamlined by the harmonisation of electronic folder structures, once the latter project is completed. The data quality overhaul project will in turn support a more proactive approach than has previously been in place to managing the annual reviews process, through minimally time-intensive but accurate forecasting of annual review due dates to enable establishment of a system of reminders to applicants and effectively incorporate annual reviews into Office workload planning.

Public Health England and the Health Research Authority

A meeting took place on 20 December 2012 attended by Dr Janet Wisely, Dr Mark Taylor, Natasha Dunkley and representatives from Public Health England (Dr Robert Kyffin, Dr Julian Flowers, Professor John Newton, Malcolm Oswald (NTA), Tony Howarth and a legal representation from the HPA). The purpose of the meeting was to introduce the role of the Health Research Authority, outline the activities taking place to develop the Confidentiality Advisory Group and to provide an overview of the considerations involved in the establishment with PHE and their subsequent link to CAG. It was agreed that further liaison via the ECC and CAG would continue, and the importance of ensuring suitable public health representation on the Group would be important when seeking to recruit to CAG.

HRA stakeholder events

Dr Mark Taylor and Ms Natasha Dunkley presented at two stakeholder events in Manchester and London, in conjunction with the Health Research Authority. The purpose of these events was to outline the work of the Ethics and Confidentiality Committee, outline progress to date on development of the Confidentiality Advisory Group and to invite attendee perspectives on what they would consider to be the key priorities for the HRA in hosting the advice function. Dr Tony Calland also attended the Manchester event, and Dr Patrick Coyle attended the London session. It was also confirmed that Rebecca Stanbrook from the Medicines and Healthcare products Regulatory Agency would be joining the HRA on a one-year secondment for approximately two days per week as the Director of Confidential Advice – s251 (TBC), and she would be line managing the current office team. Both sessions were well attended by a number of key stakeholders and applicants, and comments included the need to ensure that if the decision differed from the advice then it would need to be transparent. If other criteria would be taken into account by the HRA then attendees queried what this criteria would be, and to ensure that any approval remained aligned with the Regulations. Comments also included ensuring greater alignment with research ethics committees, potentially increasing meeting frequency and further development of proportionate review criteria. All suggestions will be taken forward appropriately within the HRA.

IRAS development

The Health Research Authority has recently published the announcement that all new development work on IRAS has been halted to maintain stability of the current IRAS platform; this includes changes to questions. Under their pre-existing contract the HRA will release version 3.5 which combines a number of updates but this is separate to development work. The office has highlighted that when a certain question is selected it reduces the dataset and does not pull up all necessary questions relevant to ECC consideration. The consequence is that this generates significant additional work for the office and the applicant and is contrary to the purpose of the IRAS form. The HRA have agreed to seek to resolve this by presenting the issue as a bug fix as this issue was

raised in July 2012. The intention is for the ECC to revise the DPA questions to enable greater alignment with the Information Commissioner's Office guidance, however this would constitute development work which is currently halted. The HRA will shortly be developing the facility to internally manage changes to question-specific guidance without recourse to the contractor. As an interim measure, the intention is therefore to develop the question specific guidance so that applicants can be directed to this when responding to the DPA compliance question, and it is anticipated that this will commence at the beginning of March 2013.

Fast Track applications

ECC 8-02(FT1)/2013 Ecological analysis of patterns of Campylobacter risk

This research application from the University of Liverpool detailed the disclosure of Health Protection Agency data to the University of Lancaster with the aim to identify the "key reservoirs, environmental and social drivers of Campylobacter that affect human disease". HPA data collected in relation to Campylobacter would be provided for four regions: North East, North West, East Anglia and the Grampian region of Scotland. This dataset would include patient postcode to allow the University of Lancaster to carry out a process of 'jittering' which the applicant stated would ensure that the data would no longer be identifiable. The application was considered under fast track criteria 4: *Time limited access to undertake record linkage/validation and to pseudonymise the data*. Members agreed that the research specified within the application was of public benefit and noted that Campylobacter was a common cause of gastrointestinal infection and serious morbidity. It was recognised that any increase in knowledge of the distribution and biology of the bacteria would be of benefit.

It was noted that consent for the large number of patients included in the retrospective dataset would be impracticable and require further identifiable data to be disclosed to the applicant. Members discussed the process of jittering postcodes and agreed that the result of this was not entirely clear, however it was noted that the applicant stated that this would ensure that the information would be anonymised. Members agreed that further information should be provided which demonstrated that it would be sufficiently difficult to reverse the jittering process to re-identify the postcode and that the data would be sufficiently anonymised in line with the Information Commissioner's Office anonymisation code of practice. Members agreed that the minimum requirements of the Regulations appeared to have been met and recommended support to the application subject to the conditions.

ECC 8-02(FT2)/2013 East Midlands Patient Experience Service (EMPES) – Patients who have experienced falls

This application from NHS Quality Health and NHS Nottinghamshire County PCT detailed a survey of patients who had experienced a fall and used the services of the East Midlands Ambulance Service (EMAS) (approximately 25,000 patients). The overall aim of the survey was to assess the amount and quality of information about preventing further falls given to patients who have experienced falls and had to call the East Midlands Ambulance Service. Quality Health would undertake mortality checks using DBS prior to sending out patient surveys. This application was considered via the proportionate review process under category 1: *Applications to identify a cohort of patients and subsequently to seek their consent.* The following information was requested about each patient; name, address, postcode, date of birth, NHS number, category of patient and call stop reason. Members noted that the survey followed the same methodology as previous applications and agreed that the outcomes of the proposed survey were clearly in the public interest. Following consideration of the ECC advice, the Secretary of State has determined that the application should be provisionally approved.

