Ethics and Confidentiality Committee (ECC) Meeting - Thursday 1 December 2011

Members:

Dr Mark Taylor (*acting Chair*), Professor Sir Denis Pereira Gray (*Deputy Chair*), Mrs Pauline Brown, Dr Tony Calland (items 5h-5n), Dr Patrick Coyle, Dr Tricia Cresswell (items 1-5j), Dr Fiona Douglas (items 1-5j), Ms Stephanie Ellis, Mr Michael Hake, Mr Stephen Hinde, Professor Julia Hippisley-Cox and Mr Terence Wiseman.

In attendance:

Ms Simone Bayes (*Department of* Health) (items 5c-5g), Mr Rick Borges (*Deputy Operations Manager),* Dr Alan Doyle *(NIGB Director),* Ms Natasha Dunkley *(Approvals Manager),* Ms Claire Edgeworth *(Deputy Approvals Manager),* Mr Martin Frowd (*Senior Business Support Officer*), Mr Chris Graham (*Picker Institute*) (item 5a), Ms Karen Hallt (*Care Quality Commission*) (item 5a), Mr Sean Kirwan (*Department of Health*), and Mr Ian Seccombe (*Care Quality Commission*), (item 5a).

1. Welcome and apologies

Apologies were received from Dr Andrew Harris, Professor Michael Catchpole, Dr Colin Harper and Dr Jane Kaye.

Declarations of Interest

The following interests were declared:

a) Dr Tricia Cresswell was not present in the room for the discussion and recommendation on item 3a as she is an employee of the Health Protection Agency.

b) Dr Fiona Douglas was not present in the room for the discussion and recommendation on item 5e as she had previously worked with the applicant. .

c) Professor Julia Hippisley-Cox was not present in the room for the discussion and recommendation on item 5f.

d) Professor Julia Hippisley-Cox did not participate in the discussion for item 4a, as she had recently received a grant on a similar topic.

e) Mr Terry Wiseman did not participate in the discussion in relation to item 5n as it was indicated that he was a colleague of the chair of the REC that had carried out ethical review of the application.

2. Minutes of last meeting [ECC 8-02(a)/2011] and matters arising

The minutes from the meeting held on 26 September 2011 were approved as an accurate record, subject to minor amendments.

2a. Matters arising

There were no matters arising.

2b. NIGB Office Report [ECC 8-02(b)/2011]

Approval process

Members were updated on progress following a legal review by the Department of Health of the process by which the Committee provided advice to the Secretary of State for Health (SofS). It was clear that the actual approval decision lay with the SofS, but previous custom and practice had been that the Committee was viewed as taking the final decision. It was clarified that the Committee provided advice on such applications to the SofS, who would consider that advice and take a final decision based upon this; obtaining further advice as necessary from DH IG colleagues. It was noted that the language in outcome letters and external correspondence would reflect this clarity. In practice, final decisions would be taken by a senior civil servant on behalf of the Secretary of State for Health.

Changes to security review arrangements

The NIGB Director advised the Committee that dialogue was ongoing with the Department of Health security team following plans to introduce new security review arrangements based on the use and results of the Information Governance Toolkit as reported at the July 2011 Committee meeting. Following an introductory meeting, suggested names had been provided in November 2011 in order for the DH IG Policy team to carry out a pilot on integrating the change into the process. Members were also informed that Mr Paul Elliott, NIGB Member, had requested to be part of this review group.

New Membership

Members were informed that following a recent recruitment exercise involving 31 applications and seven interviews, four new Members had been appointed by the NIGB and would take up post in January 2012. They were Dr Robert Carr, Ms Alison Emslie, Ms Gillian Wells and Mr Chris Wiltsher.

Four new NIGB Members had also been appointed by the Appointments Commission with immediate effect. They were Mr Neil Churchill, Mr Richard Congdon, Ms Julie Goulding; and Mr Neil Serougi.

Biographies of new ECC and NIGB members would be available on the NIGB website.

NIGB Transition Guidance and ECC Improvement Project

Members were informed that the NIGB had published transition guidance with a view to strengthen information governance (IG) and mitigate IG risks during transition to the new systems proposed by the Health and Social Care Bill. The guidance could be accessed on the NIGB website, http://www.nigb.nhs.uk/pubs/guidance/transguid

The office provided an update against the ECC Improvement Project as a number of task and finish groups had taken place and various actions were now with the office and members. Dr Doyle thanked Members for their involvement and help with the improvement project to date.

Healthcare Efficiency through Technology Expo, 4 October 2011, London Olympia

Members were informed that the NIGB had a stand at the Healthcare Efficiency through Technology Expo on 4 October 2011 in London. The NIGB Chair, Dame Fiona Caldicott, presented on the *Information Revolution: NIGB and Emerging Information Strategy*, which had attracted much media coverage in addition to an interview with the Health Services Journal. James Wood, Head of Infrastructure Security at NHS Connecting for Health led two afternoon seminars due to popular demand, entitled: *The Information Revolution: How can new technological innovation support the Information Revolution and ensure robust Information Governance in Health and Social Care*. Both seminars were chaired by Dr Tony Calland, NIGB Representative Member and ECC Member and Sir Rodney Brooke, NIGB Board Member.

Request under the Freedom of Information Act 2000 for Secondary Uses Service application and supporting documentation

The Committee was informed that the Office received a request under the Freedom of Information Act 2000 to receive the Secondary Uses Service (SUS) application considered by the Committee in 2009, supporting documentation and correspondence between the Office and the applicant.

Fast Track applications

The following sets out applications that were considered outside of the formal Committee meeting schedule as they were either considered under the fast track criteria, or related to amendments that did not require full Committee consideration.

1. **ECC 8-02 (FT1)/2011 - Acute Inpatient Survey 2011**

This application was processed under fast track category 9 and set out details of the transfer of patient identifiable data from acute and specialist trusts to defined survey contractors for the purpose of mailing out questionnaires for the 2011 acute inpatient survey. These survey contractors would be one of the following: Picker, Quality Health, Patient Perspective, or Capita. It was also noted that the Care Quality Commission (CQC) had commissioned Picker Institute Europe to manage and co-ordinate the survey programme under the title of the acute survey co-ordination centre. The cohort would relate to inpatients aged 16 years or over who were discharged from acute and specialist NHS hospitals in June, July or August 2011 (earlier for smaller trusts), who had one overnight stay in hospital. Inpatients treated for obstetrics/maternity or psychiatric reasons, private patients, current inpatients, those without a full UK postal address, and those who were found to be deceased prior to the start of the mailings would not be included in the cohort. Such checks would be carried out locally by the Trusts.

A recommendation of support was requested to cover the transfer of patient identifiable information (as listed within the application) from NHS Trusts and the subsequent processing of this information by specified contractors. It was indicated that NHS Trusts would be advised to employ the service of one of these 'approved contractors' to reduce the cost, burden and risk in the provision of survey data.