ECC 8-02 (FT3)/2013 Understanding failure in Unicompartmental Knee Replacement

This service evaluation application from the University of Oxford detailed the linkage of HES and PROMS data to NJR data using the Health and Social Care Information Centre trusted data linkage service. Data would be linked using NHS number, date of birth and postcode. Patient identifiable data would be removed from the dataset prior to disclosure to the applicant and the identifiable data will be destroyed as soon as linkage is complete. This application was considered via proportionate review under category 4: *Time limited access to undertake record linkage/validation and to pseudonymise the data.* Members agreed that the proposed methodology appeared to be the most suitable to meet the aims of the application and noted that minimal disclosure of identifiable data would take place. Members agreed that the minimum requirements of the Regulations appeared to have been met and agreed to provide a recommendation of approval for this activity.

ECC 8-02 (FT4)/2013 CQC 2013 Community Mental Health Survey

This application from the Care Quality Commission (CQC) detailed a patient survey which aimed to improve the mental health and well-being of the nation and improve outcomes for people with mental health problems. The community mental health services survey was one of the key sources of information to assess progress in improving the experience of healthcare for people with a mental illness. A recommendation for class 3, 5 and 6 support was requested to provide a legitimate basis for the transfer of confidential patient information from mental health trusts (up to 58 trusts) and PCTs providing mental health services to one of three 'approved' contractors and to the central coordinator (Picker Institute Europe), to enable contractors to send out questionnaires. Patients over the age of 18 only would be included.

Access was requested to name, full postal address, gender, year of birth, ethnicity, date of last contact, Care Programme Approach (CPA) status and GP code in order to send questionnaire and allow subsequent analysis. This application was considered via the proportionate review process under criteria 14: *repeat projects*. This application was reviewed by two Members and the Chair outside a formal committee meeting. It was noted that the survey methodology proposed was identical to previous surveys and that the justification for the use of particularly sensitive data had been considered to be satisfactory by the committee for the 2012 Community Mental Health survey. The committee had requested that the applicant provide information in relation to a number of points following the initial Community Mental Health survey in December 2011: evidence of the benefit of the patient survey to patient care; evidence of engagement with service users; exploration of alternative methods to ensure that CPA status could be disclosed in a pseudonymised format, which could then be linked to survey responses; and provision of guidance to trusts in relation to meeting fair processing requirements to ensure reasonable efforts are made to inform patients. The applicant provided a cover letter with the current application which addressed each of these points in detail. This letter was forwarded to Members who agreed that each point had been addressed satisfactorily and that support could be recommended for the 2013 survey.

ECC 8-02(FT5)/2013 – Defining the Long Term Consequences of Acute Kidney Injury: A pilot for the AKI risk in Derby

This application from the Royal Derby Hospital detailed a study which aimed to determine the long term effects of AKI on the development and progression of CKD, as well as the effects of AKI on patient survival. Section 251 was requested to allow the nephrology team to access contact details for patients who have suffered AKI, as well as those who were screened for AKI but did not suffer AKI, across all departments. It was expected that only 7.5% of these patients would have been cared for by the nephrology team and therefore they would not constitute part of the patients clinical care team. Contact details would be used to write to participants in order to obtain consent to review medical notes and request mortality data from the Central Register. This application followed a previous application (ECC 7-02(FT2)/2011) which detailed to pilot phase of this study. The

application was considered by the Chair under fast track criteria 14: *Repeat projects.* The Chair noted that the main study followed the same methodology as the pilot which had been previously approved. Queries were raised in relation to the measures the applicant would take in order to ensure that patients were not deceased prior to sending out consent forms. It was confirmed that a number of local checks would be undertaken on hospital systems to ensure that this would not take place. The Chair recommended provisional support under section 251 to this application.

Amendments

ECC 5-05 (f)/2012 MBRRACE-UK – Delivering the Maternal, Newborn and Infant Clinical Outcome Review Programme (MNI-CORP). UPDATE

Written notification was received on 18 December 2012 that Homecare at Home would no longer be data processors for the Maternal & Perinatal Mortality Notification (MPMN) Portal from midnight on 31 December 2012. Notification was also received that the NPEU would be taking over this role from 01 January 2013 and the MPMN portal would be decommissioned to be replaced by the MBRRACE-UK data collection system. The letter dated 14 December 2012 provided notification of a change in security arrangements as follows:

- the MBRRACE-UK system will be a secure web-based electronic data collection system
- It will operate through the N3 gateway
- Registered users will be required to change passwords on first use with only strong passwords being accepted
- Users will only be eligible to register as data providers once authorised in writing by the appropriate senior staff member
- Access will be restricted to authorised IP addresses
- Data will be securely stored at the University of Oxford in line with previously reviewed arrangements

The letter also provided details of the removal and addition of various data items, along with justifications. The letter was reviewed by Dr Tricia Cresswell and it was agreed that in terms of the additional data items, these were considered to have a good evidence base, met the overall objectives and the justifications provided for inclusion were considered valid. In this instance, the additional data items were not considered to add significantly to the identifiability of the overall data collection and therefore no further approval would be advised, although notification of these changes was strongly welcomed.

ECC 6-05(c)/2011 Conservative Kidney Management Assessment of Practice Patterns (CKMAPPS)

This application from the University of Southampton aimed to determine the practice patterns for conservative kidney care management (CKM) of older patients with stage 5 Chronic Kidney Disease (CKD5). It also set out the intention to inform service development and design of a future prospective multicentre study to evaluate the effectiveness, cost effectiveness and appropriateness of CKM compared to dialysis for treatment of elderly patients. Identifiable data including NHS number, GP registration and date of birth were requested in order to allow linkages of laboratory and renal IT system files by the UK Renal Registry to define the location of kidney care at initial diagnoses, subsequent referral and any use of dialysis. Additionally NHS numbers were requested to allow cases to be referred to when GP interviews took place. The application was approved with the caveat that linkages took place using NHS number and date of birth only. This request detailed that in two renal laboratories (Lister Hospital and Luton and Dunstable Hospital) NHS number was not completed sufficiently to allow linkage to take place using these data items alone. To rectify this it was proposed that one of the renal consultant's at Lister hospital would request the laboratory data for patients and carry out the linkage. It was confirmed that this would apply to around 200-225 patients and the majority of these would be known to the renal department at Lister, however it was

estimated that 20% of these would not have been referred to the renal department at as they would have been treated only by their GPs. The renal consultant would receive name, date of birth and NHS number for all patients recorded in laboratory data who met the inclusion criteria and use the hospital PAS system to locate NHS numbers where these were missing, if NHS numbers could not be found, which was thought to be unlikely, the consultant would call the patient's GP and request NHS number from them. The dataset disclosed to the CKMAPPS research team would include NHS number and date of birth only as per the original approval. The Chair noted that the renal consultant in question would have access to the majority of patients' information as part of their clinical care and agreed that the amendment was acceptable. It was advised that identifiable data should be destroyed as soon as linkages had taken place. In addition, it was noted that the flow of data to the Lister Hospital was not included within the existing SLSP and therefore the applicant was advised to note the change in the security assurance process below and provide satisfactory confirmation of an IG toolkit return which includes Lister Hospital.

ECC 6-06(b)/2009 - Validation of Risk assessments for patients from MSS (VoRAMSS)

This is a prospective study that aims to validate and assess the reliability and utility of recently developed risk assessment instruments in a group of 560 patients across 38 medium secure units in England and Wales with a diagnosis of Schizophrenia. Section 251 support was sought in order for the research group to access patient medical notes at 6 and 12 months to link with information on the Police National Computer. The amendment request detailed further collection of follow up data after 2 years (the existing support covered follow up data collection at 6 and 12 months). This amendment was considered by the Chair and approved.

Access to cancer registration data

A request to access anonymised cancer registration data was received by the National Cancer Intelligence Network from Dr Foster. The applicant was referred to the office as the cancer registries requested confirmation as to whether the dataset was considered sufficiently de-identified. The dataset included date of death and in combination with other data items was considered to be potentially identifiable. This was considered by Dr Patrick Coyle, and following confirmation that date of death would be reduced to month and year, it was agreed that the dataset was reasonably de-identified, and therefore the applicant was informed that a recommendation of support would not be advised in order to receive the dataset.

Update on existing applications

ECC 6-02(FT16)/2012 – CQC 2013 Maternity Survey

This application was originally considered via the proportionate review process and support was recommended, subject to conditions. One condition was the exclusion of patients under 18 years old. An appeal against this condition was made to the Committee. The Committee was asked to consider retracting the above condition and the applicant submitted a paper to demonstrate the necessity of including data from patients who were under the age of 18. The Committee were unable to reach a consensus view at the December meeting and it was suggested that a meeting take place between the CQC and a sub-group of Members to facilitate a conclusion. Members agreed that this would assist exploration into whether an alternative approach would be more appropriate with this group to enable the survey aims, and therefore the public interest, to be met. A teleconference took place on the 19 December 2012. Dr Tony Calland, Professor Julia Hippisley-Cox and Dr Robert Carr attended on behalf of ECC, Karen Hailt and Hannah Atherton attended from the Care Quality Commission, Chris Graham, Esther Ainsley and Mark Waters attended from the Picker Institute and Claire Edgeworth and Martin Frowd attended from the NIGB Office. Further information was provided from the applicant following the teleconference on the 21 December 2012, which detailed that, as the number of 16 and 17 year olds within each trust were low, there would be

an opportunity for trust staff to inform this age group about the survey at discharge and prior to the disclosure of patient information. Patients would also be given information relating to opting out of the survey and it would be ensured that there was opportunity to register their dissent. This proposal was forwarded to Members who agreed that they were supportive of this approach, which should ensure that all 16 and 17 year olds were informed about the survey and given adequate opportunity to opt out. Members thanked the applicant for working towards an acceptable solution to both parties. Members agreed that the minimum requirements of the Regulations appeared to have been met and recommended support to the application subject to sight of the amended questionnaire and confirmation that the survey and use of information would be explained to all patients under the age of 18 by NHS trust staff prior to the disclosure of information and patients would be given adequate opportunity to opt out.