It was agreed that this survey was important in terms of monitoring quality of care and therefore there was a high public interest in this activity taking place. It also appeared that the CQC had undertaken considerable improvements to the information governance arrangements and this was welcomed. In particular, it was noted that the CQC would explore the feasibility for trusts to seek consent from patients for future surveys, for example by including a request to obtain and record consent as part of the admissions process. This was strongly welcomed and the expectation was that significant steps would be taken to progress this in future. Taking this commitment into account, it was agreed that due to the retrospective nature and the large numbers involved, the seeking of consent would not be practicable.

Members raised several queries, which subsequent correspondence clarified. In particular, correspondence focused on stop noted patients i.e. those patients listed through the Personal Demographic Service (PDS) as having a Sensitive Record Flagging (S flag) which restricted the patient's location details from being shown in the Patient Administration System (PAS). The applicant indicated that the reason for this was that some records were S-flagged for data quality reasons and some because of concerns about their contact details being available on a national system. It was stated that as the first reason was not sufficient to exclude these records from the sample, and the latter should be recorded locally in some way, a blanket removal of all S-flagged patients would be inappropriate. While understanding this was in the context of guidance to be sent to Trusts, the Committee noted this point, and highlighted that recommendations of support could not be used to override dissent, and this would be for the applicant to manage appropriately with those locally submitting data to the contractors.

It was understood that the applicant had been liaising directly with the Department of Health in relation to review of security arrangements. Confirmation had been received by the NIGB on 19 September 2011

from the Department of Health security review team that they were prepared to make a conditional recommendation of satisfactory security arrangements.

Based upon the details above and in line with the responses to clarifications, it was agreed that the minimum threshold for application of the Regulations had been achieved, and the Committee advised that this application be approved subject to the following specific conditions of support: a) a commitment from the CQC that it would submit relevant applications in good time and in line with published submission deadlines; b) this recommendation of support would not cover the transfer of patient identifiable information where a patient had indicated dissent.

2. ECC 8-02(FT2)/2011 - National Review of Asthma Deaths (NRAD)

This application, considered under criteria 2 (access to deceased person's data only) from the Royal College of Physicians of London detailed a review of asthma deaths within the UK by an in-depth multidisciplinary confidential enquiry, with the aim of understanding the circumstances surrounding current asthma deaths. This was in order to identify avoidable factors and make recommendations for implementing changes to improve care and reduce the number of avoidable deaths. A recommendation of support was requested for the collection of basic demographic and clinical information from a variety of sources (i.e. hospitals, GP practices, ambulance services) about all people who died from asthma within the UK during 12 months from 1 February 2012.

Members agreed that this was a worthwhile study. They noted that next of kin name and address were specified within section (m) of the application form as a data item to be held in relation to each patient, but that this was subject to Research Ethics Committee (REC) approval. Members agreed that they could not currently recommend support for the collection of this data item as it did not relate specifically to the patient, this would be third party data and therefore would be excluded from the scope of any recommendation.

The Committee agreed that the minimum criteria under the Regulations had been met, and advised that this application be approved, subject to confirmation of who would act as the information custodian and exclusion of collection of next of kin information.

3. ECC 8-02(FT3)/2011 - A study of how domestic violence is named and responded to in accident and emergency departments

Considered under fast track criteria 4 (access on site to extract anonymised dataset), this application was from Lancaster University and detailed a study in which patient medical notes would be examined over three NHS Trusts with the aim to investigate how domestic violence was responded to within emergency departments. Trust staff at each site would identify records of patients treated from January 2006 to 31 December 2010 who met the researcher's inclusion criteria. For those patients who were found to have suffered domestic violence it was proposed that records at that Emergency Department would be requested over a 10 year period from trusts in order to extract anonymised data.

Members agreed that this was an important study and the benefits would be in the public interest. Members considered under section 251 (4) of the NHS Act 2006 whether or not a practicable alternative to the disclosure of patient identifiable data without consent existed, taking into account the cost and technology available. Members agreed that the retrospective nature of the cohort and the safety implications in seeking consent meant that consent would be particularly difficult to obtain. It was agreed that in this instance it would not be feasible to request the clinical care team to anonymise patient records.

Regulation 7 (1) of the Health Service (Control of Patient Information) Regulations 2002 does not allow the processing of more confidential patient information than necessary to achieve the stated purposes. This requirement is also in line with the third principle of the Data Protection Act 1998. With this in mind, Members considered the extent of confidential patient information requested for the purpose and queried

how many notes the researcher would require to access. It was confirmed that around 870 records in total would meet the sample criteria and would be reviewed as part of the research. NHS staff would identify patient records on behalf of the researcher so that access would be restricted to those records required for the purposes of the study.

Members requested further information about how small numbers would be managed when patient level data was published. It was confirmed that the research would follow the disclosure rules of the Hospital Episode Statistics Online and that counts of 5 or less would not be disclosed.

In line with the considerations above, the Committee agreed that the minimum criteria under the Regulations had been met, and advised that this application be approved, subject to a favourable REC opinion and local confirmation of satisfactory security arrangements to access records from each NHS trust involved.

4. ECC 8-02(FT4)/2011 - Investigating the burden of gender identity disorder (GID) in children and adolescents: a surveillance study of incidence, clinical presentation, co-morbidities and natural history

This application from University College London detailed a study following the British Paediatric Surveillance Unit (BPSU) "orange card" methodology. The study aimed to collect information about the prevalence and features of childhood/adolescent gender identity disorder (GID) and measure how the condition progressed over time. A recommendation of support was requested to provide a legitimate basis to access patient identifiable data without consent in order to ensure the de-duplication of data, match follow up data and describe the population presenting with GID. Access to NHS number, Hospital ID, date of birth and first part of postcode were requested.

Members noted that this was a study into a rare condition, the prevalence of which was not known, and agreed that the outcomes would be of significant benefit. Due to the small numbers involved it was noted that the BPSU methodology would be suitable in this instance.

In line with Regulation 7 (1) of the Health Service (Control of Patient Information) Regulations 2002 and the third principle of the Data Protection Act 1998, which prevents the processing of more confidential patient information than necessary to achieve the stated purposes, Members considered the extent of information requested for the purpose and agreed that the requested data items were justifiable in order to ensure de-duplication and verification of follow up data.

Members noted recommendations of support could not be inconsistent with the provisions under the Data Protection Act 1998 (DPA). In particular, the first principle of the DPA requires personal data to be processed fairly and lawfully, and that reasonable effort should be made to inform the data subject of the uses of their data. This was of particular importance when processing confidential patient information without consent. Members queried when the public information sheet would be disseminated to patients, and agreed that notification of the study should take place at a local level via consultants.

The fifth principle of the DPA specifies that personal data should not be kept for any longer than necessary for the purposes specified. With this in mind, Members considered the retention period for identifiable data specified within the application and noted that BPSU/ Child and Adolescent Psychiatry Surveillance System (CAPSS) number, date of birth, sex, first part of post code and clinical information would be stored electronically and used for analysis purposes. Members were of the view that full date of birth should not be retained within this database and requested that this be reduced to month/year of birth.