ECC 6-05(d)/2012 Vascular Governance North West Database

This application from University of South Manchester NHS Foundation Trust (UHSM) detailed linking HES and mortality data to the existing Vascular Governance North West (VGNW) database. The data collected would include information regarding patients undergoing carotid endarterectomy or abdominal aortic aneurysm repair in the North West of the UK. The database would be anonymised and disclosed for research purposes. Data would be collected from hospital records, HES and DBS at a trust level. Access to name, NHS number, hospital ID, date of birth and postcode would be required in order to carry out DBS mortality checks within the trust and link to HES readmission data. Members agreed that the minimum requirements of the Regulations appeared to have been met and agreed to provide a recommendation of support for this activity subject to satisfactory responses to points of clarification. A response from the applicant on 3 January 2013 clarified that the University of South Manchester NHS Foundation Trust (UHSM) would be the data controller and three University of Manchester staff with honorary NHS contracts would maintain and have access to the database. The applicant submitted further information in relation to verbal consent and purposes of retrospective data collection, and confirmed that no identifiable data would be disclosed to researchers and that a unique code would allow reference to other data relating to the same patient. The applicant advised that any request for data would be submitted to a steering committee for assessment prior to disclosure, and confirmed that identifiable data could be destroyed once a patient had died. The response was forwarded to the Chair who agreed that the responses were reasonable. It was confirmed that support could apply only to prospective data collection as indicated above. The Chair advised that appropriate confidentiality contracts should be in place to ensure that suitable disciplinary measures would be undertaken for any breach of confidentiality and that this would be a condition of support.

2c. CAG Transition Update

The Chair advised the Committee that eleven new Confidentiality Advisory Group (CAG) Members had been appointed, following recruitment and interviews, to join the ECC Members transferring in to CAG. ECC staff had all received their transfer letters and the Health Research Authority (HRA) had appointed a Director of Confidential Advice, Rebecca Stanbrook, who would oversee the staff team for a 12-month period following the transfer.

3. For consideration

3a. Amendment: Clinical Outcome Review Programme: Child Health Reviews UK - removal of anonymisation requirement [ECC 4-03 (c)/2012]

The original application set out a case review project as part of the child health component, commissioned by HQIP and contractually awarded to the RCPCH, of the Confidential Enquiries work programme. It set out the aim to improve service provision and quality of clinical care through learning by adverse outcomes. It also involved a case note review of mortality and morbidity in children and young people (aged between their 1st and 18th birthdays) with epilepsy who received

intensive or high dependency care following a prolonged seizure, or who died of any cause throughout the care pathway. Support was requested to provide a legitimate basis for accessing confidential patient information to permit accurate identification of eligible cases, avoid duplicate reporting and collection of clinical information; case note assessments and a change to the typical methodology. Particular scrutiny was given by the Committee when originally considering the application, as there was a change in methodology from that previously utilised within the Confidential Enquiries, and the detail within was likely to act as a precedent. As a whole, Members were persuaded that the specified identifiers were necessary and the initial identification, similar to the BPSU methodology, was appropriate. In relation to the detailed case review, Members noted that this was an evolution of the enquiry methodology in that an external person (practising nurse) would go on-site to hospitals and review case notes and interview key clinicians. It was agreed following discussion that this methodology was robust, anonymisation at source would not be feasible, and Members were particularly reassured by the strength of the protocol in reaching this view.

The amendment request noted that the methodology, while differing in some respects, had been based upon the original Confidential Enquiry methodology. The letter indicated that the methodology differed significantly from the more established adult health model, and that the RCPCH had been commissioned to cover all aspects of the care pathway including primary and community care. The letter indicated that the activity involved the receipt of multiple notes from different healthcare settings. This distinguished this child health component from other methodologies which often focus on a narrower episode of care. This had led to the receipt of a significant amount of information which required anonymisation in line with the usual Confidential Enquiry methodology. The letter indicated that the resource required to carry out the anonymisation meant that the team would be unable to review sufficient numbers of cases in the time available for data collection. The amendment proposed that as support was in place for CHR-UK to carry out non-confidential case note assessments onsite in hospitals, that the risk of the change would be small. An example in support of this approach was anecdotally provided though reference to Dr Heather Payne from the Independent Advisory Group. Further points supporting this amendment were also made available to the Committee. Ultimately, the RCPCH requested support to amend the previous approval so that the assessments could be carried out non-confidentially.

In reviewing this amendment, Members had agreed that the original application was well-presented and clearly thought through. Previous deviations from the confidential enquiry methodology had been clearly defined and approved on the basis this was an evolution of the methodology. Members also agreed that the overall activity was an important issue as there were an excess number of deaths in England in comparison to other countries, therefore the public interest in carrying this activity out was high. It was noted that changing the process to essentially a non-confidential case review would mean that this was no longer a confidential enquiry. If this were to be the case, Members noted that this would then raise issues around children who were alive in terms of consent and practicable alternative considerations. Such a change would subsequently require clear justification why consent would not be feasible from those children (via their parents where applicable) who were living.