The sixth principle of the DPA requires data to be processed in line with the rights of the data subject. Where confidential patient information was being processed without prior consent it was considered important by the Committee that the patient was given reasonable opportunity to register objection to the processing of data where it was likely to cause, or was causing significant damage or distress. In line with the Committee's standard conditions of support a recommendation of support could not be used to override patients' objections and therefore where dissent was registered this should be respected.

Members requested that the applicant should ensure that local consultants were aware of their responsibilities in relation to the rights of the data subject.

In line with the considerations above, the Committee agreed that the minimum criteria under the Regulations had been met, and therefore advised that this application be approved, subject to: a) reduction of date of birth data stored in the dataset to month/year only; b) provision of patient information leaflets and posters to participating clinics in order to ensure reasonable attempts were made to inform the local cohort; c) respect of dissent; and d) provision of a favourable REC opinion.

3. Annual reviews

3a. Health Protection Agency (HPA) Annual Review

Members noted that the HPA had specific support under Regulation 3 of the Health Service (Control of Patient Information) Regulations 2002 to process confidential patient information for a number of purposes in relation to communicable diseases and other risks to public health. The review documentation provided evidence of the current information governance arrangements within the HPA, details of specific policies and arrangements, and the procedure by which the HPA consider potential applications for support. The final section provided an update against existing projects. Members considered the information submitted as part of the annual review.

Members noted that the first principle of the Data Protection Act 1998 requires personal data to be processed fairly and lawfully, and that reasonable effort should be made to inform the data subject of the uses of their data. Members welcomed the patient information leaflet provided with the annual review but queried how maximum distribution would be ensured and requested that this be reported upon at the next annual review. Members queried the level of patient involvement undertaken by the HPA and were of the view that the HPA should explore an enhanced level of user involvement in their activities, and undertaking this would help to meet the requirements of the first principle.

Members noted that details of activities carried out by the HPA, and in future Public Health England, would be forwarded to the NIGB office as part of the transitional arrangements and prospectively welcomed this information.

Members advised that the specific support for the activities of the HPA should continue for a further year.

New HPA project – Enhanced surveillance of human papillomavirus (HPV) genotypes in cervical disease

The protocol of a new study, which aimed to monitor the effectiveness of HPV vaccination against cervical cancer and severe cervical disease, was included with the annual review. Members were asked for a view on whether the project could fall within the specific support provided to the HPA. The original data collection purpose of the biopsies was seen to be key in determining the appropriate legal framework under which identifiable information could be processed. Members noted that if the collection of the biopsies was part of a routine cervical cancer smear campaign, then the view was that they would not have been provided in the context of examination or treatment for a sexually transmitted disease, and would therefore not be covered by the NHS Trusts and Primary Care Trusts (Sexually Transmitted Diseases) Directions 2000. However, if generated specifically for the purpose of an examination or treatment of a sexually transmitted infection, then the processing of this data would come under the Directions. The Committee advised that the HPA should seek advice and then clarify back to the Committee their understanding on the original purpose of the data collection on this specific aspect.

4. Resubmissions

4a. ECC 6-05(c)/2010 - International Study of Incidence Cancer (ISICA) Breast Cancer and Diabetes

This application from Edinburgh Cancer Research Centre, sponsored by LA-SER Europe Ltd detailed the establishment of a registry of diabetic patients diagnosed with breast cancer since January 2008. This would be used to ascertain whether or not there was a risk of breast cancer associated with particular medications in patients with diabetes using a case control methodology. Research assistants would carry out the identification of breast cancer patients using pathology records or discharged diagnosis listings. Potentially diabetic patients would then be identified from patient records. A recommendation for class three and six support was requested to provide a legitimate basis for access to confidential patient information to identify and extract information about potential participants, prior to their consent being obtained.

This application was originally considered at the July 2010 meeting. The Committee did not advise recommending support at that time as there appeared to be a feasible alternative to the use of confidential patient information without consent. Some NHS Trusts had confirmed that they would be willing to carry out the consent processes and therefore the applicant was asked to attempt to identify further Trusts that had resource to carry out the activity. Members had advised that if the applicant experienced problems identifying the required number of Trusts they should make a further application evidencing this. In addition, members had requested that the following issues were addressed within any resubmission:

1. Ethical review by a REC. This opinion should be obtained in any event and, if resubmitting, a copy of the REC outcome letter should be provided to the NIGB Office.

2. Members were of the view that user involvement within the context of applying for support under the Regulations had been misunderstood and suggested consulting INVOLVE.

3. Members had queried why the UK Cancer Registries could not carry out this activity and requested that this be explored further.

4. If resubmitting, the Committee requested to see a copy of the contract of employment. This was in line with the requirement under Regulation 7(2) of the Health Service (Control of Patient Information) Regulations 2002 which states that "*No person shall process confidential patient information under these Regulations unless he is a health professional or a person who in the circumstances owes a duty of confidentiality which is equivalent to that which would arise if that person were a health professional*".

5. Members had also expressed concern that the GPs were not fully informed about the study, and would welcome the REC's views on this aspect.

6. Members queried what would occur with the results of the study and what would be published as it was unclear whether the results would be published in the UK.

7. Members requested more UK involvement in the study, and that the applicant should identify and engage a NHS clinical academic collaborator. Members also understood that it would be a REC requirement as part of research governance that a contract should be held with the NHS (which could be achieved via this clinical academic collaboration). Members recommended that the applicant should discuss this aspect further with the REC.

The resubmitted application provided correspondence with Trusts regarding the difficulties that were being experienced at a local level within those Trusts who had agreed to undertake the work. It was confirmed that current recruitment rates were not sufficient to meet the 2 year timescale specified by the

European Medicines Agency (EMA).A copy of the REC's favourable opinion letter was also submitted to the NIGB office.

Review of the resubmitted documentation indicated that there had been no direct user involvement in the development of the study but that the Primary Care Research Network and the National Cancer Research Network, who actively sought patients and service users' representative feedback, were involved in the conduct and implementation of the study.

The applicant advised that the cancer registry approach would be much more complex in terms of the governance approvals required. A copy of the contract of employment was submitted. It was confirmed that the results of the study would be provided to the EMA and made available for scientific publication in the UK.

The applicant confirmed that in terms of fulfilling the requirement for greater UK involvement, the Chief Investigator for the study was confirmed as Professor David Cameron, Professor of Oncology at the University of Edinburgh, Clinical Lead of Edinburgh Cancer Research Centre and Consultant Medical Oncologist, Western General Hospital, Edinburgh.

Members noted that under the current circumstances recruitment would not be possible within the two year time scales specified by the EMA. Members were of the view that the cancer registry alternative should have been explored in greater detail, but recognised that exploring the feasibility of this alternative would be likely to prolong recruitment further. Members noted that the EMA required the analysis to be completed by June 2012 and given the urgency and public interest in the activity taking place, the practicable alternatives suggested would not be feasible in this particular instance.