Based upon this significant change, Members agreed that they would be unable to process this as an amendment and a new application would be necessary to cover this strand of work. This application would need to explicitly cover alternatives to seeking support under these Regulations such as consent, and a strong justification would need to be provided to support why this would not be feasible. Consideration was given to the points raised around the security and it was agreed that the integrity of the security considerations were not the primary focus of the committee in this context; rather it was the step-change to a non-confidential enquiry and that it would no longer be operating under the previously approved confidential enquiry methodology. In conclusion, the Committee supported the change in principle, however it was clear that this would no longer be a confidential enquiry as previously carried out under CMACE and therefore considerations would need to change in terms of submitting an application. The new application would need to demonstrate that anonymised information could not be utilised and that consent would not be reasonably practicable for those children who are living. However, the Committee supported the use of redaction technology as specified in the letter but it was unclear whether it would be able to sufficiently redact the information. If it was sufficient, then there

would be no need to amend the methodology. If not, and the intent was to pursue a non-confidential methodology, a new application should be submitted as soon as possible.

3b. Amendment: South London and Maudsley (SLaM) IG Clinical Dataset Linkage Service – expansion of mental health research topics [ECC 3-04 (f)/2011]

This application from the South London & Maudsley NHS Foundation Trust set out the purpose of investigating the associations between specific mental disorders in secondary mental health care (schizophrenia, schizoaffective disorder, bipolar disorder and dementia) and physical illness. This would use a new linked dataset containing health records for patients with these disorders from the SLAM BRC Case Register Interactive Search (CRIS) and general hospital records from the English national Hospital Episode Statistics (HES) database. Review of this application was sought so as to provide a legitimate basis for the processing of this patient identifiable information; to effectively test this 'honest broker' capability and to permit the linkage and subsequent anonymisation. This required access to name, date of birth, sex, address, postcode and NHS Number. The CRIS participant recruitment model had previously been reviewed and endorsed by the Ethics and Confidentiality Committee.

The original application had set out clear boundaries on the types of research projects to be carried out (listed specific mental health diagnoses and defined HES outcomes). The amendment sought to extend the scope of the type of research to be carried out using the linked dataset e.g. mental disorders in children and adolescents. Examples were provided on how the scope could be broadened, and could potentially include mental disorders occurring in childhood and adolescence, personality disorders in adults and unipolar as well as bipolar affective disorder. Alternative uses of HES such as receipt of maternity care data to identify pregnancy in order to explore the health outcomes of women with a history of psychotic disorder who become pregnant was also provided as an example of the potential broadening of scope. It was noted that a separate application for consideration involving data linkage would also considered at the same meeting, so Members were mindful of the links between the two applications, although these were considered separately to each other.

While supportive in principle of the activity, as a whole, Members considered this proposed amendment to be a relatively significant deviation from the details of the original application. It was noted that the amendment would mean that all mental health diagnoses would be open to potential research so in future there would be the ability to look for associations. In the original application research would be carried out on incidents of physical disease with a specific mental health diagnosis. The amendment would also extend to children and adolescent diagnoses and these were considered to involve particular sensitivities that would need to be considered and justified. Members firstly considered whether there was a practicable alternative to this approach. It was suggested that pseudonymisation could be carried out within SLaM and the HSCIC could carry out the linkages if this was the case then this would enable a broader range of research to be carried out without using identifiable information. Members were unsure whether this was feasible and requested exploration of this approach to determine whether it would be practicable or not. In terms of the public interest, Members sought further information on the value of this amendment and requested that the benefits be articulated in greater detail, along with the relevant safeguards in place. Members also indicated that they were supportive in principle of the widening of research into children and adolescents as these were under-researched areas of the population. However, they expressed concern about the inclusion of pregnant women and requested specific information to justify this type of inclusion. Queries were also made over how future dissent would be managed. Members considered the issue of mental health considerations, and sought clarification on the limits of the research in the future, including how patient information leaflets would be updated and how criteria for access would be defined and applied internally. Finally, Members requested the applicant provide evidence of consideration of changes to internal governance arrangements. Members agreed that while they were supportive in principle of the amendment, provided that there was no other practicable alternative, further justification would be necessary. They therefore agreed to defer reaching a conclusion until this information was received, if necessary outside of the formal meeting schedule.

4. New Applications

4a. South London and Maudsley NHS Foundation Trust (SLAM) Child and Adolescent mental health (CAMHS) data linkage with Department for Education (DfE) National Pupil Database (NPD) [ECC 8-04(a)/2013]

This application from South London and Maudsley NHS Foundation Trust (SLAM) detailed the linkage of the SLAM CAMHS database with the NPD. The linkage would be undertaken with the aim of aiding health and education policy makers by providing information on the frequency and characteristics of children referred to CAMHS. The application detailed disclosing demographic patient information including name, date of birth, address and NHS number to DfE. This information would be used to allow disclosure of pseudonymised NPD data to SLAM for linkage to CAMHS data. No clinical information would be disclosed, but the demographic data would indicate to DfE that a patient had been treated by mental health services.

Members noted that the specified purposes within the application form were particularly broad and this made it difficult to assess the key medical purposes and public interest of the activity taking place. This point was of particular importance as support under the Regulations can only be provided where a medical purpose and public interest are sufficiently defined. It was noted that the intended benefits were to influence both health care and education policy; however Members requested that the applicant provide specific examples of the medical purpose and patient benefit of the activity. It was agreed that examples of medical research studies that would use the data would help reflect this. Members noted that it appeared that in order to satisfy one of the conditions in schedule 3 of the Data Protection Act 1998 (DPA) a medical purpose would also need to be specified. Members therefore advised that the applicant should seek to define the medical purpose for the additional key purpose of satisfying the DPA requirements.