Members therefore advised recommending support to the Secretary of State for Health that the application be provisionally approved subject to the provision of a plan to consult patient groups in relation to the study.

4b. ECC 7-05(c)/2011 - A prospective UK population-based study of incidence, biology, treatment and outcomes of Non-Hodgkin's Lymphoma in Young Adults

Members noted that the applicant was due to take office as a Committee member from 1 January 2012, but no conflicts of interest were identified.

This application from the University of Manchester set out details of a prospective cohort study to collect diagnosis, treatment and outcome data on every 15 to 29 year old patient diagnosed with non-Hodgkin's lymphoma (NHL) over a three year period with the aim of establishing the incidence of each NHL type, document treatments and record readmission and cure rates. A recommendation for class four, five and six support was requested to provide a legitimate basis to access confidential patient information without consent to collect notifications, link information from different sources and to audit, monitor and analyse current treatment.

The application requested access to name, NHS number, GP registration, date of birth, date of death and postcode from pathologists making the diagnosis of the patient and from the young adult cancer registry, located within the North West Cancer Intelligence Service (NWCIS). The patient's clinical care team would be asked to provide them with patient information and the option to opt out of the study. Follow up data would then be requested from treatment centres for each case with two years from diagnosis and patients would be flagged for mortality on the NHS Central Register for five years.

This application was originally considered at the September 2011 meeting where members identified that practicable alternatives appeared to exist which would negate the use of confidential patient information without consent. In particular members had noted that the cohort would consist of only 600-650 cases and agreed that it would be feasible to seek consent from a cohort of this size. Members had queried whether the lead cancer registry could provide the information required in an anonymised format without a breach of patient confidentiality.

The resubmission clarified that the study was investigating a very rare cancer with even rarer subtypes. In order to ensure statistical validity minimum numbers of each disease treated on a given regimen would be required to provide meaningful outcome data for understanding the causes of the variation in event free survival. All cases would need to be identified.

The resubmission clarified the data flows and opt-out arrangements in place for the study. It was confirmed that the only patient details disclosed before patients had the opportunity to opt out would be name of hospital, hospital ID number and name of clinician responsible for treating the patient. The opt-out mechanism was favoured as it was asserted that the use of an opt-in mechanism would be likely to result in low response rates. The resubmission described the level of detail that would be required in order to fulfil the study aims and asserted that cancer registry data would not be sufficient. Members appreciated that this would not be a feasible alternative.

Members recognised that the very low numbers of sub types would mean that a high level of case ascertainment would be crucial for the study. Members welcomed the assertion within the resubmission that minimal patient data would be provided to the research team prior to the patient being given information about the study and the chance to opt out. Members advised that the applicant should make the opt-out provision prominent in all correspondence with the cohort to ensure that they were aware of their rights as data subjects.

Having considered the resubmission, the Committee advised recommending to the Secretary of State for Health that the application be approved.

5. New applications

5a. ECC 8-05(a)/2011 - 2012 Community Mental Health Survey

This application from the Care Quality Commission (CQC) detailed proposals for 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 classes five and six support was requested to provide a legitimate basis for the transfer of confidential patient information without consent from mental health trusts (up to 61 trusts) and PCTs providing mental health services to one of four 'approved' contractors and to the central coordinator (Picker Institute Europe), to enable contractors to send out questionnaires. 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 questionnaires and allow subsequent analysis.

Members welcomed the opportunity to discuss the application with attendees from the CQC and Picker Institute Europe. Mr Chris Graham (*Picker Institute*), Ms Karen Hallt (*Care Quality Commission*) and Mr Ian Seccombe (*Care Quality Commission*) were in attendance. Members queried why the suggested methodology (disclosure to a contractor to send out the survey) was the most appropriate one and why the activity could not be carried out by trusts, particularly taking into consideration that the information disclosed would relate to an individual's mental health status. The Committee were informed that the methodology detailed took the burden and costs away from trusts and it was likely that the survey would be carried out with fewer errors. In addition, as patients were being asked for details about the treatment that they had received there were concerns that they would not return the questionnaire or answer honestly due to concerns that the staff treating them would receive the replies.

Members noted that 16-17 year old patients would be included within the survey and queried why this age group was necessary as they understood that the survey was to evaluate adult mental health services. It was confirmed that the Department of Health had requested young people's views be included within the survey. The Committee discussed that they would expect to see the aims of targeting this age group specifically referenced within the application, in order to make a judgement as to whether or not their inclusion was necessary. Members suggested that inclusion of this age group should have been discussed with relevant organisations such as the Children's Commissioner in England.

Members queried why CPA status would be required prior to patient consent and discussed options to minimise that disclosure of the most sensitive data items to the approved contractors. The Committee were informed that collecting a patient's CPA status prior to consent allowed the applicant to reference CPA status with non-response rates. It was confirmed that sample (containing CPA status) and mailing files, would be sent to the chosen approved contractor who would then distribute questionnaires. The Committee queried why the sample file would be required by the approved contractor and were informed that this would be used to match the responses to CPA codes. Members queried whether or not a separate list of CPA codes could be made and only sent to the coordination centre with the unique identifying number to allow pseudonymous linking with survey responses.

Members suggested that the CQC should provide guidance to trusts on meeting fair processing requirements. Members queried the level of patient involvement that had been undertaken in relation to the use of confidential patient information, and were advised that a number of focus groups meetings had been undertaken at the start of implementation of the patient survey. Members queried why question 52 was included in the questionnaire, as it referred to employment type of an individual. The Committee was informed that the question was included to measure social inclusion and access to work for the cohort. Members advised that an option to not reply to question 52 of the survey should be included as this was also an option for many of the other questions.

Members were mindful of the highly sensitive nature of the information that had been requested and advised that in these cases the threshold of patient benefit in the disclosure would be higher. Members noted that the patient survey would be used to provide performance related payments to NHS Trusts and that this would bring about significant public benefit. However, members were of the view that further work should be undertaken to define the benefits the patient survey would have to patient care. Members advised that they would expect to see this detail in any future applications.

Members considered the extent of confidential patient information requested for the purpose. Members agreed that in line with the points raised above with attendees, alternative methods to ensure that CPA status was disclosed in an anonymised format which could then be linked to survey responses should be explored for future surveys.

Members advised that due to the nature of the cohort it was possible that some would lack capacity to provide consent. Members suggested that guidelines included within the Mental Capacity Act should be followed and were pleased to note that the application would also be subject to review by a REC.

Members were also of the view that insufficient justification had been provided to allow the inclusion of those patients aged 16-17 years old. It was agreed that the recommendation of support would not include this age group, unless further justification could be provided.

Following consideration of the issues above and responses, the Committee advised recommending to the Secretary of State for Health that the application be provisionally approved, subject to confirmation of a favourable opinion from a REC and exclusion of patients aged 16-17 from the survey.

Members advised that any future application should include explicit evidence of the benefit of the patient survey to patient care; evidence of engagement with service users; consideration of alternative methods to ensure that CPA status could be disclosed in a pseudonymised format, which could then be linked to survey responses; and guidance to be provided to trusts in relation to meeting fair processing requirements to ensure that reasonable efforts were made to inform patients.

5b. ECC 8-05(b)/2011 - End of Life Care Repository

Members undertook a preliminary review of the documentation, however, as the applicants would be providing a presentation on the 02 December, it was agreed that members would discuss the application with the aim of directing questions to the applicants after their presentation. A summary of the presentation, queries and applicant responses are set out in the minutes dated 02 December 2011.

5c. ECC 8-05(c)/2011 - Diagnostic Imaging Dataset

This application from the NHS Information Centre (NHS IC), sponsored by the Department of Health, detailed a national dataset of all diagnostic imaging requests collected via the local Radiation Information Systems (RIS). The aims of this data collection were:

- To inform GP utilisation of diagnostic imaging tests, as part of the strategy to achieve earlier cancer diagnosis for English NHS patients set out in *Improving Outcomes: A Strategy for Cancer* (IOSC);
- To extend the information available for a cancer pathway, by linking data to Cancer Registry information;
- To improve the data on frequency of X-ray exposure, as analysed by the Health Protection Authority (HPA);
- To enable analysis of demographic and geographic variation in access to diagnostic imaging tests;
- To provide data on the use of high value equipment.

A recommendation for class four, five and six support was requested to provide legitimate access to confidential patient information without consent by the NHS Information Centre. Access was requested to NHS number and date of birth for all patients who underwent diagnostic imaging tests to allow cancer registries to retrospectively link data on diagnostic image testing for patients who developed cancer. Cancer registries already had a legitimate access to data on those patients diagnosed with cancer via their specific support under the Health Service (Control of Patient Information) Regulations 2002.

Members noted that consent would be difficult to obtain due to the extent of the data collection. Members welcomed the applicant's assertion that mechanisms for recording dissent would be explored so that clinicians could formally request consent from individuals. Members queried how this would be managed and requested that further information be provided at annual review.

Members considered the extent of confidential patient information requested for the purpose. Members noted that identifiable data on all tests carried out within England were to be collected; this was in order to ensure that those patients diagnosed with cancer at a later date could then be linked with cancer registry data. Members welcomed the opinion provided from the Information Commissioner's Office that the data collection would be in line with the third principle of the Data Protection Act 1998 and would be considered as adequate and relevant for the purposes.

In addition, Members discussed whether it might be feasible for cancer registries to link patient data using NHS number only, negating the need for collection of date of birth. They agreed that this should be explored further and reported upon at annual review stage.

In line with the considerations above, the Committee agreed that the minimum criteria under the Regulations appeared to have been met and therefore advised recommending to the Secretary of State for Health that the application be provisionally approved, subject to inclusion in the first annual review of a report on the feasibility of linking data using only NHS number and further details on management of the consent process.

5d. ECC 8-05(d)/2011 - The 2012 TYA Cancer Cohort Study

This application from University College London detailed a cohort study to determine whether specialist Teenage and Young Adult (TYA) specialist care affected outcomes. All patients aged 13-24 diagnosed with cancer in England would be invited to participate.

A recommendation for class two, three and six support was requested to allow National Cancer Research Network (NCRN) nurses to access data from the North West Cancer Intelligence Service (NWCIS) in order to identify patients and request their consent to participate in the study.

Access to identifiers including name, NHS number, and Hospital ID number, date of birth, hospital name and diagnosis was requested to allow a link research nurse to identify and delegate consent duties to the most appropriate researcher within their network.

Members recognised that consent would be obtained from participants through a designated research nurse following the disclosure of confidential patient information. Members noted the assertion that carrying out consent processes via the NCRN would allow optimum recruitment for a national cohort.

Members considered the extent of confidential patient information requested for the purpose and identified that there might be an alternative method that would negate the disclosure of confidential patient information from NWCIS prior to patient consent. Members queried whether or not the same optimum recruitment could be obtained by identifying the consultant responsible for the patient, rather than the patient themselves, who would be contacted by NCRN with a view to asking them to approach the patient for consent for a research nurse to speak to them.

Members noted that individuals would be asked why they did not wish to take part and felt that individuals were not obliged to explain this. A view was raised that it may be intrusive to ask, especially for the specified cohort. Members advised that patient leaflets should make it clear that people were under no obligation to explain why they were responding in any particular way.

Members discussed that those children who were under 16 would be asked to assent to participation in the study and their parents would be asked to consent. Members were of the view that those young people who were Gillick competent should be asked for consent. The Committee suggested that there should be a patient information leaflet especially designed for young people.

The Committee requested clarification be sought and passed to the original reviewers, prior to any recommendation to the Secretary of State for Health, as to whether consultants could be identified to NCRN so the latter could contact clinical care teams to ask them if they could seek consent from patients to speak to a research nurse.

5e. ECC 8-05(e)/2011 - Pilot study to assess patient services involved in treating adults with Histiocytic Disorders

This application from Newcastle University detailed a study into the occurrence and treatment of histiocytic disorders in Newcastle. It set out the intention to describe the treatment and services received and assess how many had died. The results of the study aimed to encourage co-operation and planning of treatments and services for patients in the Newcastle region and would potentially inform a national study.

A recommendation for class four, five and six support was requested to provide a legitimate basis to identify cases from the pathology database, and then collect further information from treating clinicians and the Northern Region Young Person's Malignant Disease Registry. Identifiers were requested to link data from all sources. Access to name, date of birth, sex, hospital number and NHS number was requested to allow data linkage to take place.

Members agreed that the study outcomes would have significant benefits for the care of patients with histiocytic disorders and noted that the study formed a pilot which might inform a national study at a later date. Members appreciated the retrospective nature of the study and noted that some of the cohort might have died or be seriously ill. Additionally, it was discussed that as the disorder was rare there was a chance that potential bias might be introduced from excluding those from whom consent could not be obtained.

The use of identifiable data would be to undertake linkage activities from different data sources only. Analysis would be undertaken using anonymised data. Members noted that the dataset would be retained for three years in order to inform the potential national study that could follow. Members advised that the dataset should be retained by the sponsor, Newcastle Hospitals NHS Trust, rather than the University.

The Committee advised recommending to the Secretary of State for Health that the application be provisionally approved, subject to agreement that the dataset would be retained by the sponsor, Newcastle Hospitals NHS Trust, rather than by the University.

5f. ECC 8-05(f)/2011 - Does London's Low Emission Zone improve children's respiratory health?

This application from the Queen Mary University of London (QMUL) detailed the linkage of GP record data, derived from Egton Medical Information Systems (EMIS) across Tower Hamlets, to local authority data and air quality data in order to assess whether or not the introduction of the Low Emission Zone had improved young people's respiratory health. A recommendation for class four and six support was requested to provide a legitimate basis for confidential patient information to be accessed without consent by researchers from QMUL. Name, NHS number, date of birth, address and postcode were requested to allow linkage across a number of data sources.