In order to ensure that support under the Regulations is provided only where necessary Members consider whether there may be a practicable alternative to the use of confidential patient information without consent. With this in mind Members queried whether the applicant had considered whether the Health and Social Care Information Centre (HSCIC) could carry out the linkages on the applicant's behalf using the Trusted Data Linkage Service (TDLS). Members were of the view that this would negate the requirement for SLAM to disclose confidential patient information to DfE and minimise the disclosure of patient information. Members were also of the opinion that the patient information leaflet did not appear to cover the specified activity and concerns were raised that, if relying upon the current patient information leaflet, patients might be misled that no identifiable data would leave the CRIS system. Members advised that the leaflet be updated to reflect the activity to ensure that the processing of information was sufficiently transparent and met the requirements of the DPA in relation to fair processing. Members requested further information in relation to what governance arrangements would be in place around the processing of patient data by DfE. In particular Members requested information around retention periods, access arrangements and the extent of identifiable data requested. In addition, it was noted that the applicant intended NHS number to be transferred to DfE and Members queried why DfE would need this data item. Members agreed that the current application did not include sufficient information to meet the minimum requirements of the Regulations and therefore could not provide a recommendation of support at this time, but invited the applicant to resubmit the application, provided all the points raised were addressed.

4b. Road Accident In-Depth Studies (RAIDS) [ECC 8-04(b)/2013]

This application from the Department of Transport detailed the establishment of a research database with the aim to be used in studies to reduce the risk of injury or death in road traffic accidents. Support was requested to allow confidential patient information (name, address and date of birth) to be provided by the ambulance services to the Accident Investigation Team (AIT) and to request information from hospitals in relation to patient injuries. In approximately 50% of cases identifiable data would be used to send questionnaires to participants. Members agreed that the purposes specified were of particular

public interest and agreed that they were supportive of the application in principle. Members noted that in instances where it was not feasible for the police to provide information to the AIT, data would be requested from the ambulance services. Members agreed that this would be appropriate if ambulance service data was only used where absolutely necessary. The Committee discussed the plan to send questionnaires to around 50% of all participants. Members noted the exclusion criteria and requested further information in relation to why particular exclusion categories had been identified. In particular, Members queried why the applicant did not intend to send questionnaires to participants over the age of 75. Members commented that if most patients were written to the majority would receive information about the study and a chance to opt out. Members therefore agreed that defining the exclusion criteria and considering whether all patients could be written to were of particular importance. Members noted that the questionnaire included questions in relation to potential driving offences, such as whether the driver had been under the influence of drugs or alcohol at the time of driving. Members queried whether this information would be disclosed further or acted upon. It was suggested that any potential disclosure of this data to the police or other organisations in an identifiable format should be explicitly stated within the patient information letter so that individuals would be aware.

In reviewing the patient information leaflet, it was noted that the letter appeared to imply that the data was being collected for a specific research study and Members suggested that it may be more accurate to reflect that the data may be used across a range of studies and by different organisations. In addition, Members noted that there was no intention to provide patient information to those who could not speak English or who had special communication needs and requested further information in relation to how efforts would be made to inform these individuals about the use of their information and, in line with the paragraph above, why they would be excluded from receiving questionnaires. It was noted that the RAIDS database was intended to be used by a range of researchers across different organisations and that the applicant had requested advice in relation to ensuring that disclosed data would not be identifiable. Members felt that this was a particularly complex question which would mainly be driven by the context in which data was to be used. Members recommended that methods could be used which would reduce the chance of identifying individuals by obfuscating data as much as possible, such as converting age to age bands and dates to months rather than days. Members advised that if patient information were to be disclosed it should be ensured that this was fully anonymised and if identifiers were required a further application under the Regulations may be needed prior to disclosure. Members requested further information in relation to the disclosure protocols in place to manage further use of the data. For example, details of the membership of the committee who consider disclosures, what criteria would be used to assess whether certain data items (particularly those that were potentially identifiable) should be disclosed and whether there was a set application form for access to RAIDS data. Members noted that data might potentially be disclosed outside the EU and advised that it should be ensured that the data was fully anonymised prior to this disclosure. Members agreed that they were supportive in principle of the application and agreed that the minimum criteria of the Regulations appeared to be met, but requested clarification, prior to final recommendation of support, in line with the points raised.

4c. Out of Hospital Cardiac Arrest Outcomes Project (OHCAO) [ECC 8-04(c)/2013]

This application from the University of Warwick detailed the establishment of a research database which would include outcomes of patients who had had a cardiac arrest out of hospital and where resuscitation was attempted. Support was requested to allow the study team to collect identifiable data from ambulance services and request mortality information from the NHS Central Register. NHS number would be used to link mortality data to clinical data. The application indicated that identifiable data would be retained as data might be used in future to link datasets such as ICNARC and MINAP to the database. Members agreed that the purposes that the activity set out to achieve were largely in the public interest and noted that currently this data was not routinely collected.