Members appreciated that the study required data from a large (31,000 individuals) retrospective cohort and recognised that consent would not be feasible. It was noted that at the point datasets were linked the data would be pseudonymised, and only a unique patient ID would be used.

Members considered the extent of confidential patient information requested for the purpose and queried why mental health data would be required. As this data was of a particularly sensitive nature, members agreed that a strong justification would need to be provided and currently could not advise recommending support to the use of mental health data.

Members queried whether the Unique Property Reference Number (UPRN) would remain in the dataset once it was linked to clinical data and were of the view that this should be removed prior to linkage as it would allow identification of residences.

Members discussed the proposals within the application that the demographic dataset would need to be retained for a further 5-10 years as the full effect of the Low Emission Zone might not yet be realised. Members agreed that as this was on a prospective basis a separate application would need to be made to request support for this aspect.

The Committee agreed that they would advise recommending to the Secretary of State for Health that the application be provisionally approved, subject to provision of a favourable opinion from a Research Ethics Committee; removal of UPRN prior to any linkage with clinical data; exclusion of mental health data from the application; and exclusion of all prospective activities using confidential patient information, for which a separate application would be required.

5g. ECC 8-05(g)/2011 - The mortality of workers with occupational lead exposure

This application from the Institute of Occupational Medicine, and sponsored by The Colt Foundation, detailed a study into the effect of inorganic lead compounds on causes of mortality within a cohort of 10,000 patients recruited by the Health and Safety Executive (HSE) between 1975 and early 1980s. A recommendation for class four and six support was requested to access mortality data from MRIS. Access was requested to date and cause of death from MRIS for those patients recruited by the HSE. Members noted that the study would have beneficial outcomes and were supportive in principle of the application.

The Committee discussed the assertion made by the applicant that the original consent was likely to have been valid to allow mortality data to be obtained from MRIS in the original study undertaken by the HSE. However, as the consent form could not be provided, the Committee agreed that they would have to assume that the consent was not valid for access to MRIS data.

Members discussed whether or not data would be collected from MRIS on a prospective basis and if this was the case whether or not consent could be obtained prospectively. Members were of the view that

insufficient information had been provided to allow an assessment of whether the applicant would be able to obtain consent from the living for further uses of their data. The Committee advised that clarification would be required on this point if access to confidential patient information was required on an ongoing basis, such as continued flagging on the NHS Central Register. Members referred to thefirst principle of the Data Protection Act 1998, which requires personal data to be processed fairly and lawfully and reasonable effort to be made to inform the data subject of the uses of their data, as having particular importance when processing confidential patient information without consent.

Members noted the applicant's assertion that many of the cohort would have died since the initial recruitment had taken place. Whilst members were mindful that this might be the case it was discussed and agreed that where patients were found to be alive they should be informed of any further uses of their data where practicable. In line with concerns regarding practicability of consent, members were unsure whether or not the applicant would be in receipt of sufficient data to inform the cohort in the event that confidential patient information would be required on a prospective basis. The Committee were of the view that support could be recommended for access to demographic details in order to inform the cohort and seek consent, if required.

The Committee considered that where confidential patient information was to be used without consent the study should seek a representative view from a relevant patient group or directly from a sample of patients themselves in order to test the acceptability of using identifiable data without consent. Members raised concerns that limited patient involvement had been undertaken and advised that they would expect the provision of a plan to involve members of the public and patients in the study design. Members queried whether or not the applicant intended to include a control arm to the study to ensure valid and comparable results. Members requested that the applicant should provide further information regarding the requirement for the ten year retention period, particularly if identifiable details were to be retained without the cohort's consent.

The Committee agreed to advise recommending to the Secretary of State for Health that the application be approved subject to: a) clarification as to whether or not a control arm of the study would be required and if so how this would be managed; b) confirmation of a plan for patient involvement and submission of a copy of the same to the NIGB Office; c) notification of living cohort of the uses, if any, of their data within the framework of prospective acquisition of MRIS data, using the Personal Demographics Service to source contact details; and d) a favourable opinion letter from a Research Ethics Committee.

5h. ECC 8-05(h)/2011 - Study of MRSA carriage and infection in the UK

This application from the University of Cambridge detailed an observational cohort study of patients with MRSA infection or colonisation admitted to hospitals within the East of England. The study would collect clinical data and bacterial isolates from patients with MRSA colonisation and infection in the UK. The primary objective of the study was to perform bacterial whole genome sequencing of MRSA isolates to determine its population genetic structure in the UK. The secondary objectives of the study were to use bacterial sequence data to determine MRSA transmission pathways within and between hospitals in the UK, to use bacterial sequence data to determine the accuracy of using phenotypic drug susceptibility patterns (antibiograms) to track MRSA in the hospital setting and to look at associations between clinical features, bacterial phenotype and bacterial genotype in patients with MRSA carriage and infection.

A recommendation for class four and six support was requested for researchers to access confidential patient information without prior consent in order to extract data, including date of birth and postcode, from records of patients with MRSA at Addenbrooke's hospital and use data to track the patient throughout their hospital stay. Access to data including date of birth through existing collaborations with microbiologists in the East of England (regional isolates), the British Society of Antimicrobial Chemotherapy (national isolates), the United Kingdom Clinical Infection Research Group (UKCIRG) and the Health Protection Agency was requested for the national aspect of the study.

Members considered whether or not consent would be feasible for those patients who were admitted to Addenbrooke's Hospital. They discussed that consent could be obtained from the patients, via the clinical care teams, for an approach by a member of the research team in order to extract further

information on a case report form. Members were of the view that, as in these instances informed consent would provide a legitimate basis for the review of the patient's medical notes, support would not be necessary if following this methodology. It was agreed that clarification over this aspect would be sought from the applicant.

Members were not persuaded that a sufficient explanation for initial contact by researchers, rather than by the clinical care team, had been provided, and suggested that Addenbrooke's hospital infection control team, following identification of a new case, should contact a member of the clinical care team of a patient and identify the need for an initial consent for subsequent contact by a researcher. Members appreciated that, in addition to the prospective Addenbrooke's study, MRSA isolates and date of birth would be collected both prospectively and retrospectively from existing stored collections at other sites. Members recognised that in these circumstances it would be impracticable to obtain consent and in these instances agreed that it would be appropriate for the research team to collect confidential patient information without consent.

In relation to the Addenbrooke's detailed patient review component of the study, it was agreed that an approach using anonymised or pseudonymised data was clearly not feasible. However, Members were of the view that a consent based methodology could be used as above. In relation to the regional/national part of the study, Members were supportive of the use of microbiological information plus date of birth.

Members queried what fair processing information would be provided to patients or displayed within the hospital, in line with the first principle of the Data Protection Act 1998, to inform patients of the potential uses of their data and, if necessary, allow them to exercise their rights as data subjects under the sixth principle.