Members could not identify any fair processing specified within the application. Members noted that providing information in relation to the processing of information for these purposes would be difficult. However, in line with the fair processing requirements of the first principle of the Data Protection Act 1998 (DPA), reasonable efforts should be made to ensure that patients are aware of the uses of their data. It was suggested that this could be aided by increasing patient involvement in the study as this would increase awareness within the target population. It was noted that the applicant intended to retain

identifiable data to link to further datasets such as MINAP and ICNARC. As this was not yet confirmed Members agreed that any recommendation would not include this aspect and that the applicant should return with an amendment to the application if further linkages were to take place in future. Members advised that identifiable data items should be retained separately from treatment data to ensure that where identifiable data was retained, it was only accessed for linkage purposes. Members queried whether it would be possible to request that the Health and Social Care Information Centre (HSCIC) retain the data, given that they would be in receipt of identifiers in order to link to the NHS Central Register, and whether the applicant had considered whether linkages could take place using less identifiable data, such as NHS number only, which would allow minimal patient identifiable data to be retained for future purposes. Members noted that the applicant intended for the database to be used by other researchers in an anonymised format and queried what data would be disclosed and how it would be ensured that data was fully anonymised prior to disclosure. Members agreed that this data collection was particularly important and queried whether any consideration had been given to establishing this as a routine data collection rather than the establishment of a research database. Members advised that the applicant could make efforts to raise awareness of the importance of the data collection and consider the lessons learnt from the establishment of the database.

Members agreed that the minimum requirements of the Regulations appeared to have been met and agreed to provide a recommendation of support for this activity, with respect to access to ambulance service and NHS Central Register data only, subject to satisfactory clarification of data to be disclosed to other researchers and anonymisation arrangements prior to any such disclosure; provision to the NIGB office of a plan for raising patient awareness of the database; and consideration of whether identifiable data items could be retained separately within the HSCIC for linkage using NHS number only. The Committee advised that an amendment should be submitted for any further data linkages desired.

4d. A Comparison of fEVAR with Alternative Treatment Strategies [ECC 8-04(d)/2013]

This research application from the Royal Liverpool University Hospital detailed a retrospective cohort study of all patients who underwent aneurysm repair in the Cheshire and Merseyside region between 1 April 2006 and 31 March 2008 (approximately 200 patients) to compare the outcomes of three different types of operation for abdominal aortic aneurysms. Support was requested to allow a researcher to identify patients by accessing various hospitals and theatre databases and consulting with surgeons themselves. Once a full list had been prepared CT scans and case notes for each patient would be accessed and reviewed. Members noted that the research was to be undertaken by a medical student and requested further information in relation to their role. In particular, Members queried whether the data would originate from one hospital and the student's role within that hospital. Members were mindful of the policy that had been established by the Committee in relation to medical students processing identifiable data for research purposes: that medical students attached to a senior clinician (consultant or general practitioner) for the purposes of providing care should also be considered part of the clinical care team when contributing to audit or research; that the senior clinician would remain responsible for both the research or audit and the handling of confidential information in medical records; and that an application for section 251 support would not be necessary in these situations.

Members noted that the application specified a particularly small cohort and queried whether it would be feasible to request that a member of the local clinical care team extract the data in an anonymised form on the applicant's behalf. Whilst it was noted that the applicant asserted that the clinical team would have limited resources to carry out the activity, the Committee requested further information regarding what exploration had been made into this alternative. Members noted that it would not be feasible to contact the entire cohort in order to seek consent as the retrospective nature meant that many would have moved or have died since treatment. However, Members queried whether those who were alive could be written to by the care team in order to seek consent and whether there was any mechanism to enable those who were still alive to be identified to allow this to be possible. Members could not identify specific data sources from the application and requested further information in relation to what databases would be accessed and from which NHS organisations. Members noted that the application did not include any information relating to fair processing and recommended that the applicant explore ways to increase awareness of the processing, in line with the transparency requirements of the Data Protection Act 1998. Members agreed that they were broadly supportive of the aims of the application.

However, before a final recommendation could be made, the Committee sought clarification whether the medical student was attached to a senior clinician and thus would be considered part of the care team, and if not, whether consent could be sought or anonymised information extracted by the clinical care team.

4e. Mortality study of UK hard-metal workers [ECC 8-04(e)/2013]

This research application from the Institute of Occupational Medicine aimed to identify all workers that had worked at two hard metal manufacturing facilities since 1950 and assess whether their mortality patterns were higher than normal and whether this might be associated with increased exposure to substances in the hard metal manufacturing process. Support was requested to allow access to mortality data (date and cause of death) from the NHS Central Register.

Members noted that the application detailed carrying out a nested case control study but this was not part of the current request. Members noted the applicant's assertions that consent would not be feasible due to the retrospective nature of the cohort and that explicit consent would not be feasible within current workers as only a small amount would actively opt in to the study. Members noted that it was unclear whether the inclusion of current workers would be required and requested clarification regarding whether the retrospective cohort would suffice for the purposes of the study. It was noted that the application detailed transferring data to the University of Pittsburgh, which would include both date of birth and date of death. Members advised that the applicant consider what the minimum data items required by the University were and where possible ensure that de-identified data only was being transferred outside the EU. If identifiable data was required, then a full justification for this should be provided and would need to be compliant with the DPA where the participant was still alive. With respect to the current working cohort, Members requested clarification whether there was intent to flag this cohort on the NHS Central Register and if so why it would not be possible to seek consent from these participants as this would appear to be feasible.

Members agreed that the minimum requirements of the Regulations appeared to have been met for part of the application, to access data in relation to the retrospective cohort only, and agreed to provide a recommendation of support for aspect of the activity.

4f. Scottish Air Pollution and Mortality [ECC 8-04(f)/2013]

This research application from the University of Manchester detailed a study which aimed to investigate the lagged relationship between exposure to air pollution and non-accidental mortality. In order to achieve this HES and mortality data would be linked with the UK Air Quality Archive. Support was requested to allow access to mortality data regarding all deaths from cardiovascular, respiratory, digestive causes, lung cancer, diabetes and other related deaths. Information relating to deaths between 1998 and 2011 in Manchester, Newcastle and Leeds would be accessed (approx 191,000 deaths). Identifiable data would be required in order to link with air pollution data from DEFRA's UK Air Quality Archive. HES data in relation to all hospital attendances recorded on the HES database would be requested.

Members considered whether the Health and Social Care Information Centre could carry out the linkage of datasets and disclose a reduced dataset to the applicant which was effectively anonymised, as a practicable alternative to support under the Regulations. Members recognised that there might be some issues in following this approach as the applicant might need to carry out further specialist analysis into time periods and require specific dates for this, such as date of death. However, it was agreed that the applicant should explore this alternative approach and consider whether it would be feasible in terms of practicability and cost. It was agreed to defer providing advice while this alternative was explored, but responses could be considered by a smaller sub-group.

Consideration of this item also raised the issue as to how funders could be involved at an early stage to provide suitable funding to enable appropriate practicable alternatives. It was indicated that the Health Research Authority would be looking at this aspect in terms of their role to facilitate research, and it was agreed that this would be flagged to the HRA.

4g. Bridging the Age Gap In Breast Cancer: Improving Outcomes for Older Women [ECC 8-04(g)/2013]

This research application from the University of Sheffield detailed a study which aimed to determine the age, co-morbidity, frailty and disease characteristics of women over 70 with early breast cancer in order to provide guidance on the personal and cancer characteristics of women who could be safely advised that surgery was unlikely to confer any advantage to them, and the personal and cancer characteristics of women who should be advised to have adjuvant chemotherapy after surgery. Support was requested in order to access linked HES and cancer registry data which included date of death.

Members agreed that the questions posed by the study were important and were supportive of the activity taking place. Members discussed whether there was a practicable alternative to the use of identifiable data in this instance that could be carried out pseudonymously, however, it was agreed that the requirement for full date of death had previously been discussed at length and approved in relation to previous cancer studies due to the importance of calculating survival dates. However, members noted that the West Midlands Cancer Intelligence Unit would also include women who were not deceased.

Mindful that one of the requirements of the Regulations is that applications should not be inconsistent with the Data Protection Act 1998 (DPA), Members noted that the application did not detail any fair processing activities in relation to the activity. Members advised that reasonable efforts should be made to ensure that the cohort is informed about the processing of data for the specified purposes. Members agreed that the minimum requirements of the Regulations appeared to have been met and agreed to provide a recommendation of approval for this activity, subject satisfactory fair processing efforts.

4h. Computer Alerting Monitoring System 3 (CALMS 3) [ECC 8-04(h)/2013]

This research application from Oxford University Hospitals NHS Trust detailed the establishment of a database including upper-gastrointestinal surgical patients in two groups, those who were discharged alive without returning to intensive care and those who returned to intensive care or died. The aims of the project included deriving a risk prediction model and determining whether alert systems could be improved by using the information. Approximately 400 patients would be included within the database. Support was requested to allow access to identifiable data held on 4 hospital databases in order to link datasets. The application also indicated that data would be linked to the PICRAM database in future. Members agreed that the outcomes of the proposed activity would have a clear benefit to patient care. Members considered whether consent would be feasible for the activity, as a practicable alternative to support under the Regulations, and noted that the data collection would be retrospective, that some patients would have died and some would be very unwell. Members agreed that consent would be particularly difficult in this instance. Members queried what attempts would be made to inform the cohort about the potential uses of their data. Whilst it was recognised that this may be difficult, Members agreed that reasonable efforts should be made to ensure that the requirements of the first principle of the Data Protection Act 1998 (DPA) were being met and that the uses of data were as transparent as possible.

Members noted that the application detailed retaining postcode for analysis purposes. Members queried whether it would be possible to reduce postcode to either Lower Super Output Area or partial postcode to ensure that the minimum amount of information possible was retained. Members noted that the application detailed potential linkage to the PICRAM database and requested further information in relation to timescales for the activity and how the linkage of the two datasets would take place. Members noted that the DPA registration quoted was not included on the register held by the Information Commissioner's Office. It was agreed that this would need to be valid before the study could be given final approval. Members agreed that, subject to the clarifications above, the minimum requirements of the Regulations appeared to have been met and agreed to provide a recommendation of support for this activity, subject to receiving clarification of the need to retain full postcode following linkages, confirmation of when and how the linkage to the PICRAM database would be achieved, and confirmation of a valid DPA registration number.

6. Any other business

The Chair advised Members that a conflict of interest policy was being drafted and would be circulated to Members following approval by the HRA, for discussion at the April meeting. Contact details for the office team would be circulated when confirmed. Biography details and photographs of new and transferring Members would be published on the HRA website once collated.