The Committee agreed to advise recommending to the Secretary of State for Health that the portion of the application dealing with the regional/national aspect of the study should be approved, subject to a) clarification of methodology by which patients would be informed of the use of their data in line with the first principle of the Data Protection Act 1998; b) submission of patient information leaflets; c) provision of outcomes of consultation with patients and members of the public; and d) confirmation of a favourable opinion from a Research Ethics Committee.

In relation to the portion of the application dealing with access to confidential patient information for those patients who remain in hospital, the Committee agreed that they would advise the Secretary of State for Health, that this aspect be rejected on the grounds that consent appeared to be feasible at the present time. , and would expect further evidence that the clinical care team could not obtain consent for this cohort.

5i. ECC 8-05(i)/2011 - TransATAC Screening Study

This application from University College London detailed a study using an established tissue bank to investigate the benefits of screening patients in relation to their 21 gene Recurrence Score, which could help to determine whether or not chemotherapy was of benefit to individual patients. Consent had originally been taken from the participants that included permission to use tissue blocks for future research. A recommendation for class four and six support was requested to provide a legitimate basis for one individual from a research team at the University Hospital of South Manchester to access the National Breast Screening database in order to link screening data to the TransATAC (Translational research studies in the Arimidex compared to Tamoxifen, Adjuvant Breast Cancer trial) database. Access to information on the National Breast Screening database relating to 1,400 patients was requested to allow data to be extracted and linked to the TransATAC database. Name, NHS number and date of birth would be used to link the data sources.

Members recognised that consent had been obtained in the first instance to allow tissue blocks to be used for research and were of the view that this additional purpose could be considered to be in line with the consent that was originally given, although it was noted that access to screening data was not explicitly stated.

It was noted that identifiable information would be required to identify patients on the National Breast Screening Database and to carry out linkage with the TransATAC database. Members sought confirmation that identifiable data would be used for linkage purposes only and that pseudonymised information would be used for analysis.

It was noted that section (r) of the application form, which allowed the applicant to demonstrate that the principles of the Data Protection Act 1998 had been met, had not been completed. Members requested that this was addressed by the applicant prior to any final recommendation. In line with this, it was also noted that a Data Protection registration had not been provided within section (v).

Members noted that the application specified that Research Ethics Committee (REC) approval would not be required for this additional data collection. It was a requirement that all research applications include adequate REC approval; Members therefore sought confirmation from the REC that an amendment would not be required in order to carry out this data linkage.

The Committee noted that the data would be retained for fifteen years following the death of the final patient. Members queried whether or not identifiable data would be retained on patients following their death, and advised that it would be good practice to ensure that identifiable information was destroyed once it was no longer required.

The Committee agreed to advise recommending to the Secretary of State for Health that the application be provisionally approved subject to: a) clarification of Data Protection Act 1998 compliance; b) confirmation of the applicant's Data Protection registration number; c) confirmation that only pseudonymised data would be accessed for analysis purposes; d) confirmation of the employment contract governing the individual accessing the National Breast Screening Database and specific confidentiality clauses therein; e) confirmation from the Research Ethics Committee that an amendment to the application was not required for their purposes.

5j. ECC 8-05(j)/2011 - Assessing the impact of the Universal Form of Treatment Options

This application from the University of Cambridge detailed a cohort study to assess whether or not the introduction of the newly developed Universal Form of Treatment Options (UFTO), as an alternative to the 'Do Not Attempt Cardiopulmonary Resuscitation' (DNACPR), improved satisfaction with care in all patients treated within two wards at Addenbrooke's Hospital. A recommendation for class one, five and six support was requested to provide a legitimate basis for the research team to review patient administration systems to identify patients who were ready for discharge and to ask a member of the clinical care team to provide these patients with a questionnaire; to review medical records to identify patients with a life limiting illness to inform the clinical care team to approach them for consent to interview; and to access medical records for those patients who died within 90 days of admission in order to retrospectively review the care provided. Access to patient admission systems, the hospital "Realtime" system and patients' medical records within two wards at Addenbrooke's hospital was requested.

Members noted that consent would be taken from the patients via the clinical care team for completion of a questionnaire and to participate in an interview, following access to confidential patient information by researchers in order to identify the cohort. The Committee queried why it was necessary for the researchers to access the patient administration systems in order to identify those patients about to be discharged, as Members were of the view that the clinical care team could be informed to provide a questionnaire to all patients being discharged from the wards. In addition, Members considered whether or not sampling for patients who would be approached for interview could be undertaken by a member of the clinical care team, which would negate the requirement for access to medical records by the researcher without prior consent. Members felt that they had not been provided with sufficient evidence that this was not a practicable alternative and advised that this should be explored.

Members noted that consent for those patients who died within 90 days of admission would not be feasible and agreed to advise recommending support to allow the care of those patients to be retrospectively reviewed.

Members queried what fair processing information would be provided to patients or displayed within the hospital, in line with the first principle of the Data Protection Act 1998 to inform patients of the potential uses of their data, and allow them to exercise their rights as data subjects under the sixth principle.

The Committee agreed to advise recommending to the Secretary of State for Health that the portion of the application dealing with access to the data of deceased persons without consent should be approved, subject to confirmation of a favourable opinion from a Research Ethics Committee and confirmation of satisfactory security arrangements covering each NHS trust involved.

The Committee agreed that they would not advise supporting the remaining portion of the application, dealing with access to confidential patient information in order to approach the cohort for consent as a practicable alternative appeared feasible, and would expect further evidence that the clinical care team could not carry this out to e provided before advising further on this aspect..

5k. ECC 8-05(k)/2011 - Improving the responses of health services to domestic violence part 2

This application from the University of Bristol detailed two work streams of a larger research project which aimed to improve the quality of health care for victims and perpetrators of domestic violence. The work streams would be used to pilot an educational intervention, with the aim to improve enquiry about domestic violence, documentation and referral to specialist community agencies, with health professionals in general practice and sexual health clinics. A recommendation for class one and six support was requested to access general practice patient records in order to identify rates of domestic violence recorded for male patients, 12 months prior to and following the intervention. 'Read' codes indicating domestic violence would be identified using computerised records; however individual patient records would need to be accessed in order to identify whether domestic violence was specified and what referrals took place.

A recommendation of support had also been requested to allow access to patient records at a sexual health clinic. The NIGB Office advised the applicant prior to the meeting that access to identifiable sexual health records was subject to the NHS Trusts and Primary Care Trusts (Sexually Transmitted Diseases) Directions 2000. In summary, these Directions require that any information obtained by a Trust or PCT in relation to a patient being treated for sexually transmitted disease should not be disclosed in a format that could identify that individual, unless it is for treatment or the prevention of the spread of infection. Where this was the case, an application to the ECC could not be used to override the requirements of the Directions and arrangements should be made to ensure that consent was taken from the cohort or that the information disclosed to the researchers was in an anonymised format. The Committee could not, therefore, provide advice in relation to access to the sexual health clinic records as it was likely that these would include information collected in the course of treatment for a sexually transmitted disease.

Access was requested to a total of 400 general practice records across practices in the South West of England, in order to extract anonymised data.

Members noted and recognised the assertion within the applicant's response to the Research Ethics Committee that obtaining consent for access to records would be problematic due to the potential impact writing to the cohort would have on their safety.

The Committee discussed the assertion that the record of a 'Read' code would be insufficient to allow a judgement of domestic violence to be made. They noted that the applicant had advised the REC that the request to verify the 'Read' code by examining the general practice record had been made following previous research which showed that the codes were not used consistently and had an "uncertain relationship" with domestic violence. Therefore, for the purposes of the research, 'Read' codes were not a valid measure.

Members were of the view that as the information requested was of a highly sensitive nature, the justification for access to the records by researchers would have to be particularly strong in these circumstances, taking all practicable alternatives into consideration. In line with this, Members queried whether or not general practices could provide resource to enable anonymised data to be extracted from the record and negate the requirement for external researchers to have access to confidential patient information. The Committee understood that there might be a cost involved in this. However, in these circumstances, Members were of the view that measures to preserve patient confidentiality should be estimated and planned for. Taking into consideration the costs involved in general practices providing resource, and the overall grant provided to the research project, Members agreed that they had not been provided with sufficient evidence that this would not be a practicable alternative in this instance.

Members agreed it was an important topic with a clear public interest benefit. However, as the study involved highly sensitive data the Committee advised that the threshold for the public interest requirement would be higher and therefore evidence on practicable alternatives would be required.

The Committee agreed that they would advise the Secretary of State for Health that this application should be rejected, and requested that the alternatives to the use of confidential patient information without consent be explored further and evidence provided if the applicant intended to resubmit in the future.

5l. ECC 8-05(l)/2011 - Understanding Immune and genetic factors in hepatitis C protection

This application from the Plymouth Hospitals NHS Trust detailed a study which intended to use data collected as part of a previous study (Lookback Programme) carried out by NHS Blood and Transplant (NHSBT), which had investigated outcomes for patients exposed to hepatitis C (HCV) infected blood. The application aimed to identify immune and genetic factors that protected those exposed to HCV infected blood that did not develop HCV, with the aim of assisting the development of a vaccine. A recommendation for class three and six support was requested to enable access to the database held by NHS Blood and Transplant on those patients who were exposed to HCV affected blood, but who did not develop HCV. The information would be used to check whether the patient was still alive, contact the patient's GP and write to patients to gain consent for inclusion into the current study. Access was requested to name, NHS number, hospital ID number, GP registration, date of birth, date of death and postcode.

Members agreed that the study would have beneficial outcomes and that it was in the public interest that the activity went ahead.

Members noted that consent would be obtained following the disclosure of confidential patient information. Members welcomed the safeguards the applicant proposed to ensure that patients were not contacted if it was not appropriate to do so.

The Committee agreed to advise recommending to the Secretary of State for Health that the application be provisionally approved, subject to provision of a favourable opinion from a Research Ethics Committee.

5m. ECC 8-05(m)/2011 - The Liverpool Lung Project: A molecular epidemiological population-based study into early lung cancer detection

This application from the University of Liverpool detailed a study which aimed to increase scientific understanding of interactions between the different risk factors for lung cancer, to develop a model to predict lung cancer risk from an extensive record of epidemiological, clinical, molecular/genetic risk factors and identify changes in molecular biomarkers. The project had two components including a case control study and a population cohort study. A cohort of 11,000 patients made up both and had been recruited between 1998 and 2010.

A recommendation for class one and four support was requested to access data relating to the cohort held by the NHS Information Centre (NHS IC) on the Hospital Episode Statistics (HES) database. The

cohort had returned a consent form which stated: "*I agree to provide data about my lifestyle, medical, occupational and family history and give permission for my medical and related records (e.g. medical registers) to be examined and information taken from them for confidential use in the Liverpool Lung Project (LLP)."* The NHS IC had advised the applicant that the consent was insufficient to cover HES linkage and therefore requested that an application was made to the Committee. Confidential patient information was requested from HES for all admissions and diagnosis codes to allow linkage to data held by the Liverpool Lung Project. Linkage would be carried out using name, NHS number, date of birth and postcode.

Members considered the consent form which had been provided by the applicant, in particular they noted that patients had consented to; *medical and related records (e.g. medical registers) to be examined and information to be taken from them for use in the Liverpool Lung Project.* The Committee were of the view that this consent was sufficient to allow access to the requested HES data and agreed that in this instance they would advise the Secretary of State that support was not necessary.

Members considered the extent of confidential patient information requested for the purpose and noted that name had been specified as an item for data linkage. It was understood that the HES database did not hold name and Members advised that this should not be provided to the NHS IC.

The Committee agreed that they would advise recommending to the Secretary of State for Health that consent was already in place and therefore approval was not required.

5n. ECC 8-05(n)/2011 - Statistically Proving Shaken Baby Syndrome Study

This application from Nottingham Hospitals NHS Trust detailed a study into the causes of shaken baby syndrome. Access to confidential patient information was requested to carry out data linkage of all babies treated at Nottingham University Hospitals NHS Trust for shaken baby syndrome within the past six years with police records. The police would require access to confidential patient information in order to identify and link to relevant police files.

The Committee noted that a REC favourable opinion had not yet been received as there were concerns over the scientific validity of the study. The Committee agreed that they were therefore unable to provide advice to the Secretary of State for Health at this time as without confirmation of scientific validity, the public interest of the activity could not be assessed.

Members agreed that the applicant should be advised to take into account comments below, to amend the application accordingly, and to resubmit once a REC favourable opinion had been obtained and the scientific validity had been confirmed. The Committee would then be in a position to consider the application with a view to providing advice to the Secretary of State.

The Committee requested that the applicant provide further information in relation to the benefit that the study would have to the care and treatment of patients within the NHS. In line with the comments from the REC, the Committee also advised that an assessment of the scientific validity should be carried out, which would help to evidence the public interest.

The Committee considered that where confidential patient information was to be used without consent, the study should seek a representative view from a relevant patient group or directly from a sample of patients themselves in order to test the acceptability of using identifiable data without consent. In line with this the Committee noted that no service users had been involved in the design of the research and agreed that they would expect relevant patient groups to be consulted.

Members agreed that they could not make a recommendation of support for linkages to non-NHS data where the legality of access to other databases was unclear. In line with this they requested that the applicant confirm the legality of access to police data, in accordance with the Data Protection Act 1998 principles. As advised recommendations of support could not be inconsistent with the Data Protection Act 1998 principles, the Committee noted that question 87 of the IRAS form should be amended to

specifically reflect compliance. In particular Members queried how the fair processing requirements would be met by making reasonable efforts to inform data subjects of the uses of their data.

Members agreed that if a resubmitted application were to be received which addressed all issues raised; it could potentially be processed via a fast track process in the first instance, with the caveat that if any issues arose it might need to be referred to a full Committee meeting.

6. Any other business

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

7. Upcoming meeting dates

1 and 2 February 2012
27 and 28 March 2012